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Part III

Consumer Product Safety Commission

16 CFR Part 1102

**Publicly Available Consumer Product
Safety Information Database; Final Rule**

**CONSUMER PRODUCT SAFETY
COMMISSION****16 CFR Part 1102****Publicly Available Consumer Product
Safety Information Database****AGENCY:** Consumer Product Safety
Commission.**ACTION:** Final rule.

SUMMARY: The Consumer Product Safety Commission (“Commission,” “CPSC,” or “we”) is issuing a final rule that would establish a Publicly Available Consumer Product Safety Information Database (“Database”). Section 212 of the Consumer Product Safety Improvement Act of 2008 (“CPSIA”) amended the Consumer Product Safety Act (“CPSA”) to require the Commission to establish and maintain a publicly available, searchable database on the safety of consumer products, and other products or substances regulated by the Commission. The final rule interprets various statutory requirements pertaining to the information to be included in the Database and also establishes provisions regarding submitting reports of harm; providing notice of reports of harm to manufacturers; publishing reports of harm and manufacturer comments in the Database; and dealing with confidential and materially inaccurate information.

DATES: *Effective Date:* This rule is effective January 10, 2011.**FOR FURTHER INFORMATION CONTACT:** Mary Kelsey James, Director, Information Technology Policy and Planning, Consumer Product Safety Commission, 4330 East West Highway, Bethesda, MD 20814; telephone (301) 504-7213; mjames@cpsc.gov.**SUPPLEMENTARY INFORMATION:****I. Background**

Section 212 of the CPSIA requires the Commission to establish and maintain a product safety information database that is available to the public. Specifically, section 212 of the CPSIA amended the CPSA to create a new section 6A of the CPSA, titled “Publicly Available Consumer Product Safety Information Database.” Section 6A(a)(1) of the CPSA requires the Commission to establish and maintain a database on the safety of consumer products, and other products or substances regulated by the Commission. The Database must be publicly available, searchable, and accessible through the Commission’s Web site. Section 6A of the CPSA sets forth specific content, procedures, and search requirements for the publicly

available database. On May 24, 2010, we published a notice of proposed rulemaking at 75 FR 29156, which set forth the Commission’s proposed interpretation and implementation of the Database provisions of section 6A of the CPSA. The comment period on the proposed rule ended on July 23, 2010. After reviewing and considering significant issues raised by the comments, the Commission is now promulgating a final rule on the statutory requirements of section 6A.

For several decades, the Commission has gathered and maintained a database of consumer complaints, known as consumer product incident reports. Such incident reports describe safety-related incidents involving the use of consumer products that fall within the scope of the Commission’s jurisdiction. Pursuant to section 5(a) of the CPSA, the Commission collects information related to the causes and prevention of death, injury, and illness associated with consumer products. The Commission conducts studies and investigations of deaths, injuries, diseases, other health impairments, and economic losses resulting from accidents involving consumer products. In addition, pursuant to section 5(b) of the CPSA, the Commission may conduct research, studies, and investigations on the safety of consumer products and on improving the safety of such products. Currently, the Commission obtains information about product-related deaths, injuries, and illnesses from a variety of sources, including newspapers, death certificates, consumer complaints, and hospital emergency rooms. In addition, the Commission receives information from the public through its Internet Web site via forms reporting on product-related injuries or incidents.

To date, the data that the Commission collects and maintains on product safety have not been immediately available and searchable by the public. Before the CPSIA’s enactment, the CPSA required that the Commission follow the notice provisions of section 6 of the CPSA before publicly disclosing any information that allowed the public to readily ascertain the identity of a manufacturer or private labeler of a consumer product. Section 6 of the CPSA contains requirements for giving notice of such information to the manufacturer or private labeler and providing them with an opportunity to comment on the information prior to public disclosure. Section 6 of the CPSA also requires the Commission to take reasonable steps to assure that disclosure of such information is accurate, fair in the circumstances, and reasonably related to effectuating the

purposes of the CPSA. The Commission has applied the requirements in section 6 of the CPSA to Freedom of Information Act (“FOIA”) requests as well. See *Consumer Product Safety Commission et al. v. GTE Sylvania*, 447 U.S. 102 (1980). The Commission issued regulations interpreting section 6 notice requirements at 16 CFR part 1101. Thus, consumers currently have access to incident data through reports and studies published by the Commission or through information provided in response to FOIA requests.

Section 6A of the CPSA creates a new disclosure requirement with respect to product safety-related incident reports, referred to as “reports of harm” in both the statute and the proposed rule. Specifically, section 6A of the CPSA excludes any incident report submitted for inclusion in the Database from the notice requirements of section 6(a) and (b) of the CPSA. Instead, section 6A of the CPSA sets up a new framework for collecting reports of harm, transmitting them to the manufacturer and private labeler for comment, and then posting them on a Database that is accessible on the Commission’s Web site.

The notice of proposed rulemaking provided the public with an opportunity to understand how the Commission is intending to implement the new procedures in section 6A of the CPSA, and to provide comment. Prior to issuing a notice of proposed rulemaking, however, the Commission provided stakeholders with information about Database implementation, as well as offered several opportunities for stakeholder input and comment, all of which were discussed in the preamble to the proposed rule at 75 FR 29156–57. Prior Commission activities related to the Database include: Providing a detailed implementation plan to Congress; holding a public hearing on Database implementation; holding a public workshop, which sought comments on Database implementation; attending and speaking about the Database at various conferences; and creating the <http://www.saferproducts.gov> Web site, where updates on implementation of the Database are provided. Information on all of these Commission activities and public comments are available on the CPSC Web site at <http://www.cpsc.gov/about/cpsia/sect212.html>.

We received 37 comments on the proposed rule. After reviewing the comments, the Commission made several changes to the final rule, all of which are discussed in detail in section III below.

II. Statutory Authority

The Commission is issuing this rule pursuant to section 3 of the CPSIA which provides the Commission authority to issue regulations, as necessary, to implement the CPSIA.

III. Description of the Final Rule, Comments on the Proposed Rule, and the Commission's Responses

The final rule establishes a new 16 CFR part 1102, "Publicly Available Consumer Product Safety Information Database." The new part consists of four subparts:

Subpart A—Background and Definitions;

Subpart B—Content Requirements;

Subpart C—Procedural Requirements;

Subpart D—Notice and Disclosure Requirements.

Below, we describe and explain each subpart and section of the final rule, as well as describe and respond to significant issues raised by the comments on the proposed rule (75 FR 29156, May 24, 2010) pertaining to each section. In addition to comments on each of the subparts of the final rule, we have added a section "E" below to address Database implementation comments that are not directly related to a section of the proposed rule. To make it easier to identify comments and the Commission's responses, the word "Comment" will appear in italics before each comment description, and the word "Response" will appear in italics before the Commission's response. We have grouped comments based on the section of the proposed rule to which they pertain and their similarity, and we have numbered the comments to help distinguish between different comment themes. The number assigned to each comment summary is for organizational purposes only and does not signify the comment's value, importance, or order in which it was received.

A. Proposed Subpart A—Background and Definitions

1. Proposed § 1102.2—Purpose

Proposed § 1102.2 would describe the purpose for a new 16 CFR part 1102 titled "Publicly Available Consumer Product Safety Information Database," which is to set forth the Commission's interpretation, policy, and procedures to establish and maintain such Database.

We have finalized this section and made one clarification, which is to add the words "Publicly Available" to the full name of the Database.

2. Proposed § 1102.4—Scope

Proposed § 1102.4 would describe the scope of the rule to include the content,

procedure, notice, and disclosure requirements for all information published in the Database.

We received one comment related to this section. The section has been finalized with one correction, which is to add the words "Publicly Available" to the full name of the Database.

Comment 1—One commenter states that incident reports involving over-the-counter drugs and dietary supplements should not be included in the Database because food and drugs are regulated and monitored by the U.S. Food and Drug Administration ("FDA"). The commenter notes that the Commission has regulatory authority only over product packaging, and asserts that consumers will inadvertently submit drug or supplement safety information to the Commission rather than to the manufacturer or the FDA. If the Commission includes complaints regarding product packaging in the Database, the commenter states that the Commission should not only instruct consumers that only product packaging complaints can be reported in the Database, but should also regularly monitor the Database to ensure that complaints involve only products over which the Commission has jurisdiction.

Response—Section 1102.10(d)(1) of the final rule states that to be included in the Database, a report of harm must, "at a minimum, include a word or phrase sufficient to distinguish the product as a consumer product, a component part of a consumer product, or a product or substance regulated by the Commission." A report of harm that does not identify a product or substance over which the Commission has jurisdiction will not be included in the Database. Every report of harm will be reviewed to ensure that the minimum requirements for publication are met before being published in the Database. Also, as with our current online incident report form, the Database will describe the products that are not within the Commission's jurisdiction, including food and drugs. This information will include links to the appropriate government agencies that do have jurisdiction. We have no intention of including reports of harm solely involving products or substances not within our jurisdiction, but will include all products and substances that do fall within our jurisdiction, including complaints about drug product packaging.

3. Proposed § 1102.6—Definitions

Proposed § 1102.6 would define certain terms related to the establishment and maintenance of the Database.

a. Proposed § 1102.6(a)—Terms Defined in § 3 of the CPSA Apply to the Database Rule

Proposed § 1102.6(a) would explain that, except as provided in proposed § 1102.6(b), the definitions set forth in section 3 of the CPSA apply to the Database rule. For example, section 3(a)(11) of the CPSA defines a "manufacturer" as "any person who manufactures or imports a consumer product." Because section 3(a)(11) of the CPSA defines "manufacturer," any reference to "manufacturer" in proposed part 1102 would have the same meaning.

One comment was received related to this section, which we have finalized without change.

Comment 2—One commenter states that the term "private labeler" should be defined in § 1102.6 of the final rule.

Response—Section 3(a)(12) of the CPSA defines "private labeler" as "an owner of a brand or trademark on the label of a consumer product which bears a private label." Because the CPSA defines "private labeler," there is no need to include such a definition in the final rule.

b. Proposed § 1102.6(b)—Terms Defined Relevant to § 1102

Proposed § 1102.6(b) would define certain terms or, in some cases, interpret terms already defined in section 3 of the CPSA.

Proposed § 1102.6(b)(1) would define "additional information" as any information that the Commission determines is in the public interest to include in the Consumer Product Safety Information Database.

No comments were received related to this definition, and we have finalized it with one change, which is to add "Publicly Available" to the full name of the Database.

Proposed § 1102.6(b)(2) would define "Commission" or "CPSC" as meaning the Consumer Product Safety Commission.

No comments were received related to this definition, and we have finalized it without change.

Proposed § 1102.6(b)(3) would define "consumer product" as having the same meaning as defined in section 3(a)(5) of the CPSA, but would further explain that "consumer product" includes any other products or substances regulated by the Commission. This further clarification is based on the statutory requirement in section 6A(b)(1)(A) of the CPSA for submission of reports of harm relating to the use of consumer products and other products or substances regulated by the Commission.

No comments were received related to this definition, and, for clarity, we have added “under any other act it administers” to the end of the definition.

Proposed § 1102.6(b)(4) would define “Consumer Product Safety Information Database,” which is also referred to as the “Database,” as the database on the safety of consumer products required to be established and maintained by the Commission as described in section 6A of the CPSA.

No comments were received related to this definition. However, on our own initiative, we did incorporate the shortened name of “Database” in the final rule and added the words “Publicly Available” to the full name of the Database.

Proposed § 1102.6(b)(5) would define “harm” as any injury, illness, or death, or any risk of injury, illness, or death, as determined by the Commission. This definition is taken from section 6A(g) of the CPSA, which states that “[i]n this section, the term ‘harm’ means (1) injury, illness, or death; or (2) risk of injury, illness, or death, as determined by the Commission.”

We received several comments related to this definition which did not lead us to make any changes. However, we are changing this definition to be consistent with the statutory language.

Comment 3—Some commenters would remove from the definition of a report of harm the terms “or any risk of injury, illness, or death as determined by the Commission, relating to the use of a consumer product.” The commenters argued that such a determination requires an arbitrary assessment that would require Commission resources to determine whether the report of harm represents a legitimate risk. According to these commenters, reports of harm addressing risks should come from the Commission in recall notices only, not from the general public.

Response—Section 6A(g) of the CPSA defines “harm,” as used in this section of the statute, as “(1) injury, illness, or death; or (2) risk of injury, illness, or death, as determined by the Commission.” Because the definition of “harm” is dictated by Congress in the statute, and Congress has plainly expressed its intent in the statute that the Database include reports of harm involving risks of harm, we will not remove this phrase from the definition of a report of harm. Moreover, the Database is meant to help us in our mission to protect the public against unreasonable risks of injury associated with the use of consumer products. Use of agency resources to assess risks is essential to our mission. While

submitters must describe an illness, injury, or death, or risk of illness, injury, or death on the incident report form, each report of harm will be reviewed before publication to ensure that it meets the minimum requirements for publication set forth in § 1102.10(d).

Comment 4—Some commenters propose that “any risk of injury” be defined narrowly to account for the level of risk or the potential for injury to exclude reports of harm that “have near zero risk of causing injury.” These commenters would strike the term “any” and replace it with a phrase such as “substantial risk of serious injury,” which they state has historically been used by the Commission.

Response—We disagree with the commenters because they would have us interpret the statute in an unnecessarily narrow manner. However, we have stricken the word “any” and changed the comma to a semicolon after the first occurrence of the word “death” to make the definition consistent with the statutory language. Section 3(a)(14) of the CPSA already defines “risk of injury” as “a risk of death, personal injury, or serious or frequent illness.”

We also decline to use the phrase “substantial risk of serious injury” to qualify the types of harm or risk of harm that may be placed into the Database. Such phrase is used once in 16 CFR 1115.13(c) to describe a firm’s initial obligation to report hazards under section 15(b) of the CPSA. It applies to manufacturers, importers, retailers, and distributors who have received information that reasonably supports the conclusion that one of the factors in section 15(b) of the CPSA has been met. The phrase has no relevance to the types of information included in a report of harm.

Comment 5—One commenter states that the Commission should establish criteria for making determinations about risks of harm, arguing that speculative assertions or unsubstantiated opinions that a consumer could have been injured, without any supporting factual information indicating a nexus between the product or incident and a discernable and credible risk of injury, cannot provide the CPSC with the necessary basis for making the required determination to include these reports in the Database.

Response—The Commission has many years of experience categorizing harm or hazards and their risks related to the use of a consumer product based on a reported incident scenario. We will continue to rely on our expertise to review reports of harm submitted for inclusion in the Database and will

determine whether the minimum requirements for publication are met.

Comment 6—One commenter states that the proposed rule does not delineate how the Commission will determine “harm” or “report of harm,” and it does not define “risk.”

Response—Section 6A(g) of the CPSA defines “harm,” and we will adhere to this definition. We have maintained a database on injuries and risks of injury associated with the use of consumer products for many years, and will use our experience in reviewing reports of harm to ensure that the minimum requirements for inclusion in the Database are met. “Risk,” by itself, is not defined in the proposed rule or in the CPSA, but section 3(a)(14) of the CPSA defines “risk of injury” as “a risk of death, personal injury, or serious or frequent illness.”

Proposed § 1102.6(b)(6) would define “mandatory recall notice” as any notice to the public ordered by the Commission pursuant to section 15(c) of the CPSA.

No comments were received related to this definition, and we have finalized it with one grammatical change.

Proposed § 1102.6(b)(7) would define “manufacturer comment” as a comment made by a manufacturer or private labeler in response to a report of harm transmitted by the CPSC to the manufacturer or private labeler.

No comments were received related to this definition, and we have finalized it without change.

Proposed § 1102.6(b)(8) would define “report of harm” as any information submitted to the Commission through the manner described in § 1102.10(b) regarding an incident concerning any injury, illness, or death, or any risk of injury, illness, or death as determined by the Commission relating to the use of the consumer product.

We received comments regarding the definition of “harm” used in the proposed rule. As noted above in response to Comments 3 through 6, we are making minor modifications to the definition of “harm” as contained in section 6A(g) of the CPSA. Thus, we have finalized the definition of “report of harm” with one grammatical change, changing “an injury” to “any injury.” We also changed the comma to a semicolon after the first occurrence of the word “death” and inserted a comma after the second occurrence of the word “death” to ensure that the definition in the final rule is more consistent with the definition of “harm” in the statute.

Proposed § 1102.6(b)(9) would define “submitter of a report of harm” as any person or entity that submits a report of harm.

No comments were received related to this definition, and we have finalized it without change.

Section 1102.6(b)(10) of the proposed rule would define “voluntary recall notice” to mean any notice to the public by the Commission relating to a voluntary corrective action, including a voluntary recall of a consumer product taken by a manufacturer in consultation with the Commission.

No comments were received related to this definition, and we have finalized it without change.

Comment 7—One commenter objects to use of the term “victim” in the proposed rule. The commenter states that the use of such a term implies a criminal or civil wrong, and suggests use of the word “consumer” as a more neutral term.

Response—We will not remove the term “victim” in the final rule, but agree that the term may be confusing to some without further clarification. We have used the term “victim” for many years to describe persons actually suffering a harm or risk of harm related to the use of a consumer product as compared to others who simply may have purchased or observed the product being used. The term “victim” is used on the current incident reporting form to collect information about the individual who was injured or exposed to a possible product related hazard. In the context of that form, the use of the term “victim” does not imply a criminal or a civil wrong. Thus, for purposes of this rule, “victim” continues to refer to any individual exposed to harm or risk of harm related to a possible product related hazard, and the term does not imply that the product caused an incident.

B. Proposed Subpart B—Content Requirements

1. Proposed § 1102.10—Reports of Harm

Proposed § 1102.10 would explain the requirements for reports of harm to be included in the Database.

a. Proposed § 1102.10(a)—Who May Submit

Proposed § 1102.10(a) would identify the category of submitters specified in section 6A(b)(1)(A) of the CPSA and further clarify the persons who may fall within each of the identified groups. The list of persons under each category is not exclusive, and the proposed lists are intended to provide a greater understanding of the type of person or entity that could fall within each category of submitter.

Proposed § 1102.10(a)(1) would state that the term “consumers” includes not

only users of consumer products, but also family members, relatives, parents, guardians, friends, and observers of a consumer product being used.

We received one comment related to this section, and other comments relating to the definitions under proposed § 1102.10(a) resulting in a revision to the definition of “consumers” as described in response to Comment 8 through 17.

Comment 8—Several commenters state that the interpretation of “consumer” should not be so broad as to include those persons who were not injured by the product or who are not reliable reporters of the incident, such as those persons lacking firsthand knowledge of the product, its manufacturer, or the injury. The commenters also state that the proposed interpretation of “consumer” expands the potential for inaccurate information in the Database and goes beyond a reasonable interpretation of the term. Some commenters note, however, that information from these sources could be collected for the Commission’s use, but should not be included in the Database.

Response—The plain statutory language does not require a submitter of a report of harm to have “firsthand knowledge.” We have chosen an interpretation of “consumer” that comports with our experience in maintaining a database of consumer product incident reports. Historically, we have received reports of harm from any and all consumers in order to protect individuals who may use or enjoy consumer goods. Currently, parents, guardians, and family members are a major and important source of information collected for the most vulnerable segments of the population. In the most basic example, if the user of a consumer product is killed or seriously injured in the incident, or is an infant, he or she will be unable to enter the incident report. Parents, for example, may enter information related to consumer products used by their children, regardless of whether they personally witnessed the incident or purchased the product. Other consumers may possess important product safety information and, as a practical matter, the Commission does not have the resources to ascertain whether every submitter of a report of harm has firsthand knowledge or actually used the product. Therefore, following our current practice of receiving reports of harm from any and all consumers serves the purpose and intent of the Database and of our primary statutory mission, which is to protect consumers from unsafe products. Furthermore, a manufacturer

is free to post a comment indicating whether they know if the submitter had firsthand knowledge or not. For these reasons, we disagree that inclusion of inaccurate information will necessarily result from our definition of “consumer.” Moreover, everyone who submits reports of harm to the Database is legally obligated to provide truthful and accurate information as evidenced by their verification that they have done so.

We also note that reports of harm received from individuals in some of the other statutory categories, such as other government agencies, health care professionals, and public safety entities, will likely lack firsthand knowledge about an incident. For example, a physician who treats an individual who was injured by a consumer product is unlikely to have witnessed how or when the injury occurred, but the statute permits the physician to submit a report of harm. If we find that false and fraudulent reports are being submitted for inclusion in the Database, we will consider what legal actions to take to address the problem and proceed accordingly.

Proposed § 1102.10(a)(2) would state that the definition of “local, state, or federal government agencies” includes, but is not limited to, local government agencies, school systems, social services, child protective services, state attorneys general, state agencies, and all executive and independent federal agencies as defined in Title 5 of the United States Code.

No comments were received on this provision, and we have finalized it with only typographical changes.

Proposed § 1102.10(a)(3) would state that the definition of “health care professionals” includes, but is not limited to, medical examiners, coroners, physicians, nurses, physician’s assistants, hospitals, chiropractors, and acupuncturists.

No comments were received on this provision, and we have finalized it with one grammatical change.

Proposed § 1102.10(a)(4) would state that the definition of “child service providers” includes, but is not limited to, day care centers, day care providers, pre-kindergarten school, and child care providers.

No comments were received on this provision, and we have finalized it with minor modifications changing “day care” to “child care.”

Proposed § 1102.10(a)(5) would state that the definition of “public safety entities” includes, but is not limited to, police, fire, ambulance, emergency medical services, federal, state, and

local law enforcement entities, and other public safety officials.

No comments were received on this provision, and we have finalized it with one change for clarity. In response to comments relating to the definitions under proposed § 1102.10(a)(6), we added “and professionals, including consumer advocates and individuals who work for nongovernmental organizations, consumer advocates, consumer advocacy organizations, and trade associations so long as they have a public safety purpose” to the end of the definition.

Proposed § 1102.10(a)(6) would add “Others” to the list of submitters. The “Others” category is intended to include those persons who may not fit clearly within an identified category, but who may otherwise file a report as a “consumer.” The “Others” category would include, but is not limited to, attorneys, professional engineers, investigators, nongovernmental organizations, consumer advocates, consumer advocacy organizations, and trade associations.

We received several comments on proposed § 1102.10(a)(6). Many commenters misinterpreted the proposal as an expansion of the list of people who can submit reports. This was not the intention. The proposal states, the five statutory categories of submitters are quite broad and, given that breadth, we had concluded that the list was intended to be nonrestrictive. See 75 FR at 29162. Currently, persons listed as examples under “Others” file reports of harm with us using our online incident reporting form by self-reporting as “consumers.” However, anyone can be classified as a consumer even if they are also acting as a doctor, lawyer, investigator, consumer advocate, or trade complainant. Moreover, many individuals who report to us work for organizations with a public health and safety purpose and, thus may be included under the category “public safety entity.” Since most if not all of the people listed in the “Others” category can fit in the categories Congress listed, we have deleted reference to “Others” in response to the comments.

Comment 9—Some commenters state that adding “Others” is contrary to the plain meaning of the statute. The commenters argue that section 6A(b)(1)(A) of the CPSA expressly limits who may submit reports, so the Commission is acting outside its authority by adding an “Others” category.

Response—Congress listed five broad categories of submitters and we have the authority to interpret these categories. As discussed above, the term

“consumer” is quite broad, and we have consistently interpreted it in this rulemaking to include any and all consumers. This interpretation comports with our mission to protect individuals who may use or enjoy consumer products. Most of the persons and entities captured in the “Others” category are covered by the five broad categories of submitter listed in the statute. We have decided to delete the reference to “Others.”

Comment 10—Some commenters argue that section 6A(b)(2)(B) of the CPSA, which establishes the minimum requirements for reports of harm to be included in the Database, uses the phrase “at a minimum” to set a floor to which the Commission may add requirements. Because this “at a minimum” language is missing from section 6A(b)(1)(A) of the CPSA, the commenters claim that we cannot add “Others” as a category of submitters.

Response—The five categories of submitters set forth in section 6A(b)(1)(A) of the CPSA are so broad that they include most submitters, eliminating the need to state that these categories are “at a minimum.” Nevertheless, the category of “Others” will be deleted.

Comment 11—Some commenters state that adding an “Others” category contradicts existing regulations that require incident reports to be verified by those with personal or firsthand knowledge. The commenters argue that including reports from those without such knowledge would reduce the Database to a blog consisting of hearsay reports from people without personal knowledge who have a vested interest in increasing the number and severity of negative reports. The commenters state that there is no indication that Congress intended to override the Commission’s long-standing requirements for verification of information it intends to make public.

Response—Congress provided a clear indication that the requirement in section 6(b) to take reasonable steps to assure accuracy does not apply to reports of harm included in the Database. Section 6A(f)(1) of the CPSA specifically provides that the provisions of sections 6(a) and (b) of the CPSA do not apply to reports of harm. Instead, verification is required for reports of harm as described in section 6A(b)(B)(v) of the CPSA, where a person submitting a report must verify that it is “true and accurate to the best of the person’s knowledge.” This requirement is set forth in § 1102.10(d)(7) of the final rule. Moreover, Congress intended for the Database to include reports by those without “firsthand knowledge” or

“personal knowledge,” as the statute expressly allows reports of harm to be submitted by those unlikely to have personal knowledge, such as other government agencies and public safety entities. However, Congress implemented three mechanisms to help control inaccuracies: The ability of the manufacturer to comment as set forth in section 6A(c)(2)(A) of the CPSA; the ability to remove material inaccuracies as set forth in section 6A(c)(4) of the CPSA; and the disclaimer requirement provided in section 6A(b)(5) of the CPSA.

Comment 12—Some commenters state that, other than consumers, the other categories of submitters listed in sections 6A(b)(1)(A)(2) through (b)(1)(A)(5) of the CPSA have various legal obligations to accurately and objectively record and report safety incidents, injuries, and suspected child abuse as part of their professional responsibilities. The commenters claim that adding an “Others” category will increase inaccurate reports of harm being entered into the Database and will also increase the possibility of duplicative reports being entered about the same incident.

Response—Everyone who reports information to the Database, whether a consumer, governmental entity, health care professional, child care provider or public safety entity, has a legal obligation to provide accurate information and will be required to verify that they have done so. For example, attorneys are subject to numerous ethical obligations and are likely to have a legal obligation to submit a report of harm if the client directs them to do so. As another example, 18 U.S.C. 1001 makes the knowing and willful submission of a materially false, fictitious or fraudulent report to a government agency criminal. In our experience, the category of submitter is more indicative of the type of detail that can be provided about an incident, rather than the quality or veracity of the data entered. Moreover, nothing in section 6A of the CPSA dictates that the individual who enters reports of harm be someone who purchased or used a product or who has a legal responsibility to report safety incidents to another government agency. Such a limitation would not serve the purpose of the Database. For these reasons and because the categories of “consumer” and “public safety entity” include most of the persons and entities listed in the proposed rule as reporting under the “Others” category, the commenters’ concerns are unpersuasive.

With regard to duplicative reports, we note that the statutory list of submitters

allows for the submission of multiple reports of harm about the same incident because a consumer can submit a report as well as their health professional. In the Joint Explanatory Statement of the Committee of Conference on the CPSIA, the Conferees recognized the value of possible multiple reports regarding the same incident because they “could provide different relevant details and that information from those reports could be helpful to the public.” The Database system software is designed to look for potential duplicates and multiple reports and to display them to staff. Commission staff will review potential duplicate and multiple reports and “associate” them, where appropriate, so that all reports on one incident will be reflected. As explained more fully below under § 1102.10(d), we are adding one more required field: “Incident date” so that Database users are provided a date, or approximate date, of the incident. We are also clarifying the field, “Category of submitter,” by separating it from the verification requirement and displaying it in the Database as another required field so that Database users can see the category of submitter of the report of harm. We already had required this field in the NPR, but now we are separating it from the required verification. Such information should make the perspective of the submitter transparent and assist the agency in locating duplicate reports.

Comment 13—Some commenters state that adding an “Others” category of submitter is unreasonable and contrary to sound public policy. The commenters claim that the Database’s purpose is to advance public safety by better informing consumers of potential product hazards, and that Congress selected reporters who contribute to this purpose—“those who use or observe the use of the consumer product (and thus the resulting harm or risk of harm) and those who may be involved in treating or responding to the harm.” Congress chose to exclude those persons who may be commercially or financially motivated to submit reports of harm.

Response—Having decided that the five statutory categories of submitters include most of those individuals who had previously been included in the “Others” category, these persons shall be permitted to submit reports to the Database. The purpose of the Database is to provide timely access to safety-related consumer product incidents. The timeliness of the data release is a crucial aspect of the Database. Congress has expressed a public policy favoring prompt disclosure of these incidents in the interest of public safety. Indeed,

Congress would not have us refuse to publish reports of harm involving deaths and serious injuries simply because the report was submitted by the consumer’s counsel or the consumer’s survivors. Accordingly, our evaluation of what is “unreasonable and contrary to sound public policy” differs from the commenters’ evaluation. Our goal is to provide the public with timely product safety information, which would not be served by excluding valid reports of harm based on criteria that have little or nothing to do with the quality or validity of a report.

Nothing in the statute states that product safety information can come only from those who “use or observe the use” of the consumer product, and/or those who may be involved “in treating or responding” to the harm. Creating an artificial limitation that is not present in the statute would conflict with our experience in maintaining a database on the safety of consumer products. As explained above, not all submitters will personally use the consumer product or view the incident; however, that does not make their report invalid (*i.e.*, parents of minor children, relatives of victims who died or were seriously injured as a result of the incident, friends and family of elderly or disabled persons, and attorneys whose clients were killed or seriously injured may also submit reports). Persons included in the “Others” category may not have viewed the incident, but still may have a distinct, educated, and valuable understanding of the facts, either learned from the victim, or derived from investigation and analysis. Moreover, as a practical matter, the Commission cannot research every submission to the Database to determine who submitted it, whether they used or observed the use of the product, or whether they have some other bias or financial interest.

The fact that a submitter may have a professional interest in the report does not negate the truth of the report. If the Commission determines that a report is false, it will be removed or corrected. If the Commission determines that false incident reports are being filed, we will consider what legal actions to take to address the problem and proceed accordingly.

Comment 14—Some commenters say that limiting submitters to the five statutorily enumerated categories is supported by the legislative history of section 6A of the CPSA. The commenters state that the House and Senate versions of the bill were different regarding who could submit reports of harm. The Senate version originally permitted “other nongovernmental sources” to submit reports of harm for

inclusion in the Database, but this version was not incorporated into the final bill. Thus, the commenters suggest that the removal of this provision indicates the intent to exclude “Others” from submitting reports of harm.

Response—We have previously noted the breadth of the entities listed in the statute that can file a report of harm and our conclusion that the list is intended to be nonrestrictive. 75 FR at 29162. The original Senate version of the bill also stated that health care professionals include “physicians, hospitals, and coroners” and that public safety entities include “police and fire fighters.” All of these entities were removed in the final legislation. Nevertheless, we are unwilling to interpret section 6A of the CPSA as prohibiting physicians, hospitals, coroners, police, and fire fighters from submitting reports of harm. Having decided to remove the “Others” category, we conclude this comment is now moot.

Comment 15—Some commenters state that if the Commission intends to use section 6A(b)(3) of the CPSA [pertaining to additional information] to add reports of harm from “Others” to the Database, then the Commission must find that inclusion of those reports of harm are “in the public interest,” and that the reports must also meet the requirements of sections 6(a) and (b) of the CPSA. Adding an “Others” category under section 6A(b)(1)(A) of the CPSA, the commenters allege, improperly evades the requirements for including additional information under section 6A(b)(3) of the CPSA, and makes that section superfluous.

Response—We interpret section 6A(b)(3) of the CPSA to mean that, in addition to the information required to be in the Database, including reports of harm, manufacturer comments, and recall notices, any additional categories of information must be in the public interest and subject to sections 6(a) and (b) of the CPSA. This interpretation is set forth in § 1102.16, which includes other categories of information in the Database other than reports of harm, manufacturer comments, and recall notices. Our interpretation is that additional information does not refer to reports of harm because all reports of harm meeting the minimum requirements for publication already are included in the Database. Additional categories of information could include, for example, internal CPSC reports, such as in-depth investigations, and product safety assessments.

Comment 16—Some commenters state that if the Commission includes reports of harm in the Database submitted by those in the proposed “Others” category,

then the increase in such submissions will “significantly increase the costs and burdens on both the Commission and manufacturers and distributors of consumer products to review, verify, and respond to the filings.”

Response—This comment is speculative and contrary to our research and experience. We review every report of harm and send the reports to manufacturers for comment under section 6(c) of the CPSA. Thus, even if we could choose to exclude reports of harm from “Others” in the Database, we would still collect this information for our use, and would still send it to manufacturers under section 6(c) of the CPSA. Accordingly, we do not believe that the submission of reports of harm by “Others” would have significantly increased costs or burdens, and we will receive such reports from most of those submitters under one of the five enumerated categories in the statute.

Comment 17—Several commenters state that while reports of harm from those in an “Others” category may not be placed in the Database, the Commission may collect and use such reports for other hazard analysis purposes.

Response—As explained above, we believe that reports of harm submitted by most of those included in the “Others” category should be included in the Database under the five categories enumerated by the statute. We do not have the authority to exclude valid reports of harm from the Database. No valid public health and safety reason exists to exclude data that meet the minimum requirements for inclusion in the Database. Such an action would be contrary to the purpose and intent of the Database. We are focusing on the quality of the data submitted, as opposed to who submitted the report. Preserving reports of harm submitted by consumers in the “Others” category strictly for Commission use would not serve the purpose of timely providing the public with access to product safety information.

b. Proposed § 1102.10(b)—Manner of Submission

Proposed § 1102.10(b) would describe how a report of harm can be submitted for inclusion in the Database. Section 6A(b)(2)(A) of the CPSA requires that the Commission establish electronic, telephonic, and paper-based means for submitting a report of harm for inclusion in the Database. Accordingly, proposed § 1102.10(b) would describe four methods (Internet, telephone, electronic mail, and paper) for submitting reports. Proposed § 1102.10(b)(1) also would explain that submitters using the Internet will use an

electronic form specifically developed to collect the report of harm in the Database. Proposed § 1102.10(b)(2) would further explain how submissions over the telephone will be accepted. Proposed § 1102.10(b)(3) and (b)(4) would explain how the Commission will deal with email, facsimile, and written submissions. Proposed § 1102.10(b)(5) would give the Commission the flexibility to provide other means of submission if new means become available.

The proposed rule left open for the final rule the office names and contact information to use for email, facsimile, and paper submissions of reports of harm. Accordingly, § 1102.10(b) has been finalized with several additions. First, we included the appropriate office names and contact information in § 1102.10(b)(3) and (b)(4). Second, we made a grammatical correction to use the short name for the Database adopted in § 1102.6(b)(4).

c. Proposed § 1102.10(c)—Size Limits of Reports of Harm

Proposed § 1102.10(c) would impose potential size limits on reports of harm where the size of such reports of harm, including attachments, might negatively impact the technological or operational performance of the system.

No comments were received on this section, which we have finalized without change.

d. Proposed § 1102.10(d)—Minimum Requirements for Publication

Proposed § 1102.10(d)(1) through (d)(6) would describe the minimum requirements for publication of reports of harm in the Database. The proposal would identify the minimum required categories of information stated in sections 6A(b)(2)(B)(i) through (v) of the CPSA, and further elaborate on the type of information included under each category.

We received several comments generally related to the minimum requirements for publication, which resulted in no substantive changes to the final rule. On our own initiative, however, we have made a grammatical correction to the full name of the Database and added the words “Publicly Available” to the full name of the Database.

Comment 18—One commenter states that the Commission should remind submitters to only file reports of harm for incidents of which they have firsthand knowledge, and actively should discourage complaints based on hearsay.

Response—For the reasons set forth in response to Comment 8 above, we will

not restrict submissions of reports of harm for inclusion in the Database to only those who have firsthand knowledge. Reports of harm that meet the statutory minimum requirements for inclusion, and the requirements as set forth in § 1102.10(d) of the final rule, will be included in the Database.

Comment 19—Some commenters suggest that the final rule impose a time limit on when reports of harm may be included in the Database, to exclude old or stale data. Several commenters suggest a time limit of one year from the incident date, claiming that over time, data becomes inherently suspect.

Response—As a matter of statutory interpretation, we have decided to allow submitters to enter reports of harm about product related incidents regardless of when the incident occurred because Congress imposed no limitation in section 6A of the CPSA. Because many consumer products have a long use period, and many consumer products are purchased second hand or used rather than new, it is important to collect and maintain information on these products over time. Moreover, in our experience, consumers sometimes fail to submit a report of harm until after a recall is announced in the media. Regardless of the date of occurrence and the date of entry, all reports of harm must meet the minimum requirements for inclusion in the Database as set forth in section 6A of the CPSA and § 1102.10(d) of the final rule. Moreover, as set forth in response to Comment 30 below, the Commission has decided to require the incident date, or an approximate incident date, to include a report of harm in the Database. Users can determine for themselves what weight to accord an incident that is entered long after the date of occurrence. If a manufacturer or private labeler believes that the date of the incident is relevant to users of the Database, it may highlight this fact in its comment to the report of harm.

Comment 20—Several commenters note that the proposed rule does not indicate how long reports of harm and associated comments will remain in the Database. The commenters state that the final rule should impose a time limit after which information will be removed from the Database to ensure that the information remains helpful. The commenters also state that unless data has a time limit or sunset period, the Database may become overloaded with outdated information. The commenters suggest that if no recall occurs within one year of a report being entered, then the information should be removed but remain available through a FOIA request. Alternatively, the commenters

suggest that the Commission could tag information as “active reports” and “resolved reports.”

Response—Setting a time limit or expiration date for reports of harm and related comments is inconsistent with the purpose of the Database. Certain hazard patterns may not emerge from the data within a specific time limit. Many consumer products have a long use period, and many consumer products are purchased used. Accordingly, it is important to collect and maintain information on products over time.

Moreover, there is no easy way to determine across all industries and all products when data about products may lose importance. For example, durable infant products, which may be purchased used, may become the subject of incident reports years after a product was purchased or even recalled. We have several examples of children being seriously injured by products that were recalled for the defect many years before. Consumers should have access to all data that the Commission has on file when they research recalls and reports of harm made about consumer products in the Database. As for the suggestion of making information available through FOIA, we believe that such a change would be contrary to the purpose and intent of the Database and would compel us to allocate resources to respond to FOIA requests concerning data that should be made available in the Database. Finally, as set forth in § 1102.10(i) of the final rule, all reports of harm submitted to the Commission become official records of the Commission in accordance with 16 CFR § 1015.1 and will be treated in accordance with that regulation, which defines agency records for purposes of the FOIA.

Comment 21—Several commenters state that the minimum information required to submit a report of harm for inclusion in the Database in § 1102.10(d) is not detailed enough to allow those reviewing the report to understand the incident adequately, to weed out duplicate reports, and to promote investment in the report and Commission activities by the submitter. One commenter states that, without more detailed information, manufacturers will not be able to respond meaningfully to reports of harm, which will mean that the Database contains inaccurate information about their products. Thus, in cases where the incident details are insufficient to make a determination of why an event occurred, one commenter believes that the Commission should not publish the report in the Database.

Response—We decline to amend the rule as suggested by the commenters. Determining why an incident occurred can sometimes be a time-consuming process; yet section 6A of the CPSA established procedural requirements that are measured in days. Congress is requiring us to create an “incident” database of “reports of harm,” not causation determinations. Section 6A of the CPSA requires reports of harm to be posted in the Database quickly. Thus, we cannot refrain from processing or publishing reports of harm to determine why an incident occurred.

In response to comments on the proposed rule, however, we are clarifying that one additional minimum field requirement was added in the proposed rule, and has been maintained in the final rule, the “Category of submitter.” We have considered comments on this issue, as described below, and decided to display this field in the Database. Also, in response to comments, we have decided to require an additional field “Incident date” for inclusion in the Database. These two additional field requirements will assist users in distinguishing duplicate or multiple reports and in determining what, if any, weight to give a particular report of harm. Moreover, these two additional pieces of information should be readily available and typically known by submitters of a report about a consumer product. On balance, those additional requirements should not deter a submitter from entering a legitimate report of harm.

Proposed § 1102.10(d)(1), “Description of the consumer product,” would require a word or phrase sufficient to distinguish a product identified in a report of harm as a consumer product, a component of a consumer product, or a product or substance regulated by the Commission. This description could include the name (including the brand name) of the product. Other information, such as where the product was purchased, price paid, model, serial number, date of manufacture (if known), date code, or retailer, is identified as information that would be helpful to the description of a consumer product, but not required.

We received several comments about this section of the proposed rule, and for clarity we have finalized the rule with grammatical changes to reflect the original intent of the provision that certain information in the description of the consumer product will be optional.

Comment 22—Some commenters state that the proposed rule does not require a product name, model number, manufacture date, date code, date of purchase, or other descriptive

information about a product. The commenters assert that the statute requires that the Database be searchable by date, product description, model name, and manufacturer’s name to the extent practicable; therefore, at a minimum, a report of harm must contain a model number and a product name. Some commenters state that poor product identification will make it impossible for a manufacturer to comment, and that requiring that the information be included will make the Database more useful and less misleading.

Response—We agree that the more information included about a product, the easier it will be for the Commission and Database users to identify the product. Accordingly, the Database will prompt submitters for additional information about the product at issue, including, for example, product brand, model number, serial number, and date of manufacture. We encourage submitters to enter additional, helpful information for product identification in their reports of harm; however, we will not require submitters to provide all of the information suggested by the commenters. We have amended § 1102.10(d)(1) to reflect this position. Requiring too much detail about a product may deter individuals from submitting reports. In addition, we note that section 6A(b)(2)(B)(i) of the CPSA states that reports that provide a “description of the consumer product” meet the statutory minimum for product identification. We will review each report of harm to ensure that a consumer product over which the Commission has jurisdiction is identified. Section 1102.10(d)(1) states that “the description of the consumer product must, at a minimum, include a word or phrase sufficient to distinguish the product as a consumer product, a component part of a consumer product, or a product or substance regulated by the Commission.” Thus, if we cannot identify a consumer product over which we have jurisdiction based on information in the report of harm, then the report will not meet the minimum requirements for publication.

As for the commenters’ argument regarding the searchability of the Database, section 6A(b)(4) of the CPSA does not set forth minimum field requirements; rather it describes how users must be able to access data that already exists within the Database. In addition, section 6A(b)(4) of the CPSA requires that the Commission “categorize the information available in the Database in a manner consistent with the public interest and in such manner as it determines to facilitate

easy use by consumers and shall ensure, *to the extent practicable*, that the Database is *sortable and accessible* by * * * (B) the name of the consumer product * * *; [and] (C) the model name * * *.” (emphasis added). We interpret this language to mean that when a report of harm contains information such as a model number, it should be “sortable and accessible” by such information. Thus, if a report of harm contains a model name or number, users will be able to search and sort based on this information.

Comment 23—Some commenters state that the description of a consumer product should be detailed enough so that the CPSC, the manufacturer, and a user of the Database will be able to identify the product.

Response—We agree that a description of the consumer product should be detailed enough to identify the product. Section 1102.10(d)(1) states that “the description of the consumer product must, at a minimum, include a word or phrase sufficient to distinguish the product as a consumer product, a component part of a consumer product, or a product or substance regulated by the Commission.” Each report of harm will be reviewed before entry into the Database.

Comment 24—Some commenters ask us to clarify: (1) What information is required for a sufficient product description, and (2) how the staff will determine what the product is, and whether to post the report of harm in the Database.

Response—Section 1102.10(d)(1) establishes the minimum requirements for a description of the consumer product, and is consistent with section 6A(b)(2)(B)(i) of the CPSA, which simply requires that the report of harm contain “a description of the consumer product (or other product or substance regulated by the Commission) * * *.” We will review each report of harm before entry into the Database. If we cannot distinguish the item described in a report of harm as a consumer product within the Commission’s jurisdiction, then the report of harm will not satisfy the minimum requirements for inclusion in the Database.

Comment 25—Several commenters state that a product UPC Code should be required for entry into the Database. Another commenter suggested using Global Trade Item Numbers.

Response—We are interested in refining the ability of the Database to identify consumer products using these automatic identification technologies and our information technology staff currently is evaluating automatic identification technologies for use in

future software versions of the Database. The rule is drafted broadly enough to enable such future operational change.

Proposed § 1102.10(d)(2) titled “Identity of the manufacturer or private labeler,” would describe that a report of harm must name a manufacturer or private labeler for the report to be published.

One comment related to this section of the rule was received, which resulted in no changes to the final rule. However, on our own initiative, we clarified in the second sentence of the description that additional contact information may be provided for a manufacturer or private labeler, but is not required. Accordingly, the second sentence now states: “In addition to a firm name, identification of a manufacturer or private labeler may include, but is not limited to, a mailing address, phone number, or electronic mail address.”

Comment 26—One commenter would require submitters to include traceability information in a report of harm. If the traceability information does not match to the stated importer, manufacturer, or retailer records, the name of that entity should not appear in the Database without further investigation and proof that the subject product belongs to the named firm, the commenter argued.

Response—We interpret this comment to mean that if a consumer product cannot be verified as belonging to a particular manufacturer or private labeler, then the name of such entity should not be included in the Database. Section 6A of the CPSA requires that if a report of harm meets all of the minimum requirements for publication, including identification of a manufacturer or private labeler, it must be transmitted to the manufacturer or private labeler identified. Such manufacturer or private labeler may comment on the report of harm, including identifying materially inaccurate information. If the product does not belong to the identified manufacturer or private labeler, the manufacturer or private labeler should inform us immediately, and if we are unable to determine the true identity of the manufacturer or private labeler, the report of harm will not be published in the Database.

The incident report form allows submitters to include additional details to help identify the consumer product. For example, the incident report form also asks the submitter for a description of the product (prompting for product name), brand name, model name or number, serial number, and manufacturer date code. The form also allows the submitter to upload photos or

other attachments that may help us or the manufacturer or private labeler to identify the product.

Proposed § 1102.10(d)(3) titled “Description of the harm,” would explain the requirements for describing a harm for a report of harm to be included in the Database. “Harm” as provided in section 6A(g) of the CPSA and in § 1102.6(b)(5), is an illness, injury, or death, or a risk of illness, injury, or death. The proposed rule contained a nonexclusive list of examples of the types of harm that could be included. Additionally, this section would explain that reports of harm, which relate solely to cost or quality of a product, without identifying any discernable bodily harm or risk of bodily harm, would not constitute “harm” for purposes of this part. A description of harm may include additional information, such as the severity of the injury.

We received several comments on this section of the proposed rule. We have finalized this section of the rule with corrections. We removed part of a sentence stating that the date on which the incident occurred is an example of the type of description that may be entered. We removed this language because “incident date,” or an approximation of the incident date, is now a required field, as described in response to Comment 30 below. In addition, the rule has been revised to conform to the definition of “harm” in the statute.

Comment 27—Some commenters would remove the terms “risk of bodily harm” and “risk of injury” from § 1102.10(d)(3), and anywhere else in the proposed rule, because “[t]his database must be based on concrete instances and not on issues or injuries that may (or may not) occur.”

Response—Section 6A(g) of the CPSA defines “harm” as used in this section of the statute as “(1) injury, illness, or death; or (2) *risk* of injury, illness, or death, as determined by the Commission” (emphasis added). Because Congress intended that risks of harm be included in the Database, we decline to revise the rule as suggested by the commenters. The Database is meant to help the Commission protect the public against unreasonable risks of injury associated with the use of consumer products. Submitters must describe an illness, injury, or death, or risk of illness, injury, or death on the incident report form. We will review each report of harm before publishing it in the Database to ensure that it meets the minimum requirements for publication.

Comment 28—Some commenters state that the severity of risk, meaning whether and what type of medical treatment was sought, should be a required field on a report of harm if the report of harm is to be included in the Database. The commenters argue that, without knowing the severity of the risk, the public, the Commission, or a manufacturer cannot judge the magnitude of the risk presented and, in turn, assess the appropriate response to that risk.

Response—Consistent with section 6A(b)(2)(B)(iii) of the CPSA, the final rules require the submitter to enter a description of the harm, which means the identification of a discernable illness, injury, or death, or risk of illness, injury, or death related to the use of a consumer product. While we agree that understanding whether medical treatment was sought is useful in determining the severity of a harm or risk of harm, the statute, by referring to risk of injury, illness, or death in defining “harm,” does not require injury, illness, or death to have occurred. Accordingly, we will not require specific information about whether medical treatment was sought for a report of harm to be included in the Database. The incident report form, however, will allow for entry of such information.

Comment 29—Several commenters would define an incident causing harm more explicitly in § 1102.10(d)(3) by excluding reports of harm that relate solely to the cost, quality, customer satisfaction, or warranty disputes, or those that fail to state any discernable bodily harm or risk of bodily harm. The commenters state that Commission staff should review reports of harm and exclude those that do not address a safety issue so that the Commission and industry can focus on reports containing actual or potential harm. One commenter would limit harm to include both an actual incident and an injury as set forth in 16 CFR 1117.3 (which pertains to reporting requirements for choking incidents involving marbles, small balls, latex balloons, and other small parts).

Response—The proposed rule already would exclude reports relating solely to cost or quality. We agree that a report of harm that identifies only quality or cost issues and does not identify a bodily harm or risk of bodily harm does not meet the minimum requirements for inclusion in the Database. “Harm” is defined in § 1102.6(b)(5), consistent with section 6A of the CPSA, as “injury, illness or death; or risk of injury, illness or death, as determined by the Commission.” Thus, reports of harm

containing no discernable injury, illness, or death, or risk thereof, will not meet the minimum requirements for inclusion in the Database. Therefore, § 1102.10(d)(3) continues to state that “Incident reports that relate solely to the cost or quality of a consumer product, with no discernable bodily harm or risk of bodily harm, do not constitute ‘harm’ for purposes of this part.”

We will not make the reporting requirements in 16 CFR 1117.3 for choking incidents involving marbles, small balls, latex balloons, and other small parts applicable to reports of harm for inclusion in the Database. Section 1117.3 creates a reporting requirement for firms that become aware of both an incident and, as a result of the incident, that a child died, suffered a serious injury, ceased breathing for any length of time, or was treated by a medical professional. In contrast, section 6A of the CPSA, through the definition of “harm” in section 6A(g) of the CPSA, covers a broader range of adverse events. The statute goes beyond “injury, illness, or death” (terms that would seem to encompass the events in § 1117.3) by adding “risk of injury, illness, or death * * *.” Thus, imposing the reporting requirement in § 1117.3 onto § 1102.10(d) would be inconsistent with section 6A of the CPSA.

Comment 30—Several commenters would make the date of the incident a required field to help develop a response, minimize duplication, and reduce the likelihood of counterfeit reports being added to the database. For the same reasons, some commenters also would require the location of the incident to be noted. The commenters state that the burden on submitters is low, while manufacturers have only 10 days to respond. Accordingly, the commenters assert that requiring this information will help screen out duplicate reports.

Response—We agree that requiring the date of the incident or the approximate date of an incident to be included will help in associating reports of harm submitted concerning the same incident, without deterring submission of reports. The incident date, or an approximation, should be information that is readily known and, on balance, likely will be helpful to the Commission, Database users, and those who investigate incidents. For example, the incident date will help us locate and associate multiple reports of harm submitted about the same incident. Reports of harm submitted by different persons about the same incident will not be deleted, but will be associated so that Database users can discern that only one incident occurred, for

example, as opposed to two or three if several reports are filed concerning the same incident. Gathering information from different sources may assist the Commission and other users in understanding the nature of the incident, the product involved, and any injuries sustained. Additionally, because we will not restrict reports of harm to recent incidents, the ability to display both an incident date and the report filing date will help users assess that report. Accordingly, we have revised § 1102.10(d)(4) to require an “Incident date,” or an approximation, to be entered to display a report of harm in the Database.

As for the location of the incident, the form allows, but does not require, submitters to enter the location of the incident. Information regarding the location of the incident is not critical to product or hazard identification. Nevertheless, because the incident date and incident location fields are located adjacently on the form, we anticipate that submitters will be sufficiently prompted to include such information.

Proposed § 1102.10(d)(4) titled “Contact information” would require a submitter of a report of harm to provide his or her first and last name and a mailing address for the report to be published. Submitters also may provide other contact information, such as an email address or a telephone number, but such information is not required in order to publish the report.

We received several comments on this section, which we have finalized without substantive modification. “Contact information” has been renumbered in the final rule to § 1102.10(d)(6) to accommodate the addition of “Incident date” and “Category of submitter.”

Comment 31—Several commenters address reports of harm by anonymous submitters. Some commenters state that we should not include these reports of harm in the Database. Some commenters state that we should not maintain anonymous reports for Commission use because veracity and trustworthiness are at issue and that such reports should not be used for compliance or enforcement proceedings because firms have no opportunity to investigate or refute the claims.

Response—Reports of harm submitted anonymously do not meet the minimum requirements for inclusion in the Database and will be excluded. Section 6A(b)(2)(B)(iv) of the CPSA requires that the report contain “contact information for the person submitting the report”; therefore, an anonymous report would not satisfy this statutory requirement. Although the submitter’s contact

information will not be published in the Database, it must be included for the report of harm to meet the minimum qualifications for inclusion in the Database.

As for our use of anonymous reports, the Commission has accepted incident reports submitted anonymously for many years, and we will not change this practice now. Accordingly, we will maintain anonymous reports of harm for internal use. The Commission is concerned with product safety, regardless of who submits the information to the agency, and we cannot assume that anonymous reports of harm will not contain real and significant product safety issues. While it is preferable to have contact information to enable us to follow up and investigate incident reports with greater ease, the absence of contact information does not prevent us from investigating a consumer product as long as the product is identifiable.

With regard to the use in enforcement proceedings of reports submitted anonymously, this issue involves the Commission's exercise of enforcement power and discretion and our consideration of specific facts. Such information will continue to be considered on a case-by-case basis.

Comment 32—One commenter states that when consent is given, a submitter's contact information should be provided to the manufacturer to facilitate evaluation of the complaint. This same commenter states that we should require contact information to be given to the Commission to prevent fraud.

Response—When a submitter of a report of harm gives consent, his or her name and contact information will be provided to the manufacturer or private labeler. This provision, contained in § 1102.20(a)(1), is consistent with section 6A(b)(6) of the CPSA. Anonymous reports will not meet the minimum requirements for inclusion in the Database and will be excluded. As set forth above, we will continue to accept and maintain anonymously submitted reports for our own use, and we decline to make contact information required information for submission of such reports to the Commission.

Comment 33—One commenter suggests that we require every submitter to provide a phone number, and that Commission staff affirm the legitimacy of every report filed, and verify the contact information submitted in order for a report of harm to meet the minimum requirements for publication in the Database.

Response—We decline to revise the rule as suggested by the commenter.

Section 6A(b)(5) of the CPSA and § 1102.42 direct us to provide clear and conspicuous notice to Database users that we do not guarantee the accuracy, completeness, or adequacy of the contents of the Database, and Section 6A(b)(2)(B)(v) of the CPSA and § 1102.10(d)(7) specify the form of verification required from submitters of reports of harm. No additional verification is required by the statute and would be contrary to the intent of 6A to provide prompt public release of reports of harm that otherwise meet the requirements for posting in the Database.

Comment 34—Several commenters state that the Database should encourage the release of contact information to manufacturers to enhance accuracy and product safety. One commenter states that consent to release contact information to manufacturers should be required to post a report of harm because it is the only way that manufacturers can resolve complaints and determine whether products are counterfeit. Another commenter notes that absence of contact information for the submitter is a complete bar to a manufacturer's ability to respond to a report of harm.

Response—We will transmit contact information to the manufacturer or private labeler pursuant to section 6A(b)(2)(B)(iv) of the CPSA. The statute does not permit us to disclose the name, address, or other contact information of a submitter of a report of harm without the submitter's express written consent. Neither transmission of a report of harm to a manufacturer or private labeler nor publication of a report in the Database is conditioned on a submitter agreeing to provide contact information to the manufacturer or private labeler. Consequently, we are not amending the rule to create such a requirement. We do not agree that the absence of contact information on a particular report prevents a manufacturer from commenting on a report of harm. Manufacturers may have received similar claims from other consumers. In fact, manufacturers often receive far more incident reports directly from consumers than the CPSC receives. In those cases, manufacturers and private labelers may be able to distinguish product issues more quickly than the CPSC and may be in a better position than the CPSC to respond, regardless of whether contact information is provided.

With regard to counterfeit products, neither section 6A of the CPSA nor the final rule addresses counterfeit products. We previously have conducted recalls on counterfeit

products. A product's status as counterfeit does not change the safety implications and the potential need to remove such a product from the hands of consumers. We work with manufacturers to ascertain the true manufacturer of such counterfeit products when there is an issue concerning consumer safety.

Comment 35—One commenter would require identification of the victim by name for a report of harm to appear in the Database, although the information would be provided only to the Commission and would not be published. The commenter explains that identifying the victim would allow the Commission to cross-check data and prevent duplication, especially where different people report the same incident. The victim's identification would allow the Commission to clarify which reports are about the same incident if multiple reports are submitted.

Response—Section 6A(b)(2)(B) of the CPSA does not require identification of the victim by name, and we are not revising the rule as suggested by the commenter. Although knowing the victim's name would help associate reports of harm for the same incident, we can appreciate how a submitter might consider such information to be private. For example, some parents, while eager to report an incident and to provide details about the injury sustained and the age and gender of their child, may not want to provide the child's name. Likewise, other submitters, such as health care professionals or government agencies, may want to report details about a victim's injury, age, and gender, but may not know the victim's name or may have a legal obligation to keep the victim's name confidential. To help identify and associate duplicate reports, we have decided to add "Incident date," or an approximation, as a required minimum field. Providing such information should not be burdensome because typically it would be known or could be approximated.

Comment 36—Some commenters would require the submitter of a report of harm to provide either an e-mail address or a phone number as part of the required contact information in § 1102.10(d)(4) to allow for timely contact of the submitter and verification of the report of harm. The commenters argue that, without this information, it will be impossible for manufacturers to have a meaningful chance to verify the report of harm within the required 10 business days.

Response—Section 6A(b)(6) of the CPSA does not require the Commission

to release contact information to the manufacturer or private labeler unless the submitter provides written consent to do so. Accordingly, manufacturers and private labelers are not entitled to verify the report of harm with the submitter before they submit comments or before the report of harm is posted in the Database. We recognize, however, that when a submitter does consent to release his or her contact information to the manufacturer or private labeler, having an e-mail address or a phone number is the preferred method for contacting the submitter because of the time limitations imposed by section 6A of the CPSA. Thus, when a submitter consents to releasing his or her contact information to a manufacturer or private labeler, the Database will ask, but not require, the submitter to provide an e-mail address or phone number to allow for timely follow up.

Proposed § 1102.10(d)(5), entitled “Verification,” would require submitters to verify that they have reviewed the report of harm and that the information contained in the report is true and accurate to the best of the submitters’ knowledge, information, and belief. As originally proposed, this section also required, as part of the verification process, that submitters of reports of harm indicate into what category they fit (*i.e.*, consumer, government agency, health care professional).

We received several comments related to this section. We have finalized the first two sentences without modification. We deleted the last two sentences regarding the category of submitter, as discussed below in response to Comment 40, and this section has been renumbered to 1102.10(d)(7).

Comment 37—Several commenters state that the final rule should require submitters to make an affirmation or oath regarding the truth of the information submitted in order to be included in the Database.

Response—We agree. This is already a statutory requirement, and we have required this in § 1102.10(d)(7).

Comment 38—Several commenters state that the incident report form should include a notation regarding the penalties for filing a false report to ensure that accurate information is submitted. The commenters say that the Commission should take an aggressive stance to discourage malicious and false information from being submitted and pursue enforcement actions, including seeking monetary penalties.

Response—If we receive false reports, we will take all appropriate actions available to remove materially inaccurate information from the

Database and seek appropriate legal remedies against those involved. We have declined to add a reference about penalties because we agree with some of our public hearing participants who indicated that such a statement could chill or intimidate a submitter from filing a legitimate report. We reviewed other agency databases like Safercar.gov and noted that no such statement exists on their incident reporting forms. Therefore, we determined that to make the Database user friendly to all submitters of reports of harm, we would not include the notation.

Comment 39—Several commenters state that a report to Congress, which included a mock up of the incident report form, displayed a static, noncheckable verification of the report of harm. These commenters assert that the Database should require consumers to make an attestation by clicking on a button in the online incident report form. One commenter states that submitters should be able to “opt in” to submitting their contact information to the manufacturer or private labeler, and that, if they do not agree to provide the information, then we should collect statistical information on the reasons for refusal.

Response—We agree that submitters should be required to affirmatively check a box for verification of the report of harm. However, the commenters appear to have been examining an early mockup of Database screens that were meant solely as an illustration and not an actual representation of the Database. Submitters of reports of harm will, in fact, be required to select or check a box to identify that they are verifying the report of harm in the online incident report form. Submitters will also be able to affirmatively select, or “opt in,” to send their contact information to the manufacturer. If such an option is not selected, however, we will not collect statistical information on the reasons for refusal. Congress gave submitters the option of whether to provide their contact information to manufacturers and private labelers, and we believe it would be an unproductive use of CPSC resources to collect data on a submitter’s reasons for refusing to submit their contact information to manufacturers and private labelers.

Comment 40—One commenter would require the category of person submitting the report of harm for a report to be included in the Database. The commenter states that such information would provide context for database users who may place different weight on the report based on this information. The commenter adds that it is important to distinguish multiple

reports of harm submitted on the same incident and to see the value and insight provided by each reporter.

Response—Proposed § 1102.10(d)(5) would include the category of submitter as a minimum field requirement. Although identification of the category of submitter is required information, the proposed rule stated that the information would not be published in the Database. We agree that the category of submitter is an important piece of information to collect and display so that Database users can better understand not only who submitted the report of harm but also the relationship of the submitter to the victim. It is especially important to help users understand the submitter’s perspective when the Database may include multiple reports on the same incident. Accordingly, to clarify that “Category of submitter” is a minimum requirement for inclusion of a report of harm in the Database, we have revised the final rule to create a new § 1102.10(d)(5) titled “Category of submitter,” and the “Verification” section previously at § 1102.10(d)(5) has been renumbered as § 1102.10(d)(7). Section 1102.10(d)(5) now reads as follows: “Category of submitter. Indication of which category the submitter is in (consumer, government agency, health care professional, etc. * * *) from § 1102.10(a).” We have removed similar language from the “Verification” section.

Comment 41—One commenter would have us provide the category of submitter for a report of harm to manufacturers. The commenter notes that § 1102.10(d)(5) states that the information will be required at verification but will not be published in the Database. The commenter also claims that there is no reason or justification for depriving Database users of this information.

Response—As set forth above in response to the previous comment, the category of submitter remains a required field, and has been removed from the “Verification” section to § 1102.10(d)(5) of the final rule. For the reasons discussed above, information on the category of submitter will be transmitted to the manufacturer or private labeler, and will be displayed in the Database.

Comment 42—Some commenters suggest using e-mail verification and validation to ensure that reports of harm are not “spam” (*i.e.*, a form of e-mail where the same message is sent in large quantities to multiple parties). The commenters state that a report of harm should not be published unless the report can be validated.

Response—We considered using e-mail verification and validation

technologies, but decided not to incorporate these features because we did not want to deter submitters by creating additional steps, external to the incident report form, for them to enter a report of harm. However, we have incorporated other software design features to minimize computer-generated reports of harm, such as implementing Completely Automated Public Turing test to tell Computers and Humans Apart (“CAPTCHA”) challenge-response tests. CAPTCHA is a technology intended to enable a computer system to distinguish between humans and computers. The computer challenges the user to complete a test (such as retyping text that has been distorted); a human will be able to complete the test, but a computer would not. As new technologies become available, we will incorporate them consistent with industry and federal government best practices.

Proposed § 1102.10(d)(6) titled “Consent” would explain that the submitter of a report of harm must consent to inclusion of the report of harm in the Database for the report to be published. If no consent is provided by the submitter, then the report will not be published in the Database.

Several comments were received, resulting in no substantive changes to the final rule. We renumbered “Consent” in the final rule to § 1102.10(d)(8), to accommodate the addition of “Incident date” and “Category of submitter.”

Comment 43—One commenter suggests that, on the incident report form, the language related to consents be consistent and suggests using “May we” for the consent to provide contact information to manufacturers as well as the consent to include the report of harm in the Database. The commenter states that this language may encourage consumers to provide contact information to manufacturers to enhance consumer safety and would allow for proper investigation of the complaint.

Response—The commenter is focusing on language contained on a draft of the incident report form rather than language in the proposed rule itself. We agree that it would be appropriate to make the language consistent for the consents collected from submitters of reports of harm; therefore, we have changed the language on the incident report form so that both of the consents collected begin with “May we.”

Comment 44—One commenter states that the term “verification” implies a level of CPSC validation of reports of harm that is unlikely to exist and that is in contrast to the disclaimer. The

commenter suggests using the term “self-verification.”

Response—Section 6A(b)(2)(B)(v) of the CPSA uses the term “verification” to explain that the submitter must state that the information is true and accurate to the best of the person’s knowledge. One dictionary definition of “verify” is “to confirm or substantiate by oath.” See <http://www.merriam-webster.com/dictionary/verify>. Because the term is correctly applied, easy to understand, and consistent with section 6A(b)(2)(B)(v) of the CPSA, we are not amending the rule as suggested by the comment.

e. Proposed § 1102.10(e)—Additional Information Requested on a Report of Harm

Proposed § 1102.10(e), regarding “Additional information requested on a report of harm,” would describe the Commission’s ability to seek other categories of voluntary information. In the preamble to the proposed rule, we invited comment on whether additional categories should include demographic data, such as race, or additional data about the product in question, such as whether the product still contained all of its original parts, or had been altered in any way that was not in accordance with a manufacturer’s instructions.

Several comments were received related to this section, which has been finalized with a clarification as to the appropriate consent for minors.

Comment 45—One commenter states that the Commission should request, but not require, the following information on a report of harm to substantiate the claim: (1) Verification that the label instructions were followed; (2) the date on which the harm occurred; (3) a brief description of the incident, including how the product was being used, where it was being used, a description of what happened, whether other products were being used, how much product was used over time; and (4) whether the manufacturer was contacted before submitting the report of harm.

Response—We will collect more information about an incident on a report of harm than is minimally required to include the report in the Database. We will display such additional information, if consent is provided. For example, the current online incident report form asks whether the manufacturer has been contacted before filing a report of harm. We will continue to collect this information on the new reporting form. Also, as set forth in response to Comment 30, we have decided to make the incident date, or an approximate incident date, required information on a

report of harm. The detail of an incident has been, and will continue to be, important information on a report of harm. The incident report form will have space for a narrative description of the incident, with guidance on the types of information that should be included. Finally, we will not specifically ask whether label instructions were read or followed because it unnecessarily implies that the consumer may be at fault. Manufacturers must evaluate safety with respect to the intended use, as well as the reasonably foreseeable misuse of a product.

Comment 46—One commenter states that the Commission should require the submitter to retain the product for at least one year.

Response—Currently, we request, but do not require, that a submitter retain the product for at least 30 days so that a CPSC investigator can review and inspect the product, if necessary. We will continue to advise submitters on the new version of the incident report form to retain the product for at least 30 days. We do not believe that section 6A of the CPSA gives us the authority to impose product retention requirements on individuals as a condition of their submitting reports of harm to the Database.

f. Proposed § 1102.10(f)—Information Not Published

Proposed § 1102.10(f), “Information not published,” would describe the information that will not be published in the Database, including the name and contact information of the submitter of a report of harm; the victim’s name and contact information (if provided); photographs depicting a person or injury because of privacy concerns or because the Commission has determined that they are not in the public interest; medical records without the consent of the person about whom such records pertain (or that person’s parent or guardian if the person is a minor); confidential information; materially inaccurate information; reports of harm retracted by submitters who indicate in writing to the Commission that they supplied materially inaccurate information; and/or any other material submitted on or with a report of harm that the Commission determines is not in the public interest to publish. In making such a public interest determination, the Commission will consider whether the information is related to a product safety purpose served by the Database, including whether the information helps Database users to identify a consumer product; identify the manufacturer or private labeler of a

consumer product; understand the risk of harm related to the use of a consumer product; or understand the relationship between the submitter of a report of harm and the victim.

Several comments were received related to this section. We changed “materially inaccurate information” to “information determined to be materially inaccurate” to be consistent with the statute. We have also made two grammatical changes, one to (f)(7), changing it from “Submitters of reports of harm may retract reports at any time * * *” to “Reports of harm retracted at any time by the submitters of those reports,” and one to (f)(8) deleting the words “to publish.” In addition, we added language clarifying that the Commission will exclude from publication in the Database consents and verifications associated with the submission of a report of harm. This change reflects our response to comment 65 and is consistent with § 1102.12(e).

Comment 47—One commenter states that § 1102.10(f)(3) should limit photographs to pictures of whole products, solely for identification purposes. The commenter asserts that the Commission should prohibit photographs of injuries, components, or people, and states that such pictures are not in the public interest and should not be published.

Response—We agree that, for product identification purposes, photographs of the whole product are often the most useful. However, close-up photographs of the product labeling or the defect at issue may involve photographing a component part of the product. We also have jurisdiction over component parts of consumer products. Accordingly, we are not revising the rule as suggested by the commenter.

Section 1102.10(f)(3) provides that photographs that the Commission determines are not in the public interest will not be published, “including photographs that depict a person or injury or constitute an invasion of personal privacy based on the Privacy Act of 1974, Public Law 93–579 as amended.” Upon reflection, we will not and cannot, prevent submitters from uploading photographs and documents that may be helpful to the Commission in any subsequent investigation, including photographs of injuries. However, we recognize that some photographs may be inappropriate for publishing in the Database. Therefore, we will review every photograph and attachment to determine whether it is relevant to the report of harm, violates any person’s privacy, and is in the public interest to publish. Product

photographs are likely to always be found to be in the public interest to display. Photographs from which a person can be identified will not be published, unless the photograph is altered in such a way that it could not be used to identify a person. Photographs of injuries where a person cannot be identified may be published.

Thus, we changed “photographs that depict a person or injury or constitute an invasion of personal privacy” to “photographs that could be used to identify a person or photographs that would constitute an invasion of personal privacy.” This change reflects the Commission’s desire to allow photographs of injuries to be published, including those that depict or represent an image of a person, as long as the image could not be used by a Database user to determine the identity of the individual in the picture. The Commission will still exercise discretion and may decline to post a picture it determines is not in the public interest because it is too gruesome.

Comment 48—Some commenters approve of the Commission’s use of criteria under proposed § 1102.10(f)(8) when exercising discretion regarding what goes into the Database when it is in the “public interest.” The commenters state that the proposed criteria will ensure that a wide variety of information will be published.

Response—We agree and have finalized this section with one grammatical change deleting the word “determination.”

Comment 49—One commenter states that, if the Commission publishes attachments to a report of harm, the Commission should ensure that a submitter’s or a victim’s private information is not published in the Database.

Response—Consistent with § 1102.10(f), we will not publish a submitter or victim’s name or personally identifying information contained in any attachment, or any other information inconsistent with the Privacy Act of 1974, or the public interest, without the appropriate legal consents. Each attachment will be reviewed for content, and if necessary, not displayed or will be redacted before publication to exclude such information.

Comment 50—Some commenters ask whether a submitter can withdraw a report of harm.

Response—As set forth in § 1102.10(f)(7), a submitter may retract a report at any time, if he or she indicates, in writing, to the Commission that he or she supplied materially inaccurate information. The reason that we are not

permitting submitters to freely withdraw a report of harm is our concern that submitters may be subject to external pressure to withdraw reports of harm for any number of reasons, including settlement agreements with manufacturers conditioned on such withdrawal.

g. Proposed § 1102.10(g)—Reports of Harm From Persons Under the Age of 18

Proposed section 1102.10(g), entitled “Reports of harm from persons under the age of 18,” would state that the Commission will not accept reports of harm submitted by persons under the age of 18 years without the consent of the parent or guardian of that person. The rationale for requiring consent on reports by a minor is the fact that age of legal consent in many jurisdictions is 18 years old. Review of a report of harm by a parent or guardian will also ensure that information about a harm or risk of harm is being disclosed publicly with the parent’s consent, which addresses concerns related to the privacy of such information. Further, if a parent or guardian reviews the report, consent may also improve the accuracy of the information that the report contains.

Two comments were received related to this section, which has been finalized without change.

Comment 51—One commenter says that the minimum age to submit a report of harm should be 18 years old. Reports regarding injuries to minors should be submitted by a parent or guardian rather than the injured minor to ensure a degree of maturity in submitters and to increase accuracy.

Response—We agree. This requirement is already contained in § 1102.10(g). No one under 18 may submit a report of harm without a parent or guardian submitting his or her own contact information and approving the submission.

Comment 52—One commenter states that the proposed rule does not require a reporter to provide his or her age, but does restrict those under 18 from submitting a report of harm. The commenter states that, while the CPSC may intend to include this in the reporting form, age and consent are omitted from § 1102.10(d)(4).

Response—The language in § 1102.10(g) accurately reflects the intended requirement and how the information is conveyed on the reporting form. Age of the submitter of a report of harm is not, and was not intended to be, a required field. However, submitters will be prompted to certify that they are 18 years old or older. If they are not, a parent or guardian must provide a name and

complete mailing address, and submit the report of harm. A submitter cannot complete a report of harm without certifying that he or she is 18 years of age or older.

h. Proposed § 1102.10(h)—Incomplete Reports of Harm

Proposed § 1102.10(h) on “Incomplete reports of harm” would explain that information received related to a report of harm that is incomplete because it does not meet the requirements for submission or publication will be maintained for internal use.

Several comments were received related to this section, which has been finalized without modification.

Comment 53—Several commenters address incomplete reports of harm in proposed § 1102.10(h). The commenters claim that incomplete reports of harm should not be published in the Database. Some commenters suggest that consumers be able to return to incomplete reports of harm to finish them at a later date. The commenters also state that the Commission may keep incomplete reports of harm for its own use, but other commenters state that the Commission should not maintain incomplete reports of harm for its own use.

Response—The comments raised a point of clarification regarding reports of harm. An abandoned report of harm is a report that may be complete or is incomplete but is never “submitted” by the consumer by pressing the “submit” button in the online form. Abandoned reports will not be kept by the Commission. In contrast to an abandoned report, an incomplete report of harm is submitted by pressing the “submit” button in the online form. Incomplete reports of harm are considered incomplete reports because they do not meet the minimum requirements for publication in the Database, as set forth in § 1102.10(d), and therefore, will not be published in the Database. Under section 5(a)(1) of the CPSA, we have an obligation to “maintain an Injury Information Clearinghouse to collect, investigate, analyze, and disseminate injury data, and information, relating to the causes and prevention of death, injury, and illness associated with consumer products.” Because of this mandate, for many years we have maintained a database on consumer product safety incidents, including information submitted online. The incident report form for reports of harm developed for the Database, both online and paper formats, will replace the incident report form currently in use. Regardless of whether reports of harm meet all of the

requirements for submission into the Database, we will continue to maintain useful data for internal use under section 5(a)(1) of the CPSA as long as such information is submitted. A report that is not eligible for inclusion in the Database may still contain important information. For example, some reports will not meet publication requirements because the submitter failed to enter a required field. Other submitters may enter all of the substantively required fields, but the report may fail to qualify for inclusion in the Database because the submitter did not consent to publication.

Regarding the ability to save a report of harm, submitters who register a password will be able to save a report of harm, and to return to the report for up to 30 days to edit and submit it. Once the submitter presses “submit,” the report of harm is deemed officially submitted. Once the report has been submitted, we will review the report to determine whether the minimum requirements for publication have been met. Reports of harm that are not submitted within 30 days of initiating the report are considered abandoned, and will not be maintained by the Commission.

Comment 54—Some commenters ask whether we will notify a manufacturer if an incomplete report of harm is filed.

Response—Reports of harm that do not meet the minimum qualifications for publication in the Database will not be sent to the manufacturer or private labeler pursuant to section 6A of the CPSA. However, such reports of harm may be sent to the manufacturer or private labeler pursuant to section 6(c) of the CPSA. We are currently considering whether notices under section 6(c) of the CPSA will be sent to the manufacturer through the Business Portal being developed for notices under section 6A of the CPSA. Regardless of how they are transmitted, a notice of incident report under section 6(c) of the CPSA will follow the time frames in existence now, and will not be subject to the shorter time frames for notices under section 6A of the CPSA.

i. Proposed § 1102.10(i)—Official Records of the Commission

Proposed § 1102.10(i), “Official records of the Commission,” would explain that reports of harm accepted by the Commission become official records of the Commission in accordance with 16 CFR 1015.1, and that alteration (or disposition) of these records can only be undertaken in accordance with the procedures specified in this Part.

No comments were received related to this section, which has been finalized

with one modification to reflect that reports “submitted to” the Commission will become official records of the Commission.

2. Proposed § 1102.12—Manufacturer Comments

Proposed § 1102.12 would identify the process for who may submit manufacturer comments in response to receiving a report of harm.

a. Proposed § 1102.12(a)—Who May Submit

Proposed § 1102.12(a) would state that manufacturers or private labelers who receive a report of harm from the CPSC may submit a comment if the report of harm identifies such manufacturer or private labeler.

We received several comments related to this section, which has been finalized without change.

Comment 55—One commenter felt that industry members, other than those specifically identified in the report of harm, should be able to submit comments on a report of harm. According to this commenter, § 1102.16 authorizes the Commission to include in the Database any additional information it determines to be in the public interest.

Response—We are not revising the proposed rule as suggested by the commenter. Section 6A(c)(1) of the CPSA contains the procedural requirements for transmission of a report of harm to a manufacturer or private labeler. Transmission is required when a report contains the minimum requirements for publication, as set forth in section 6A(b)(2)(B) and § 1102.10(d) of the final rule. If these minimum requirements are satisfied, then the statute requires the Commission, to the extent practicable, to transmit the report to the *manufacturer or private labeler identified in the report*. If the Commission transmits such report to a manufacturer or private labeler pursuant to section 6A(c)(1) of the CPSA, the manufacturer or private labeler who receives the report from the Commission may submit comments to the Commission on the information contained in such report, pursuant to section 6A(c)(2) of the CPSA (containing the procedural requirements for submitting comments in response to a report of harm). Therefore, based upon a plain reading of the statute, we believe that the procedural requirements of section 6A(c) of the CPSA, concerning both transmission and commenting, are unambiguous, and relate only to manufacturers or private labelers who are identified in a report of harm and

allowing only that manufacturer or private labeler to post a responsive comment.

Comment 56—One commenter suggests that the Database present only anonymous, aggregated information regarding the submitters, but allow the named, registered manufacturer to see the information on the submitter for follow up purposes. The commenter states that withholding submitter contact information would inhibit premature litigation by shielding submitters from general searches by unsolicited law firms, and at the same time allow submitters to seek and retain counsel at their own initiative, if necessary.

Response—We agree but for reasons other than those offered by the commenter. We believe that the statute is unambiguous in its exclusion from the Database of a submitter's contact information; therefore, we will not make a submitter's contact information publicly available in the Database. Section 6A(b)(6) of the CPSA expressly prohibits the disclosure of the name, address, or other contact information of any individual or entity that submits a report of harm to the Commission. The only exception to this is where the submitter consents, for verification purposes, to provide his or her contact information to the manufacturer or private labeler identified in the report of harm. In such a case, this information will be provided to the manufacturer or private labeler identified in the report of harm.

Comment 57—One commenter states that manufacturers and private labelers should have sufficient opportunity to comment on reports of harm in the Database. The commenter is concerned that the private labeler should have the opportunity to comment on a report of harm, regardless of whether a manufacturer identified in such report provides comments or not. Additionally, this commenter asks for additional time to comment on reports of harm.

Response—Where both a manufacturer and private labeler are identified in a report of harm, we will provide the opportunity to comment to each. Prior to publication, each entity will then have up to 10 days to provide comments on the report of harm. If we receive comments from both the manufacturer and private labeler, along with the consent to publish such comments, we will publish both comments in the Database. If transmission is made to both a manufacturer and a private labeler, yet we only receive comments from one entity, along with the consent to publish

such comments in the Database, we will publish those comments in the Database. However, we disagree that additional time to comment is necessary or even permitted under the statute, given that simultaneous transmission will be made to any identified manufacturer or private labeler in a report of harm, and the existence of unambiguous statutory timeframes for transmission of reports of harm and publication of such reports to the Database.

Comment 58—One commenter asks whether licensors would be considered private labelers and, if so, what would be the procedure for handling reports of harm relating to a consumer product with multiple licenses.

Response—We do not consider licensors to be separately addressed by the statute, so a licensor must be identified as either a private labeler or manufacturer in order to receive a report of harm for comment.

b. Proposed § 1102.12(b)—How To Submit

Proposed § 1102.12(b) would provide the mechanism by which comments would be submitted; it would be via an online Business Portal, where the manufacturer would be able to register to submit comments on a secure, nonpublic portal provided through the Commission's Database. The proposal also would allow comments to be submitted by electronic mail or regular mail directed to the Commission's Office of the Secretary.

Several comments were received related to this section, resulting in no substantive changes to the final rule. On our own initiative, we made two corrections in the final rule. We corrected an internal citation error in § 1102.12(b)(1), changing the citation from § 1102.20(e) to (f), and we updated § 1102.12(b)(2) to include an email address for the Office of the Secretary.

Comment 59—One commenter suggests that manufacturers or private labelers be allowed to designate more than one employee or representative to comment on their behalf.

Response—We have designed the Business Portal such that transmission of a report of harm will be made to the registered account user and additional recipients who can receive the notification of that transmission. Through the Business Portal, we will permit businesses to designate multiple email recipients, but allow only one account holder to submit a response. This will enable notification to more than one person per account in the event that someone is out of the office or not available; at the same time it will

ensure that duplicate or multiple reports are not received from the same manufacturer/private labeler.

Comment 60—One commenter suggests that manufacturers or private labelers be able to group common reports of harm found in the Business Portal, and provide a single response that can be tied to all of such reports of harm.

Response—The ability of a manufacturer or private labeler to group common reports of harm and provide a single response is not currently a design feature of the Database software program. However, we are currently evaluating how this may be incorporated into the technology for inclusion in a subsequent release of the software. The rule is drafted with sufficient flexibility to accommodate such a future modification without requiring revision of the rule.

C. Proposed § 1102.12(c)—What Must Be Submitted

Proposed § 1102.12(c)(1) through (c)(4) would specify that the Commission will publish a manufacturer's comments related to a report of harm if the comment specifically relates to a report of harm; contains a unique identifier assigned to the report; includes the manufacturer's verification of the truth and accuracy of its comment; includes a manufacturer's affirmative request that its comment be published; and consents to such publication. These requirements must be met for the manufacturer's comment to be published in the Database.

We received no comments on this provision. On our own initiative, however, we have finalized this section with clarifications. Section 1102.12(c) has been corrected to state that manufacturer comments will be published subject to § 1102.24 (on confidential information) and § 1102.26 (on materially inaccurate information). In addition, § 1102.12(c)(2) clarifies that every report of harm has a unique identifier that must be stated by the manufacturer or private labeler submitting a comment on a report of harm.

d. Proposed § 1102.12(d)—Information Published

Proposed § 1102.12(d) would explain that the Commission will publish a manufacturer's comments and the date such comments were submitted to the CPSC in the Database.

No comments were received on this section of the proposed rule. However, on our own initiative, we clarified that a manufacturer's comments will be published in the Database subject to

§ 1102.24 (on confidential information) and § 1102.26 (on materially inaccurate information).

e. Proposed § 1102.12(e)—Information not Published

Proposed § 1102.12(e) would explain that the Commission will not publish the actual consents and verifications obtained from the manufacturer for such publication.

We received no comments on this provision, and have finalized it without change.

3. Proposed § 1102.14—Recall Notices

Proposed § 1102.14 would state that information in a voluntary or mandatory recall notice will be made accessible and searchable to the public in the Database.

We received one comment on this section of the rule, which we have finalized without modification.

Comment 61—One commenter states that mixing recall information with incident report information may cause confusion, and that recall information must be clearly identified.

Response—Including recall information in a product search is vital to Database users, so that they can immediately see whether a product has been recalled, in addition to viewing reports of harm involving the product. Accordingly, the search display screen will clearly identify recall information. Reports also will be displayed in a manner that identifies the nature of such information. Both will be clearly distinguishable as separate items in the Database.

4. Proposed § 1102.16—Additional Information

Proposed § 1102.16 would state that in addition to reports of harm, manufacturer comments, and recall notices required to be in the Database pursuant to section 6A(b)(1) of the CPSA, the Database will include any additional information that we determine is in the public interest, consistent with the requirements of section 6(a) and (b) of the CPSA.

Several comments were received related to this section, which has been finalized without modification.

Comment 62—One commenter states that this provision does not specify who may submit the additional information that the CPSC decides to include in the Database. The commenter states that this section provides the ideal location for industry members—other than the named company or other professional organization—to comment on the incident or injury.

Response—Section 6A(b)(3) of the CPSA states that, in addition to the reports of harm received by the Commission, the Database shall include, consistent with the requirements of Section 6(a) and (b) of the CPSA, any additional information that we determine to be in the public interest. The statute does not require that manufacturers or private labelers, other than those who are identified in a report of harm, be able to submit comments on that report of harm. Therefore, we are not revising the rule as suggested by the commenter. However, where information is not contained in a report of harm, but is contained in other material that we may be reviewing for release under the FOIA, we will follow the provisions of section 6(a) and (b) of the CPSA for any proposed disclosure of such information.

Comment 63—Some commenters say that we should act expeditiously to include staff reports, research, and other relevant information in the Database pursuant to section 6A(b)(3) of the CPSA and proposed § 1102.16.

Response—The initial Database requirements are set up so that the initial Database launch will only include the statutorily required contents, including reports of harm, manufacturer comments, and recall information. This provides us with the opportunity to observe and analyze the operation of the Database, and to assess how many reports of harm are actually submitted; how many meet minimum requirements and are sent to manufacturers for comment; and how many, and in what time frame, reports are posted to the Database. Therefore, the decision to include additional information in the Database under this provision, such as staff research reports, reports of epidemiologic in-depth investigations, or any other information, will be determined based on the operational requirements of the Database, and after sections 6(a) and (b) of the CPSA have been followed. Note, however, that many Commission staff research and reports are already publicly available on the Commission's Web site at <http://www.cpsc.gov> and will continue to be available at this site.

C. Proposed Subpart C—Procedural Requirements

1. Proposed § 1102.20—Transmission of Reports of Harm to Identified Manufacturer or Private Labeler

Proposed § 1102.20 would describe the information contained in a report of harm that would and would not be transmitted to a manufacturer or private labeler.

a. Proposed § 1102.20(a)—Information Transmitted

Proposed § 1102.20(a) would state that the name and contact information of the submitter of a report of harm, photographs, and medical records will not be transmitted to the manufacturer or private labeler without consent of the submitter and any other legally responsible person (in the case of photographs and medical records).

We received several comments on this section, which resulted in no changes. However, on our own initiative, we clarified the opening sentence of this section to clearly state that manufacturers and private labelers will receive all information on a report of harm, provided that the report meets the minimum requirements for publication. We also clarified (a)(1) to indicate that written consent could be in the form of checking a box on a report of harm. We also revised the discussion of “photographs that will not be transmitted” to conform the language used to the change to 1102.10(f)(3) discussed in response to comment 47 above.

Comment 64—Some commenters ask whether manufacturers will be notified when an incomplete report of harm is filed.

Response—Although the comment does not explain the reference to incomplete reports of harm, we interpret the commenter's statement as asking whether manufacturers will be notified if an incomplete report of harm is filed. Under section 6A(b)(2) of the CPSA, we would not notify a manufacturer or private labeler if a report of harm does not contain the minimum requirements for publication as set forth in the statute and § 1102.10(d). Therefore, we would not transmit such a report to the manufacturer or private labeler for comment, nor publish such a report in the Database. However, under section 6(c) of the CPSA, the Commission has adopted a practice of notifying identified manufacturers in incident reports that it receives from submitters, based on the requirement in section 6(c) of the CPSA to “communicate to the extent practicable information as to any significant risk of injury associated with such product.” Therefore, to the extent that a specific product and manufacturer is identified in an incomplete report of harm, we will continue to follow the practice of notifying the manufacturer pursuant to section 6(c) of the CPSA. Although such information will not be published in the Database, the information will continue to be transmitted to the manufacturer for

possible comment and release under section 6(b) of the CPSA.

Comment 65—One commenter states that the consumer's consent about whether his or her contact information should be provided to the manufacturer should be displayed in the Database. The commenter says that providing such information is important, and that the absence of consent for contact information to be transmitted to the manufacturer may indicate less capability to verify the report. The commenter claims that the preamble to the proposed rule stated that this information would be displayed, but the codified text did not.

Response—We are not revising the rule as suggested by the commenter. We recognize that section 6A(b)(2)(B)(iv) of the CPSA requires a report of harm submitted for inclusion into the Database to include contact information for the person submitting the report, and that section 6A(b)(3) of the CPSA authorizes the Commission to include in the Database “any additional information it determines to be in the public interest.” However, it is difficult to see how a submitter's decision not to transmit his or her contact information to a manufacturer or private labeler could be sufficiently in the public interest to display in the Database. Submitters may have a variety of reasons for withholding their consent to transmit contact information, including simply an unwillingness to talk to the manufacturer. In any case, the submitter's refusal to consent to the transmission of his or her contact information does not necessarily reflect on the accuracy or truthfulness of the information presented in the report of harm. Given that a submitter's reasons for withholding consent may be varied, we do not see any public interest in having the Database declare whether the submitter of a report of harm consented to the transmission of his or her contact information to the manufacturer or private labeler. Thus, we have chosen not to display this information.

Absence of submitter contact information is not a bar to an investigation, but we recognize that the absence of contact information may make it more difficult for firms to investigate specific reports of harm. However, if a manufacturer or private labeler believes that such information would have been helpful, it can address that fact in a comment on the report of harm.

b. Proposed § 1102.20(b)—Limitation on Use of Contact Information

Proposed § 1102.20(b) would follow the statutory limitation in section

6A(b)(6) of the CPSA on the use of a submitter's contact information by the manufacturer or private labeler for verification only and no other purpose. Proposed § 1102.20(b)(1) through (b)(4) would explain that verification could be related to the identity of the requester; the consumer product, including name, serial or model number; the harm or risk of harm described in the report of harm; and/or a description of the incident related to the use of the consumer product.

We have finalized this provision by deleting the words “and/or” after proposed § 1102.20(b)(3); and adding a new (b)(5) Incident Date; and a new (b)(6) Category of submitter, consistent with the changes to § 1102.10(d) for minimum requirements of information contained in a report of harm; by replacing the words “is limited to” to “may include;” and making typographical changes.

Comment 66—Some commenters state that we should discourage manufacturers, retailers, distributors and their representatives from harassing or intimidating submitters of reports because the consumer will suffer harm from misuse of the contact information. The commenters claim that the Commission should set the expectation that serious consequences will occur if a manufacturer misuses such information. In contrast, another commenter states that the Commission should make the submitter's name and contact information available if requested by the manufacturer or retailer, and that contact of a consumer by a manufacturer should not be restricted once the consumer consents. Commenters argue that the language is inflexible in this sense.

Response—With regard to the comment on making a submitter's name and contact information available if requested by a manufacturer or retailer, or not restricting contact between a manufacturer and submitter after the submitter has consented to have his or her contact information sent to the manufacturer, the commenter may have misinterpreted the statute. Section 6A(b)(6) of the CPSA explicitly prohibits us from disclosing a submitter's contact information if the submitter has not consented; and, as explained immediately above, it also declares that the consumer information provided to a manufacturer may not be used or disseminated to any other party for any purpose other than verifying a report. We agree that the manufacturer can verify any information in the report of harm transmitted to them. We have revised the rule to ensure consistency with the statute. For the same reason,

however, we are not revising the rule to allow manufacturers to use the information it receives from the consumer for purposes unrelated to verifying the report (such as offering a remedy to the consumer). However, we believe that section 6A(b)(6) of the CPSA and the final rule do not prohibit a consumer from asking the manufacturer to provide a remedy.

Further, Section 6A(d) of the CPSA requires the Commission to report to Congress annually on the Database. The report must include information on the Database's operation, content, maintenance, functionality, and cost. Therefore, we intend, as part of our review of the Database's operation and functionality, to determine if a manufacturer or private labeler has treated contact information transmitted to them according to the verification parameters outlined in section 6A(b)(6) of the CPSA. Section 6A(b)(6) of the CPSA expressly states, in part, that “Consumer information provided to a manufacturer or private labeler * * * may not be used or disseminated to any other party for any purpose other than verifying a report” submitted under section 6A(b)(1)(A) of the CPSA.

c. Proposed § 1102.20(c)—Timing

Proposed § 1102.20(c) would explain the timing of the transmission of reports of harm to the manufacturer. The proposal would identify circumstances where transmission of a report of harm to the manufacturer within five business days may be impracticable. The circumstances would include: Where the identified manufacturer or private labeler is out of business with no identifiable successor; the submitter misidentified the manufacturer or private labeler; the report of harm contained inaccurate or insufficient information for identification of a manufacturer or private labeler; or when the Commission cannot locate valid contact information for a manufacturer or private labeler.

We received no comments on this provision. We have finalized this section with modification, adding a sentence to reiterate that if the Commission cannot determine the identity of the manufacturer or private labeler of a product from the report of harm, or otherwise, the report of harm will not be included in the Database. We have also made typographical changes and a grammatical correction to remove the additional “or” at the end of § 1102.20(c)(2).

d. Proposed § 1102.20(d)—Method of Transmission

Proposed § 1102.20(d) would describe a method for transmission of reports of harm to a manufacturer or private labeler based on registration by the manufacturer or private labeler in the online Business Portal. The proposal would explain that if a manufacturer or private labeler has not registered for electronic transmission, we will send reports of harm through the United States mail to its principal place of business, unless the Commission selects another equally effective method of transmission.

One comment was received related to this section, which has been finalized without substantive modification. On our own initiative, we have corrected an erroneous cross reference in this provision by changing (e) to (f), and finalized this section with that typographical change.

Comment 67—One commenter states that the final rule should allow for input and comments from licensors so that timely and accurate notification can be made to the correct product manufacturer or product labeler. The commenter explains that the proposed rule does not account for the fact that many consumer products on the market are licensed products that are manufactured by entities other than the brand owner. A licensor owns intellectual property, such as characters and logos, which it licenses for use on consumer products. The commenter states that most consumers will misidentify a licensor as a manufacturer or private labeler, noting that the brand owner is not necessarily the product manufacturer. The commenter asserts that false information will be published in the 10 day time frame when licensors are incorrectly identified and no comment regarding misidentification is made in a timely fashion.

Response—We disagree regarding the transmission of reports of harm to licensors who do not fall within the definition of a “manufacturer” or “private labeler” as set forth in the CPSA. Section 6A(c)(1) of the CPSA requires the Commission to transmit reports of harm that meet the minimum requirements for publication to “the manufacturer or private labeler identified in the report.” Under section 3(a)(11) of the CPSA, a “manufacturer” is defined as “any person who manufactures or imports a consumer product.” Section 3(a)(12)(A) of the CPSA defines a “private labeler” as “an owner of a brand or trademark on the label of a consumer product which bears a private label.” The CPSA further

clarifies that “[a] consumer product bears a private label if (i) the product (or its container) is labeled with the brand or trademark of a person other than a manufacturer of the product, (ii) the person with whose brand or trademark the product (or container) is labeled has authorized or caused the product to be so labeled, and (iii) the brand or trademark of a manufacturer of such product does not appear on such label.” Thus, a licensor who meets the definition of a manufacturer or private labeler may register with the Commission to receive notice of reports of harm. If a licensor is named by the submitter of a report of harm, and the named entity appears to be a manufacturer or private labeler, it will receive notice of a report of harm.

With regard to the “wrong” firm receiving notice of a report of harm, firms are free to make their own agreements regarding when they must inform certain business partners of reports of harm. We also encourage firms receiving notice of a report of harm that incorrectly identifies them as the responsible manufacturer or private labeler of a product to immediately inform the Commission so that we can stop the 10 day clock for publication of the report in the Database, if appropriate. Timing is critical here because if the recipient of the report of harm is not the manufacturer or private labeler, the Commission can decide not to post the report either because it is materially inaccurate or because it has determined that the report of harm is missing one of the minimum requirements for publication. Given our experience with the incident reporting system, we recognize that consumers may misidentify the product manufacturer or private labeler, and such claims of material inaccuracy generally are resolved quickly and easily if the receiving firm provides sufficient information. Firms have an incentive to immediately report errors to prevent reports of harm from being published in the Database that misidentify them as the manufacturer or private labeler.

e. Proposed § 1102.20(e)—Size Limits of Manufacturer Comments

Proposed § 1102.20(e) would state that we may, in our discretion, limit the data size of comments, including attachments, where such comments and attachments may negatively impact the technological or operational performance of the system.

No comments were received on this section, which has been finalized without modification.

f. Proposed § 1102.20(f)—Manufacturer Registrations

Proposed § 1102.20(f) would describe the process of manufacturer registration in the Business Portal and would require a manufacturer or private labeler to provide updated contact information.

Several comments were received on this section, resulting in no changes to the final rule.

Comment 68—One commenter states that we should adopt procedures to ensure and confirm that the correct manufacturer received the report of harm and actively promote registration by manufacturers. The commenter also suggests developing and adopting procedures informing unintended recipients to notify the CPSC immediately to stop the clock so that the report of harm does not get posted without a chance for the correct manufacturer to comment. The commenter notes that we should develop a procedure to verify that a manufacturer is notified and that transmitted incident reports are actually received by the manufacturer verification in the Business Portal.

Response—A manufacturer or private labeler that registers a user account with us will receive an email transmission of batched reports of harm to its registered users and will have user privileges to the Web based Business Portal where further details of the reports of harm will be accessible. Manufacturer or private labeler users will be enabled through the Business Portal to notify us if the product is not their own. Manufacturers or private labelers should notify us immediately so that we may determine disposition of the report of harm. Additionally, the manufacturer or private labeler may invoke the provisions governing materially inaccurate information as described in § 1102.26. We cannot identify any procedure that would ensure that the correct manufacturer or private labeler received notice of a report of harm when we use an electronic transmission of such report. Support of email received or read notification depends on the email client¹ used by the manufacturer or private labeler. Many popular email clients do not support this feature. There are security and permission considerations even for email clients that do support this feature. Therefore, it is currently not feasible to develop a meaningful validation procedure for manufacturer or private labeler receipt verification for electronically

¹ An e-mail client is software used to manage a user's e-mail.

transmitted notifications of a report of harm.

Comment 69—One commenter asks whether a foreign corporation can register in the Business Portal or whether registration would be limited to domestic entities only.

Response—We encourage registration by foreign manufacturers and private labelers of consumer products. The statute does not contain any restrictions related to the incorporation status of a manufacturer or private labeler. Registration by foreign manufacturers and private labelers will facilitate communication of potentially important product safety information to the entity with the most knowledge about the product identified in a particular report of harm. The transmission of reports of harm to foreign manufacturers and private labelers, combined with the resulting opportunity to comment, including the opportunity to make a claim of inaccurate information in a report of harm, will also contribute to the accuracy of the information in the Database.

g. Proposed § 1102.20(g)—Manufacturer Comments Received After One Year

Proposed § 1102.20(g) would address manufacturer comments received after one year, and would explain that a manufacturer or private labeler may comment on information received about a report of harm. The proposal would allow the Commission not to publish a manufacturer's comment that is received more than one year after transmission of the report of harm to the manufacturer or private labeler where it would not be in the public interest to do so.

We received one comment on this section, resulting in a change to the final rule deleting the phrase “received after one year” from the section heading and deleting the words “if such comment is received more than one year after transmission of the report of harm to the manufacturer or private labeler.”

Comment 70—One commenter states that comments should be posted to the Database regardless of when we receive them. The commenter states that the proposed rule contains no explanation or justification for a one year time limit on comment submissions, and argues that the statute requires publication, without such a time limitation. The commenter adds that many reasons for a delay exist, including, for example, where an incident is reported and the submitter files a lawsuit much later, but within a two year statute of limitations. During such litigation, a manufacturer will gain many facts during the discovery period relating to the

underlying incident report. The commenter states that there should be no limitation for submission of such information. Also, allowing rejection of comments after one year under an amorphous “public interest” standard will lead to arbitrary decisions and be contrary to the statute, the commenter asserts.

Response—While there was no intention to create the appearance of a per se one year limitation on the submission of manufacturer and private labeler comments in the proposed rule, we recognize that many people may have reasonably interpreted the proposed rule this way. Further, we agree with the commenter that manufacturer comments relating to a report of harm can provide helpful information to consumers, no matter when they are received and published. Accordingly, we have removed any language that suggests the Commission would not post manufacturer comments based upon the submission date of the comment. Nevertheless, the Commission strongly encourages manufacturers and private labelers to submit timely comments. The Commission reserves the right to determine whether it is in the public interest to publish a manufacturer comment. For example, it may not be in the public interest for the Commission to publish comments that, in the unlikely event, contain language reasonably described as lewd, lascivious, or obscene. We added language to this effect in the final rule.

2. Proposed § 1102.24—Designation of Confidential Information

Proposed § 1102.24 would address “confidential information” and would set forth criteria that must be followed to assert a claim of confidentiality. The proposed rule would define when claims should be submitted, the affirmative statements required to assist the Commission in an evaluation of the merits of the request, and the procedure we will follow for determining whether the information claimed is or is not confidential.

a. Proposed § 1102.24(a)—“Confidential Information” Defined

Proposed § 1102.24(a) would interpret “confidential information” in a manner similar to its meaning in section 6(a) of the CPSA to be information that contains or relates to a trade secret or other matter referred to in 18 U.S.C. 1905, or that is subject to 5 U.S.C. 552(b)(4).

We received one comment on this section, which we have finalized without change.

Comment 71—One commenter cautions about manufacturers and others being overbroad with claims of confidentiality in order to avoid public sharing of safety hazards.

Response—We must redact those portions of a report of harm that contain confidential information as described under section 6A(c) of the CPSA and § 1102.24. Most information submitted in a report of harm is not likely to contain confidential information because the submitter is likely to be someone who is not in a confidential relationship with the manufacturer or private labeler, or otherwise in a position to obtain confidential information. Therefore, broad claims of confidentiality are unlikely. However, for those claims on those portions of information that are confidential, we will follow section 6A(c)(2)(C) of the CPSA, redact the portion of the report that is confidential, notify the manufacturer, and follow the statutory and regulatory requirements for publication of the remainder of the report. If a claim does not meet the standard for confidential information, we will notify the claimant of the determination that the information is not confidential, and follow the procedures for publication in the Database. Finally, any manufacturer that makes a claim of confidentiality must be willing to assist in the defense of such claim and this should also inhibit overuse of confidentiality claims not made in good faith.

b. Proposed § 1102.24(b)—Designation of Confidential Information

Proposed § 1102.24(b) would state that a manufacturer may designate portions of information contained in a report of harm as confidential and would describe, at paragraphs (b)(1) through (b)(6), the statements required to support the claim of confidential information.

We received one comment on this provision, which resulted in a change to the final rule. In addition, we have made typographical changes.

Comment 72A—One commenter noted that because the contact information of a submitter of a report of harm is not required to be disclosed to the manufacturer/private labeler, it may be impossible for the manufacturer/private labeler to meet the requirement of § 1102.24(b)(4) that requires, as part of the designation of confidential information, the manufacturer to identify its relationship to the victim and/or submitter of the report of harm.

Response—We agree with the commenter and have accordingly changed this provision to state that this

information is required to the extent it is known to the manufacturer/private labeler.

c. Proposed § 1102.24(c)—Manner of Submission

Proposed § 1102.24(c) would describe the manner of submission where confidentiality is asserted for a designated portion of a report of harm. The proposal would allow submission of confidentiality assertions in the same manner as manufacturer comments described in § 1102.12(b) and would require such requests to be conspicuously marked.

We received no comments on this provision, and have finalized it without change.

d. Proposed § 1102.24(d)—Timing

Proposed § 1102.24(d) would explain that a request for confidential treatment must be received in a timely manner. If the request was received in a timely manner, the Commission may, in its discretion, withhold the report of harm from publication in the Database until it makes a determination regarding confidential treatment.

We received several comments on this section and have clarified Commission policy regarding the treatment of a request for a designation of confidential information.

Comment 72B—Several commenters address the timing of a determination of a claim of confidential information in a report of harm. One commenter states that confidentiality claims should be permitted only up until the day the report is published in the Database. Another commenter states that reports identified as confidential should remain in the Database while we review such a claim. Another commenter states that we must make a determination of confidential information before posting because most reports will not contain confidential commercial data and, because of the support necessary to sustain a confidentiality claim, manufacturers are unlikely to abuse confidentiality claims. Another commenter suggests that we set a time limit to determine whether information is confidential. One commenter states that we should carefully manage confidential business information in the Database by providing additional guidance on the interaction between section 6 of the CPSA and confidentiality determinations; the commenter says we should consider options, such as coded identifiers and devices, to provide confidential business information. Other commenters state that protection of confidential information is paramount

and is protected under section 6(a) of the CPSA. Some commenters add that release of confidential commercial information is a violation of 18 U.S.C. § 1905 and can cause serious competitive harm.

Response—The final rule, at § 1102.24(b), sets forth the process by which a manufacturer or private labeler identified in a report of harm and who receives a report of harm may: (1) Review the report for confidential information; and (2) ask that we designate portions of the report as confidential information. Section 1102.24(b) also describes the information that must accompany the submission of a claim of confidential information and, as stated in the preamble to the proposed rule (75 FR at 29160), the criteria are similar to the requirements for submission of confidential information under section 6(a) of the CPSA. Section 6A(c) of the CPSA requires the Commission to redact portions of reports of harm where such portions are claimed as confidential, if such information meets the criteria for confidential information under 18 U.S.C. 1905 or is subject to Exemption 4 under 5 U.S.C. 552(b)(4). This process is similar to the practice we currently follow for determination of confidential information under section 6(a) of the CPSA. The operational design of the Database Business Portal will allow manufacturers to provide designations of confidential information to be submitted over a secure portal, and will allow manufacturers to provide comments through a secure portal. Therefore, additional coded identifiers would not be necessary. The Commission anticipates that it will be able to resolve most, if not all, confidentiality determinations within 10 days of transmitting the report to the manufacturer or private labeler, so long as designations of confidentiality have been raised in a timely manner. Further, as discussed in response to comment 73 below, the Commission's experience suggests that it is exceedingly rare that a report of harm will contain confidential or trade secret information. If for whatever reason we are unable to make a confidentiality determination in the time frame specified in the statute, we will redact the alleged confidential information until such a determination is made. The rule specifies that the burden of proof concerning confidential information is on the manufacturer or private labeler. However, because we will, as a matter of policy, redact the alleged confidential information before publication, information that is claimed as confidential cannot be displayed, as

one commenter suggested, during this time period when the Commission is assessing whether the information meets the standard for confidentiality.

Comment 73—Some commenters would have us withhold publication of manufacturer requests for confidential treatment until we have made a determination and set a time limit for resolution.

Response—If we receive a request for confidential treatment, we will review it and withhold the information if it meets the interpretation of confidential information. We will follow already established procedures for such a review, as well as rely on our long history in reviewing such information. We also will follow the procedure specified in section 6A(c)(1)(C) of the CPSA for treatment of information we deem not confidential, and for notifying the manufacturer or private labeler of that determination. Section 6A(c)(1)(C) directs us to notify the manufacturer and include the information in the Database. The manufacturer may seek action in U.S. District Court for removal of such information from the Database. With regard to designations of confidential information, we already have procedures for determining claims of confidentiality under section 6(a) of the CPSA, and thus, few, if any, manufacturers and private labelers have contested our determinations. Because we already have a process for the determination of confidential information and have substantial experience in making such determinations pursuant to section 6(a) of the CPSA, and because it is unlikely that reports of harm will contain confidential information, we have not added additional requirements related to designations of confidential information to the final rule. We expect that confidentiality claims that are timely submitted to the CPSC will be reviewed, and a determination will be made, before the report of harm is posted.

e. Proposed § 1102.24(e)—Assistance With Defense

Proposed § 1102.24(e) would explain that a request for confidentiality should be made only by those who intend, in good faith, and so certify in writing, to assist in the defense of confidentiality by the Commission in any later judicial proceeding that could be sought to compel disclosure.

We received no comments on this provision, and have finalized it without change.

f. Proposed § 1102.24(f)—Commission Determination of Confidentiality

Proposed § 1102.24(f) would describe the procedure for notifying the manufacturer or private labeler of a determination of a confidentiality designation. Proposed § 1102.24(f) would state that if a portion of a report is deemed confidential, the Commission will notify the manufacturer or private labeler, redact the information deemed confidential, and publish the report of harm as redacted in the Database.

One comment was received regarding this section. Typographical changes to the final rule were made.

Comment 74—One commenter states that records flagged as confidential should remain in the Database during the CPSC review period.

Response—Any request that we receive designating a portion of a report of harm as confidential will be reviewed in accordance with the relevant case law, and we will make a determination. If the comment is received in a timely manner and is substantiated, we will make the determination before the information is posted in the Database. As stated in response to Comment 72, in the unlikely event that we are unable to make a determination in the time frame specified, we will redact the alleged confidential information while we continue to make a determination.

g. Proposed § 1102.24(g)—Commission Determination of No Confidentiality

Proposed § 1102.24(g) would state that, if a portion of a report is not deemed confidential, the Commission will notify the manufacturer or private labeler of the Commission's determination and will publish the report of harm in the Database.

No comments were received on this section of the rule. We have finalized with typographical changes.

h. Proposed § 1102.24(h)—Removal of Confidential Information

Proposed § 1102.24(h) would explain that a manufacturer or private labeler may sue in the appropriate U.S. District Court to seek removal of alleged confidential information published in the Database.

No comments were received on this section of the proposed rule, and we have finalized it without change.

3. Proposed § 1102.26—Designation of Materially Inaccurate Information

Proposed § 1102.26 would contain the definitions and procedures for how claims of materially inaccurate information in reports of harm and manufacturer comments can be asserted and how we will evaluate such claims.

We have changed the heading of this section to “Determination of Materially Inaccurate Information.”

a. Proposed § 1102.26(a)—Definition of Materially Inaccurate Information

Proposed § 1102.26(a)(1) would define “materially inaccurate information in a report of harm” as information that is false or misleading in a significant and relevant way that creates or has the potential to create a substantially erroneous or substantially mistaken belief about information in a report of harm. We linked the “substantially erroneous or substantially mistaken” element to required information in the report of harm.

Several comments were received on the definition of materially inaccurate information. In response to the comments and to clarify our definition, we have revised the definition consistent with the Commission's original intent. In addition, on our own initiative, we have revised the list of fields that may contain materially inaccurate information in § 1102.26(a)(1) to include the required field, “Incident date.” In addition, we have made typographical changes.

Proposed § 1102.26(a)(2) would define “materially inaccurate information in a manufacturer comment” as information that is false or misleading in a significant and relevant way that creates or has the potential to create a substantially erroneous or substantially mistaken belief about information in a manufacturer's comment. We linked the “substantially erroneous or substantially mistaken belief” element in a manufacturer comment to specific information set forth in § 1102.26(a)(2)(i) through (v), all of which relate to information about the product, any Commission investigation, the identification of a responsible party, and any corrective action or other action taken by the manufacturer or private labeler of the product.

Several comments were received on the definition of materially inaccurate information, resulting in some changes to the final rule as described below. In addition, we identified the description of the product as information upon which a claim of material inaccuracy could be made. We have also made typographical changes.

Comment 75—Some commenters support the proposed definition of materially inaccurate information and state that it appears to cover material information only and not superficial or nonsubstantive errors. In contrast, a commenter criticizes the definition of materially inaccurate information as setting too high a standard and states

that we should adopt a standard of reasonableness instead. The commenter points to the standard in U.S. Securities and Exchange Commission (“SEC”) cases on misrepresentation and claims that the SEC standard focuses on whether the misrepresentation misled a reasonable investor.

Response—A definition of materially inaccurate information was proposed to explain what we view to be material and indicate that we were setting a high bar as we did not want to waste resources disputing nonsubstantive errors in Database entries. *Black's Law Dictionary* defines “material” as “important” and a representation “relating to a matter which is so substantial and important as to influence a party to whom the representation is made” and “of such a nature that knowledge of the item would affect a person's decision making in a significant way.” In response to this comment, we are revising the definitions of materially inaccurate information in a report of harm and a manufacturer comment to read “information that is false or misleading, and which is so substantial and important as to affect a reasonable consumer's decision making about the product.” This incorporates the concepts outlined in the proposed definition, follows the *Black's Law Dictionary* meaning of “material,” and captures the commenter's concern about “reasonableness” by indicating that something is material if a reasonable consumer using the Database might be affected by the false or misleading information.

Comment 76—Several commenters object to the particular phrases used in the definition. Two commenters claim that “preconditions” in the proposed definition create the potential to cause confusion and inappropriate limitations on what can be claimed to be materially inaccurate from a report. These commenters allege that we just want to publish reports of harm and manufacturer comments side by side, and they argue that this is insufficient to avoid reputational harm. The commenters state that manufacturers have a right not to have inaccurate information in a government-sanctioned Database. The commenters say that preconditions create an inappropriate limitation on what can be claimed to be materially inaccurate from a report of harm.

Response—We agree that the Database should strive for accuracy. However, we note that Congress also required a disclaimer to be placed on the Database, understanding that we would receive information that would present challenges in terms of content and/or

descriptions of products. The proposed definition of materially inaccurate information was designed not only to ensure that information that is inaccurate and material could be claimed and not published, but also to ensure that information that was inaccurate, but not material (such as a non-substantive mistake in a report of harm), still would be subject to manufacturer comment and later publication in the Database. For example, if a report of harm contains a misspelling of the product brand name, we would not consider this error as materially inaccurate. If, however, it is claimed that the report of harm misidentifies the product or the manufacturer, we would consider such errors to be possible evidence of material inaccuracy. We are cognizant of the issues concerning harm to reputation and will review claims of material inaccuracy with such concerns in mind.

Comment 77—One commenter would have the definition relate to the key elements required in the report of harm, and states that the definition was correct to the extent that it would define information as materially inaccurate if it is false or misleading in a significant and relevant way. The commenter would simplify the definition to “information that is false or misleading in a significant and relevant way.” Other commenters claim that the definition contains redundant words. The commenters state that the phrase “create or have the potential to create a substantially erroneous or substantially mistaken belief in a Database user” is redundant as compared to “false or misleading in a significant and relevant way.” The commenters would remove the allegedly redundant text, and claim it adds no value, and potentially creates room for argument and subjective interpretation of what a Database user may or may not think, especially where the CPSC is intent on limiting the scope of comments on reports of harm.

Response—We adopted the referenced descriptive words and phrases in the definition to give context to evaluating the information and to provide additional guidance to submitters of reports of harm, manufacturers, and Database users as to what we mean by “materially inaccurate.” We view the referenced words as descriptive and not redundant. They emphasize that the bar for determining materially inaccurate information is a high one. One aspect of the definition focuses on the information stating that it must be false or misleading. The other aspect of the definition focuses on the Database user indicating the allegedly inaccurate

information must have a potential to create a substantially erroneous or substantially mistaken belief in the Database user. We are revising the definition in response to comments but will still focus on these two aspects of materiality which we do not believe to be redundant.

Comment 78—One commenter objects to the word “substantially” in the definition as an additional, unreasonably restrictive criterion with no basis in the statute. The commenter states that the rule fails to define the word and inappropriately narrows the types of false or misleading information that would be considered materially inaccurate. The commenter states that the word “substantially” also creates an extra step that the CPSC must interpret, which will be inherently subjective and will lead to arbitrary decisions about whether to remove or correct information that is concededly false or misleading. The commenter also states that the rule contains no criteria or procedures that spell out how the Commission staff will make such determinations. The commenter states that if the CPSC leaves the word “substantially” in the rule, we should spell out how the evaluation will be made and what qualifications CPSC staff must possess to be assigned to make such determinations.

Response—Our prior use of the word “substantially” in the definition of materially inaccurate information was consistent with the statute’s requirement of materiality. “Substantial” goes to the element of materiality in a Database user’s belief. *Black’s Law Dictionary* defines “material” as “important” and a representation “relating to a matter which is so substantial and important as to influence a party to whom the representation is made” and “of such a nature that knowledge of the item would affect a person’s decision making in a ‘significant’ way.” However, our revision of the definition addresses the commenter’s concern. For example, if we receive a report with a date of incident identified, and then we receive a manufacturer comment that the product was not manufactured at the time of the date of incident, we believe that such a report, if properly substantiated, would meet the definition of materially inaccurate. With regard to staff qualifications to make such assessments regarding information contained in incident reports since the inception of the agency.

Comment 79—One commenter objects to the word “liability” in determining whether a manufacturer’s comment is

materially inaccurate. Proposed § 1102.26(a)(2)(i) would include “liability” as information that could be inaccurate in a manufacturer comment. The commenter points out that if the information were submitted under section 15 of the CPSA and § 1115.12(a), a company may deny that the information it submits reasonably supports the conclusion that its product contains a defect that could create a substantial product hazard. The commenter states that manufacturers may wish to make a similar statement in response to a report of harm to be included in the Database indicating that the report does not reasonably support the conclusion that the product contains a defect. The commenter states that proposed § 1102.26(a)(2)(i) could be construed as a statement of liability, and thus might expose the manufacturer’s comment to challenge by the submitter or some other interested party as being materially inaccurate because the product is defective. The commenter states that such a scenario would set up a “mini-litigation” in which the CPSC essentially is being asked to make a defect determination regarding the product, under the guise of making a determination regarding material inaccuracy, as opposed to appropriately conducting a preliminary investigation of the potential product hazard. The commenter contends that the Database is not the appropriate venue for the Commission to make a defect determination, and the collateral effect would be to complicate material inaccuracy determinations regarding manufacturer comments.

Response—The Commission agrees that we do not want to set up a “mini-litigation” regarding causation when we are determining claims of material inaccuracy. For this reason, we have revised the rule to delete reference to the nature, scope or cause of the harm and liability. Instead, we have indicated that manufacturers can claim material inaccuracy regarding the harm or risk of harm identified in the report.

b. Proposed § 1102.26(b)—Request for Designation of Materially Inaccurate Information

Proposed § 1102.26(b) would establish the procedure for designating materially inaccurate information. In the preamble to the proposed rule (75 FR at 29161), we asked whether this section should include a burden of proof requirement for materially inaccurate information and, if so, what would be the meaning of the term, and what standard would be imposed under it.

One comment was received, resulting in the addition of a burden of proof

requirement for claims of material inaccuracy, as set forth in response to Comment 80 below. We have made a clarification in the heading which now reads “(b) Request for determination of materially inaccurate information.”

Comment 80—One commenter states that we should impose a burden of proof requirement in § 1102.26(b), the same way we defined it for making a determination and supporting a claim of confidential information in § 1102.24(b). A requester seeking a designation of materially inaccurate information should bear the burden of proof on defining the information that is materially inaccurate and supporting the claim.

Response—We agree that we should impose a burden of proof requirement for materially inaccurate information, similar to how we request designation and support for confidential information claims. Therefore, we have revised § 1102.26(b) to state that a requester seeking removal or correction of alleged materially inaccurate information, before or after posting in the Database, bears the burden of proving that such information meets our definition of materially inaccurate information and that such requester bears the burden of supporting the claim of materially inaccurate information with documentation or other information showing that the information meets the requirement.

c. Proposed § 1102.26(c)—Manner of Submission—Length of Request and Expedited Review

Proposed § 1102.26(c) would explain the manner of submission for manufacturers and private labelers and all other requesters. The proposal also would address the length of the request and would allow for expedited review of requests that are no more than five pages in length, including attachments. This provision also would state that, regardless of the length, all submissions would be reviewed.

We received several comments on this section, which resulted in no changes to the final rule.

Comment 81—One commenter suggests that the expedited review proposal is inherently flawed and that we should rethink this proposal. Sections 1102.26(c) and 1102.26(i)(2) of the proposed rule provide manufacturers and private labelers with a short, 10-business-day time frame to allege a material inaccuracy, meet the burden of proof, and comply with the lengthy evidentiary requirement. Companies must decide whether to provide: (a) Sufficient evidence, which may be greater than five pages, and risk

that the inaccurate report of harm be posted before review by the Commission staff, or (b) a shortened version of the evidence, which meets the five pages or less requirement, and then have the report of harm reviewed and posted to the Database because of insufficient evidence of material inaccuracy.

Response—The provision for expedited review is based on the statutory time frames in section 6A(c)(3) of the CPSA, where we must publish the reports of harm not later than the tenth business day after transmission of such report to the manufacturer or private labeler. A determination of material inaccuracy is tied to the substance of the claim and should be capable of expression in five pages. Our experience in reviewing comments submitted under section 6(b) of the CPSA is that manufacturers often repeat comments and arguments; this repetition adds to the length, but not necessarily to the substance, of an argument. We emphasize that we will accept any length of submission, but that it may be more difficult to make the required determinations in the time allotted if the length and content are voluminous. The expedited review procedure is designed to give manufacturers a process for responding quickly and in a way that will allow us to evaluate their claims more quickly. Therefore, we are not revising this provision.

Comment 82—One commenter states that we should provide for an expedited claim review within the 10 day period before publication of the report of harm in the Database. Another commenter states that an expedited review gives the CPSC no deadlines to complete such a review, and that such a completion time should be provided. The commenters state that the expedited review provision does not ensure that claims of material inaccuracy will be resolved before the report is published in the Database. Another commenter states that a five page limit for expedited review is unreasonably restrictive adding that we did not provide any time period for investigating or resolving a claim. Another commenter would revise the rule so that, where a manufacturer limits a claim to 10 pages, including attachments, and submits the request within five days of receiving the report of harm, the CPSC would render a decision within five days, before the report of harm is posted in the Database. Another commenter urges us to implement specific procedures for handling expedited claims of material inaccuracy to resolve them within one to three business days before publication, and says we should

prioritize resolution of these claims quickly and fairly.

Response—We will try to decide claims of material inaccuracy as expeditiously as possible, but it would be impractical to revise the rule to impose specific time frames on our decision making process. The number of claims of material inaccuracy and the possibility of other priorities that demand our attention may affect the timing of our decisions. We will use our best efforts to review submissions and make determinations within the 10-business-day time frame, when submissions are received timely. But if no determination is made by the tenth business day, we must post the report of harm in the Database pursuant to section 6A(c)(3)(A) of the CPSA. Once a report of harm has been posted in the Database, we will follow the procedures set forth in section 6A(c)(4)(B) of the CPSA, and § 1102.26(h), for removing any material inaccuracies after such a determination is made.

Comment 83—One commenter states that proposed § 1102.26(c)(3) would allow any person to challenge a comment as materially inaccurate, including many persons who have no relationship to the alleged incident, such as class action attorneys, competitors, and others who might have an inappropriate motive to claim materially inaccurate information. The commenter states that the Commission would be creating a “free for all” atmosphere by encouraging such people to collaterally battle about issues using the CPSC’s Database. The commenter states that the proposal would have the CPSC serve as referee. The commenter states that the value of inviting such comments is extraordinarily low; therefore, the commenter would have us delete the provision.

Response—Nothing in the statutory text allows us to limit who may submit a claim of material inaccuracy. Accordingly, we will consider any claim of material inaccuracy as long as it meets the minimum requirements for submission of a claim and is appropriately supported.

d. Proposed § 1102.26(d)—Timing of Submission

Proposed § 1102.26(d) would address the timing of a request for a determination of materially inaccurate information and state that, if a request was received prior to publication, we may withhold the report of harm from publication in the Database until we make a determination. Absent such a determination, the report of harm would publish on the tenth business day after

we transmitted the report to the manufacturer or private labeler.

We received several comments regarding this section, which resulted in a clarification of the final rule. The section previously stated that the Commission “may withhold a report of harm from publication in the Database until it makes a determination” and will now read that the Commission “cannot withhold a report of harm from publication in the Database until it makes a determination.” The word “generally” has also been deleted from the next line.

Comment 84—Several commenters note that we did not impose any time frame by which our determinations had to be made, and that the statute gives us seven days to post the determination in the Database after we have concluded our investigation. Some commenters state that, without a time frame reference, the determination could take forever, so we should either set a deadline for determination, or delay the posting of reports of harm that are challenged until a determination is made. The commenters also note that the need for an expedited determination would be removed if we make a determination before posting, or adopt a time limit. Other commenters assert that we should clarify both the requirement for challenging a report as false or inaccurate within the response window and the process for filing such challenges if relevant information becomes available beyond the response time. Another commenter says that any report undergoing a material inaccuracy review after publication should be identified or marked in the Database so that users will be aware that the report is undergoing such a review. Other commenters suggest that we identify and suspend from the 10-day publication requirement, any information in a report of harm identified as materially inaccurate, pending investigation by our staff, until we have completed the investigation or made necessary corrections.

Response—Section 6A of the CPSA allows us to review information alleged to be materially inaccurate, both before the information is published in the Database and after it is published. Requests from commenters that we suspend the 10-day publication requirement and not publish any information in a report of harm claimed to be materially inaccurate until we have completed an investigation caused us to re-examine the requirements of the statute. The plain language of section 6A(c)(4)(A) states that if the determination that information is materially inaccurate has been made

prior to posting, then the Commission must remove, correct, or add information to correct the materially inaccurate information. Further, read together, sections 6A(c)(3)(A) and 6A(c)(4)(A) of the CPSA require that we must publish reports of harm or manufacturer comments in the first instance, not later than the tenth business day after transmission to the manufacturer unless we have “determined” that the information is materially inaccurate. The rule has been revised to ensure consistency with the statute.

Moreover, section 6A(f) of the CPSA states that reports of harm included in the Database are not subject to section 6(b) of the CPSA. Allowing delay of the posting of reports of harm beyond the tenth business day while the Commission considers a claim of material inaccuracy would be tantamount to reinstating section 6(b) of the CPSA with regard to that report of harm. Such a result would be inconsistent with the statute as Congress intentionally excluded reports of harm from section 6(b). Additionally, two provisions in section 6A contemplate that the Database may contain materially inaccurate information. Section 6A(b)(5) of the CPSA requires a disclaimer regarding the accuracy of the data. Section 6A(c)(4)(B) of the CPSA provides a mechanism for removal of information determined to be materially inaccurate by the Commission. As evidenced by the statute, Congress balanced the accuracy of the information in the Database with the public’s need for more immediate access to public safety related data. The better reading of Congressional intent is not to upset this balance.

Our timeline for any investigation of whether information is materially inaccurate once it has been published will depend on an evaluation of the information claimed to be materially inaccurate. We are not adopting an arbitrary time frame based on estimates of yet unknown information. The Commission will endeavor to act on such requests in a timely manner.

We also are not adopting the suggestion to delay posting of the information, especially if no determination can be made from the information submitted about a claimed material inaccuracy, because section 6A(c)(4) of the CPSA does not give us that option. The final rule builds in a process within the confines of the statute to address the timing concerns expressed by stakeholders. The rule creates an electronic process for notification of manufacturers and private labelers of reports of harm,

thereby expediting transmission of the reports for comment. Recognizing the 10-day time frame built into the statute, by this rule, the Commission has created a fast track review system expediting review of claims of material inaccuracies to ensure that manufacturers’ concerns are addressed in a timely fashion. While we can address manufacturers’ comments operationally by building systems such as these to ensure a timely comment and response process, we cannot ignore the timelines built into the statute. Nor would we want to do so as the purpose of the Database is to provide critical safety information to consumers who up until now have not had access to incident data in a timely manner. If information has not been determined to be materially inaccurate, it must be published in the Database. Finally, the statute does not require us to designate that any such report is under investigation for material inaccuracy, and we decline to add such information to the Database.

Comment 85—One commenter states that when a *prima facie* case of inaccuracy is made, we should exercise our discretion not to publish the report of harm pending confirmation of the veracity of the claim.

Response—Section 6A(c)(4) of the CPSA requires that if we determine information in a report of harm or a comment is materially inaccurate prior to posting the information in the Database, we must take one of three specific options to address the material inaccuracy. Section 6A(c)(3) of the CPSA requires that we publish reports of harm (that otherwise meet the requirements for publication) not later than the tenth business day after the date we transmit it to the manufacturer. Moreover, section 6A(c)(3) also requires publication of manufacturer comments upon request. Unless we have determined that the information in the report of harm or the comment is materially inaccurate, we must publish the report or comment in the Database. The language “except as provided in paragraph 4(A),” allows us to withhold from publication any information in a report of harm or a manufacturer comment where we can make that determination before posting based on the claim submitted. However, absent such a determination, we must publish a report of harm or manufacturer comment. We do not have authority, beyond what is specified in the referenced statutory provision, to withhold from publication a report of harm or manufacturer comment absent a determination of material inaccuracy. We must be provided with legitimate

and substantiated information supporting such claims and have built an expedited review system to respond, within the confines of the statute, to our stakeholders' timing concerns. We will not withhold from publication any report of harm or manufacturer comment where such claim is unsupported.

e. Proposed § 1102.26(e)—Assistance With Defense

Proposed § 1102.26(e) would explain that a manufacturer or private labeler's request for a determination of material inaccuracy should be made only by those who intend in good faith to assist in the defense of the correction of a material inaccuracy by the Commission in any later judicial proceeding that could be sought to compel disclosure. This provision is similar to one found in the Commission's FOIA regulations concerning the assertion of confidentiality. The Commission believes that this provision requires those seeking a determination that information in a report of harm or manufacturer comment is materially inaccurate to stand behind their assertion where the Commission is being sued to compel disclosure of such information.

We received no comments on this provision, and have finalized it without change.

f. Proposed § 1102.26(f)—Notice

Proposed § 1102.26(f) would state that we will notify the person or firm requesting a determination regarding materially inaccurate information and the method of resolution after resolving such a request.

We received one comment related to this section of the proposed rule, but have finalized it without modification.

Comment 86—One commenter states that the proposed rule may be fatally flawed for not providing adequate procedural due process for manufacturers and private labelers regarding determinations of confidential and materially inaccurate information. For example, the rule does not specify: Who will make initial determinations about confidential information and materially inaccurate information; whether there will be an appeal procedure to challenge initial determinations, or whether manufacturers and private labelers must challenge determinations in a U.S. District Court; whether an appeal is provided, who will make decisions on appeal; and whether there will be a chance to submit evidence, or make oral argument for the record.

Response—We have not revised the rule to add process mechanisms for the determination of confidential and materially inaccurate information. We address the confidentiality requirements under that provision.

First, Congress established a statutory scheme that favors disclosure of reports of harm over a lengthy review process for manufacturers, such as what currently exists for FOIA requests and the requirements of section 6(b) of the CPSA. One purpose of the Database is to eliminate that lengthy process, and to provide timely consumer access to product safety information. Moreover, the statute specifically states that section 6(b) of the CPSA does not apply to the publication of reports of harm in the Database. The statute also does not require us to provide a formal hearing for those contesting our decision with regard to confidential and materially inaccurate information, and we decline to use resources in this manner.

Second, with regard to claims of material inaccuracy, manufacturers and private labelers will have an opportunity to review a report of harm before publication, to comment on the report, and to claim that a report contains a material inaccuracy. We will take claims of material inaccuracy seriously, and give proper consideration to each claim. If a claim of inaccuracy is denied based on the information provided, manufacturers and private labelers may submit new or additional information to establish the claimed inaccuracy at any time.

Finally, with regard to due process, the Commission believes strongly in maintaining adequate due process protections. Due process is a flexible concept, depending on the circumstances, and essentially requires notice and an opportunity to be heard, both of which are sufficiently present in the final rule. *Mathews v. Eldridge*, 424 U.S. 319, 333 (1976); *Silvernail v. County of Kent*, 385 F.3d 601, 604 (6th Cir. 2004) (“The essential elements of due process are notice and an opportunity to be heard.”); *United States v. Shelton Wholesale, Inc.*, 34 F.Supp.2d 1147, 1151–53 (W.D. Mo. 1999) (holding that informal consultations with personnel empowered to correct a mistake constitutes a due process hearing in appropriate circumstances). Thus, at this time, we do not think that it is necessary to establish additional process or appeal procedures in the final rule without a statutory obligation to do so.

g. Proposed § 1102.26(g)—Commission Determination of Material Inaccuracy Before Publication

Proposed § 1102.26(g) would outline the steps we would take if we determined that information in a report of harm or manufacturer comment is materially inaccurate before it is published in the Database. Under the proposal, we would: (1) Decline to add the report of harm or manufacturer comment to the Database; (2) correct the materially inaccurate information, and if the minimum requirements for publication, as set forth in 1102.10 and 1102.12(c) are met, publish the corrected report of harm or manufacturer comment in the Database; or (3) add information to the report of harm or the manufacturer comment to correct the materially inaccurate information, and if the minimum requirements for publication, as set forth in 1102.10 and 1102.12(c) are met, publish the updated report of harm or manufacturer comment in the Database.

We received one comment on this section, with no resulting changes to the rule. However, on our own initiative, we have corrected two internal citation errors, changing the cite contained in § 1102.26(g)(2) and (g)(3) from § 1102.10(c) to § 1102.10(d). We also have reiterated that the Commission may make determinations of material inaccuracy without the necessity of a request from an outside party and have changed the word “may” to “shall” prior to (1) to be consistent with the statutory language. In addition, in 1102.26(g)(1) we have changed the language to ensure consistency with the statute. We also made typographical changes.

Comment 87—One commenter states that if we will not withhold reports with pending material inaccuracy claims until resolution, we should make a determination that if a claim has merit, but needs more investigation, we should give an additional 10 business days to resolve the claim before publishing.

Response—A determination that a claim has merit is not a determination of materially inaccurate information. Section 6A(c)(4) of the CPSA requires a determination of whether there is materially inaccurate information to resolve the claim. We do not believe that section 6A(c)(4) of the CPSA allows us to extend the time without making such a determination of material inaccuracy before publishing in the Database. If we determine that the information is not materially inaccurate, it will be posted in the Database.

h. Proposed § 1102.26(h)—Commission Determination of Material Inaccuracy After Publication

Proposed § 1102.26(h) would address a Commission determination where information in a report of harm or comment has been published and would explain that the Commission may, after an investigation, determine that information in a report of harm or manufacturer comment is materially inaccurate. The proposal would state that the Commission shall, no later than seven business days after such determination: (1) Remove the report of harm or manufacturer comment, including any attachments, from the Database; (2) correct the materially inaccurate information, and if other minimum requirements for publication are met, maintain the corrected comment or report of harm in the Database; or (3) add information to the report of harm or comment to correct the materially inaccurate information, and if the minimum requirements for publication are met, we would maintain the updated comment or report of harm in the Database.

We received several comments on this section of the rule, which has been finalized without substantive modification. However, on our own initiative, we have corrected two internal citations in § 1102.26(h)(2) and (h)(3) from § 1102.10(c) to § 1102.10(d). In addition, in 1102.26(h)(1) we have changed the language to ensure consistency with the statute. We have also made typographical changes.

Comment 88—One commenter asserts that the process for subsequent correction or cure of materially inaccurate information will not serve to cure the material misinformation that could happen where such information is published and later downloaded. The commenter states that the issue must be resolved first, if submitted timely by the manufacturer or private labeler, to prevent the Database from being filled with inaccurate information. The commenter further states that the harm resulting from posting inaccurate information far outweighs any delay in posting for investigation, and that rectification after publication may be too late to prevent significant brand damage. Other commenters state that the rule should clarify our discretion to delay posting, and further should provide that, where a manufacturer has demonstrated a good faith process for timely investigating reports of harm, we should exercise this discretion to delay publication of such reports until claims of material inaccuracy are resolved.

Response—Under section 6A(c)(3)(A) of the CPSA, we do not have the discretion to delay posting reports of harm in the Database past the tenth business day. We will use our best efforts to resolve claims of material inaccuracy before publication when timely submitted, but absent such determination, we will publish the report on the tenth business day. Congress provided in section 6A(c)(4) of the CPSA that we could review the claim of material inaccuracy after publication, by investigating, and then making such a determination. The ability to investigate a claim after publication is an acknowledgement that there may be instances where we need to review and investigate the publication of materially inaccurate information after publication. We encourage the submission of timely and specific comments that will be posted along with the report of harm. In this way, the manufacturer has the opportunity to address and refute any perceived issue relating to brand or reputation.

In addition, section 6A(b)(5) of the CPSA addresses the issue of the content of the information in the Database, by requiring us to provide a clear and conspicuous notice to users of the Database that we do not guarantee the accuracy, completeness, or adequacy of the contents of the Database. Section 1102.42 declares that this information will also appear on all documents that are printed from the user interface in the Database. Therefore, we cannot create procedures to delay publication of reports of harm and manufacturer comments beyond the parameters set forth in section 6A of the CPSA.

Comment 89—Some commenters express concern about potential reputational harm resulting from publicly viewable reports of harm, regardless of the manufacturer's ability to comment on the report. One commenter argues that as soon as a report of harm is made available for public download in the Database, the report takes on a "new, independent existence with no restriction to guarantee it will not reappear in some other forum," even if the report was later removed from the Database because it contained inaccurate information. Another commenter is concerned about the reputational harm caused to a licensor when the licensor is neither the manufacturer nor the private labeler and, therefore, does not have the opportunity to submit a comment prior to the publication of a (materially inaccurate) report of harm in the Database. The commenter's concern is that it would be difficult to "unring the

bell" once materially inaccurate information in a report of harm is published in the Database, and this concern is compounded by the fact that the Database is operated by the Federal Government.

Response—Proposed § 1102.26(b) would allow any person or entity reviewing a report of harm or manufacturer comment, either before or after publication in the Database, to request that the report of harm or manufacturer comment, or portions of such report of harm or manufacturer comment, be excluded from the Database or corrected by the Commission, because it contains materially inaccurate information. Because the commenters appear to be concerned about inaccurate information in reports of harm, we also note that § 1102.26(a) would define materially inaccurate information in a report of harm, confining it to four categories of information: (1) Identification of a consumer product; (2) identification of a manufacturer or private labeler; (3) description of the harm or risk of harm related to the use of the consumer product; and (4) incident date. In many instances, a manufacturer or private labeler should be able to identify quickly whether inaccurate information in a report of harm exists with respect to any of these categories.

As an additional matter, we will provide expedited review of claims of materially inaccurate information in a report of harm, where the manufacturer or private labeler files such request within the page limits specified by proposed § 1102.26(c)(1). In such cases, we will attempt, where practicable, to expedite the determination of a claim of material inaccuracy before publication of the report of harm in the Database. Even if a report of harm is published in the Database, if we have determined that materially inaccurate information is contained in such report, we will make any necessary correction, exclusion, or addition in no more than seven business days having made such determination.

With regard to licensors that do not receive notification of a report of harm, as we stated earlier in response to Comment 67, firms are free to make their own agreements regarding when they must inform certain business partners of reports of harm.

Finally, we note the disclaimer that will appear on any documents that are printed from the Database, in addition to being posted on every page, including the entrance screen, of the Database. The statutorily-provided disclaimer states that the Commission does not guarantee the accuracy, completeness, or adequacy of the contents of the

Database, especially concerning the accuracy, completeness, or adequacy of information submitted by persons outside of the CPSC. The disclaimer, combined with the various measures for claiming inaccurate information in a report of harm, balances the statutory requirements for publication against the interest in preventing inaccurate information from being published in the Database.

i. Proposed § 1102.26(i)—Commission Discretion

Proposed § 1102.26(i)(1) would state that we would exercise our discretion, consistent with the statutory requirements, to remove, correct, or add information to correct materially inaccurate information contained in a report of harm or manufacturer comment, and that we favor correction and addition to correction, over exclusion of entire reports of harm or manufacturer comments.

We received several comments on this section, which has been finalized without substantive modification. On our own initiative, we have corrected an internal citation error in § 1102.26(i)(1) from § 1102.10(c) to § 1102.10(d) and for clarity have changed “addition to correction” to “the addition of information to correct.”

Proposed § 1102.26(i)(2) would state that if we received a request for correction or exclusion of materially inaccurate information from a manufacturer within the recommended five-page limit, we would attempt to make an expedited determination of a claim of material inaccuracy. The proposal would explain that we generally would publish reports on the tenth business day after transmitting a report of harm, where either the recommended page limit of comments has been exceeded, or where we otherwise have been unable to make a determination of material inaccuracy prior to the statutorily mandated publication date. We would make any necessary correction, exclusion, or addition not later than seven business days after making a determination that there is materially inaccurate information in the report of harm. Manufacturer comments would be published at the same time as the report of harm or as soon thereafter as is practicable.

We received several comments on this section, which we have finalized with grammatical changes. In addition, we have deleted the words “generally,” “either the recommended page limit of comments has been exceeded or where,” and “otherwise.” The sentence now reads “the Commission will publish

reports of harm on the tenth business day after transmitting a report of harm where the Commission has been unable to make a determination regarding a claim of material inaccuracy prior to the statutorily mandated publication date.” These changes are consistent with changes made to § 1102.26(d) and would reconcile these two sections. As stated earlier, it reflects our belief that, as required by the statute, unless the Commission has determined that the information in the report of harm or the comment is materially inaccurate, we must publish the report or comment in the Database on the tenth business day after transmitting a report of harm.

Comment 90—One commenter states that we should consider creating a more expedited process than what we have proposed to resolve issues as fully as possible before publication.

Response—The process we have set up for expedited review is designed to enable us to make the required statutory determination of material inaccuracy without getting overwhelmed by repetitive and duplicative claims. We believe that the process we have set up addresses this issue, and therefore, we are not revising the rule as suggested by the commenter.

Comment 91—One commenter states that with respect to notifications to the manufacturer about a claim in proposed § 1102.26(f) and (j) on material inaccuracies, we should include text of proposed redaction, correction, or addition to be made to the disputed report of harm. Otherwise, the commenter claims that we would be making arbitrary statements concerning the inaccuracy.

Response—As section 6A(c)(4) of the CPSCA requires, we will notify the manufacturer where we have determined that information is materially inaccurate. This notification will include information on how we propose to address the material inaccuracy consistent with the statutory provisions. As noted in § 1102.26(i)(1), we will favor correction over removal where we determine that such correction can address the material inaccuracy.

Comment 92—One commenter states that unless necessary to permit publication in the Database, we should not rewrite the text of documents, but should simply redact disputed information to ensure that additional issues regarding accuracy do not arise.

Response—Section 6A(c)(4) of the CPSCA gives removal as one option for addressing information determined as materially inaccurate in the Database. Correction of the materially inaccurate information is also a specified option to

resolve a material inaccuracy claim. Section 6A(c)(4) of the CPSCA also allows us to add information to correct the material inaccuracy. We will not adopt the suggestion to adopt redaction as our only option and reject the suggestion that we not correct such information where correction would address the material inaccuracy. While it is possible that such a correction might somehow create a new issue, we do not believe that it would create more inaccuracy issues. Manufacturers are free, however, to point out to us any issue about the correction after receiving notification of it. We do not intend the correction process to turn into a negotiation over the correction language, but we will provide notice to the manufacturer as stated in § 1102.26(f).

j. Proposed § 1102.26(j)—Commission Determination of No Material Inaccuracy

Proposed § 1102.26(j) would describe the process for what we would do if we determine that the requested information in a report of harm does not contain materially inaccurate information. The proposal would have us notify the requestor of our determination, and publish the report in the Database, if it meets the minimum requirements for publication.

Several comments were received regarding this section, but no changes to the final rule resulted from the comments. However, on our own initiative, we clarified in the final rule that the Commission determination of no material inaccuracy may be made to a manufacturer comment, in addition to a report of harm. We also made an internal citation correction in § 1102.26(j)(2) to correctly state where the minimum requirements for reports of harm and manufacturer comments may be found in the rule: In § 1102.10(d) and § 1102.12(c) and added the word “and” between (1) and (2) to be consistent with the statutory language.

Comment 93—One commenter addresses the resource issue surrounding the Database, and states that if section 6(b) of the CPSCA is any guide, lack of staff could make determinations on material inaccuracy “indefinite.” The commenter would have the final rule specify a 20-business-day deadline for resolution of a claim of material inaccuracy. If the Commission cannot resolve any claim of material inaccuracy within 20 days, the commenter would have the report removed from the Database until the claim is resolved. The commenter notes that such a procedure would promote

timely consideration, and provide an impetus for quick resolution.

Response—We are considering how best to allocate resources to address a possible increase in information submitted through the Database. We are committed to providing sufficient resources for a successful Database. We take seriously the obligation to review reports of harm and manufacturer comments for minimum content requirements, and for determination of claims of confidential or materially inaccurate information. However, because section 6A of the CPSA establishes clear deadlines for specific actions, we cannot amend the rule to allow additional time for review.

Comment 94—One commenter says it may be in the best interest of the public for the Commission to provide notification on its Web site that reports of harm may be updated, revised, or corrected, but in a manner that will not chill submissions by consumers. The commenter adds that if a report is altered, consumers automatically should receive via e-mail, updated information regarding their report of harm.

Response—Section 6A(c)(4) of the CPSA allows the Commission to redact or correct reports of harm for materially inaccurate information. The current system requirements do not provide for updates on individual reports via e-mail. However, consumers are free to check the Web site for changes.

Comment 95—Some commenters would have us audit material inaccuracy claims to ensure that manufacturers and others are making such claims in good faith—instead of frivolous claims to block public disclosure of critical safety hazard information.

Response—Section 6A(d) of the CPSA requires the Commission to submit to the appropriate congressional committees an annual report on the Database, which must include the number of reports and comments for the year, and the number of corrected or removed reports and comments for the year from the Database. We believe this statutory requirement will allow us to address the suggestion by the commenters that the Commission audit material inaccuracy claims to ensure that such claims are being asserted in good faith and not frivolously. We also believe that by clarifying the burden of proof requirement to § 1102.26, such claims will be supported and made in good faith.

k. Proposed § 1102.26(k)—Commission Action in Absence of a Request

Proposed § 1102.26(k) would provide that the Commission may review a

report of harm or manufacturer comment on its own initiative following the same notices and procedures set forth in § 1102.26(g) through (j).

We received several comments related to this section, which resulted in no changes to the final rule.

Comment 96—One commenter states that Commission-initiated reviews of materially inaccurate information should be reviewed with the submitter or the manufacturer before publication or correction of any material inaccuracy.

Response—We will provide notice of the result of a Commission-initiated review to the manufacturer, where such a review results in the Commission taking an action under section 6A(c)(4) of the CPSA to address information it deems materially inaccurate. However, the statute does not require us to await a manufacturer's comment or to inform the submitter of the report of harm before taking any action to address the material inaccuracy, and so we will not revise the rule as suggested by the commenter.

Comment 97—One commenter asserts that any inaccuracy in a report should warrant removal of the entire report until all other facts can be verified and a corrected report can be posted.

Response—Section 6A(c)(4) of the CPSA requires that the Commission make a determination regarding a material inaccuracy claim before we may take steps to resolve the claim. Adopting the commenter's suggestion to remove a report for any inaccuracies would be contrary to section 6A(c)(4) of the CPSA, which allows materially inaccurate information to be removed, added to, or corrected only after a determination of material inaccuracy. Under the commenter's suggestion, a report with an error in the description of the incident, such as the time of day, or the color of the product, would have to be removed. We do not believe that such information would meet the threshold for material inaccuracy, and so we will not revise the rule as suggested by the commenter.

4. Proposed § 1102.28—Publication of Reports of Harm

Proposed § 1102.28(a) would explain that reports of harm will be published in the Database as soon as practicable, but no later than 10 business days after such report of harm is transmitted by the CPSC to the manufacturer or private labeler.

Proposed § 1102.28(b) would explain an exception to the 10-business day deadline where reports of harm may be published beyond the 10-day time frame if we determine that the report of harm misidentifies or fails to identify all

manufacturers or private labelers. The information would have to be corrected through the procedures for materially inaccurate information. The provision also would state that once the manufacturer or private labeler has been identified correctly, the time frames in § 1102.28(a) will apply.

We received several comments related to this section, which did not result in any modifications to the final rule. On our own initiative, we have corrected an internal citation error in § 1102.28(b) from § 1102.10(c) to § 1102.10(d).

Comment 98—Several commenters assert that § 1102.28(b) would not provide sufficient time to investigate meaningfully and respond to reports of harm. Some commenters state that a company “needs the time to review its files, retrieve test reports, confer with its many suppliers, etc. A meaningful comment period is essential to the development of a meaningful consumer complaint database.” The commenters note that this places a heavy burden on manufacturers, and that we should consider adopting provisions for exceptions and extensions, perhaps up to 30 days, where the 10-day time frame is not possible, or would be “manifestly unfair.” The commenters also state that we should work with industry to develop realistic time frames for businesses to respond.

Response—We are bound by the time frame set forth in section 6A(c)(3)(A) of the CPSA and do not have the authority to establish a different time frame. Moreover, establishing a different time frame would be inconsistent with the direction given in section 6A(f)(1) of the CPSA to not apply the provisions of section 6(a) and (b) of the CPSA to reports of harm. Section 6(b) of the CPSA requires that we wait 15 days after notifying a manufacturer of our intent to publicly disclose manufacturer-specific information to the public. In contrast, under section 6A of the CPSA, once we transmit a report of harm to a manufacturer or private labeler, we must publish the report of harm no later than the tenth business day after transmission unless a determination of material inaccuracy has been made.

Comment 99—A commenter states that reports of harm submitted after a certain time period (e.g., one year) following the alleged harm should not be published.

Response—For the reasons provided in response to Comment 19 above, we are not adopting this suggestion, which is not required by section 6A(b) of the CPSA.

5. Proposed § 1102.30—Publication of Manufacturer Comments

Proposed § 1102.30 would explain that the Commission will publish manufacturer comments that meet the minimum requirements in proposed § 1102.12(c) at the same time as a report of harm is published or as soon as practicable thereafter. The proposal would provide examples of circumstances that may make it impracticable to publish a manufacturer comment at the same time as a report of harm: (1) The Commission did not receive the comment until on or after the publication date of the report of harm; or (2) the Commission is resolving a claim that the manufacturer comment contains materially inaccurate information.

We received several comments on this section, which has been finalized with modification. On our own initiative, we have corrected the internal citations to state that publication of a manufacturer comment is subject to §§ 1102.12, 1102.24, and 1102.26 of the final rule. This correction is consistent with § 1102.28(a), stating that publication of reports of harm are subject to §§ 1102.10, 1102.24, and 1102.26. In addition, we struck the second example of a circumstance that would make it impracticable to publish a manufacturer comment at the same time as a report of harm because it was inaccurate. A claim by a third party that a manufacturer comment contains a material inaccuracy could be made only after the manufacturer comment had already been published in the Database. A manufacturer comment would remain in the Database until the Commission made a determination about any alleged material inaccuracy.

Comment 100—One commenter suggests that information published in the Database (reports of harm and manufacturer comments), and the fact of its publication, should be declared inadmissible as evidence to establish the truth of such information.

Response—The commenter's suggestion goes beyond the scope of this rulemaking. We do not believe that section 6A of the CPSA authorizes us to issue a regulation that would address the admissibility in judicial proceedings of information in the Database. Such matters are left to the legislative and judicial branches. For example, courts can decide whether to exclude database entries as inadmissible based on the arguments advanced by the commenter.

However, we will treat information contained in the Database (reports of harm and manufacturer comments) in the same manner in which we currently

treat other official agency records that are sought by litigants for use in private litigation. Current regulations, at 16 CFR 1016.3(b), provide a process for authentication of official agency records by the Secretary of the Commission, and requests for authentication of information contained in the Database should be made in accordance with that regulation.

Comment 101—One commenter is concerned about whether comments would always be displayed when a report of harm is accessed through the Database. This commenter reasons that, absent such a requirement, there is a risk that a search of the Database might reveal a report of harm without also revealing a related comment.

Response—Comments associated with a report of harm will always be displayed when a report of harm is accessed through the Database, provided the comment meets the minimum requirements for publication (see § 1102.12(a)). However, if a comment does not meet the minimum requirements for publication, for example, when we do not have the consent of the manufacturer or private labeler to publish the comment to the Database, it will not be published in the Database and, therefore, will not be displayed when the corresponding report of harm is accessed.

D. Proposed Subpart D—Notice and Disclosure Requirements

1. Proposed § 1102.42—Disclaimers

Proposed § 1102.42 would require a disclaimer stating that the CPSC does not guarantee the accuracy, completeness, or adequacy of the contents of the Database, particularly with respect to the accuracy, completeness, or adequacy of the information submitted by persons outside the CPSC. This provision requires that the Database prominently and conspicuously display such a disclaimer on the Database and on any documents printed from the Database.

Several comments were received on this section, which has been finalized with one slight modification, shortening the second mention of the Database to “Database.”

Comment 102—One commenter would have the disclaimer for the Database read as follows: “The fact of publication in whole or in part in the Consumer Product Safety Information Database, or later modification, retraction or removal therefrom, may not be used to establish the truth or falsehood of any reported allegations or comment in any related litigation.”

Response—In proposed § 1102.42 we provided the following disclaimer, which would be displayed prominently and conspicuously on the Database and on any documents that are printed from the Database: “The Commission does not guarantee the accuracy, completeness, or adequacy of the contents of the Consumer Product Safety Information Database, particularly with respect to the accuracy, completeness, or adequacy of information submitted by persons outside of the CPSC.” The commenter's proposed revision of the disclaimer regarding the use of information in any related litigation speaks to the issue of whether Database information is inadmissible in other forums. We will not revise the rule because admissibility is a matter for the legislative and judicial branches.

Comment 103—One commenter would amend the Disclaimer section to have the disclaimer read: “prominently and conspicuously displayed on the database and on any documents that are downloaded, printed or otherwise transferred from the Database.” This commenter suggests the use of an electronic watermark. Another commenter notes that the disclaimer should be repeated at every chance on the Database, on any intake complaint forms, and on the information released in the Database.

Response—The disclaimer was specified in section 6A(b)(5) of the CPSA and is described in § 1102.42. We will conspicuously display the disclaimer on Web pages, including the online incident report form, and documents that can be printed or otherwise transferred from the Database. At this time our system does not create, via software, a permanent disclaimer that goes on any data exported from the Database.

Comment 104—One commenter notes that we should clarify that the disclaimer will be “prominently and conspicuously” displayed on each document in the Database when it is displayed for electronic review, as well as if and when the document is printed (even remotely to nongovernmental computers). This commenter states that it is important so as not to be viewed as self-authenticating public records under the Federal Rules of Evidence and state rules of evidence.

Response—We have described how the disclaimer will be displayed on the Database and on printed documents. How a court will treat any document printed from the Database is dependent upon how the document is presented and whether a court would view the document as self-authenticating under

the appropriate Federal or State evidentiary rules.

Comment 105—Some commenters criticize the proposed disclaimer, stating that the Commission did not indicate clearly that reports of harm included in the Database contained information submitted by persons outside of the Commission.

Response—Section 1102.42 uses the disclaimer found in section 6A(b)(5) of the CPSA, which states that the Commission does not guarantee the accuracy, completeness, or adequacy of the contents of the Database; however, we added language strengthening this disclaimer by drawing particular reference to the accuracy, completeness, or adequacy of information submitted by persons outside of the CPSC. Therefore, we believe that we have addressed sufficiently the concerns raised by the commenters, by notifying users of the Database that information in the Database has been provided by individuals outside of the Commission.

Comment 106—One commenter states that the disclaimer in § 1102.42 does not go far enough in explaining the limitations of the data, particularly in “data sets” produced by conducting a search of the Database. This commenter states that the disclaimer should explain the anecdotal nature of the data, and that it cannot be used for broad, statistical purposes; the commenter also states that the disclaimer should state clearly the concerns about accuracy, completeness, or adequacy. The commenter suggests that the disclaimer explain the lack of verification by the CPSC of the “facts” in the reports, and caution users against drawing conclusions about the named products based on these data.

Response—We believe that we have addressed adequately these concerns by proposing a disclaimer that closely tracks the statute, but draws particular attention to the fact that the Database contains information submitted by persons outside of the Commission. The Database is not a Database of government-generated data. The information is generated by external third parties. The Database will be searchable and sortable, as required by section 6A. The disclaimer speaks to the anecdotal nature of the data.

2. Proposed § 1102.44—Applicability of Sections 6(a) and (b) of the CPSA

Proposed § 1102.44(a) would explain that sections 6(a) and (b) of the CPSA do not apply to the submission, disclosure, and publication of information provided in a report of harm. Proposed § 1102.44(b) would apply sections 6(a) and (b) of the CPSA to information

received by the Commission pursuant to section 15(b) of the CPSA, and to information received by the Commission pursuant to any other voluntary or mandatory reporting program established between a retailer, manufacturer, or private labeler.

We received several comments related to this section, which has been finalized without substantive change. We have made two internal citation corrections. In § 1102.44(a), we corrected a citation from § 1102.10(c) to § 1102.10(d), and in § 1102.44(b), we corrected a citation from § 1102.42 to § 1102.44(a), and we shortened the name of the Database to “Database.”

Comment 107—One commenter states that, “notwithstanding Congressional direction for this database,” section 6 of the CPSA should apply to information in the Database. The commenter further states that “Section 6(b) of the CPSA was not repealed by the CPSIA.” The commenter asserts that the Commission should take reasonable steps to ensure that the information published in the Database is “accurate and fair in the circumstances” and that accuracy protections of section 6 of the CPSA contribute to the “ultimate release of information that consumers can reasonably rely upon.”

Response—We do not agree that we can “opt” to apply sections 6(a) and (b) of the CPSA to the submission, disclosure, and publication of information provided in a report of harm when section 6A(f)(1) of the CPSA provided an express exemption to sections 6(a) and (b) of the CPSA for reports of harm submitted to the Database. Thus, § 1102.44 continues to state that sections 6(a) and (b) of the CPSA do not apply to the submission, disclosure, and publication of information provided in a report of harm that meets the minimum requirements for publication in § 1102.10(c).

Comment 108—One commenter is concerned about whether we will retain, as agency records, the originals of documents that have subsequently been modified or excluded from the Database because of claims of material inaccuracy. The commenter explains that it believes that the Database provisions in the statute required that the originals be purged as records of the agency. The commenter asks that, if we disagree or believe that the Federal Records Act requires those documents to be maintained, we make it clear that the documents are still subject to sections 6(a) and (b) of the CPSA if requested under FOIA or otherwise.

Response—We disagree with this commenter’s analysis that information

purged from the Database does not comprise official agency records subject to the Federal Records Act; therefore, when we receive requests for information purged from the Database under the FOIA or otherwise, we will invoke all applicable Federal laws, including sections 6(a) and (b) of the CPSA, prior to the release of any such information.

Comment 109—One commenter asks that we clarify that reports submitted under section 15 of the CPSA and reports submitted under other voluntary retailer reporting programs would not be disclosed in the Database. The commenter’s concern is that the current confidentiality protections surrounding this data facilitate dialogue between retailers and the CPSC. The commenter is concerned that, if that level of trust is compromised, or confidentiality is reduced, it would affect the ability of the CPSC to have full and frank discussions with manufacturers and retailers.

Response—Section 6A of the CPSA exempts reports of harm submitted to the Database from sections 6(a) and (b) of the CPSA; however, it clearly states that it does not exempt reports submitted under section 15 of the CPSA or reports submitted under any other mandatory or voluntary retailer, manufacturer, or private labeler reporting program with the Commission. Therefore, § 1102.44 specifically states that information received by the Commission pursuant to section 15 of the CPSA or any other mandatory or voluntary reporting program established between a retailer, manufacturer, or private labeler and the Commission is not exempted from the requirements of sections 6(a) and (b) of the CPSA. This means that the Commission could not publish such information in the Database without first complying with the notice provisions of sections 6(a) and (b) of the CPSA. In this phase of the Database, we are not publishing reports submitted under section 15(b) of the CPSA or reports submitted under any other mandatory or voluntary retailer, manufacturer, or private labeler reporting program. Comments Regarding Implementation of the Database Unrelated to a Specific Section in the Rule.

Comment 110—The Commission should commit resources for educational outreach and training, and publish an official guidance tailored specifically to manufacturers and private labelers.

Response—We have committed staff and support resources dedicated to industry and consumer education

regarding the Database. This effort includes developing a process to identify, confirm, register, and train businesses that wish to utilize the Business Portal to electronically respond to reports of harm.

We are working with industry trade associations and consumer advocacy organizations in this effort. Documentation and other support materials, as well as information sessions will be available in the months preceding the “go-live” date. Calendar dates for information sessions will be posted on the Public Calendar on our Web site.

Comment 111—One commenter states that unverified reports in the Database should not create section 15 reporting obligations. The commenter states that because submitters are not required to provide contact information to manufacturers, unverified and inaccurate reports are bound to end up in the Database. The commenter states that the rule should state that transmitted reports of harm will not trigger any CPSA reporting requirement, due to the nature of the contents of the Database and its purpose, and that the overall purpose is to provide a tool for consumers to obtain reliable information, rather than be a source of information to manufacturers about potential product issues.

Response—Section 6A does not specifically exempt Database information from consideration in section 15 cases and, therefore, we will not adopt the suggestion that we specifically exclude information in the Database from consideration in such cases. While it is true that the Database is subject to a disclaimer that the Commission does not guarantee the accuracy, completeness, or adequacy of the contents of the Database, information in the Database will be verified by the submitter. Information in the Database may be used for a variety of purposes, not the least of which could be identifying potential hazards associated with consumer products whether by the manufacturer or the Commission.

Comment 112—A commenter states that the rule should ensure that users do not circumvent minimum requirements for Database entry by posting incidents and comments through Commission social media outlets. It would be appropriate to obtain some assurances that this will not be permitted.

Response—On the Web pages of all of the social media accounts utilized by the Commission, clear and conspicuous policies are posted regarding the appropriate way to post content related

to incident reporting and directing users to the Database for such purposes.

Comment 113—Some commenters state that it is “crucial” for the CPSC to implement the Database in the narrowest scope possible and then expand it (*i.e.*, start with specific product categories that present the most risk and gradually open up the Database) to other products. Commenters state that this would ensure reliability and the long-term success of the Database by minimizing mistakes, minimizing the impact of mistakes, providing the CPSC with flexibility to make changes, reducing the burden on CPSC resources, and enabling time to work out an efficient means of handling the paperwork involved in maintaining the Database. The commenters estimate that it would take 22 dedicated full-time employees to handle the potential increase in incident reports. The commenters state that the CPSC has the opportunity to engage stakeholders in discussions on how to improve and resolve problems as they arise. Commenters state that the Database should include a forum for this type of implementation discussion, naming *Facebook* development as an example. Commenters allege that staged implementation is consistent with congressional intent and the commenters point to the General Accounting Office study requirement as indication that Congress knew the Database would need to be modified and improved as time progresses.

Response—Congress required that implementation of the Database occur 18 months after our implementation report to Congress. We submitted our implementation report in September 2009. We are on track to fulfill that mandate.

We already have started the process of planning and testing internal business processes against the requirements of the implemented software. This includes planning for data intake, processing, and notification of manufacturers and private labelers. We are aligning staff and support resources to new business processes in anticipation of the implementation. We anticipate this alignment around new processes to be completed several months before the “go-live” date in March 2011. We believe these steps address the commenters concerns and would obviate the need for a phased introduction of the Database.

Comment 114—“[T]he regulation does not include crucial information on how this database will be implemented. Although the CPSC has shared some of its plan with the public, much is still not known. It is quite possible that the

format for submitting reports of harm and the data input techniques to be used for reporting, will have a major impact on the accuracy of the data in the database.”

Response—The implementation plan is not appropriate for the text of a regulation. Starting in September 2009, we submitted a report to Congress on implementation of the Database. We held a public hearing on November 10, 2009, regarding implementation. In addition, we held a two-day workshop in January 2010, regarding implementation, and requested comments. All of this information is available on the Commission’s Web site at <http://www.cpsc.gov>. Thus, we have committed staff and support resources through the “go-live” date in a dedicated effort to inform industry and educate consumers regarding the Database. This effort further includes creation of a Web site on <http://www.saferproducts.gov> devoted to Database education and implementation issues, which is periodically updated with new content. The Commission has also conducted focus groups on the input forms and Database screens. The Commission plans to send staff to attend and speak at conferences to teach on the Database. It also plans to develop a process to identify, confirm, register, and train businesses that wish to utilize the Business Portal to electronically respond to reports of harm.

We are working with industry trade associations and consumer advocacy organizations in this effort. Documentation and other support materials are being developed, and information sessions will be available in the months preceding the “go-live” date. Calendar dates for information sessions will be posted on the Public Calendar on our Web site.

Comment 115—Some commenters state that the manner of registering and contacting manufacturers and private labelers will greatly affect their ability to comment on the data in a timely fashion. A first look at the proposed manufacturer registration system identified a number of significant issues. To insure that the Database properly serves its intended purpose, the details of the Database should be shared with the public for comment before it is implemented.

Response—Our education and outreach efforts are described above in response to Comment 115. We are actively engaged in an industry and consumer education effort that includes developing a process to identify, confirm, register, and train businesses that wish to utilize the Business Portal to electronically respond to reports of

harm. Documentation and other support materials, as well as information sessions will be available in the months preceding the “go-live” date. Calendar dates for information sessions will be posted on the Public Calendar on our Web site.

Comment 116—Some commenters state that valid reports of harm may come from the same IP address, such as government, health facilities, and consumer organizations, and that these multiple, but valid, reports should be accepted.

Response—Multiple, valid reports will be accepted from the same IP address. The first release of the software will contain features to protect against computer-generated reports and flag potentially duplicate reports for staff review.

The software and mechanisms that we use to detect multiple reports from the same IP address will be used to detect a nefarious denial of service type of attack. A denial of service attack is an attempt to make a computer resource unavailable to its intended users. Commonly, the perpetrator of such an attack would saturate a public Web site with extraordinarily high numbers of information requests. Such computer-generated high volume would limit the target’s ability to respond to legitimate (human) use.

Comment 117—One commenter states that the Report to Congress mockup shows a static, noncheckable verification, and suggests that we require consumers to affirmatively attest by clicking on something in the portal.

Response—We noted this suggested requirement/feature in several forums, and have implemented it by requiring that submitters select a check mark box on the incident report form for it to be submitted and published.

Comment 118—Commenters discuss discouraging false complaints regarding consumer products. The commenters suggest that the final rule contain a mechanism for the prompt removal of false complaints. Computer-generated reports should not be accepted. Another commenter states that the system should detect multiple reports from the same IP address, which are then flagged for further inspection.

Response—We agree that the Database should not contain materially fraudulent or false complaints about consumer products. Section 1102.26 details the designation and disposition of materially inaccurate information. Also, the Database software will assist with fraud prevention. The Database implementation team is working closely with the enterprise information security team to ensure that the Database uses

industry best practices for security and complies with federal and CPSC specific security requirements. For example, the first release of the software will contain features to protect against computer-generated reports and flag potentially duplicate reports for CPSC review. However, despite our best efforts to ensure that legitimate reports of harm are being filed, we cannot independently verify that every report of harm submitted is legitimate and accurate. Congress required that the Database contain a disclaimer, which is set forth in § 1102.42 of the final rule.

IV. Environmental Impact

The Commission’s regulations at 16 CFR 1021.5(a) are considered to “have little or no potential for affecting the human environment,” and environmental assessments and impact statements are not usually prepared. See 16 CFR 1021.5(c). The final rule contains the Commission’s interpretation of the statutory requirements set forth in section 6A of the CPSA, as added by section 212 of the CPSIA, for the inclusion of information related to reports of harm involving the use of consumer products or other products or substances regulated by the Commission in a publicly available and searchable database. As such, the proposed rule is not expected to have an adverse impact on the environment. The Commission concludes that no environmental assessment or environmental impact statement is required.

V. Paperwork Reduction Act

The final rule contains information collection requirements that are subject to public comment and review by the Office of Management and Budget (OMB) under the Paperwork Reduction Act of 1995 (44 U.S.C. 3501–3520). In a May 24, 2010 **Federal Register** notice regarding the proposed rule (75 FR 29156, 29173–75), we described the information collection and the annual reporting burden. Our estimate included the time for reviewing instructions, searching existing data sources, gathering and maintaining the data needed, and completing and reviewing each collection of information.

We invited comments on: (1) Whether the collection of information is necessary for the proper performance of the CPSC’s functions, including whether the information will have practical utility; (2) the accuracy of the CPSC’s estimate of the burden of the proposed collection of information, including the validity of the methodology and assumptions used; (3) ways to enhance the quality, utility, and clarity of the

information to be collected; and (4) ways to minimize the burden of the collection of information on respondents, including through the use of automated collection techniques, when appropriate, and other forms of information technology. We received one comment about the burden estimates contained in the proposed rule. The comment summary and response appear below.

Comment: A commenter states that the annual reporting burden is significantly underestimated because the Commission based the estimate on current reporting figures. Also, the commenter states that it will take manufacturers and private labelers more than 4 hours to investigate and respond to a report of harm.

Response: With regard to the estimated annual reporting burden and time needed for manufacturers and private labelers to investigate and respond to a report of harm, the preamble to the proposed rule explained that we based our estimates on our experience with our incident report forms for fiscal year 2009 (75 FR at 29174). The commenter has not provided any alternative data or methodology that would support adjusting our estimates. We also note that in our research on other agency databases, we were unable to determine conclusively whether CPSC will experience an increase in reports when the public facing database is launched. Accordingly, we decline to alter or amend the estimated burdens.

Title: Publicly Available Consumer Product Safety Information Database.

Description: The final rule allows consumers to submit reports of harm involving the use of consumer products or other products or substances regulated by the CPSC, and also allows manufacturers of such products or substances to comment on the reports of harm. The reports and comments will be part of the Database operated and maintained by the CPSC. A manufacturer identified in a report of harm and who receives a report of harm from the CPSC may request that portions of the report be designated as confidential information. Any person or entity reviewing a report of harm or manufacturer comment may request that the report or comment, or portions thereof, be excluded from the Database or corrected by the CPSC because it contains materially inaccurate information.

Description of Respondents: Persons who wish to submit reports of harm involving the use of consumer products or other products or substances regulated by the CPSC and

manufacturers of such products or substances who wish to comment on those reports of harm, pursuant to section 6A of the Consumer Product Safety Act (CPSA) (15 U.S.C. 2055a). In addition, any person or entity reviewing

a report of harm or manufacturer comment, either before or after publication in the Database, may request that the report of harm or manufacturer comment, or portions thereof, be excluded from the Database or corrected

by the CPSC because it contains materially inaccurate information.

We estimate the burden of this collection of information as follows:

TABLE 1—ESTIMATED ANNUAL REPORTING BURDEN

16 CFR Section	Number of respondents	Frequency of responses	Total annual responses	Minutes per response	Total burden, in hours
16 CFR 1102.10(b)(1), (3) Reports of harm—electronic	11,534	1	11,534	12	2,307
16 CFR 1102.10(b)(2) Reports of harm—telephone	3,329	1	3,329	10	555
16 CFR 1102.10(b)(4) Reports of harm—paper	277	1	277	20	92
16 CFR 1102.12(b)(1), (2) Manufacturer comments—electronic	5,753	1	5,753	255	24,450
16 CFR 102.12(b)(3) Manufacturer comments—paper	1,817	1	1,817	270	8,177
16 CFR 1102.24 Requests to treat information as confidential—electronic	345	1	345	15	86
16 CFR 1102.24 Requests to treat information as confidential—paper	109	1	109	30	54
16 CFR 1102.26 Requests to treat information as materially inaccurate—electronic	1,726	1	1,726	30	863
16 CFR 1102.26 Requests to treat information as materially inaccurate—paper	545	1	545	60	545
Total					37,129

There are no capital costs or operating and maintenance costs associated with this collection of information.

Our estimates are based on the following:

The CPSC is in the process of developing the forms that will be used by consumers and manufacturers to submit reports and comments for inclusion in the Database. Because those forms are still under development, for present purposes, we based our burden estimates on our experience with similar forms and processes, and on information gleaned from manufacturers. Specifically, the CPSC currently has an incident report form that consumers and others use to report consumer safety incidents to the agency. The CPSC provides most of those consumer complaints to the manufacturer, and the manufacturer may provide comments to the agency.

For present purposes, we assume that the Database will receive the same number of reports of harm as the CPSC received of incident reports in fiscal year 2009, and that the numbers by manner of submission to the CPSC (*i.e.*, electronic, telephone, paper) will be the same. Thus, using the data from fiscal year 2009, we estimate that we will receive a total of 15,140 reports of harm (11,534 by electronic means, 3,329 by telephone, and 277 by paper submissions). We had already estimated the time associated with the electronic and telephone submission of incident reports at 12 and 10 minutes, respectively and so used those figures

for present purposes as well. We estimate that the time associated with a paper form would be 20 minutes on average. Thus, we estimate the total burden hours associated with the submission of reports of harm to be 2,954 hours ((11,534 electronic report × 12 minutes per report) + (3,329 telephone reports × 10 minutes per report) + (277 paper reports × 20 minutes per report) = 177,238 minutes or approximately 2,954 hours).

In 2008, manufacturers submitted comments to the CPSC in response to a consumer complaint forwarded to the manufacturer about 40 percent of the time. We estimate that the response rate will increase in the case of the Database; currently, neither the incident reports nor manufacturer comments are routinely public. We estimate that the manufacturer response rate will increase 25 percent, up to a 50 percent response rate. Therefore we expect to receive half as many total manufacturer comments as reports of harm (15,140 reports of harm × 0.5 manufacturer comments per report of harm = 7,570 manufacturer comments). In terms of the manner of commenting, currently we do not keep track of how many manufacturer comments are submitted electronically versus in paper form. Because the Database will be online, we will assume that most manufacturers will utilize electronic options for participating in the Database, especially when the Database (unlike the current incident reporting system) will not give manufacturers the option of submitting

their comments by phone. However, to ensure that we avoid inadvertently underestimating the burden, we will assume that manufacturers would submit electronically at the same rate. That equates to an estimate of 5,753 manufacturer comments submitted electronically, and 1,817 submitted on paper.

We also will assume that there are two actions involved in a manufacturer comment: (1) The research and preparation necessary to comment; and (2) the act of providing the comment. To estimate how much time manufacturers will spend researching and preparing to comment, we contacted three manufacturers that have experience submitting comments in response to incident reports. The manufacturers each reported a range of time, because time required in preparing a comment can vary greatly. The three ranges were 15 minutes to 4 hours, 10 minutes to 5 hours, and 10 minutes to 3 hours. For purposes of estimating the burden, we used the average high end of these ranges, 4 hours, for that portion of the burden estimate. Based on our experience with the current manufacturing comment process, we estimate that manufacturers will spend between 5 and 30 minutes actually providing the comment, depending on the length and complexity of their comment. For the purposes of this estimate, we use the high end of that range for paper submissions (30 minutes) and the midpoint for electronic (15 minutes). Thus, the

estimated burden associated with manufacturer comments is approximately 32,607 hours ((5,753 electronic comments \times 255 minutes per comment) + (1,817 paper comments \times 270 minutes per comment) = 1,957,605 minutes or approximately 32,627 hours).

Regarding requests to designate information as confidential, we anticipate that there are very limited circumstances under which confidential information will be included in a report of harm; by its very nature, such information is not available to the public. Accordingly, we assigned a value of 3 percent to our estimation of the rarity with which we expect to receive such requests. Three percent of the total number of reports of harm estimated (15,140) results in an estimate of 454 requests to designate information as confidential. The proposed rule would specify what must be included in such a request (§ 1102.24(b)); it is concrete information that we expect will be known or readily attainable by the entity filing the request. We estimate that it will take 15 minutes to submit such a request electronically. Because it would take longer to convey the necessary information on paper, and to avoid inadvertently underestimating the burden, we estimate that it will take twice as much time, or 30 minutes, to submit the request on paper. We employed the same assumptions as used above to predict how many requests will be submitted electronically (454 requests \times 76 percent electronic submission) to arrive at an estimate of 345 electronic requests and 109 paper requests. We multiplied 345 electronic requests by 15 minutes, resulting in 5,175 minutes, or about 86 burden hours for the electronic requests. Similarly, we multiplied 109 paper requests by 30 minutes, resulting in 3,270 minutes, or about 54 burden hours for the paper requests.

Regarding requests to designate information materially inaccurate, roughly 10 percent of the manufacturer comments that we currently receive contain a claim that the incident report contained inaccurate information. We used that figure to estimate that the number of requests to treat information as materially inaccurate will be 10 percent of the total number of reports of harm and manufacturer comments that we expect, or 2,271 ((15,140 reports + 7,570 comments) \times 10 percent). Section 1102.26(b) of the proposed rule would specify what must be included in such a request. Most of the information will be known or readily attainable by the person or entity filing the request, but we estimate it will take longer to file a

request to treat information as materially inaccurate than to file a request to treat information as confidential because with a request related to material inaccuracy one must provide evidence of the inaccuracy as described in § 1102.26(b)(4). We anticipate that this will double the amount of time it takes to file the request, or require 30 minutes for an electronic request and 60 minutes for a paper request. Employing the same assumptions concerning the method of submission, we estimate that there will be 1,726 electronic requests to treat information as materially inaccurate (2,271 total requests \times 76 percent electronic = 1,726). Because each electronic request is estimated to take 30 minutes, we estimate the resulting burden to be 863 hours (1,726 requests \times 30 minutes = 51,780 minutes, or 863 burden hours). Similarly, 545 paper requests (2,271 requests \times 24 percent paper = 545), at 60 minutes each to complete, results in a burden of 545 hours (545 paper requests \times 60 minutes = 32,700 minutes, or 545 hours).

The total estimated burden, therefore, is 37,129 hours.

VI. Executive Order 12988

According to Executive Order 12988 (February 5, 1996), agencies must state in clear language the preemptive effect, if any, of new regulations. This regulation is issued under the authority of the CPSA, wherein preemption is discussed in section 26 of the CPSA. Section 26 of the CPSA only addresses the preemptive effect of consumer product safety standards under the CPSA. The current rule is not a consumer product safety standard under the CPSA. Accordingly, the Commission has determined that this rule does not contain requirements that impact the states.

VII. Regulatory Flexibility Act

The Regulatory Flexibility Act ("RFA") generally requires that agencies review proposed rules for their potential economic impact on small entities, including small businesses. Section 603 of the RFA calls for agencies to prepare and make available for public comment an initial regulatory flexibility analysis describing the impact of the proposed rule on small entities and identifying impact-reducing alternatives. 5 U.S.C. 603. Section 605(b) of the RFA, however, states that this requirement does not apply if the head of the agency certifies that the rule will not, if promulgated, have a significant economic impact on a substantial number of small entities, and the agency

provides an explanation for that conclusion.

The proposed rule did not contain an initial RFA analysis, stating that preliminary analysis establishes that the proposed rule will have little or no effect on small businesses. While the agency anticipates that the new Database likely will increase the number of consumer-generated reports over the number of incident reports currently filed with the Commission, this will not have a significant impact on a substantial number of small businesses. Because of the small increase in the expected number of incident reports, relative to the large number of small manufacturers that produce consumer products, relatively few small manufacturers will receive even a single incident report. Moreover, because small manufacturers have smaller sales volumes than large manufacturers, they are less likely than large manufacturers to receive an incident report for comment. Even if a small firm does receive an incident report and chooses to respond, the amount of time to do so likely would not be more than approximately 4 hours, on average.

The Commission invited comment on this analysis and the preliminary certification statement. One comment was received as discussed below. Based on this, we decline to provide a complete RFA analysis on the economic impact of the rule on small businesses prior to implementation of the final rule, and certify that no such analysis is required.

Comment—One commenter disagrees that the proposed rule will have little or no impact on small businesses based on the time and resources required to respond to reports of harm. The commenter states that small businesses must contract out for legal, engineering, and testing services, which will all likely take more than a few hours to complete an analysis and which will place a significant financial burden on these small firms. Furthermore, when "a few hours" is multiplied by the number of small businesses subject to this rule, the commenter claims the time burden becomes substantial. Based on the resource allocation required of small businesses, the commenter states that the Commission should complete a regulatory flexibility analysis on the economic impact of the rule on small businesses prior to implementation of the proposed rule.

Response—Our analysis does not rule out the possibility that some small businesses may be adversely affected by the rule. However, under the RFA, the inquiry is whether the rule would have a significant economic impact on a

substantial number of small entities. If a severe safety defect is alleged in an incident report, a small business may need to devote substantial resources to investigate the incident. However, such an investigation would not necessarily be attributable to the Database, because a severe product defect would need to be investigated, even in the absence of the Database. Moreover, it is expected that only a small proportion of small businesses will receive even a single incident report.

According to our analysis, no more than an additional five percent of small manufacturers of consumer products will be affected by the Database rule annually. Of these, only a very small percentage of the incidents reported would merit a large investigation effort. Based on the CPSC's Freedom of Information Act ("FOIA") experience, it is rare that a small firm devotes substantial time and effort responding to incident reports. Thus, while it is possible that a small number of small businesses may experience a "significant" impact in investigating certain incidents, the number of small businesses experiencing such an impact would not be "substantial."

Moreover, many impacts attributed to the Database rule are indirect in that they do not arise from direct regulation of the production activities of entities. Consequently, these impacts generally are not subject to the analytical requirements of the RFA. Nevertheless, in forming a basis for certification, we performed a threshold analysis, which quantifies the expected impact of a regulation, and to a large degree, forms the analytical substance of a formal RFA analysis. In sum, it is expected that the average cost of responding electronically to one incident report is \$280, and that the impact on an average small manufacturer (with revenue of \$6.4 million) would amount to about 0.0044 percent of sales. Even if an average small manufacturer received and responded to 10 incident reports during the year, the cost still would be considerably less than one-tenth of one percent of the value of shipments. Further analysis would not change these results or provide additional insight into the expected impacts of the rule. Accordingly, we decline to provide a complete RFA analysis on the economic impact of the rule on small businesses, and will certify that no such analysis is required.

VIII. Effective Date

The Administrative Procedure Act ("APA") generally requires that the effective date of a rule be at least 30 days after publication of a final rule. 5

U.S.C. 553(d). Accordingly, the effective date of the final rule is 30 days after the date of publication of a final rule in the **Federal Register**.

List of Subjects in 16 CFR Part 1102

Administrative practice and procedure, Business and industry, Consumer protection, Reporting and recordkeeping requirements.

■ For the reasons stated above, the Commission amends Title 16 of the Code of Federal Regulations by adding a new Part 1102 to read as follows:

PART 1102—PUBLICLY AVAILABLE CONSUMER PRODUCT SAFETY INFORMATION DATABASE

Subpart A—Background and Definitions

Sec.

1102.2 Purpose.

1102.4 Scope.

1102.6 Definitions.

Subpart B—Content Requirements

1102.10 Reports of harm.

1102.12 Manufacturer comments.

1102.14 Recall notices.

1102.16 Additional information.

Subpart C—Procedural Requirements

1102.20 Transmission of reports of harm to the identified manufacturer or private labeler.

1102.24 Designation of confidential information.

1102.26 Determination of materially inaccurate information.

1102.28 Publication of reports of harm.

1102.30 Publication of manufacturer comments.

Subpart D—Notice and Disclosure Requirements

1102.42 Disclaimers.

1102.44 Applicability of sections 6(a) and (b) of the CPSA.

Authority: 15 U.S.C. 2051, 2051 note, 2052, 2055, 2055a, 2065, 2068, 2070, 2071, 2072, 2076, 2078, 2080, 2087.

Subpart A—Background and Definitions

§ 1102.2 Purpose.

This part sets forth the Commission's interpretation, policy, and procedures with regard to the establishment and maintenance of a Publicly Available Consumer Product Safety Information Database (also referred to as the "Database") on the safety of consumer products and other products or substances regulated by the Commission.

§ 1102.4 Scope.

This part applies to the content, procedure, notice, and disclosure requirements of the Publicly Available Consumer Product Safety Information

Database, including all information published therein.

§ 1102.6 Definitions.

(a) Except as specified in paragraph (b) of this section, the definitions in section 3 of the Consumer Product Safety Act (CPSA) (15 U.S.C. 2052) apply to this part.

(b) For purposes of this part, the following definitions apply:

(1) *Additional information* means any information that the Commission determines is in the public interest to include in the Publicly Available Consumer Product Safety Information Database.

(2) *Commission or CPSC* means the Consumer Product Safety Commission.

(3) *Consumer product* means a consumer product as defined in section 3(a)(5) of the CPSA, and also includes any other products or substances regulated by the Commission under any other act it administers.

(4) *Harm* means injury, illness, or death; or risk of injury, illness, or death, as determined by the Commission.

(5) *Mandatory recall notice* means any notice to the public required of a firm pursuant to an order issued by the Commission under section 15(c) of the CPSA.

(6) *Manufacturer comment* means a comment made by a manufacturer or private labeler of a consumer product in response to a report of harm transmitted to such manufacturer or private labeler.

(7) *Publicly Available Consumer Product Safety Information Database*, also referred to as the Database, means the database on the safety of consumer products established and maintained by the CPSC as described in section 6A of the CPSA.

(8) *Report of harm* means any information submitted to the Commission through the manner described in § 1102.10(b), regarding any injury, illness, or death; or any risk of injury, illness, or death, as determined by the Commission, relating to the use of a consumer product.

(9) *Submitter of a report of harm* means any person or entity that submits a report of harm.

(10) *Voluntary recall notice* means any notice to the public by the Commission relating to a voluntary corrective action, including a voluntary recall of a consumer product, taken by a manufacturer in consultation with the Commission.

Subpart B—Content Requirements

§ 1102.10 Reports of harm.

(a) *Who may submit.* The following persons or entities may submit reports of harm:

(1) *Consumers* including, but not limited to, users of consumer products, family members, relatives, parents, guardians, friends, attorneys, investigators, professional engineers, agents of a user of a consumer product, and observers of the consumer products being used;

(2) *Local, state, or federal government agencies* including, but not limited to, local government agencies, school systems, social services, child protective services, state attorneys general, state agencies, and all executive and independent federal agencies as defined in Title 5 of the United States Code;

(3) *Health care professionals* including, but not limited to, medical examiners, coroners, physicians, nurses, physician's assistants, hospitals, chiropractors, and acupuncturists;

(4) *Child service providers* including, but not limited to, child care centers, child care providers, and prekindergarten schools; and

(5) *Public safety entities* including, but not limited to, police, fire, ambulance, emergency medical services, federal, state, and local law enforcement entities, and other public safety officials and professionals, including consumer advocates or individuals who work for nongovernmental organizations, consumer advocacy organizations, and trade associations, so long as they have a public safety purpose.

(b) *Manner of submission.* To be entered into the Database, reports of harm must be submitted to the CPSC using one of the following methods:

(1) Internet submissions through the CPSC's Internet Web site on an electronic incident report form specifically developed to collect such information.

(2) Telephonic submissions through a CPSC call center, where the information is entered on the electronic incident form.

(3) Electronic mail directed to the Office of the Secretary at *info@cpsc.gov*, or by facsimile at 301-504-0127, provided that the submitter completes the incident report form available for download on the CPSC's Internet Web site specifically developed to collect such information.

(4) Written submissions to the Office of the Secretary, Consumer Product Safety Commission, 4330 East West Highway, Bethesda, MD 20814-4408. The Commission will accept only those written reports of harm that use the incident report form developed for the CPSC's Internet Web site; or

(5) Other means the Commission subsequently makes available.

(c) *Size limit of reports of harm.* The Commission may, in its discretion, limit

the data size of reports of harm, which may include attachments submitted, where such reports of harm and attachments may negatively impact the technological or operational performance of the system.

(d) *Minimum requirements for publication.* Subject to §§ 1102.24 and 1102.26, the Commission will publish in the Publicly Available Consumer Product Safety Information Database reports of harm containing all of the following information:

(1) *Description of the consumer product.* The description of the consumer product must, at a minimum, include a word or phrase sufficient to distinguish the product as a consumer product, a component part of a consumer product, or a product or substance regulated by the Commission. In addition to a word or phrase sufficient to distinguish the product as a consumer product, a description of a consumer product may include, but is not limited to, the name, including the brand name of the consumer product, model, serial number, date of manufacture (if known) or date code, date of purchase, price paid, retailer, or any other descriptive information about the product.

(2) *Identity of the manufacturer or private labeler.* The name of one or more manufacturers or private labelers of the consumer product. In addition to a firm name, identification of a manufacturer or private labeler may include, but is not limited to, a mailing address, phone number, or electronic mail address.

(3) *Description of the harm.* A brief narrative description of illness, injury, or death; or risk of illness, injury, or death related to use of the consumer product. Examples of a description of harm or risk of harm include, but are not limited to: Death, asphyxiation, lacerations, burns, abrasions, contusions, fractures, choking, poisoning, suffocation, amputation, or any other narrative description relating to a bodily harm or risk of bodily harm. Incident reports that relate solely to the cost or quality of a consumer product, with no discernable bodily harm or risk of bodily harm, do not constitute "harm" for purposes of this part. A description of harm may, but need not, include the severity of any injury and whether any medical treatment was received.

(4) *Incident date.* The date, or an approximate date, on which the incident occurred.

(5) *Category of submitter.* Indication of which category the submitter is in (*i.e.*, consumers, government agencies, *etc.*) from § 1102.10(a).

(6) *Contact information.* The submitter's first name, last name, and

complete mailing address. Although this information will not be published in the Database, it is required information for the report of harm. Submitters also may, but are not required to, provide an electronic mail address and a phone number to allow for efficient and timely contact regarding a report of harm, when necessary.

(7) *Verification.* A submitter of a report of harm must affirmatively verify that he or she has reviewed the report of harm, and that the information contained therein is true and accurate to the best of the submitter's knowledge, information, and belief. Verification procedures for each method of submission will be specified.

(8) *Consent.* A submitter of a report of harm must consent to publication of the report of harm in the Database if he or she wants the information to be included in the Database.

(e) *Additional information requested on report of harm.* The minimum requirements (at § 1102.10(d)) for publication of a report of harm in the Database do not restrict the Commission from choosing to seek other categories of voluntary information in the future.

(f) *Information not published.* The Commission will exclude the following information provided on a report of harm from publication in the Database:

(1) Name and contact information of the submitter of a report of harm;

(2) Victim's name and contact information, if the victim or the victim's parent, guardian, or appropriate legally authorized representative, has not provided appropriate legal consent;

(3) Photographs that in the determination of the Commission are not in the public interest, including photographs that could be used to identify a person or photographs that would constitute an invasion of personal privacy based on the Privacy Act of 1974, Public Law 93-579 as amended;

(4) Medical records without the consent of the person about whom such records pertain or without the consent of his or her parent, guardian, or appropriate legally authorized representative;

(5) Confidential information as set forth in § 1102.24;

(6) Information determined to be materially inaccurate as set forth in § 1102.26;

(7) Reports of harm retracted at any time by the submitters of those reports, if they indicate in writing to the Commission that they supplied materially inaccurate information;

(8) Consents and verifications associated with a report of harm; and

(9) Any other information submitted on or with a report of harm, the inclusion of which in the Database, the Commission determines is not in the public interest. The Commission shall consider whether the information is related to a product safety purpose served by the Database, including whether or not the information helps Database users to:

- (i) Identify a consumer product;
- (ii) Identify a manufacturer or private labeler of a consumer product;
- (iii) Understand a harm or risk of harm related to the use of a consumer product; or
- (iv) Understand the relationship between a submitter of a report of harm and the victim.

(g) *Reports of harm from persons under the age of 18.* The Commission will not accept any report of harm when the report of harm is or was submitted by anyone under the age of 18 without consent of the parent or guardian of that person.

(h) *Incomplete reports of harm.* Any information received by the Commission related to a report of harm that does not meet the requirements for submission or publication will not be published, but will be maintained for internal use.

(i) *Official records of the Commission.* All reports of harm that are submitted to the Commission become official records of the Commission in accordance with 16 CFR 1015.1.

Alteration (or disposition) of any such records will only be in accordance with the procedures specified in this part.

§ 1102.12 Manufacturer comments.

(a) *Who may submit.* A manufacturer or private labeler may submit a comment related to a report of harm if the report of harm identifies such manufacturer or private labeler.

(b) *How to submit.* A manufacturer or private labeler may submit comments to the CPSC using one of the following methods:

(1) A manufacturer or private labeler who registers with the Commission as described in § 1102.20(f) may submit comments through a manufacturer portal maintained on the CPSC's Internet Web site;

(2) A manufacturer or private labeler may submit comments by electronic mail, directed to the Office of the Secretary at info@cpsc.gov; or

(3) A manufacturer or private labeler may submit written comments directed to the Office of the Secretary, Consumer Product Safety Commission, 4330 East West Highway, Bethesda, MD 20814-4408.

(c) *What must be submitted.* Subject to §§ 1102.24 and 1102.26, the

Commission will publish manufacturer comments related to a report of harm transmitted to a manufacturer or private labeler in the Database if such manufacturer comment meets the following requirements:

(1) *Manufacturer comment relates to report of harm.* The manufacturer or private labeler's comment must relate to information contained in a specific report of harm that identifies such manufacturer or private labeler and that is submitted for publication in the Database.

(2) *Unique identifier.* A manufacturer comment must state the unique identifier provided by the CPSC.

(3) *Verification.* A manufacturer or private labeler must verify that it has reviewed the report of harm and the comment related to the report of harm and that the information contained in the comment is true and accurate to the best of the firm's knowledge, information, and belief.

(4) *Request for publication.* When a manufacturer or private labeler submits a comment regarding a report of harm, it may request that the Commission publish such comment in the Database. A manufacturer or private labeler must affirmatively request publication of the comment, and consent to such publication in the Database, for each comment submitted to the CPSC.

(d) *Information published.* Subject to §§ 1102.24 and 1102.26, the Commission will publish a manufacturer comment and the date of its submission to the CPSC in the Database if the comment meets the minimum requirements for publication as described in paragraph (c) of this section.

(e) *Information not published.* The Commission will not publish in the Database consents and verifications associated with a manufacturer comment.

§ 1102.14 Recall notices.

All information presented in a voluntary or mandatory recall notice that has been made available to the public shall be accessible and searchable in the Database.

§ 1102.16 Additional information.

In addition to reports of harm, manufacturer comments, and recall notices, the CPSC shall include in the Database any additional information it determines to be in the public interest, consistent with the requirements of section 6(a) and (b) of the CPSA.

Subpart C—Procedural Requirements

§ 1102.20 Transmission of reports of harm to the identified manufacturer or private labeler.

(a) *Information transmitted.* Except as provided in paragraphs (a)(1) through (a)(3) of this section, the Commission will transmit all information provided in a report of harm, provided such report meets the minimum requirements for publication in the Database, to the manufacturer or private labeler identified in a report of harm. The following information will not be transmitted to a manufacturer or private labeler:

(1) Name and contact information for the submitter of the report of harm, unless such submitter provides express written consent (for example, by checking a box on the report of harm) to provide such information to the manufacturer or private labeler;

(2) Photographs that could be used to identify a person; and

(3) Medical records, unless the person about whom such records pertain, or his or her parent, guardian, or appropriate legally authorized representative, consents to providing such records to the manufacturer or private labeler.

(b) *Limitation on use of contact information.* A manufacturer or private labeler who receives name and contact information for the submitter of a report of harm and/or a victim must not use or disseminate such information to any other party for any other purpose other than verification of information contained in a report of harm.

Verification of information contained in a report of harm must not include activities such as sales, promotion, marketing, warranty, or any other commercial purpose. Verification of information contained in a report of harm may include verification of the:

(1) Identity of the submitter and/or the victim, including name, location, age, and gender;

(2) Consumer product, including serial or model number, date code, color, or size;

(3) Harm or risk of harm related to the use of the consumer product;

(4) Description of the incident related to use of the consumer product;

(5) Date or approximate date of the incident; and/or

(6) Category of submitter.

(c) *Timing.* To the extent practicable, the Commission will transmit a report of harm to the manufacturer or private labeler within five business days of submission of the completed report of harm. If the Commission cannot determine whom the manufacturer or private labeler is from the report of

harm, or otherwise, then it will not post the report of harm on the Database but will maintain the report for internal agency use. Examples of circumstances that may arise that may make transmission of the report of harm impracticable within five business days include, but are not limited to:

(1) The manufacturer or private labeler is out of business with no identifiable successor;

(2) The submitter misidentified a manufacturer or private labeler;

(3) The report of harm contained inaccurate or insufficient contact information for a manufacturer or private labeler; or

(4) The Commission cannot locate valid contact information for a manufacturer or private labeler.

(d) *Method of transmission.* The Commission will use the method of transmission and contact information provided by the manufacturer or private labeler. The Commission will transmit reports of harm to a manufacturer or private labeler who has registered with the Commission as described in paragraph (f) of this section. If a manufacturer or private labeler has not registered with the Commission, the Commission will send reports of harm through the United States mail to the firm's principal place of business, unless the Commission selects another equally effective method of transmission.

(e) *Size limits of manufacturer comments.* The Commission may, in its discretion, limit the data size of comments, which may include attachments submitted, where such comments and attachments may negatively impact the technological or operational performance of the system.

(f) *Manufacturer registration.* Manufacturers and private labelers may register with the Commission to select a preferred method for receiving reports of harm that identify such firm as the manufacturer or private labeler. Manufacturers and private labelers that choose to register with the Commission must:

(1) Register with the Commission through a process identified for such registration;

(2) Provide and maintain updated contact information for the firm, including the name of the firm, title of a person to whom reports of harm should be directed, complete mailing address, telephone number, electronic mail address, and Web site address (if any); and

(3) Select a specified method to receive reports of harm that identify the firm as the manufacturer or private labeler of a consumer product.

(g) *Manufacturer comments.* A manufacturer or private labeler who receives a report of harm from the CPSC may comment on the information contained in such report of harm. The Commission, in its discretion, where it determines it is in the public interest, may choose not to publish a manufacturer comment in the Database. For example, it may not be in the public interest for the Commission to publish comments that, in the unlikely event, contain language reasonably described as lewd, lascivious, or obscene.

§ 1102.24 Designation of confidential information.

(a) For purposes of this section, "confidential information" is considered to be information that contains or relates to a trade secret or other matter referred to in 18 U.S.C. 1905 or that is subject to 5 U.S.C. 552(b)(4).

(b) A manufacturer or private labeler identified in a report of harm and who receives a report of harm from the CPSC may review such report of harm for confidential information and request that portions of the report of harm be designated as confidential information. Each requester seeking such a designation of confidential information bears the burden of proof and must:

(1) Specifically identify the exact portion(s) of the report of harm claimed to be confidential;

(2) State whether the information claimed to be confidential has ever been released in any manner to a person who was not an employee or in a confidential relationship with the company;

(3) State whether the information so specified is commonly known within the industry or is readily ascertainable by outside persons with a minimum of time and effort;

(4) If known, state the company's relationship with the victim and/or submitter of the report of harm and how the victim and/or submitter of the report of harm came to be in possession of such allegedly confidential information;

(5) State how the release of the information would be likely to cause substantial harm to the company's competitive position; and

(6) State whether the person submitting the request for treatment as confidential information is authorized to make claims of confidentiality on behalf of the person or organization concerned.

(c) *Manner of submission.* Requests for designation of confidential information may be submitted in the same manner as manufacturer comments as described in § 1102.12(b). A request for designation of confidential

treatment must be conspicuously marked.

(d) *Timing of submission.* In order to ensure that the allegedly confidential information is not placed in the database, a request for designation of confidential information must be received by the Commission in a timely manner prior to the 10th business day after the date on which the Commission transmits the report to the manufacturer or private labeler. If a request for confidential treatment is submitted in a timely fashion, the Commission will either make a determination on the claim prior to posting on the 10th business day after transmittal to the manufacturer or, as a matter of policy, redact the allegedly confidential information from a report of harm before publication in the Database until it makes a determination regarding confidential treatment.

(e) *Assistance with defense.* No request to redact confidential information from a report of harm pursuant to 5 U.S.C. 552(b)(4) should be made by any person who does not intend in good faith, and so certifies in writing, to assist the Commission in the defense of any judicial proceeding that thereafter might be brought to compel the disclosure of information that the Commission has determined to be a trade secret or privileged or confidential commercial or financial information.

(f) *Commission determination of confidentiality.* If the Commission determines that information in a report of harm is confidential, the Commission shall:

(1) Notify the manufacturer or private labeler;

(2) Redact such confidential information in the report of harm; and

(3) Publish the report of harm in the Database without such confidential information.

(g) *Commission determination of no confidentiality.* If the Commission determines that a report of harm does not contain confidential information, the Commission shall:

(1) Notify the manufacturer or private labeler; and

(2) Publish the report of harm, if not already published, in the Database.

(h) *Removal of confidential information.* As stated at 6A(c)(1)(C)(iii) of the CPSA, to seek removal of alleged confidential information that has been published in the Database, a manufacturer or private labeler may bring an action in the district court of the United States in the district in which the complainant resides, or has its principal place of business, or in the U.S. District Court for the District of Columbia.

§ 1102.26 Determination of materially inaccurate information.

(a) For purposes of this section, the following definitions apply:

(1) *Materially inaccurate information in a report of harm* means information that is false or misleading, and which is so substantial and important as to affect a reasonable consumer's decision making about the product, including:

- (i) The identification of a consumer product;
- (ii) The identification of a manufacturer or private labeler;
- (iii) The harm or risk of harm related to use of the consumer product; or
- (iv) The date, or approximate date on which the incident occurred.

(2) *Materially inaccurate information in a manufacturer comment* means information that is false or misleading, and which is so substantial and important as to affect a reasonable consumer's decision making about the product, including:

- (i) The description of the consumer product;
- (ii) The identity of the firm or firms responsible for the importation, manufacture, distribution, sale, or holding for sale of a consumer product;
- (iii) The harm or risk of harm related to the use of a consumer product;
- (iv) The status of a Commission, manufacturer, or private labeler investigation;
- (v) Whether the manufacturer or private labeler is engaging in a corrective action and whether such action has not been approved by the Commission; or
- (vi) Whether the manufacturer has taken, or promised to take, any other action with regard to the product.

(b) *Request for determination of materially inaccurate information.* Any person or entity reviewing a report of harm or manufacturer comment, either before or after publication in the Database, may request that the report of harm or manufacturer comment, or portions of such report of harm or manufacturer comment, be excluded from the Database or corrected by the Commission because it contains materially inaccurate information. Each requester seeking an exclusion or correction bears the burden of proof and must:

(1) State the unique identifier of the report of harm or manufacturer comment to which the request for a determination of materially inaccurate information pertains;

(2) Specifically identify the exact portion(s) of the report of harm or the manufacturer comment claimed to be materially inaccurate;

(3) State the basis for the allegation that such information is materially inaccurate;

(4) Provide evidence, which may include documents, statements, electronic mail, Internet links, photographs, or any other evidence, sufficient for the Commission to make a determination that the designated information is materially inaccurate;

(5) State what relief the requester is seeking: Exclusion of the entire report of harm or manufacturer comment; redaction of specific information; correction of specific information; or the addition of information to correct the material inaccuracy;

(6) State whether and how an alleged material inaccuracy may be corrected without removing or excluding an entire report of harm or manufacturer comment; and

(7) State whether the person submitting the allegation of material inaccuracy is authorized to make claims of material inaccuracy on behalf of the person or organization concerned.

(c) *Manner of submission—*

(1) *Length of request and expedited review.* The Commission strongly recommends requesters seeking an expedited review of claims of materially inaccurate information to limit the length of the request described in § 1102.26(b) to no more than five pages, including attachments, to allow for the expedited review of the request. Regardless of length, all submissions will be reviewed.

(2) *Manufacturers and private labelers.* A manufacturer or private labeler may request a Commission determination of materially inaccurate information related to a report of harm in the same manner as described in § 1102.12(b). Such requests should be conspicuously marked.

(3) *All other requests.* All other requests for a Commission determination of materially inaccurate information contained in a report of harm or manufacturer comment made by any other person or firm must be submitted to the CPSC using one of the methods listed below. The request seeking a Commission determination of materially inaccurate information may be made through:

(i) *Electronic mail.* By electronic mail directed to the Office of the Secretary at info@cpsc.gov; or

(ii) *Paper-based.* Written submission directed to the Office of the Secretary, Consumer Product Safety Commission, 4330 East West Highway, Bethesda, MD 20814-4408.

(d) *Timing of submission.* A request for a Commission determination regarding materially inaccurate

information may be submitted at any time. If a request for determination of materially inaccurate information is submitted prior to publication of a report of harm in the Database, the Commission cannot withhold the report of harm from publication in the Database until it makes a determination. Absent a determination, the Commission will publish reports of harm on the tenth business day after transmitting a report of harm to the manufacturer or private labeler.

(e) *Assistance with defense.* No request for a determination of materially inaccurate information should be made by any person who does not intend in good faith, and so certifies in writing, to assist the Commission in the defense of any judicial proceeding that thereafter might be brought to compel the disclosure of information that the Commission has determined to be materially inaccurate information.

(f) *Notice.* The Commission shall notify the person or firm requesting a determination regarding materially inaccurate information of its determination and method of resolution after resolving such request.

(g) *Commission determination of material inaccuracy before publication.* If the Commission determines that information in a report of harm or manufacturer comment is materially inaccurate information before it is published in the Database, the Commission shall:

(1) Decline to add the materially inaccurate information to the Database;

(2) Correct the materially inaccurate information, and, if the minimum requirements for publication as set forth in §§ 1102.10(d) and 1102.12(c) are met, publish the report of harm or manufacturer comment in the Database; or

(3) Add information to the report of harm or the manufacturer comment to correct the materially inaccurate information, and, if the minimum requirements for publication as set forth in §§ 1102.10(d) and 1102.12(c) are met, publish the report of harm or manufacturer comment in the Database.

(h) *Commission determination of material inaccuracy after publication.* If the Commission determines, after an investigation, that the requested designated information in a report of harm or manufacturer comment contains materially inaccurate information after the report of harm or manufacturer comment has been published in the Database, the Commission shall, no later than seven business days after such determination:

(1) Remove the information determined to be materially inaccurate

from the Database, including any associated documents, photographs, or comments;

(2) Correct the information, and, if the minimum requirements for publication as set forth in §§ 1102.10(d) and 1102.12(c) are met, maintain the report of harm or manufacturer comment in the Database; or

(3) Add information to the report of harm or the manufacturer comment to correct the materially inaccurate information, and, if the minimum requirements for publication as set forth in §§ 1102.10(d) and 1102.12(c) are met, maintain the report of harm or manufacturer comment in the Database.

(i) *Commission discretion.*

(1) In exercising its discretion to remove, correct, or add information to correct materially inaccurate information contained in a report of harm or manufacturer comment, the Commission shall preserve the integrity of information received for publication in the Database whenever possible. Subject to §§ 1102.10(d) and 1102.12(c), the Commission shall favor correction, and the addition of information to correct, over exclusion of entire reports of harm and manufacturer comments, where possible.

(2) *Expedited determinations.* Where a manufacturer has filed a request for a correction or exclusion within the recommended page limit in § 1102.26(c)(1), the Commission shall attempt, where practicable, to make an expedited determination of a claim of material inaccuracy. Given the requirement of section 6A of the CPSA that reports of harm be published, the Commission will publish reports of harm on the tenth business day after transmitting a report of harm, where the Commission has been unable to make a determination regarding a claim of material inaccuracy prior to the statutorily mandated publication date. In such instances, the Commission will make any necessary correction, exclusion, or addition not later than seven business days after making a determination that there is materially inaccurate information in the report of harm. Manufacturer comments will be published at the same time as the report

of harm is published, or as soon thereafter as practicable.

(j) *Commission determination of no material inaccuracy.* If the Commission determines that the requested information in a report of harm or manufacturer comment does not contain materially inaccurate information, the Commission will:

(1) Notify the requester of its determination; and

(2) Publish the report of harm or manufacturer comment, if not already published, in the Database if it meets the minimum requirements set forth in §§ 1102.10(d) and 1102.12(c).

(k) *Commission action in absence of request.* The Commission may review a report of harm or manufacturer comment for materially inaccurate information on its own initiative, following the same notice and procedural requirements set forth in paragraphs (g) through (j) of this section.

§ 1102.28 Publication of reports of harm.

(a) *Timing.* Subject to §§ 1102.10, 1102.24, and 1102.26, the Commission will publish reports of harm that meet the requirements for publication in the Database. The Commission will publish reports of harm as soon as practicable, but not later than the tenth business day after such report of harm is transmitted to the manufacturer or private labeler by the CPSC.

(b) *Exceptions.* The Commission may publish a report of harm that meets the requirements of § 1102.10(d) in the Database beyond the 10-business-day time frame set forth in paragraph (a) of this section if the Commission determines that a report of harm misidentifies or fails to identify all manufacturers or private labelers. Such information must be corrected through the procedures set forth in § 1102.26 for materially inaccurate information in a report of harm. Once a manufacturer or a private labeler has been identified correctly, the time frame set forth in paragraph (a) of this section shall apply.

§ 1102.30 Publication of manufacturer comments.

Timing. Subject to §§ 1102.12, 1102.24, and 1102.26, the Commission will publish in the Database manufacturer comments submitted in

response to a report of harm that meet the minimum requirements set forth in § 1102.12(c). This publication will occur at the same time as the report of harm is published or as soon thereafter as practicable. An example of a circumstance that may make it impracticable to publish a manufacturer comment at the same time as a report of harm includes when the Commission did not receive the comment until on or after the publication date of the report of harm.

Subpart D—Notice and Disclosure Requirements

§ 1102.42 Disclaimers.

The Commission does not guarantee the accuracy, completeness, or adequacy of the contents of the Consumer Product Safety Information Database, particularly with respect to the accuracy, completeness, or adequacy of information submitted by persons outside of the CPSC. The Database will contain a notice to this effect that will be prominently and conspicuously displayed on the Database and on any documents that are printed from the Database.

§ 1102.44 Applicability of sections 6(a) and (b) of the CPSA.

(a) *Generally.* Sections 6(a) and 6(b) of the CPSA shall not apply to the submission, disclosure, and publication of information provided in a report of harm that meets the minimum requirements for publication in § 1102.10(d) in the Database.

(b) *Limitation on construction.* Section 1102.44(a) shall not be construed to exempt from the requirements of sections 6(a) and 6(b) of the CPSA information received by the Commission pursuant to:

(1) Section 15(b) of the CPSA; or

(2) Any other mandatory or voluntary reporting program established between a retailer, manufacturer, or private labeler and the Commission.

Dated: November 30, 2010.

Todd A. Stevenson,

Secretary, United States Consumer Product Safety Commission.

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