TABLE 1 TO PARAGRAPH (g)—AFFECTED PARTS—Continued

Engine S/N	Engine model	CDP seal		HPC stage 3 disk		HPT rear shaft	
		S/N	P/N	S/N	P/N	S/N	P/N
699867	CFM56–5B	GFF5LN9E	2116M25P01	XAE6932U	2116M23P01	TMT1UNLM	1864M90P04
643267	CFM56–5B	GFF5MH2	2116M25P01	XAE7182U	2116M23P01	TMT1U296	1864M90P04
779533	CFM56–5B	GFF5J6MH	2116M25P01	XAEGD645	2116M23P01	TMTD2505	1864M90P04
643444	CFM56–5B	GFF5LN7D	2116M25P01	N/A	N/A	TMT1U9RJ	1864M90P04
699887	CFM56–5B	GFF5LKGP	2116M25P01	XAE6818U	2116M23P01	TMT1U0HU	1864M90P04

Note 1 to paragraph (g): Table 1 to paragraph (g) of this AD includes, for information only, the engine serial numbers (engine S/N) and engine models on which the affected parts were installed.

(h) Installation Prohibition

(1) After the effective date of this AD, do not install any CDP seal, HPC stage 3 disk, or HPT rear shaft having a P/N and S/N specified in Table 1 to paragraph (g) of this AD on any engine.

(2) After the effective date of this AD, do not install any engine having a CDP seal, HPC stage 3 disk, or HPT rear shaft having a P/N and S/N specified in Table 1 to paragraph (g) of this AD installed on any airplane.

(i) Definition

For the purposes of this AD, a part eligible for installation is any CDP seal, HPC stage 3 disk, or HPT rear shaft that does not have a P/N and S/N specified in Table 1 to paragraph (g) of this AD.

(j) Alternative Methods of Compliance (AMOCs)

(1) The Manager, AIR–520 Continued Operational Safety Branch, FAA, has the authority to approve AMOCs for this AD, if requested using the procedures found in 14 CFR 39.19. In accordance with 14 CFR 39.19, send your request to your principal inspector or local Flight Standards District Office, as appropriate. If sending information directly to the manager of the AIR–520 Continued Operational Safety Branch, send it to the attention of the person identified in paragraph (k) of this AD and email to: *ANE-AD-AMOC@faa.gov.*

(2) Before using any approved AMOC, notify your appropriate principal inspector, or lacking a principal inspector, the manager of the local flight standards district office/certificate holding district office.

(k) Additional Information

For more information about this AD, contact Sungmo Cho, Aviation Safety Engineer, FAA, 2200 South 216th Street, Des Moines, WA 98198; phone: (781) 238–7241; email: *sungmo.d.cho@faa.gov.*

(l) Material Incorporated by Reference

None.

Issued on March 18, 2024.

Victor Wicklund,

Deputy Director, Compliance & Airworthiness Division, Aircraft Certification Service.

[FR Doc. 2024–06080 Filed 3–19–24; 11:15 am]

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

21 CFR Part 170

[Docket No. FDA–2021–N–0403]

RIN 0910–AI01

Food Additives: Food Contact Substance Notification That Is No Longer Effective

AGENCY: Food and Drug Administration, Department of Health and Human Services (HHS).

ACTION: Final rule.

SUMMARY: The Food and Drug Administration (FDA or we) is amending its regulations relating to the procedures for determining that a premarket notification for a food contact substance (FCN) is no longer effective. The final rule provides additional reasons that could form the basis for FDA to determine that an FCN is no longer effective. The final rule also ensures that manufacturers or suppliers have the opportunity to provide input before we determine that an FCN is no longer effective. We are making these changes to allow FDA to respond better to new information on the safety and use of food contact substances (FCSs), as well as manufacturers' business decisions, and also improve the efficiency of the premarket notification program.

DATES: This rule is effective May 21, 2024.

ADDRESSES: For access to the docket to read background documents or comments received, go to *https://www.regulations.gov* and insert the docket number found in brackets in the heading of this final rule into the ''Search'' box and follow the prompts, and/or go to the Dockets Management Staff, 5630 Fishers Lane, Rm. 1061, Rockville, MD 20852, 240–402–7500.

FOR FURTHER INFORMATION CONTACT:

With regard to the final rule: Sharon Koh-Fallet, Center for Food Safety and Applied Nutrition (HFS–275), Food and Drug Administration, 5001 Campus Dr., College Park, MD 20740, 301–796–7732; or Carrol Bascus, Center for Food Safety and Applied Nutrition (HFS–024), Food and Drug Administration, 5001 Campus Dr., College Park, MD 20740, 240–402–2378.

With regard to the information collection: Domini Bean, Office of Operations, Food and Drug Administration, Three White Flint North 10A–12M, 11601 Landsdown St., North Bethesda, MD 20852, 301–796–5733; *PRAStaff@fda.hhs.gov.*

SUPPLEMENTARY INFORMATION:

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I. Executive Summary

A. Purpose of the Final Rule

We are amending our regulations to provide additional reasons that may be the basis for FDA to determine that an FCN is no longer effective and to provide the manufacturer or supplier of the substance an opportunity to provide input before we make such a determination. These changes will create administrative mechanisms to improve the efficiency of the premarket notification program for food contact substances (FCSs). We are also amending related confidentiality of information regulations.

B. Summary of the Major Provisions of the Final Rule

The final rule provides reasons other than safety as the basis on which we may determine that an FCN is no longer effective. These reasons include instances where the production, supply, or use of the FCS for its intended use by the manufacturer or supplier has ceased or will cease (referred to in this rule as ''abandonment''), or where the use of an FCS identified in an FCN is either authorized by a food additive regulation or is the subject of an issued Threshold of Regulation (TOR) exemption. The final rule also provides the manufacturer or supplier, who submitted an FCN, the opportunity to address our safety concerns or to otherwise show why an FCN should continue to be effective before we could determine that an FCN is no longer effective, resulting in the use no longer being authorized. Additionally, the final rule amends the confidentiality of information provisions to provide for the disclosure of certain information relating to our determination that an FCN is no longer effective.

C. Legal Authority

We are issuing the final rule consistent with our authority in sections 201, 409, and 701(a) of the Federal Food, Drug, and Cosmetic Act (FD&C Act) (21 U.S.C. 321, 348, and 371(a)).

D. Costs and Benefits

The final rule amends the food additive regulations relating to premarket notifications for FCSs also known as Food Contact Notifications (FCNs) and the procedures by which we determine that an FCN is no longer effective. The final rule will allow manufacturers or suppliers of FCSs to request that FDA determine that an FCN is longer effective for reasons other than safety. We expect that cost savings of the final rule take the form of a reduced time burden to FCS manufacturers and suppliers responding to FDA's safety concerns with information that they no longer produce, use, or supply the FCS for the intended use. The final rule will also reduce the time burden to FDA for the review of such information. We estimate that cost savings of the final rule to manufacturers and suppliers and FDA range from zero to $0.4 million, with a central estimate of $0.1 million, annualized over 10 years at a 2 percent discount rate. We estimate that there will be little to no costs associated with the final rule.

II. Background

A. Need for the Regulation/History of This Rulemaking

Our regulations at § 170.105 set forth the process by which FDA may determine that an FCN is no longer effective. This determination currently only applies when data or other information demonstrating the intended use of an FCS is no longer safe. Presently, our regulations do not provide reasons other than safety as the basis for FDA to determine that an FCN is no longer effective. Also, our regulations do not provide manufacturers or suppliers the opportunity to show why an FCN should continue to be effective prior to FDA making a determination that the FCN is no longer effective. Rather, manufacturers and suppliers must respond to FDA after we provide notice of our determination that the FCN is no longer effective.

In the **Federal Register** of January 26, 2022 (87 FR 3949), we published a proposed rule that would amend § 170.105 to address these issues and better enable FDA to respond to new information on the safety and use of FCSs. We proposed additional reasons to permit us to make a determination that an FCN is no longer effective for reasons other than safety. We proposed that a manufacturer or supplier could request that we determine an FCN to no longer be effective because it has ceased (or intends to cease) producing, supplying, or using an FCS for the intended use. To reduce confusion created by duplicative authorizations, we proposed to remove effective FCNs for intended uses already authorized by food additive regulations or the subject of an issued TOR exemption. We proposed to provide the manufacturer or supplier of an FCS an opportunity to provide information before FDA makes a determination that an FCN is no longer effective. Additionally, we explained that the proposed changes to § 170.105 would create administrative efficiencies in the FCN program. We also proposed to amend the confidentiality of information provisions in § 170.102 to address the disclosure of certain information related to FDA's determination that an FCN is no longer effective.

B. Summary of Comments to the Proposed Rule

The proposed rule provided a 60-day comment period. We received fewer than 20 comments on the proposed rule. The comments were from individuals, a consumer advocacy group, a law firm, and an industry trade association. The comments addressed topics including: (1) improved efficiency and the reduced burden on industry; (2) FDA's authority to provide additional reasons for determining that an FCN is no longer effective; (3) the circumstances under which FDA would make a determination based on abandonment; (4) providing manufacturers or suppliers the opportunity to respond to FDA's safety questions before determining an FCN is no longer effective; (5) the confidentiality provisions; (6) providing an opportunity for affected parties to comment on the timeframe for food packaging to clear the market; and (7) requesting an additional basis for declaring an FCN no longer effective.

C. General Overview of the Final Rule

The final rule establishes procedures to enable FDA to respond better to new information on the safety and use of FCSs. The final rule ensures that a manufacturer or supplier has the opportunity to provide relevant information to FDA before we make a safety determination. The final rule also permits us to make a determination that an FCN is no longer effective for reasons other than safety. FDA can reduce duplicative authorizations by removing effective FCNs for intended uses authorized by food additive regulations or the subject of an issued TOR exemption. In addition, the final rule will allow FDA to determine that an FCN is no longer effective based on abandonment either: (1) in response to a request from a manufacturer or supplier because it has ceased (or intends to cease) producing, supplying, or using an FCS for the intended use or (2) based on other information available to FDA that a manufacturer or supplier has stopped producing, supplying, or using an FCS for the intended use.

We anticipate that a manufacturer or supplier may make such a request

because it no longer needs the authorization or because abandonment could be less burdensome than addressing potential safety concerns. Further, because the FCS would no longer be produced, supplied, or used for the intended use, declaring an FCN as no longer effective based on abandonment rather than based on safety may be a more effective and efficient use of FDA's resources. However, we may decline such a request if we determine there is a safety concern that would be more appropriately addressed by FDA making a declaration that an FCN is no longer effective based on a determination that the intended use of the FCS is no longer safe. We would not declare an FCN no longer effective based on abandonment if the manufacturer or supplier temporarily ceases production or marketing and informs us of their intention to resume producing, supplying, or using the FCS for the intended use in the future. Additionally, the final rule amends the confidentiality of information provisions to provide for the disclosure of certain information relating to our determination that an FCN is no longer effective.

III. Legal Authority

We are issuing this final rule consistent with our authority in sections 201, 409, and 701(a) of the FD&C Act. The final rule provides reasons other than safety as the basis for which we may determine that an FCN is no longer effective. The final rule modifies the procedures by which FDA determines that an FCN is no longer effective and amends the regulation relating to confidentiality of information.

The FD&C Act defines ''food additive,'' in relevant part, as any substance, the intended use of which results or may reasonably be expected to result, directly or indirectly, in its becoming a component of food or otherwise affecting the characteristics of any food (including any substance intended for use in producing, manufacturing, packing, processing, preparing, treating, packaging, transporting, or holding food; and including any source of radiation intended for any such use), if such substance is not generally recognized by experts as safe under its intended use (section 201(s) of the FD&C Act). Food additives include ''food contact substances,'' which are defined as any substance intended for use as a component of materials used in manufacturing, packing, packaging, transporting, or holding food if such use is not intended to have any technical effect in such food (section 409(h)(6) of the FD&C Act).

A food additive is deemed unsafe unless that substance and its use conform with a regulation issued under section 409 of the FD&C Act or there is an FCN submitted under section 409(h) of the FD&C Act that is effective (section 409(a) of the FD&C Act). Section 409(h) of the FD&C Act sets forth the procedure for FCNs.

Under section 409(i) of the FD&C Act, FDA must prescribe by regulation the procedure by which FDA may deem an FCN to no longer be effective (sections 409(i) and 1003(d) of the FD&C Act) (21 U.S.C. 348(i) and 393(d)). Section 701(a) of the FD&C Act gives us the authority to issue regulations for the efficient enforcement of the FD&C Act.

IV. Comments on the Proposed Rule and FDA Response

A. Introduction

We received fewer than 20 comments on the proposed rule. The comments were from individuals, a consumer advocacy group, a law firm, and an industry trade association.

We describe and respond to the comments in sections B through G of this document. We have numbered each comment to help distinguish between different comments. We have grouped similar comments together under the same number, and, in some cases, we have separated different issues discussed in the same comment and designated them as distinct comments for purposes of our responses. The number assigned to each comment or comment topic is purely for organizational purposes and does not signify the comment's value or importance or the order in which comments were received.

B. Description of General Comments

Several comments made general remarks supporting or opposing the proposed rule without focusing on a particular proposed provision.

(Comment 1) Some comments expressed general support for the proposed rule. One comment stated that the proposed rule ''would make FDA more efficient as well as putting less strain on manufacturers.'' Another comment said that ''there are cost savings to both manufacturers and suppliers as well as the FDA.'' Another comment stated that the rule would ''be an overall help to public health.''

(Response 1) We agree that the final rule will improve the efficiency of FDA's oversight of FCSs. This improved efficiency may benefit public health in helping FDA to use its resources better on oversight of the FCN program and FCS regulation.

C. Comments on a Change to the Process for Obtaining Data or Other Information To Demonstrate the Intended Use of a Food Contact Substance Is No Longer Safe

The proposed rule, at § 170.105(a)(1)(i), stated that we would inform the manufacturer or supplier specified in the FCN, in writing, of our concerns regarding the safety of the intended use of the FCS. We proposed that we would specify a date by which the manufacturer or supplier must provide data or other information to address the safety concerns. The proposed rule, at § 170.105(a)(1)(ii), stated that if the manufacturer or supplier fails, by the specified date, to supply the data or other information necessary to address the safety concerns regarding the notified use, we may determine that the FCN is no longer effective because there is no longer a basis to conclude that the intended use is safe.

(Comment 2) One comment questioned the need for a procedural change allowing a manufacturer or supplier to provide data or other information to respond to our safety concerns, given the current authorities provided by § 170.105. The comment stated that manufacturers already have the opportunity to provide input before FDA makes a determination that an FCN is no longer effective based on safety.

(Response 2) We agree that a manufacturer or supplier already has the opportunity to provide input to FDA; however, presently, we are not required to provide a manufacturer or supplier an opportunity to address safety concerns until *after* FDA has made a determination. We proposed a procedural change to the existing regulation at § 170.105(b) to help ensure that we have all the relevant information *before* making a determination on whether an FCN should remain effective. In the final rule, if the manufacturer or supplier fails to supply either the data or other information necessary to address our safety concerns, by the specified date, we may make a determination that the FCN is no longer effective. However, we will make the determination only after we have given the manufacturer or supplier an opportunity to provide data or other information to respond to our safety questions.

(Comment 3) Two comments opposed giving a manufacturer or supplier the opportunity to respond to safety concerns. One comment stated that a manufacturer or supplier should not

have a say in whether an FCN is effective and making a safety determination. One comment asserted that this would ''give manufacturers more room for exemptions from safety precautions.''

(Response 3) The final rule provides manufacturers and suppliers the opportunity to demonstrate whether an FCN should remain effective, including by providing information pertaining to safety. The manufacturer or supplier has the responsibility to demonstrate that the intended use of the FCS is safe. FDA will evaluate the information provided by manufacturers and suppliers before making a determination about the status of an FCN or the safety of an FCS use. The final rule continues to provide that we can declare an FCN no longer effective if the manufacturer or supplier fails to supply the necessary data or information to address our safety concerns.

D. Comments on Determining a Premarket Notification for a Food Contact Substance Is No Longer Effective Due to Abandonment

The proposed rule would provide that a manufacturer or supplier may request in writing that FDA determine that an FCN is no longer effective on the basis that it has ceased, or intends to cease by a specified date, producing, supplying, or using an FCS for the intended food contact use in the United States (see proposed § 170.105(a)(2)(i)(A)). It also proposed that if other data or information available to FDA demonstrate that a manufacturer or supplier no longer produces, supplies, or uses an FCS for the intended use in the United States, we would inform, in writing, the manufacturer or supplier specified in the FCN and provide them an opportunity to respond before we could determine that the FCN is no longer effective (see proposed § 170.105(a)(2)(ii)(A)).

(Comment 4) One comment disagreed with our proposal but stated that there is a need for clarity regarding the status of an FCN after a manufacturer or supplier notifies FDA of its intent to withdraw products from the market that are the subject of such an FCN. The comment recommended an alternate amendment. The comment's proposed amendment would require a manufacturer or supplier—if it previously notified FDA in writing of its intent to cease introduction into interstate commerce and delivery for introduction into interstate commerce of any FCS that is the subject of an effective FCN—to submit a new FCN before reintroducing the FCS for the same intended use into interstate commerce.

(Response 4) We do not agree with the amendment offered by the comment because it would create duplicate authorizations. Under our existing regulations, if a manufacturer or supplier notifies us of their intent to cease production, supply, or use of an FCS for reasons other than a determination by FDA that an FCN is no longer effective due to safety concerns, the FCN remains effective for its intended use. In the proposal submitted in the comment, an FCN would remain effective after the listed manufacturer or supplier informs FDA of their intent to cease introduction of the FCS into interstate commerce. The proposal would also require a new FCN to be submitted if the manufacturer or supplier would reintroduce the FCS into interstate commerce; however, the original FCN is still effective. Therefore, the proposed amendment would create duplicative authorizations. In contrast, FDA's final rule will allow us to declare that an FCN is no longer effective for reasons other than safety. If a manufacturer or supplier decides to reintroduce the FCS into interstate commerce after we determined it no longer effective, they would be required to submit a new FCN.

(Comment 5) One comment stated that a manufacturer or supplier may withdraw products covered by FCNs from the market for any reason, and that it can also ''voluntarily withdraw the FCN and dispose of the notification if it so desires.'' The comment noted that under the statute such companies ''may'' file an FCN and therefore withdrawal of an FCN should also be permitted. The comment provided as example that under section 6(f) of the Federal Insecticide, Fungicide, and Rodenticide Act [Pub. L. 80–104] an applicant may initiate cancellation of a registration. The comment stated that it is ''not appropriate for manufacturers/suppliers of FCSs covered by effective FCNs to be constrained by FDA in their business decisions.''

(Response 5) We agree that a company may remove products covered by FCNs from the market. The final rule does not regulate a company's decision to stop the production, supply, or use of FCSs that are authorized under effective FCNs. However, we disagree that a manufacturer or supplier may withdraw an effective FCN under the current regulation. Furthermore, the comment does not explain what the regulatory status of the FCS would be under such a scenario. Section 409 of the FD&C Act does not provide for withdrawal of an effective FCN and directs FDA to prescribe, by regulation, the procedure by which we are to deem an FCN to no longer be effective. Consistent with the statute, we are amending our procedural regulations to provide for abandonment as a basis for determining that an FCN is no longer effective. Under the final rule, a manufacturer or supplier will be able to request that we determine that an FCN is no longer effective based on abandonment.

(Comment 6) A few comments opposed the provision to allow FDA to declare an FCN no longer effective for reasons of abandonment and asserted that FDA does not have this authority. The comments asserted that, under section 409 of the FD&C Act, we can only determine an FCN to no longer be effective based on safety. One comment stated that it would be appropriate to grant a request based on abandonment from the manufacturer or supplier. Another comment asserted that the FD&C Act limits FDA's food additive review to safety. The comment also referred to our regulation at 21 CFR 171.130, which allows for food additive regulations to be repealed or amended for reasons other than safety. The comment asserted that section 409(i) of the FD&C Act, which states that FDA shall, by regulation, prescribe the procedure by which FDA may deem an FCN to no longer be effective, means that FCNs are to be treated differently from food additive regulations and that FDA is bound by the safety standard in section 409(c)(3)(A) of the FD&C Act for FCNs.

(Response 6) We disagree with the comments. The final rule is consistent with our authority in sections 201, 409, and 701(a) of the FD&C Act. Section 201(s) of the FD&C Act defines ''food additive.'' Section 409(h) of the FD&C Act specifies the procedures for the FCN program. Food additives include ''food contact substances,'' which are defined in section 409(h)(6) of the FD&C Act as any substance intended for use as a component of materials used in manufacturing, packing, packing, transporting, or holding food if such uses is not intended to have any technical effect in such food. Under section 409(i) of the FD&C Act, FDA must prescribe by regulation the procedure by which FDA may deem an FCN to no longer be effective. In addition, section 701(a) of the FD&C Act gives FDA the authority to issue regulations for the efficient enforcement of the FD&C Act. These provisions provide us authority to establish and modify administrative procedures to ensure the efficiency of the food contact notification program. As one comment noted, FDA has already established a

regulation under which we may repeal a food additive regulation based on abandonment. Likewise, nothing in section 409(i) of the FD&C Act precludes FDA from establishing procedures by regulation to deem an FCN no longer effective based on reasons other than safety.

(Comment 7) Some comments opposed the proposed revisions that would allow FDA to determine that an FCN is no longer effective because production, supply, or use of the FCS has stopped or will stop. One comment expressed concerns that FDA would determine that an FCN is no longer effective without considering whether a manufacturer or supplier or their customer has significant stock of an FCS on hand. The comment questioned whether FDA would make the determination without regard to whether the manufacturer or supplier intends to resume production, at a future date, based on market conditions. Another comment expressed concerns about the reasons third parties might provide information and data to FDA to support a determination that an FCN is no longer effective based on abandonment. For example, the commenter stated, ''if any third party can provide FDA with information that a product that is the subject of an effective FCN is not now being manufactured for food-contact applications, such substances could be targeted for removal without demonstrating a safety concern.''

(Response 7) We expect that, in most cases, a determination based on abandonment will be in response to a request from a manufacturer or supplier, rather than based on information from a third party. However, to address the concerns raised by the comments with respect to information provided by a third party, we have amended the provision for abandonment that is based on other data or information available to FDA. We have added ''or intends to continue in the future'' to make clear that FDA would not make a determination based on abandonment if the manufacturer or supplier informs us that it intends to resume in the future the production, supply, or use of an FCS for the intended use in the United States (see § 170.105(a)(2)(ii)(A) and (B)). If we receive information from a third party or through other means, as outlined in § 170.105(a)(2)(ii)(A), we will inform, in writing, the affected manufacturer or supplier specified in the FCN before we could determine that the FCN is no longer effective. In cases where a manufacturer or supplier informs us that its suspension of the production, supply, or use is only temporary, we will not declare an FCN no longer effective on the basis of abandonment. This information must be provided to FDA in writing, within the specified timing, as required under § 170.105(a)(2)(ii).

With respect to the comments about supplies of an FCS held by a manufacturer or supplier, or its customers, the final rule provides for compliance dates to address these situations. When a manufacturer or supplier requests that we determine that an FCN is no longer effective because it has ceased or plans to cease producing, supplying, or using an FCS, we will confirm with the manufacturer or supplier the date it has ceased or that it intends to cease production, supply, or use. Under the final rule, if we determine that an FCN is no longer effective, we will publish a notice announcing the determination in the **Federal Register**. The FCN will no longer be effective on the date of publication of the notice. If the manufacturer or supplier informs us that it intends to cease production, supply, or use at a future date, we will provide for a separate compliance date that is the future date specified by the manufacturer or supplier, and this compliance date will be reflected in the **Federal Register**. To take into consideration inventory held by downstream customers, as provided in § 170.105(b), FDA may also include a separate compliance date in the **Federal Register** for the use of the FCS in food contact articles.

(Comment 8) One comment opposed the provision to allow FDA to determine an FCN is no longer effective based on abandonment, absent a request by the manufacturer or supplier, because, according to the comment, it would cause potential harm to a business.

(Response 8) We anticipate that a determination that an FCN is no longer effective based on abandonment will not cause potential harm to businesses because the majority of these actions will be in response to a manufacturer or supplier's specific request because it has ceased or plans to cease production of the FCS. However, there may be rare cases where the manufacturer or supplier is not available because the business no longer exists. In such instances, we may determine that an FCN is no longer effective based on abandonment. We note that § 170.100(d) (21 CFR 170.100(d)) requires a manufacturer or supplier for which a notification is effective to keep a current address on file with FDA.

(Comment 9) One comment stated that the proposed rule does not assure that a manufacturer or supplier will have adequate time to respond to our request for data and information to demonstrate that they continue to produce, supply, or use the FCS for the intended use in the United States. The comment stated that a ''manufacturer or supplier may be forced to comply with an arbitrary or inadequate deadline'' to provide information to FDA.

(Response 9) In response to this comment, we revised § 170.105(a)(2)(ii), which describes the response of a manufacturer or supplier to FDA, to remove the reference to providing ''data and information to demonstrate'' a continued use, and instead are requiring that the manufacturer or supplier respond in writing indicating whether it continues, or intends to continue in the future, to produce, supply, or use an FCS for the intended use in the United States. We anticipate that there will be minimal burden on a manufacturer and supplier to provide us with such a statement. We will provide an appropriate amount of time for manufacturers and suppliers to respond, based on the information available to us at that time. We will consider a request for additional time from a manufacturer or supplier.

(Comment 10) One comment stated that if an FCN is declared no longer effective based on abandonment, a ''substantially-delayed compliance deadline would be appropriate, to assure that lawfully manufactured food packaging has a sufficient opportunity to work its way through channels of trade.'' The comment further stated that affected parties must be provided with an opportunity to provide comments to FDA on the length of time that will be required for food contact articles to clear channels of trade.

(Response 10) As provided in § 170.105(b), if we determine it would be protective of public health, we may include a separate compliance date for the use of the FCS in food contact articles. We believe the manufacturer or supplier is in a position to estimate the time it will take for the affected FCS and food contact articles to clear the U.S. market. We expect that the manufacturer or supplier will confer with its downstream customers to ascertain the time it will take to exhaust their inventory and clear the U.S. market. Therefore, in response to the comment, we revised § 170.105(a)(2)(i)(A) to require that the request from a manufacturer or supplier include information or a basis to support the estimated date for the FCS, as well as food contact articles that contain such FCS, produced, supplied, or used by the manufacturer or supplier, to clear the U.S. market. This

information will help to inform a separate compliance date for the use of an FCS in food contact articles.

E. Comments on Determining a Premarket Notification for a Food Contact Substance Is No Longer Effective Because It Is Authorized by a Food Additive Regulation or Is the Subject of an Issued Threshold of Regulation Exemption

The proposed rule would create a new provision by which we may determine that an FCN is no longer effective because the intended use of the FCS is authorized by a food additive regulation (see proposed § 170.105(a)(3)). We explained that issuing a food additive regulation can be more efficient than reviewing multiple FCNs for the same FCS and for the same use.

Additionally, the proposed rule would create a new provision by which we may determine that an FCN is no longer effective because the intended use of the food contact substance is covered by a TOR exemption (see proposed § 170.105(a)(4)). We explained that FCNs are effective only for a specific manufacturer or supplier, and multiple manufacturers or suppliers often request FCNs for the same intended use of an FCS. In contrast, a TOR exemption can cover the use of an FCS for any manufacturer or supplier who meets the requirements of the TOR. We also explained that we will grant a TOR exemption only if the likelihood or extent of migration to food of a substance used in a food-contact article (*e.g.,* food-packaging or food processing equipment) is so trivial as not to require regulation of the substance as a food additive (see 21 CFR 170.39).

(Comment 11) One comment opposed the new provisions. The comment stated that the existing FCN program does not accept FCNs for review when the proposed use of the substance is authorized through a food additive regulation or the subject of an issued TOR exemption. The comment said that the new provision would therefore only be applicable to FDA-initiated authorizations for the purpose of determining that an existing effective FCN is no longer effective. The comment stated that section 409(h)(3)(A) of the FD&C Act requires that the FCN process be used except when we determine that submission and review of a petition is necessary to provide adequate assurance of safety. The comment said that we may not determine that an FCN is no longer effective because the intended use is authorized by a food additive regulation or the subject of an issued TOR exemption because the process ''runs counter to Congressional intent'' and ''contravenes Congress' explicit requirement that the FCN process shall be used for authorizing the marketing of a food-contact substance . . .''

(Response 11) We disagree with the comment. Section 409 of the FD&C Act establishes an FCN process as the primary means by which FDA regulates food additives that are FCSs. However, it does not preclude us from relying on authorizations provided under food additive regulations or issued TOR exemptions as a basis to determine that an FCN authorization is duplicative and may be declared no longer effective. Section 409(i) of the FD&C Act gives FDA authority to prescribe by regulation the procedure by which FDA may determine an FCN to no longer be effective. Further, section 701(a) of the FD&C Act gives FDA the authority to issue regulations for the efficient enforcement of the FD&C Act. Through these provisions, Congress provided FDA with the discretion and authority to establish and modify administrative procedures to ensure the efficiency of the authorization of the safe use of FCSs. The TOR exemption provides an alternative to regulate food additives that are FCSs. As described in the Senate report associated with the Food and Drug Administration Modernization Act of 1997 (Pub. L. 105–115), the legislation by which Congress amended the FD&C Act to add the FCN program, explicitly left in place TOR exemptions and food additive regulations for FCSs (S. Rep. No. 105–43, at 46 (1997)).

Furthermore, authorizations of FCSs through food additive regulations or TOR exemptions, rather than through FCNs, may improve efficiency of our premarket programs because they are not specific to one manufacturer or supplier. As such, having these authorizations may reduce administrative burdens on FDA and on new manufacturers and suppliers of FCS for uses that we already determined are safe when manufactured or supplied for uses that comply with the listed limitations and specifications. Because an FCN would be duplicative of these authorizations, removing a duplicative FCN may help avoid confusion from other manufacturers or suppliers about whether they would also need to obtain authorization through the FCN program. Therefore, under the final rule we may determine that an FCN is no longer effective and remove the duplicate FCN from the inventory of effective FCNs, if it is the subject of a food additive regulation or the subject of an issued TOR exemption.

FDA would only take action after we inform the manufacturer or supplier specified in the FCN, in writing, that the intended use of the FCN is authorized by a food additive regulation or the subject of an issued TOR exemption. As explained in the proposed rule, the manufacturer or supplier would have the opportunity to demonstrate that the intended use is not authorized by a food additive regulation or the subject of an issued TOR exemption (87 FR 3949 at 3952 through 3954).

(Comment 12) One comment opposed the provision in the proposed rule that would allow us to determine that an FCN is no longer effective if it is the subject of an issued TOR exemption. The comment expressed concern about the process for granting TOR exemptions.

(Response 12) Our FCN regulations (see § 170.100(b)(2)) provide that FDA may choose not to accept an FCN if there is an issued TOR exemption for the intended use. Unlike an authorization provided under an effective FCN, which is specific to the manufacturer or supplier specified in the notification, a TOR exemption can be relied on for uses that comply with the limitations and specifications listed in the TOR exemption. The final rule, at § 170.105(a)(4), provides a corresponding provision that would allow FDA to declare an FCN no longer effective on the basis that this use is covered by an issued TOR exemption.

As for the comment pertaining to the process for granting a TOR exemption, we note that the process for granting a TOR exemption is not the subject of this rulemaking.

(Comment 13) One comment asserted that promulgating food additive regulations or issuing a TOR exemption to replace FCNs would result in the loss of manufacturer-specific information because new manufacturers would come to market without notification to FDA and that FDA would no longer have the benefit of the ''knowledge of which food contact substances have entered the market, who manufactured such substances, and in what amount.'' The comment said that this lack of notice and information would result in the loss of public safety benefits.

(Response 13) FDA would conduct research, gather and evaluate all relevant data, and complete the necessary analysis of an FCS before promulgating a food additive regulation or issuing a TOR exemption. We expect that we would have significant data or other information to support proposing a new food additive regulation or TOR exemption before doing so. Therefore, we do not agree that the loss of manufacturer-specific information would negatively affect public health.

(Comment 14) One comment stated that declaring an FCN as no longer effective based on an issued TOR exemption or food additive regulation would create undue burdens for industry because business documentation commonly includes references to FCN numbers. The comment stated that if FDA deems an FCN no longer effective for nonsafety reasons, this could create confusion in the marketplace. In addition, the comment stated that the companies who submitted an FCN would bear the burden and cost of data development to demonstrate safety, whereas if FDA issues a TOR exemption or a food additive regulation for that use, other companies will benefit. The comment noted that Congress specifically created a manufacturer-specific notification process for FCNs.

(Response 14) As we explained in response to Comment 12, section 409 of the FD&C Act does not preclude us from issuing a TOR exemption or a food additive regulation for the use of an FCS or from relying on these authorizations as a basis to determine that duplicative FCNs may be declared no longer effective.

FDA intends to establish and maintain a list of FCNs that are no longer effective (and the reason for the FDA's determination) on its website to limit confusion. The list will be available along with the current inventory of effective FCNs.

F. Comments on Confidentiality of Information Related to Premarket Notification for a Food Contact Substance

The proposed rule would amend § 170.102(e) to address the disclosure of certain information related to a notification, including information related to FDA's determination that an FCN is no longer effective. Specifically, proposed § 170.102(e)(1) would continue to make all safety and functionality data and information submitted with or incorporated by reference into the notification as well as all correspondence and written summaries of oral discussions relating to the notification available for public disclosure. Proposed § 170.102(e)(5) also would make all data, correspondence and written summaries of oral discussions relating to FDA's determination that an FCN is no longer effective available for public disclosure, unless the information is exempt under 21 CFR 20.61 (pertaining to trade secrets and commercial or financial information that is privileged or confidential).

(Comment 15) One comment disagreed with the proposed amendments to § 170.102. The comment stated that, besides the manufacturer's notice of market withdrawal, no new information would be provided to the FCN file, and, as such, the proposed amendments are not warranted.

(Response 15) The amendments to the confidentiality of information regulations are necessary to provide for disclosure of information related to manufacturer or supplier notifications and FDA's determination that an FCN is no longer effective for its intended use. Thus, the final rule contains the revisions to § 170.102 from the proposed rule with minor editorial changes.

(Comment 16) One comment supported the proposed change to § 170.102(e) to make publicly available data and information related to our determination that an FCN is no longer effective. The comment requested that this public disclosure not be limited to FCNs that are deemed no longer effective by FDA and be expanded to include all FCNs. The comment also emphasized that the public disclosure should entail timely publication to FDA's website, rather than public disclosure in response to a request under the Freedom of Information Act (FOIA).

(Response 16) The comment may have misunderstood our proposed change to § 170.102(e), which already addresses the public disclosure of information related to FCNs. The proposed rule would revise § 170.102(e) to address explicitly FCNs that FDA has determined are no longer effective; however, there is no difference in the public disclosure of this information. To make this clearer, we are further revising § 170.102(e) to include the reference to FCNs that are no longer effective in the same sentence as other FCNs. With respect to the comment asking FDA to disclose information about FCNs proactively on FDA's website instead of in response to a FOIA request, decisions about proactive disclosures are based on available resources and policy priorities. To ensure transparency, FDA will continue to maintain an inventory on its website that lists effective FCNs, and intends to maintain a second inventory that will list FCNs that are no longer effective (and the reason for FDA's determination).

G. Miscellaneous Comments

(Comment 17) Some comments stated that there is no need for this rule because the U.S. Department of Agriculture (USDA) can ''oversee such issues.''

(Response 17) We disagree. Pursuant to section 409(i) of the FD&C Act we, rather than USDA, have authority over FCSs.

(Comment 18) One comment asked about a pending citizen petition related to FDA's evaluation of cumulative effects of related substances. The pending citizen petition requests revisions to our regulations, including 21 CFR 170.101 (Information in a premarket notification for a food contact substance (FCN)).

(Response 18) The comment is outside of the scope of this rulemaking, as the purpose is to amend the process that we use to determine that an FCN is no longer effective.

(Comment 19) Some comments discussed the use of plastic and Styrofoam in food packaging generally.

(Response 19) The comments are outside the scope of this rulemaking and so we decline to address them.

(Comment 20) One comment requested that FDA revise the proposed rule to ''include notifiers' failure to systematically identify the class of chemically- or pharmacologically-related substances in the diet as sufficient for FDA to determine an FCN is no longer effective.'' The comment also made several recommendations for a ''revised proposed rule regarding food contact substance notifications.'' The recommendations for a revised proposed rule include: (1) requiring FDA to post our evaluation of the FCN as well as the FCN itself; (2) requesting periodic updates; (3) requiring manufacturers and suppliers to submit samples of their FCSs to FDA upon request; (4) including FDA's need for a sample as a reason to determine an FCN no longer effective; and (5) that FDA ''sunset an FCN to prompt an update.''

(Response 20) We decline to issue a revised proposed rule at this time and are not including these recommendations in the final rule because they are outside the scope of our rulemaking. With respect to the request that we post our evaluation of an FCN, as discussed in response to Comment 16, decisions about proactive disclosures are generally based on available resources and policy priorities.

H. Nonsubstantive Changes

On our own initiative, to maintain consistency and provide clarity with existing FCN program notifications and TOR exemptions, we are making nonsubstantive changes to the following:

- In § 170.102(e), we are making clarifying edits to the provision.
- In § 170.105(a)(2), we are replacing the words ''stopped'' and ''stop'' with ''ceased'' or ''cease,'' the terms used in

the FCN program identifying the FCNs that are not in interstate commerce.

- In § 170.105(a)(2)(ii)(A), because an FCN is specific to a manufacturer or supplier, we are revising the first sentence to add a reference to the manufacturer or supplier specified in the FCN.
- In § 170.105(a)(3)(i), we are revising the second sentence to clarify the data and information the manufacturer or supplier is to provide.
- In § 170.105(a)(4), we are replacing the words ''covered by a threshold of regulation exemption'' to ''the subject of an issued threshold of regulation exemption.''
- § 170.105(a)(4)(i), we are revising the second sentence to clarify the data and information the manufacturer or supplier is to provide.

V. Effective/Compliance Date(s)

The preamble to the proposed rule stated that we would make any final rule resulting from this rulemaking effective 60 days after its date of publication in the **Federal Register** (87 FR 3949 at 3954).

We did not receive any comments on the proposed effective date for the final rule. Therefore, the final rule will become effective on May 21, 2024.

VI. Economic Analysis of Impacts

A. Introduction

We have examined the impacts of the final rule under Executive Order 12866, Executive Order 13563, Executive Order 14094, the Congressional Review Act/Small Business Regulatory Enforcement Fairness Act (5 U.S.C. 801, Pub. L. 104–121), the Regulatory Flexibility Act (5 U.S.C. 601–612), and the Unfunded Mandates Reform Act of 1995 (Pub. L. 104–4).

Executive Orders 12866, 13563, and 14094 direct us to assess all benefits, costs, and transfers of available regulatory alternatives and, when regulation is necessary, to select regulatory approaches that maximize net benefits (including potential economic, environmental, public health and safety, and other advantages; distributive impacts; and equity). Rules are ''significant'' under Executive Order 12866, section 3(f)(1) (as amended by Executive Order 14094), if they ''have an annual effect on the economy of $200 million or more (adjusted every 3 years by the Administrator of [the Office of Information and Regulatory Affairs (OIRA)] for changes in gross domestic product); or adversely affect in a material way the economy, a sector of the economy, productivity, competition, jobs, the environment, public health or safety, or State, local, territorial, or tribal governments or communities.'' OIRA has determined that this final rule is not a significant regulatory action under Executive Order 12866, section 3(f)(1).

A rule is ''major'' under the Congressional Review Act/Small Business Regulatory Enforcement Fairness Act if it has resulted or is likely to result in an annual effect on the economy of $100 million or more or meets other criteria specified in the Congressional Review Act. OIRA has determined that this final rule is not a major rule under the Congressional Review Act/Small Business Regulatory Enforcement Fairness Act.

The Regulatory Flexibility Act requires Agencies to analyze regulatory options that would minimize any significant impact of a rule on small entities. Because the final rule is unlikely to impose a substantial burden on the affected small entities, we certify that the final rule will not have a significant economic impact on a substantial number of small entities.

The Unfunded Mandates Reform Act of 1995 (section 202(a)) requires us to prepare a written statement, which includes an assessment of anticipated impacts, before issuing ''any rule that includes any Federal mandate that may result in the expenditure by State, local, and tribal governments, in the aggregate, or by the private sector, of $100,000,000 or more (adjusted annually for inflation) in any one year.'' The current threshold after adjustment for inflation is $183 million, using the most current (2023) Implicit Price Deflator for the Gross Domestic Product. We do not expect this final rule to result in any 1-year expenditure that will meet or exceed this amount.

B. Summary of Cost and Benefits

We expect the final rule to lead to cost savings for manufacturers and suppliers of FCSs and FDA. The final rule would revise FDA's current process of determining whether an FCN is no longer effective. The final rule would provide manufacturers and suppliers the opportunity to demonstrate why an FCN should continue to be effective before we could determine that an FCN is no longer effective. Additionally, the final rule would revise the current process to cover situations in which it is determined that an FCN is no longer effective for reasons other than safety, including that a manufacturer or supplier may request that FDA determine that an FCN is no longer effective on the basis that the manufacturer or supplier no longer produces, supplies, or uses the FCS for the intended use. Cost savings will be incurred by manufacturers and suppliers of FCSs who will be able to request that FDA determine the FCN is no longer effective for reasons other than safety. Cost savings will take the form of a decreased time burden to FCS manufacturers and suppliers responding to FDA's safety concerns with information that they no longer produce, use, or supply the FCN for the intended use. FDA will also experience cost savings from being able to act more efficiently upon such a request by the manufacturer or supplier. As the revisions in the final rule would not require significant additional action to be taken by manufacturers and suppliers, we expect the costs of the final rule to be minimal.

The estimated total cost savings of the final rule are estimated in 2021 U.S. dollars and range from zero to $0.4 million, with a central estimate of $0.1 million, annualized at 2 percent over 10 years. We estimate that the costs of the final rule are minimal. The cost savings and costs of the final rule are summarized in table 1.

TABLE 1—SUMMARY OF COST SAVINGS, COSTS, AND DISTRIBUTIONAL EFFECTS OF FINAL RULE

Category	Primary estimate	Low estimate	High estimate	Units			Notes
				Year dollars	Discount rate (%)	Period covered (years)	
Cost Savings:							
One-time Monetized millions/year							
Annualized Quantified	$0.1M	$0	$0.4M	2021	2	10	
Qualitative							
Costs:							
Annualized							
Monetized millions/year							

TABLE 1—SUMMARY OF COST SAVINGS, COSTS, AND DISTRIBUTIONAL EFFECTS OF FINAL RULE—Continued

Category	Primary estimate	Low estimate	High estimate	Units			Notes
				Year dollars	Discount rate (%)	Period covered (years)	
Annualized							
Quantified							
Qualitative			$0	2021		10	
Transfers:							
Federal Annualized							
Monetized $millions/year							
	From:			To:			
Other Annualized							
Monetized $millions/year							
	From:			To:			

Effects:
State, Local, or Tribal Government:
Small Business: Increased cost savings of zero to $147.31 per affected small entity.
Wages:
Growth:

We have developed a comprehensive Economic Analysis of Impacts that assesses the impacts of the final rule. The full analysis of economic impacts is available in the docket for this final rule (Ref. 1) and at *https://www.fda.gov/about-fda/reports/economic-impact-analyses-fda-regulations.*

VII. Analysis of Environmental Impact

We have determined under 21 CFR 25.30(h) that this action is of a type that does not individually or cumulatively have a significant effect on the human environment. Therefore, neither an environmental assessment nor an environmental impact statement is required.

VIII. Paperwork Reduction Act of 1995

The final rule contains information collection provisions that are subject to review by the Office of Management and Budget (OMB) under the Paperwork Reduction Act of 1995 (44 U.S.C. 3501–3521). The title, description, and respondent description of the information collection provisions are shown in the following paragraphs with an estimate of the annual reporting burden. Included in the estimate is the time for reviewing instructions, searching existing data sources, gathering and maintaining the data needed, and completing and reviewing each collection of information.

Title: Food Contact Substance Notification System; OMB Control Number 0910–0495—Revision.

Description: Section 409(h) of the FD&C Act establishes a premarket notification process for FCSs. Section 409(h)(6) of the FD&C Act defines a ''food contact substance'' as any substance intended for use as a component of materials used in manufacturing, packing, packaging, transporting, or holding food if such use is not intended to have any technical effect in such food. Section 409(h)(3) of the FD&C Act states that the notification process be utilized for authorizing the marketing of FCSs except when: (1) the Secretary of HHS (Secretary) determines that the submission and premarket review of a food additive petition (FAP) under section 409(b) of the FD&C Act is necessary to provide adequate assurance of safety or (2) the Secretary and the manufacturer or supplier agree that an FAP should be submitted. Section 409(h)(1) of the FD&C Act requires that a notification include: (1) information on the identity and the intended use of the FCS and (2) the basis for the manufacturer's or supplier's determination that the FCS is safe under the intended use. FDA regulations at part 170 (21 CFR part 170) specify the information that a notification must contain.

The final rule amends the procedure by which we determine that an FCN is no longer effective. The information collection will cover situations that entail the potential reporting of additional data or other information by manufacturers or suppliers of FCSs. The final rule will augment the existing information collection that covers the FCN program at part 170, subpart D.

Description of Respondents: Respondents to the information collection are manufacturers and suppliers of FCSs sold in the United States. Respondents are from the private sector (for-profit businesses).

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

TABLE 2—ESTIMATED ANNUAL REPORTING BURDEN [1]

21 CFR section; activity	Number of respondents	Number of responses per respondent	Total annual responses	Average burden per response (hours)	Total hours
170.105(a); Manufacturer or supplier responds to FDA by providing a written response and additional data or information to demonstrate that the FCN should continue to be effective	2	1	2	75	150
170.105(a)(2)(i); Manufacturer or supplier requests that FDA determine that the FCN should no longer be effective based on nonsafety reasons	5	1	5	2	10

TABLE 2—ESTIMATED ANNUAL REPORTING BURDEN [1]—Continued

21 CFR section; activity	Number of respondents	Number of responses per respondent	Total annual responses	Average burden per response (hours)	Total hours
Total	.....	.....	.....	.....	160

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

The burden estimates in table 2 are based on our experience with our Food Contact Substance Notification Program and are unchanged from our estimates in the proposed rule.

We will inform the affected manufacturers or suppliers of the specified FCN about data or other information that their FCSs may: (1) not be safe for its intended use; (2) have stopped being produced, supplied, or used as an FCS for its intended use; (3) be authorized by a food additive regulation; or (4) be the subject of an issued TOR exemption. As such, we may determine that the specified FCN may no longer be effective for its intended use unless the affected manufacturer or supplier provides additional data or other information to demonstrate that the FCN should continue to be effective. In row 1, we estimate that, annually, two respondents will each spend about 75 hours preparing a written response followed by submission of additional data or information to demonstrate that the FCN should continue to be effective for a total of 150 hours (2 respondents × 75 hours). In the existing information collection for our Food Contact Substance Notification Program (OMB control number 0910–0495; 87 FR 7190 (February 8, 2022)), we estimate that it may take up to 150 hours to prepare and submit an FCN depending on the complexity of the submittal. We assume the time to prepare a response will take about half the time of the initial submittal because the manufacturer or supplier should already have compiled and have access to most, if not all the information demonstrating that their FCN should continue to be effective and remains safe for its intended use.

The final rule will allow a manufacturer or supplier to request that FDA determine that their FCN is no longer effective on the basis that the manufacturer or supplier no longer produces, supplies, or uses the FCS for the intended use. We believe a manufacturer or supplier will not need much time to prepare such a request as it should already have access to information that it has ceased or intends to no longer produce, supply, or use the FCS for the intended use. Based on the Final Regulatory Impact Analysis, we estimate that five respondents will voluntarily request that FDA determine that their FCN is no longer effective (Ref. 1). Accordingly, in row 2, we estimate that five respondents will each submit 1 request to us per year with each request taking 2 hours to prepare for a total of about 10 hours (2 respondents × 5 hours).

The information collection provisions in this final rule have been submitted to OMB for review as required by section 3507(d) of the Paperwork Reduction Act of 1995. Before the effective date of this final rule, FDA will publish a notice in the **Federal Register** announcing OMB's decision to approve, modify, or disapprove the information collection provisions in this final rule.

An Agency may not conduct or sponsor, and a person is not required to respond to, a collection of information unless it displays a currently valid OMB control number.

IX. Federalism

We have analyzed this final rule in accordance with the principles set forth in Executive Order 13132. We have determined that the rule does not contain policies that have substantial direct effects on the States, on the relationship between the National Government and the States, or on the distribution of power and responsibilities among the various levels of government. Accordingly, we conclude that the rule does not contain policies that have federalism implications as defined in the Executive order and, consequently, a federalism summary impact statement is not required.

X. Consultation and Coordination With Indian Tribal Governments

We have analyzed this rule in accordance with the principles set forth in Executive Order 13175. We have determined that the rule does not contain policies that have substantial direct effects on one or more Indian Tribes, on the relationship between the Federal Government and Indian Tribes, or on the distribution of power and responsibilities between the Federal Government and Indian Tribes. Accordingly, we conclude that the rule does not contain policies that have Tribal implications as defined in the Executive order and, consequently, a Tribal summary impact statement is not required.

XI. Reference

The following reference is on display at the Dockets Management Staff (see **ADDRESSES**) and is available for viewing by interested persons between 9 a.m. and 4 p.m. Monday through Friday; it is also available electronically at *https://www.regulations.gov/.* Although FDA verified the website addresses in this document, please note that websites are subject to change over time.

1. FDA, ''Food Additives: Food Contact Substance Notification That Is No Longer Effective, Final Regulatory Impact Analysis, Regulatory Flexibility Analysis.'' Also available at: *https://www.fda.gov/about-fda/reports/economic-impact-analyses-fda-regulations.*

List of Subjects in 21 CFR Part 170

Administrative practice and procedure, Food additives, Reporting and recordkeeping requirements.

Therefore, under the Federal Food, Drug, and Cosmetic Act and under authority delegated to the Commissioner of Food and Drugs, 21 CFR part 170 is amended as follows:

PART 170—FOOD ADDITIVES

■ 1. The authority citation for part 170 continues to read as follows:

Authority: 21 U.S.C. 321, 341, 342, 346a, 348, 371.

■ 2. Amend § 170.102 by revising the section heading and paragraphs (e) introductory text and (e)(1) and (5) to read as follows:

§ 170.102 Confidentiality of information related to premarket notification for a food contact substance (FCN).

* * * * *

(e) The following data and information are available for public disclosure, unless extraordinary circumstances are shown, on the 121st day after receipt of the notification by FDA, except that no data or information are available for public disclosure if the

FCN is withdrawn under § 170.103; and on the date of publication in the **Federal Register** of an FDA determination that an FCN is no longer effective.

(1) All safety and functionality data and information submitted with or incorporated by reference into the notification, or submitted in reference to an effective FCN. Safety and functionality data include all studies and tests of a food contact substance on animals and humans and all studies and tests on a food contact substance for establishing identity, stability, purity, potency, performance, and usefulness.

* * * * *

(5) All correspondence and written summaries of oral discussions relating to the notification or to FDA's determination that an FCN is no longer effective, except information that is exempt under § 20.61 of this chapter.

* * * * *

■ 3. Revise § 170.105 to read as follows:

§ 170.105 The Food and Drug Administration's (FDA's) determination that a premarket notification for a food contact substance (FCN) is no longer effective.

(a) FDA may determine that an FCN is no longer effective if:

(1) Data or other information available to FDA, including data not submitted by the manufacturer or supplier, demonstrate that the intended use of a food contact substance is no longer safe.

(i) FDA will inform the affected manufacturer or supplier specified in the FCN, in writing, of FDA's concerns regarding the safety of the intended use of the food contact substance. FDA will specify the date by which the manufacturer or supplier must provide FDA with data or other information to respond to FDA's safety concerns.

(ii) If the manufacturer or supplier fails, by the specified date, to supply either the data or other information necessary to address the safety concerns regarding the notified use or a request described in paragraph (a)(2)(i) of this section, FDA may determine that the FCN is no longer effective because there is no longer a basis to conclude that the intended use is safe.

(iii) If FDA denies a request described in paragraph (a)(2)(i) of this section, and FDA had previously informed the manufacturer or supplier of FDA's concerns regarding the safety of the intended use of the food contact substance as described in paragraph (a)(1)(i) of this section, FDA may determine that an FCN is no longer effective because there is no longer a basis to conclude that the intended use is safe. Alternatively, FDA may provide the manufacturer or supplier with additional time to provide FDA with data or other information to respond to FDA's safety concerns. If the manufacturer or supplier fails, by the specified date, to supply the data or other information necessary to address the safety concerns regarding the notified use, FDA may determine that the FCN is no longer effective because there is no longer a basis to conclude that the intended use is safe.

(2) Data or other information available to FDA demonstrate that the manufacturer or supplier specified in the FCN has ceased or intends to cease producing, supplying, or using a food contact substance for the intended use. Such data or other information includes, but is not limited to:

(i) A request from the manufacturer or supplier.

(A) The manufacturer or supplier specified in the FCN may request in writing that FDA determine that an FCN is no longer effective on the basis that it has ceased producing, supplying, or using a food contact substance for the intended food contact use in the United States or that it intends to cease producing, supplying, or using a food contact substance for the intended food contact use in the United States by a specified date. The request must include information or a basis to support the estimated date for the food contact substance, as well as food contact articles that contain such food contact substance, produced, supplied, or used by the manufacturer or supplier to clear the U.S. market. FDA will notify the manufacturer or supplier whether FDA is granting the request.

(B) If FDA grants the request, FDA may determine that the FCN is no longer effective on the basis that the manufacturer or supplier has ceased producing, supplying, or using a food contact substance for the intended use in the United States or that it intends to cease producing, supplying, or using a food contact substance for the intended food contact use in the United States by a specified date. When such a request is based on the intent to cease producing, supplying, or using a food contact substance for the intended food contact use in the United States at a future date, FDA will include in the notice described in paragraph (b) of this section the date specified in the request as the compliance date by which the manufacturer or supplier will cease producing, supplying, or using the food contact substance for the intended food contact use in the United States.

(ii) Other data or information available to FDA.

(A) If other data or information available to FDA demonstrate that a manufacturer or supplier specified in the FCN has ceased producing, supplying, or using a food contact substance for the intended use in the United States, FDA will inform the affected manufacturer or supplier in writing. FDA will include a specified time period by which the manufacturer or supplier must respond in writing indicating whether the manufacturer or supplier continues, or intends to continue in the future, to produce, supply, or use a food contact substance for the intended use in the United States.

(B) If the manufacturer or supplier fails, by the specified date, to respond in writing indicating that the manufacturer or supplier continues, or intends to continue in the future, to produce, supply, or use a food contact substance for the intended use in the United States; or if the manufacturer or supplier confirms that it has ceased producing, supplying, or using the food contact substance for the intended food contact use in the United States, FDA may determine that the FCN is no longer effective.

(3) The intended use of the food contact substance identified in the FCN is authorized by a food additive regulation.

(i) FDA will inform the manufacturer or supplier specified in the FCN in writing that the intended use of the food contact substance identified in the FCN is authorized by a food additive regulation. FDA will include a specified time period by which the manufacturer or supplier must respond to FDA with data or other information about whether the food contact substance and its intended use meet the identity limitations and specifications authorized by the cited food additive regulation.

(ii) If a manufacturer or supplier fails, by the specified date, to supply data or other information that demonstrates that the intended use of the food contact substance identified in the FCN is not authorized by a food additive regulation, FDA may determine that the FCN is no longer effective on the basis that the intended use of the food contact substance is authorized under a food additive regulation.

(4) The intended use of the food contact substance identified in the FCN is the subject of an issued threshold of regulation exemption.

(i) FDA will inform the manufacturer or supplier specified in the authorizing FCN in writing that the intended use of the food contact substance identified in the FCN is the subject of an issued threshold of regulation exemption. FDA will include a specified time period by which the manufacturer or supplier

must respond to FDA with data or other information about whether the food contact substance and its intended use meet the identity limitations and specifications listed in the cited threshold of regulation exemption.

(ii) If a manufacturer or supplier fails, by the specified date, to supply data or other information that demonstrates that the intended use of the food contact substance identified in the FCN is not exempt through an issued threshold of regulation exemption, FDA may determine that the FCN is no longer effective on the basis that the intended use of the food contact substance is the subject of an issued threshold of regulation exemption.

(b) If FDA determines that an FCN is no longer effective, FDA will publish a notice of its determination in the **Federal Register**, stating that a detailed summary of the basis for FDA's determination that the FCN is no longer effective has been placed on public display and that copies are available upon request. If FDA determines it would be protective of public health, FDA may include a separate compliance date for the use of the food contact substance in food contact articles, including food contact substances that were produced, supplied, or used by the manufacturer or supplier before publication of the notice in the **Federal Register** or before the compliance date described in paragraph (a)(2)(i)(B) of this section. The date that the notice publishes in the **Federal Register** is the date on which the notification is no longer effective. FDA's determination that an FCN is no longer effective is final Agency action subject to judicial review.

(c) FDA's determination that an FCN is no longer effective does not preclude any manufacturer or supplier from submitting a new FCN for the same food contact substance, including for the same intended use, after FDA has determined that an FCN is no longer effective, unless the intended use of the food contact substance is authorized by a food additive regulation or the subject of an issued threshold of regulation exemption. The new submission must be made under §§ 170.100 and 170.101.

Dated: March 12, 2024.

Robert M. Califf,

Commissioner of Food and Drugs.

[FR Doc. 2024–05802 Filed 3–21–24; 8:45 am]

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DEPARTMENT OF THE TREASURY

Internal Revenue Service

26 CFR Part 301

[TD 9984]

RIN 1545–BN59

De Minimis Error Safe Harbor Exceptions to Penalties for Failure To File Correct Information Returns or Furnish Correct Payee Statements; Correction

AGENCY: Internal Revenue Service (IRS), Treasury.

ACTION: Final rule; correcting amendments.

SUMMARY: This document includes corrections to the final regulations (Treasury Decision 9984) published in the **Federal Register** on Tuesday, December 19, 2023. Treasury Decision 9984 contained final regulations implementing statutory safe harbor rules that protect persons required to file information returns or to furnish payee statements from penalties under the Internal Revenue Code for failure to file correct information returns or furnish correct payee statements.

DATES: These corrections are effective on March 22, 2024 and applicable beginning December 19, 2023.

FOR FURTHER INFORMATION CONTACT: Alexander Wu at (202) 317–6845 (not a toll-free number).

SUPPLEMENTARY INFORMATION: This document corrects minor technical errors in 26 CFR 301.6721–0.

Background

The final regulations (TD 9984) subject to this correction are issued under section 6045(g), 6721, 6722, and 6724 of the Internal Revenue Code.

List of Subjects in 26 CFR Part 301

Employment taxes, Estate taxes, Excise taxes, Gift taxes, Income taxes, Penalties, Reporting and recordkeeping requirements.

Corrections to the Regulations

Accordingly, 26 CFR part 301 is corrected by making the following correcting amendments:

PART 301—PROCEDURE AND ADMINISTRATION

■ **Paragraph 1.** The authority citation for part 301 continues to read in part as follows:

Authority: 26 U.S.C. 7805.

■ **Par. 2.** Section 301.6721–0 is amended by revising the entries for 301.6721–1(b)(6) and 301.6724–1(o) to read as follows:

§ 301.6721–0 Table of Contents.

* * * * *

§ 301.6721–1 Failure to file correct information returns.

* * * * *

(b) * * *

(6) Application to returns not due on January 31, February 28, or March 15.

* * * * *

§ 301.6724–1 Reasonable cause.

* * * * *

(o) Applicability dates.

Oluwafunmilayo A. Taylor,

Section Chief, Publications and Regulations Section, Associate Chief Counsel, (Procedure and Administration).

[FR Doc. 2024–05744 Filed 3–21–24; 8:45 am]

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DEPARTMENT OF THE TREASURY

Internal Revenue Service

26 CFR Part 301

[TD 9984]

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