Recent plant closures in the basin are expected to result in reductions of approximately $500K annually (about 20 percent) in water sale revenues, while the costs of reservoir maintenance and operations, contractual services and administration continue to rise.

*DRBC's Current Schedule of Water Charges.* Resolution No. 71–4 provided that water rates would consist of "the weighted-average unit cost of all water stored by or on behalf of the Commission" and specified that the unit cost of all water would be determined "by dividing all of the commission's annual project cost by the net yield of the water supply in federal reservoirs authorized in the commission's Comprehensive Plan." Res. No. 71–4, par. A.2.a. *Also see* Res. No. 78–14, preamble.

In accordance with this formula, the current schedule of water charges was established by Resolution No. 78–14 in October of 1978, based on the unit cost of water stored by the Commission in the Beltzville and Blue Marsh reservoirs. It was codified at section 5.3.1 of the Commission's Administrative Manual—Part III—Basin Regulations—Water Supply Charges (hereinafter, "WSC"). Section 5.3.1 provides that the Commission "will from time to time, after public notice and hearing, make, amend and revise a schedule of water charges" and that until changed, the charges for water shall be $.06 per thousand gallons for consumptive use ($60 per million gallons) and six-tenths of a mill per thousand gallons ($.60 per million gallons) for non-consumptive use. WSC § 5.3.1. These rates which have remain unchanged for more than 30 years, lag far behind the rates charged for raw (untreated) water by the Commission's sister agency the Susquehanna River Basin Commission (SRBC) and by the New Jersey Water Supply Authority (NJWSA) for raw water from its Raritan System.

The consumptive use rate established by SRBC in May of 1992, effective January 1, 1993, was $140 per million gallons, nearly two-and-a-half times the current rate charged by DRBC. In June of 2008, SRBC approved a two-step increase to $210 per million gallons effective January 1, 2009, and $280 per million gallons (more than four-and-a-half times DRBC's current rate) effective January 1, 2010. NJWSA charged $216 per million gallons as of July 1, 2010 and will charge $220 per million gallons (more than three-and-a-half times DRBC's current rate) as of July 1, 2011, for raw water from its Raritan System. DRBC's proposed 2010 and 2011 rates for consumptively used water remain well below those of its counterparts.

*Proposed Rate Increase.* Resolution No. 71–4 provided that "[c]osts, rates and charges will be recomputed * * * as often as necessary to reflect relevant changes in any cost components associated with sustaining specific base flows." Res. No. 71–4, par. A.2.a. At this time, in order to maintain net income to the Storage Fund and ensure financial stability to address future operating and maintenance costs, the Commission is proposing its first water charging rate increase in 32 years. Because many people find the expression of the rates confusing, the Commission also is proposing that the new rates be established per million gallons rather than per thousand.

In light of the difficult economic climate, the rate change is proposed in two stages. The proposed rates, calculated using the formula established by Resolution No. 71–4 and set forth above, are as follows: The consumptive use rate is proposed to be increased from $60 to $90 per million gallons effective on January 1, 2010, and from $90 to $120 per million gallons effective on January 1, 2011. The non-consumptive use rate is proposed to be increased from $.60 to $.90 per million gallons effective on January 1, 2010, and from $.90 to $1.20 per million gallons effective on January 1, 2011.

Even with the proposed increases, Delaware Basin water will remain inexpensive when compared to raw water in neighboring jurisdictions. Notably, the proposed 2012 rate of $120 per million gallons for raw water consumptively used in the Delaware Basin is less than half the rate of $280 currently in effect in the Susquehanna Basin and only a little more than half the rate of $216 currently charged by the NJWSA for its Raritan System water, which rate will increase to $220 effective January 1, 2011. The Commission's proposed 2012 rate is below the current (2010) rate of $60 per million if adjusted for inflation, which would be approximately $200 per million gallons.

*No Change to Exempt Uses.* No change to the list of uses exempt from charges, as set forth at WSC § 5.3.3 is proposed. The following categories of uses are currently exempt from water charges: Non-consumptive uses of less than 1,000 gallons a day and less than 100,000 gallons during any quarter (§ 5.3.3 A.); ballast water used for shipping purposes (§ 5.3.3 B.); water taken, withdrawn or diverted from streams tributary to the River Master's gauging station at Montague, New Jersey (§ 5.3.3 C.); and water taken, diverted or withdrawn below the mouth of the Cohansey River and such proportion of water withdrawn above that point and below the mouth of the Schuylkill River as the Executive Director may determine would have no discernable effect upon the maintenance of the salt front below the mouth of the Schuylkill River (§ 5.3.3 D.).

**Pamela M. Bush,**

*Commission Secretary.*

[FR Doc. 2010–3219 Filed 2–18–10; 8:45 am]

**BILLING CODE 6360–01–P**

## DEPARTMENT OF HEALTH AND HUMAN SERVICES

### Food and Drug Administration

### 21 CFR Parts 16, 58, 71, 101, 170, 171, 190, 312, 511, 571, and 812

**[Docket No. FDA–2008–N–0115]**

**RIN 0910–AC59**

## Reporting Information Regarding Falsification of Data

**AGENCY:** Food and Drug Administration, HHS.

**ACTION:** Proposed rule.

**SUMMARY:** The Food and Drug Administration (FDA) is proposing to amend its regulations to require sponsors to report information indicating that any person has, or may have, engaged in the falsification of data in the course of reporting study results, or in the course of proposing, designing, performing, recording, supervising, or reviewing studies that involve human subjects or animal subjects conducted by or on behalf of a sponsor or relied on by a sponsor. A sponsor would be required to report this information to the appropriate FDA center promptly, but no later than 45 calendar days after the sponsor becomes aware of the information. This proposal is necessary because ambiguity in the current reporting scheme has caused confusion among sponsors. The proposed rule is intended to help ensure the validity of data that the agency receives in support of applications and petitions for FDA product approvals and authorization of certain labeling claims and to protect research subjects.

**DATES:** Submit written or electronic comments on this proposed rule by May 20, 2010. See section V of this document for the proposed effective date of a final rule based on this document. Submit comments regarding the information collection by March 22, 2010 to OMB (see **ADDRESSES**).

**ADDRESSES:** You may submit comments, identified by Docket No. FDA–2008–N–0115 and/RIN number 0910–AC59, by any of the following methods:

*Electronic Submissions*

Submit electronic comments in the following ways:

- Federal eRulemaking Portal: *http://www.regulations.gov*. Follow the instructions for submitting comments.

*Written Submissions*

Submit written submissions in the following ways:

- FAX: 301–827–6870.
- Mail/Hand delivery/Courier [For paper, disk, or CD–ROM submissions]: Division of Dockets Management (HFA–305), Food and Drug Administration, 5630 Fishers Lane, rm. 1061, Rockville, MD 20852.

To ensure more timely processing of comments, FDA is no longer accepting comments submitted to the agency by e-mail. FDA encourages you to continue to submit electronic comments by using the Federal eRulemaking Portal or the agency Web site, as described previously, in the **ADDRESSES** portion of this document under *Electronic Submissions*.

*Instructions*: All submissions received must include the agency name and Docket No(s). and Regulatory Information Number (RIN) for this rulemaking. All comments received will be posted without change to *http://www.regulations.gov*, including any personal information provided. For additional information on submitting comments, see the "Comments" heading of the **SUPPLEMENTARY INFORMATION** section of this document.

*Docket*: For access to the docket to read background documents or comments received, go to *http://www.regulations.gov* and insert the docket number, found in brackets in the heading of this document, into the "Search" box and follow the prompts and/or go to the Division of Dockets Management, 5630 Fishers Lane, rm. 1061, Rockville, MD 20852.

*Information Collection Provisions*: Submit written comments on the information collection provisions to the Office of Information and Regulatory Affairs, Office of Management and Budget (OMB). To ensure that comments on the information collection are received, please submit written comments to OMB by FAX to 202–395–7285 or by e-mail to *OIRA_submission@omb.eop.gov*. Mark your comments to the attention of the FDA desk officer and reference this rulemaking.

**FOR FURTHER INFORMATION CONTACT:**

*For information regarding human drugs*: Leslie K. Ball, Center for Drug Evaluation and Research, Office of Compliance, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 51, rm. 5342, Silver Spring, MD 20993–0002, 301–796–3150, FAX: 301–847–8750.

*For information regarding biologics*: Steve Ripley, Center for Biologics Evaluation and Research (HFM–17), Food and Drug Administration, 5515 Security Lane, rm. 5130, Rockville, MD 20852, 301–827–6210.

*For information regarding medical devices and radiological health*: Michael E. Marcarelli, Center for Devices and Radiological Health, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 66, rm. 3444, Silver Spring, MD 20993–0002, 301–796–5490.

*For information regarding veterinary medicine*: Gail L. Schmerfeld, Center for Veterinary Medicine (HFV–100), Food and Drug Administration, 7500 Standish Pl., Rockville, MD 20855, 240–276–8300.

*For information regarding foods*: Linda Katz, Center for Food Safety and Applied Nutrition (HFS–032), Food and Drug Administration, 5100 Paint Branch Pkwy., College Park, MD 20740, 301–436–1910.

*For information regarding good laboratory practices for nonclinical laboratory studies*: Karen Stutsman, Office of Regulatory Affairs (HFC–230), Food and Drug Administration, 15800 Crabbs Branch Way, Rockville, MD 20855, 240–632–6847.

*For information regarding good clinical practice*: Kathleen Pfaender, Office of Good Clinical Practice (HF–34), 5600 Fishers Lane, rm. 16–85, Rockville, MD 20857, 301–827–3340.

**SUPPLEMENTARY INFORMATION:**

## I. Introduction

FDA is proposing to require that sponsors[1] report information indicating that any person has, or may have, engaged in the falsification of data in the course of reporting study results, or in the course of proposing, designing, performing, recording, supervising, or reviewing studies[2] that involve human subjects (e.g., clinical investigations) or animal subjects (e.g., nonclinical laboratory studies and clinical studies in animals) conducted by or on behalf of a sponsor or relied on by a sponsor. The sponsor would be required to report this information to the appropriate FDA center promptly, but no later than 45 calendar days after the sponsor becomes aware of the information. The proposed requirement for a sponsor to report information regarding falsification of data would be ongoing and cover the periods before and after study completion, including after the review, approval, or authorization of the affected product or labeling.

We are proposing to amend the appropriate regulations that govern the conduct of FDA-regulated research and the submission of information in support of applications and petitions for FDA product approvals and authorization of certain labeling claims. This requirement would be added to FDA's regulations on:

- Good laboratory practice for nonclinical laboratory studies (21 CFR part 58),
- Color additive petitions in part 71 (21 CFR part 71),
- Petitions for nutrient content claims and petitions for health claims in part 101 (21 CFR part 101),
- Information in a premarket notification for a food contact substance (FCN) in part 170 (21 CFR part 170),
- Food additive petitions (21 CFR part 171),
- Dietary supplements (21 CFR part 190),
- Investigational new drug applications (21 CFR part 312),
- New animal drugs for investigational use (21 CFR part 511),
- Food additive petitions (21 CFR part 571), and
- Investigational device exemptions (21 CFR part 812).

[1] FDA regulations on food additive, color additive, health claim, and nutrient content claim petitions refer to petitioners, rather than sponsors. In addition, the FDA regulation for the submission of new dietary ingredient notifications refers to a manufacturer or distributor, and the FDA regulation for the submission of a food contact notification (FCN) refers to a manufacturer or supplier, rather than sponsor. For the sake of brevity, FDA is using the term "sponsor" in this document to refer to petitioners submitting food additive, color additive, nutrient content claim, and health claim petitions; manufacturers or distributors submitting new dietary ingredient notifications; and sponsors as defined in §§ 58.3(f), 312.3(b), 510.3(k), and 812.3(n) (21 CFR 58.3(f), 312.3(b), 510.3(k), and 812.3(n)). The term "sponsor" as used in this document does not include a Federal agency that sponsors research or investigations through funding or contracts or an entity identified as a "sponsor" under other Federal programs (e.g., a recipient of funding from the National Institutes of Health), except to the extent that any such Federal agency or entity is a petitioner, manufacturer, distributor, or sponsor as specified in the preceding sentence.

[2] Henceforth, the term "studies" means studies involving human subjects (e.g., clinical investigations) or animal subjects (e.g., nonclinical laboratory studies and clinical studies in animals).

*A. Background*

Falsification of data can, if not detected, undermine subject protection and the underlying basis for FDA actions. Each year, FDA discovers falsification of data at study sites and in application submissions. Sometimes, falsification at a study site is not an isolated event and can lead to a finding of falsification of information at another site, or relating to other drugs being studied at the same site. It is critical that participants in the product development process assist FDA in detecting falsification of data.

FDA's proposal to amend the regulations has its origins in events that occurred in the mid- to late-1990s, when complaints to FDA and followup through FDA's bioresearch monitoring program revealed some particularly egregious cases of falsification of data by clinical investigators. For example, in one case, an investigator falsified data that extended across studies in 91 applications submitted to FDA by 47 different sponsors.

After discovering this widespread falsification, FDA attempted to determine why so widespread a practice remained unreported to FDA. In a series of FDA meetings, as well as congressional briefings, FDA reviewed the current requirements for sponsor reporting of noncompliant investigators, reviewed study monitoring procedures, and listened to the views of an industry trade association. In addition, the Center for Drug Evaluation and Research (CDER) established an internal working group to evaluate the effectiveness of the current reporting requirements for sponsors. The working group identified several areas of ambiguity in the current regulations related to: (1) The extent to which possible falsification of data had to be reported to the agency; (2) the amount and type of information that sponsors must report when a study and/or an investigator's participation in a study has terminated; (3) whose falsification of data must be reported; and (4) the timing of reporting.

*B. Why FDA Is Proposing This Rule*

We are proposing this rule for two principal reasons. First, it is important for the agency to have confidence in any data from studies conducted by, or on behalf of, a sponsor, or relied on by a sponsor for product approvals or authorization of labeling claims. This proposed rule is intended to help ensure the integrity of data submitted to FDA because reliance on falsified data could lead to clinical testing of unsafe products, approval of ineffective or unsafe products, or marketing of products with false or misleading claims. Second, it is important that the rights, safety, and welfare of subjects be protected. This proposed rule is intended to help protect research subjects[3] by making it less likely that persons who falsify data will continue to conduct studies, come in contact with research subjects, or jeopardize the rights, safety, and welfare of such subjects through unsound scientific practices.

Although our own inspections sometimes uncover falsification of data, sponsors of studies are responsible for ensuring the integrity of study data and are in a better position to discover possible falsification of data through their monitoring, auditing, and reviewing of data. We understand that in the process of reviewing and monitoring studies, some sponsors have discovered falsification of data and have been reluctant, or uncertain as to whether it was necessary, to report the information to us. For example, we are aware that in some cases, sponsors, believing that an investigator may have falsified data, have decided to retain the investigator but exclude the investigator's data without specifying the reason. In other cases, sponsors have terminated the investigator's participation in the study without notifying us of the specific reason. We are concerned that when these situations occur, an investigator who may have falsified data might continue to conduct studies, thereby jeopardizing the rights, safety, and welfare of the subjects involved in future research and the integrity of data in other studies.

Therefore, the agency is proposing this rule to clarify sponsors' reporting requirements for studies conducted by, or on behalf of, a sponsor or on which a sponsor relies to support product approvals, new dietary ingredient notifications, or authorization of labeling claims, including nutrient content claims and health claims. This proposed rule makes it clear that sponsors would be required to promptly report information indicating that any person has, or may have, engaged in the falsification of data in the course of reporting study results, or in the course of proposing, designing, performing, recording, supervising, or reviewing studies conducted by, or on behalf of, a sponsor or relied on by a sponsor. This proposed rule, when finalized, would require sponsors to report information to the appropriate FDA center about possible falsification of data whenever (before, during, or after the completion of a study) a sponsor becomes aware of the information, but in no case later than 45 calendar days after the sponsor becomes aware of that information.

The proposed regulation would allow the agency to more rapidly identify persons who have falsified data and more effectively address problems. Such persons may include those who have falsified data submitted to FDA for product reviews, approvals, and authorizations of certain labeling claims, in addition to those who have falsified data in the course of conducting FDA-regulated research. We intend to use the information collected from sponsors who notify us of possible falsification of data to identify patterns, potential signals, or other indications of misconduct, so that we can conduct further investigations. These investigations, in turn, may form the basis of administrative or enforcement actions, such as excluding clinical trials from consideration by FDA, placing a clinical trial on hold, or initiating disqualification of investigators or criminal proceedings. Taking effective action in response to falsification could lessen the magnitude and impact of the falsification in a current study, reduce the potential for delays or compromise to other studies and applications (including studies and applications from other sponsors for whom such a person might also be working), and protect the rights, safety, and welfare of research subjects.

## II. Description of the Proposed Rule

*A. What Changes Are We Proposing to Make?*

Under proposed §§ 58.11(a), 71.1(k), 101.69(p), 101.70(k), 170.101(f), 171.1(o), 190.6(g), 312.56(e), 511.1(c), 571.1(l), and 812.46(d), sponsors would be required to report to the appropriate FDA center information indicating that any person has, or may have, engaged in the falsification of data in the course of reporting study results, or in the course of proposing, designing, performing, recording, supervising, or reviewing studies conducted by or on behalf of a sponsor or relied on by a sponsor. For the purposes of this proposed rule, "falsification of data" means creating, altering, recording, or omitting data in such a way that the data do not represent what actually occurred. These reporting requirements would apply to information related to studies including, but not limited to, clinical investigations, nonclinical laboratory studies, and clinical studies in animals.

FDA does not intend to impose any additional monitoring responsibilities under this proposed rule. This proposal

[3] For the sake of brevity, FDA is using the term "subjects" to refer to human and animal subjects.

does not relieve sponsors of any other applicable statutory or regulatory requirements.

*B. Who Would Be Required to Report Information to FDA?*

The proposed rule would require sponsors, as defined earlier in this preamble, to report certain information related to confirmed or possible falsification of data.

*C. Whose Falsification of Data Would a Sponsor Be Required to Report?*

FDA is seeking information on falsification of data by any person involved in studies conducted by or on behalf of a sponsor or relied on by a sponsor. In FDA's experience, falsification may be committed by individuals responsible for conducting studies and/or by their colleagues or subordinates. FDA believes that all persons involved in such actions must be identified so that future falsification of data can be prevented. Therefore, FDA is proposing in this regulation to require sponsors to inform FDA of any confirmed or possible falsification of data by any person involved in studies conducted by or on behalf of a sponsor or relied on by a sponsor.

*D. Can FDA Provide Any Examples of Falsification of Data That Would Be Subject to the Reporting Requirements of This Proposed Rule?*

"Falsification of data" is defined for the purpose of this proposed rule as creating, altering, recording, or omitting data in such a way that the data do not represent what actually occurred. Instances of falsification of data may fall into one or several of these categories. The following, although not comprehensive, represent examples of falsification of data that would be reportable under this proposed rule:

- Creating data that were never obtained (e.g., making up data or results and recording or reporting them; reporting enrollment in a study of a subject who did not exist; forging the signature on an informed consent form)
- Altering data by replacing original data with something different that does not accurately reflect study conduct or results (e.g., changing a laboratory measurement to a less extreme deviation from normal)
- Recording or obtaining data from a specimen, sample, or test whose origin is not accurately described or in a way that does not accurately reflect the data (e.g., changing the date of a specimen, sample, or test; adding a substance not called for in the study to a specimen or sample; identifying a specimen, sample, or test as coming from a specific subject when it came from a source other than the subject)
- Omitting data that were obtained and would be appropriate for recording based on study design and conduct (e.g., not recording exclusionary medical history or prohibited concomitant medications or treatments; omitting data so that a statistical analysis yields a result that would not have been obtained had all data been analyzed)

Although the examples above are each characterized as a particular type of falsification of data, we recognize that even these examples can fall into one or more categories. Because instances of falsification of data might fall into one or more of these categories, sponsors would not need to specifically characterize the falsification (e.g., creating, recording, altering, or omitting data) in the reports they would be required to submit to us.

*E. Would Sponsors Be Required to Report Errors Under This Proposed Rule?*

Errors, which can include, as noted in the proposed codified language, typographical errors and transposed numbers or characters, should not be reported under this proposed rule. The proposed rule is designed to address falsification of data rather than unintentional errors in recording and reporting information for several reasons:

- Falsification is more difficult for FDA to detect than errors during the normal inspectional process, in part because persons who engage in falsification are more likely to attempt to conceal their actions.
- Persons who engage in falsification of data often repeat that conduct when they are participating in multiple studies that affect multiple sponsors, so the impact of the conduct is often greater than that for errors.
- Although significant errors could potentially compromise the integrity of data submitted to FDA, it is more likely that these errors will be addressed through FDA inspections, sponsor monitoring activities, and the agency's application review processes than is the case with falsification of data.
- Requiring sponsors to report every observed error in data recording and processing could overwhelm the agency with information, much of which would already be detected through the activities noted above and would ultimately be of little concern with respect to the safety or effectiveness of regulated products.

For these reasons, at this time we are proposing to exclude errors from the proposed reporting requirement to best utilize the agency's resources.

We also are soliciting comments on whether we should include additional descriptions of what we consider "errors" and, if so, what would be specific examples of such errors.

*F. Would a Sponsor Be Required to Report Possible Falsification?*

The proposed codified language includes the phrase "has, or may have, engaged in the falsification of data" to make clear that the sponsor is required to report not only confirmed, but also possible, falsification. It is not always possible for an observer to know the intent of a person who may have falsified data. The proposed rule would not require a sponsor to determine definitively that data have been falsified, nor would the proposed rule require that a sponsor determine the intent of the person who has, or may have, falsified data. Rather, a sponsor would be required to report information of which it is aware suggesting that a person has, or may have, engaged in the falsification of data in connection with studies conducted by, or on behalf of, the sponsor, or relied on by the sponsor. This reporting obligation would exist regardless of the amount of evidence, if any, the sponsor has with regard to the intent of the person who has, or may have, falsified data.

We purposely are not proposing to specify in the regulations any particular information threshold that must be met before the reporting requirements are triggered, such as the exact form, quantity, or reliability of information about possible falsification that would require a sponsor to report to FDA. We do not believe that it is feasible to codify all forms of information on possible falsification (e.g., discovery of possibly altered document, report by coworker, complaint by study subject) or specify a quantity of information that would constitute a minimum threshold for sponsor reporting, and we do not want to inadvertently exclude information that, upon further investigation by the agency, could help uncover falsification. However, we invite comment on whether the regulation should specify some form of evidentiary standard or minimum threshold, such as what form(s) or quantity of information is needed to create a requirement to report and, if so, what the standard should be (see also section IX of this document).

*G. How Will FDA Use This Information?*

FDA would determine whether further agency investigation is warranted based on the information reported under this proposed rule in

conjunction with other information available to us. These investigations, in turn, might form the basis of administrative or enforcement actions, such as excluding clinical trials from consideration by FDA, placing a clinical trial on hold, or initiating disqualification of investigators or criminal proceedings.

Although a single sponsor may have only a small amount of information about a particular person or incident, the reporting that would be required by this proposed rule, independently or when aggregated with reports from other sources, may provide sufficient information from multiple sources about a person or situation to indicate that FDA should conduct an investigation. FDA would determine whether further agency investigation is warranted based on the information reported under this proposed rule in conjunction with other information available to FDA. Sponsors should therefore not wait to determine conclusively whether falsification actually occurred, or seek to determine the circumstances that led to it, before reporting this information to FDA.

The intent of this proposed requirement is for FDA to obtain information about possible falsification as soon as possible, with the full recognition that further investigation may be needed to substantiate allegations of possible falsification before any administrative or enforcement actions are taken. The act of being reported to FDA for possible data falsification would not necessarily mean that falsification had occurred or that the agency would make such a determination. The information likely would be assessed in light of the existing legal and regulatory framework and, as appropriate, would be considered in the context of administrative or enforcement proceedings. Persons suspected of data falsification would be entitled to the legal and procedural rights that would typically apply in any such administrative or enforcement proceedings.

Early reporting by sponsors could alert FDA to conditions that may affect data integrity and the rights, safety, and welfare of subjects. This reporting requirement would have the effect of providing FDA with an early alert to potentially serious lapses in subject protection or data integrity. If FDA were made aware of possible falsification of data sooner, FDA could undertake appropriate action, such as reviewing other studies conducted by the persons who have, or may have, falsified data to assess the reliability of the data and/or conducting site inspections.

*H. What Information Should Sponsors Include in the Required Report to FDA?*

The proposed rule would require the sponsor to report to FDA information it possesses regarding the possible falsification of data. The information a sponsor should report to FDA includes the following:

- The name of the person who has, or may have, falsified data;
- The last known address(es) and phone number(s) of that person;
- The specific identity of the potentially affected study, including, when applicable, application information such as the application number, investigational protocol number, study title, study site(s), and study dates; and
- Information suggesting that falsification occurred and describing the falsification. A sponsor may provide this information by any means, including telephone, mail, electronic mail, or facsimile.

We are considering whether additional information should be included in the report to FDA. One such element could be the National Clinical Trial (NCT) number assigned to a study when an applicable clinical trial is registered with ClinicalTrials.gov. We also are considering whether the regulations should specify what information about possible falsification must be reported to FDA.

Although the proposal would require only sponsors to report information about possible falsification of data, FDA also encourages other persons to report such information. FDA reminds sponsor-investigators that they would be responsible for reporting falsification of data under this proposed rule because they must adhere to the requirements applicable to both sponsors and investigators.

*I. How Does a Sponsor Become Aware of Data Falsification?*

There are many ways a sponsor can become aware of possible falsification, including, but not limited to, monitoring the conduct of studies, reviewing and evaluating study data (e.g., noticing unusual data in case report forms and/or analytical reports), and receiving complaints from employees or former employees.

*J. When Would a Sponsor Be Required to Report Information About Falsification of Data?*

The agency is proposing to require sponsors to report information regarding falsification of data "promptly," but no later than 45 calendar days after the sponsor becomes aware of the information. It is important for FDA to receive information about the falsification of data in a timely manner to ensure protection of the integrity of data reviewed by the agency and protection of subjects. We believe that 45 calendar days would provide a sponsor a reasonable amount of time to review the information and report any actual or suspected falsification to FDA. The proposed requirement for a sponsor to report information regarding falsification of data would be ongoing and cover the periods before and after study completion, including after the review, approval, or authorization of the affected product or labeling.

*K. What Are the Consequences of Not Reporting Confirmed or Possible Falsification?*

Failure to report possible falsification of data might constitute a violation of section 301(e) of the Federal Food, Drug, and Cosmetic Act (the act) (21 U.S.C. 331(e)) (concerning failure to make a required report) or 18 U.S.C. 1001 (concerning the submission of a false statement to the Federal government).

*L. Whom Would a Sponsor Inform About Falsification?*

As proposed, a sponsor would be required to report information it discovered regarding falsification of data to the appropriate FDA center. For investigations involving a combination product, the sponsor should report information on falsification to the FDA center that has primary jurisdiction for the premarket review and regulation of the product.

Current contact information for each center is listed below as follows:

Center for Biologics Evaluation and Research (CBER): Office of Compliance and Biologics Quality (HFM–650), Division of Inspections and Surveillance, Center for Biologics Evaluation and Research, FDA, 1401 Rockville Pike, rm. 200N, Rockville, MD 20852–1448, 301–827–6221, FAX 301–827–6748.

Center for Devices and Radiological Health (CDRH): Office of Compliance, Division of Bioresearch Monitoring (HFZ–310), Center for Devices and Radiological Health, FDA, 10903 New Hampshire Ave., Bldg. 66, rm. 3444, Silver Spring, MD 20993–0002, 301–796–5490, FAX 301–847–8136.

Center for Drug Evaluation and Research (CDER): Division of Scientific Investigations, Office of Compliance, Center for Drug Evaluation and Research, FDA, 10903 New Hampshire Ave., Bldg. 51, rm. 5311, Silver Spring, MD 20993–0002, 301–796–3150, FAX 301–847–8748.

Center for Food Safety and Applied Nutrition (CFSAN): Office of Compliance, Division of Enforcement (HFS–605), Center for Food Safety and Applied Nutrition, FDA, 5100 Paint Branch Pkwy., College Park, MD 20740–3835, 301–436–2417, FAX 301–436–2656.

Center for Veterinary Medicine (CVM): Office of Surveillance and Compliance, Division of Compliance (HFV–230), Center for Veterinary Medicine, FDA, 7500 Standish Pl., Rockville, MD 20850, 240–276–9200, FAX 240–276–9241.

Office of Regulatory Affairs (ORA): Office of Enforcement (HFC–230), FDA, 15800 Crabbs Branch Way, Rockville, MD 20855, 240–632–6853.

*M. What Is the Proposed Definition of "Data" for the Purposes of This Proposal?*

In this proposal, the term "data" includes, but is not limited to, individual facts, tests, specimens, samples, results, statistics, items of information, or statements made by individuals. This proposed rule would apply to data from studies conducted by or on behalf of a sponsor or relied on by a sponsor. Thus, it would apply not only to data from studies conducted by a sponsor, but also to data from studies not sponsored or conducted by a sponsor but cited in a petition, new dietary ingredient notification, or application to FDA in support of a claim, product marketing, or other regulatory action such as reclassification of a device.

*N. Why Does FDA Want to Issue This Proposal Given Existing Regulations on Research Misconduct?*

The Public Health Service (PHS) regulations at 42 CFR part 93 and the National Science Foundation (NSF) regulations at 45 CFR part 689 address "research misconduct." The PHS research misconduct regulations generally apply to PHS-conducted or PHS-supported biomedical and behavioral research, research training, research-related activities, and applications and proposals for such PHS-supported research, research training, and related activities. The NSF regulations on research misconduct address research proposals submitted to NSF and funded by NSF. As a result, neither of these regulations encompasses sufficiently the scope of research subject to evaluation by FDA.[4] FDA's proposed rule is intended to cover all studies that are subject to FDA evaluation, regardless of the source of funding.

Furthermore, FDA is not adopting any definition of "research misconduct" for the purpose of this proposal for two additional reasons. First, FDA's proposed definition of "falsification of data" describes the kinds of falsification of data that the agency has actually encountered that can affect both application reviews and the safety of subjects. Second, the PHS and NSF research misconduct regulations include the category "plagiarism" in the definitions of "research misconduct." Although plagiarism is an important issue in the context of Federal research grants and contracts, it is an area generally outside the scope of FDA compliance oversight. Accordingly, FDA is proposing to not include plagiarism in the category of activity that would trigger reporting under the proposed rule.

*O. Why Is FDA Proposing to Change the Section Heading of § 312.56?*

FDA is proposing to change the section heading of § 312.56 from "Review of ongoing investigations" to "Review of ongoing investigations; reporting falsification of data" to reflect the addition of this proposed reporting requirement to this section.

*P. Why Is FDA Proposing to Renumber § 58.217 to § 58.12?*

FDA is proposing to renumber § 58.217 to § 58.12 to place sponsor responsibilities under the regulations in consecutive sections. The proposed revisions to the language in current § 58.217 include changing the first sentence to read "subpart K of this part" instead of "this subpart" and several minor plain language edits.

*Q. Why Is FDA Not Proposing to Amend Parts 314, 514, 601, and 814?*

We recognize that the applicant (under 21 CFR parts 314, 514, 601, 807, and 814) is not always the sponsor for a given study and that arrangements between sponsors and applicants can sometimes be complex. We currently believe that sponsors are in the best position to detect and report falsification of data as described in this proposal. However, this proposal does not relieve applicants of any responsibilities under applicable statutes and regulations (e.g., parts 314, 514, 601, 807, and 814). It may be appropriate to extend the reporting requirements described in this proposed rule to nonsponsor applicants if we have reason to believe that they are also in a position to discover falsification of data described in this proposed rule and that existing statutes and regulations are not adequate to capture this information. Therefore, we request comment on whether we should require nonsponsor applicants to comply with the requirements in the proposed rule and whether such applicants are in a position to discover falsification of data.

**III. Environmental Impact**

The agency has 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.

**IV. Legal Authority**

FDA is proposing this rule under the authority granted to it by the act (21 U.S.C. 301 *et seq.*) and the Public Health Service Act (PHS Act) (42 U.S.C. 201 *et seq.*). By delegation from the Secretary of the Department of Health and Human Services (the Secretary), FDA is authorized to issue regulations for the efficient enforcement of the act (21 U.S.C. 371). Any final rule upon which this proposal is based would help with the efficient enforcement of provisions relating to the following: (1) Investigational use of human drugs, animal drugs, biologics, and devices; (2) investigational and approved use of food additives and color additives; (3) safety and, as appropriate, effectiveness of human and animal drugs, biological products, and medical devices; (4) accuracy of a health claim or nutrient content claim in food labeling; and (5) establishing that a new dietary ingredient will reasonably be expected to be safe.

FDA may require the establishment and maintenance of such records, and the making of such reports to FDA, of data obtained as a result of the investigational use of an animal drug (21 U.S.C. 360b(j)), a biologic (42 U.S.C. 262(a)(3)), a device (21 U.S.C. 360j(g)(2)(B)(ii)), a human drug (21 U.S.C. 355(i)), a food additive (21 U.S.C. 348(b), (j), and (h)), or a color additive (21 U.S.C. 379e(b)). FDA may require the submission of balanced information, which is necessary for FDA to evaluate: The safety of a food additive (21 U.S.C. 348), the safety and suitability of a color additive (21 U.S.C. 379e), the accuracy of a health claim or nutrient content claim in food labeling (21 U.S.C. 343(r)(2)(A), (r)(3)(B)), and the basis on which a manufacturer or distributor concluded that a new dietary ingredient will reasonably be expected to be safe

[4] References made in this proposed rule to "research" and "studies" that are "subject to evaluation by FDA" include research and studies that are otherwise within the scope of the codified provisions in this proposed rule.

(21 U.S.C. 350b(a)(2)). FDA may also require the establishment and maintenance of such records, and the making of such reports to FDA, as are necessary to determine whether there are, or may be, grounds to withdraw the approval or authorization of an animal drug (21 U.S.C. 360b(l)), a biologic (42 U.S.C. 262(a)(2)(A)), a device (21 U.S.C. 360i), a human drug (21 U.S.C. 355(k)), a food additive (21 U.S.C. 348), a color additive (21 U.S.C. 379e), a health claim (21 U.S.C. 343(r)(2)(A)), or a nutrient content claim (21 U.S.C. 343(r)(2)(B)), or when reasonably necessary to determine that a dietary supplement containing a new dietary ingredient may no longer meet the provisions in 21 U.S.C. 350b(a)(2).

Moreover, other provisions, such as 21 U.S.C. 355(i), 42 U.S.C. 262, and 21 U.S.C. 360b(j) and 360j(g)(2), confer broad authority upon the Secretary (and, by delegation, to FDA) to issue regulations governing the investigational use of new drugs, biologics, new animal drugs, and devices to protect the rights, safety, and welfare of subjects and otherwise protect the public health. Other provisions, such as 21 U.S.C. 355(b) to (d), 360b(b) to (d), 360e(2)(A), and 360e(c)(1), give the agency the authority to obtain the information we need to adequately assess the safety and effectiveness of drugs and devices. In determining whether a drug or device is "safe for use" under the conditions proposed, the agency may consider not only information such as data from studies, but also "any other information" or "new information" before the agency relevant to the approval decisions under 21 U.S.C. 355(d), 360b(d), and 360e(d)(2). The language in 21 U.S.C. 355(d), 360b(d), and 360e(c)(1) is intended to help ensure that consumers are not exposed to products for which safety and effectiveness have not been demonstrated.

Similarly, 21 U.S.C. 360e gives the agency the authority to obtain the information we need to determine whether a premarket approval application provides reasonable assurances of the safety and effectiveness of a device. Under 21 U.S.C. 360c(i), persons submitting premarket notifications are required to submit a summary of any information respecting safety and effectiveness or state that such information will be made available upon request.

In addition, under 21 U.S.C. 355(e), 360b(e)(1), and 360e(e)(1), approval of an application is to be withdrawn if, inter alia, new information shows that the drug or device is unsafe or has not been shown to be either safe or effective under the conditions of use.

As discussed previously, the proposal, when final, would help efficiently enforce provisions relating to: (1) The safety and, as appropriate, effectiveness of human and animal drugs, biological products, and medical devices; (2) the safety of food additives and new dietary ingredients; (3) the safety and suitability of color additives; and (4) the accuracy of nutrient content claims and health claims. FDA believes the proposal would help prevent the use of falsified data in evaluating the safety and, as appropriate, suitability, accuracy, or effectiveness of such products. The proposed changes would also help to protect research subjects.

Provisions for misbranding (21 U.S.C. 352 and 343) and adulteration (21 U.S.C. 351 and 342) also provide authority for issuance of these regulations.

## V. Proposed Implementation Plan

FDA proposes that any final rule that may issue based on this proposal become effective 90 days after the date of publication in the **Federal Register**.

## VI. Analysis of Impacts

FDA has examined the impacts of the proposed rule under Executive Order 12866, the Regulatory Flexibility Act (5 U.S.C. 601–612), and the Unfunded Mandates Reform Act of 1995 (Public Law 104–4). Executive Order 12866 directs agencies to assess all costs and benefits 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). The agency believes that this proposed rule is not an economically significant regulatory action as defined by the Executive order.

The Regulatory Flexibility Act requires agencies to analyze regulatory options that would minimize any significant impact of the rule on small entities. Because most firms would not generally submit more than one report of potential data falsification per year at the estimated cost of only $210 per report, the agency does not believe that this proposed rule would have a significant economic impact on a substantial number of small entities.

Section 202(a) of the Unfunded Mandates Reform Act of 1995 requires that agencies prepare a written statement, which includes an assessment of anticipated costs and benefits, before proposing "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 $133 million, using the most current (2008) Implicit Price Deflator for the Gross Domestic Product. FDA does not expect this proposed rule to result in any 1-year expenditure that would meet or exceed this amount.

The proposed rule would amend FDA's regulations to require sponsors to report information indicating that any person has, or may have, falsified data in the course of reporting study results, or in the course of proposing, designing, performing, recording, supervising, or reviewing studies conducted by or on behalf of a sponsor or relied on by a sponsor. For the purpose of this proposal, "falsification of data" means creating, altering, recording, or omitting data in such a way that the data do not represent what actually occurred. Sponsors would be required to report this information to the appropriate FDA center promptly, but no later than 45 calendar days after the sponsor becomes aware of the information.

### *A. Benefits*

The benefits of the changes being proposed would be the decreased likelihood that FDA would rely on falsified data for product reviews and approvals, or for authorization of certain labeling claims. The proposed changes would also decrease the likelihood of harm to research subjects by making it less likely that clinical studies would begin or continue if falsified data from nonclinical laboratory studies were reported. The proposed changes would also prevent researchers who falsify data from continuing studies, coming in contact with research subjects, or jeopardizing the safety of such subjects through unsound scientific practices.

### *B. Costs*

Regulatory costs will reflect the added paperwork cost of submitting the information reports. Given the great flexibility provided in the manner in which the reports can be made, FDA believes that they will be simple to complete. Therefore, FDA estimates that it will take about 5 hours to prepare and report this information to the agency. The agency is uncertain of the average number of these reports to expect annually. As explained in section VII of this document, the agency estimates that it may receive 73 reports per year in compliance with this rule (see Table 1.—Estimated Annual Reporting

Burden). FDA is basing this estimate on several types of information, including reports received from sponsors of errors and reports of suspensions and terminations of clinical investigators. Because most errors do not involve falsification and because investigators may be suspended or terminated for reasons other than for falsifying data, this estimate of 73 reports is likely to be greater than the number the agency would actually receive. At a benefit-adjusted hourly wage rate of about $42 for a regulatory affairs official, these assumptions imply a total annual cost of about $15,330 per year.[5] As mentioned previously, the agency expects the total number of reports of falsified data, and therefore the total cost, to be lower. Although a small number of firms may submit more than one report in a year, most firms would not generally submit more than one report per year. At an estimated cost of only about $210 per report, the agency concludes that the proposed rule would not have a significant economic impact on a substantial number of small entities. The Unfunded Mandates Reform Act of 1995 does not require FDA to prepare a statement of costs and benefits for the proposed rule, because the proposed rule is not expected to result in any 1-year expenditure that would meet or exceed $100 million adjusted for inflation. The current inflation-adjusted statutory threshold is $133 million.

## VII. Paperwork Reduction Act of 1995

This proposed rule contains information collection requirements that are subject to review by the Office of Management and Budget (OMB) under the Paperwork Reduction Act of 1995 (44 U.S.C. 3501–3520) (the PRA). Collections of information include any request or requirement that persons obtain, maintain, retain, or report information to the agency, or disclose information to a third party or to the public (44 U.S.C. 3502(3) and 5 CFR 1320.3(c)). A description of the information collection requirements included in this proposed rule is given below with an estimate of the annual reporting burden. Included in this 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.

FDA invites comments on: (1) Whether the proposed collection of information is necessary for the proper performance of FDA's functions, including whether the information will have practical utility; (2) the accuracy of FDA'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.

*Title*: Reporting Information Regarding Falsification of Data.

*Description*: FDA is proposing to amend its regulations on review of studies to require sponsors to report information indicating that any person has, or may have, engaged in the falsification of data in the course of reporting study results, or in the course of proposing, designing, performing, recording, supervising, or reviewing studies conducted by or on behalf of a sponsor or relied on by a sponsor. The sponsor would be required to report this information to the appropriate FDA center promptly, but no later than 45 calendar days after the sponsor becomes aware of the information. For the purpose of this proposal, "falsification of data" means creating, altering, recording, or omitting data in such a way that the data do not represent what actually occurred.

FDA believes that this proposal is necessary because ambiguity in the current regulations has caused considerable confusion among sponsors. FDA intends to make it absolutely clear that sponsors would be required to report information pertaining to the possible falsification of data as described in this proposal. This proposal is intended to help ensure the integrity of data received by FDA in support of applications and petitions for product approval and authorization of certain labeling claims and to help protect research subjects. In addition, this proposal would protect research subjects by making it less likely that falsified nonclinical laboratory studies would be relied on by the agency and that researchers who falsify data could continue to conduct studies, come in contact with research subjects, and/or jeopardize the rights, safety, and welfare of such subjects through unsound scientific practices.

Based on data concerning the number of reports of falsification received annually by FDA, FDA estimates that it will receive approximately 73 reports of falsification of data per year. FDA bases this estimate on the fact that CDER receives approximately 20 reports a year from sponsors, CBER receives approximately 30 per year, and CDRH receives approximately 15. There are approximately three incidents a year concerning nonclinical laboratory studies. CFSAN receives approximately three reports a year concerning food additive petitions and color additive petitions. CFSAN has received no reports concerning nutrient content claims, health claims, or new dietary ingredients. CVM receives approximately two reports a year.

FDA estimates that it will take approximately 5 hours to prepare and submit to FDA each report. FDA bases this estimate on the time it would take a sponsor to gather the information to report to FDA, contact FDA to report the information, and meet with FDA to present the report, if necessary.

The reporting burden posed by the proposed rule is considerably less than the burden posed by the PHS research misconduct regulations, primarily because the proposed rule would require fewer specific actions by sponsors. The PRA section of the final rule on the PHS research misconduct regulations (70 FR 28370, 28382 to 28384; May 17, 2005) describes the extensive efforts that a research institution must undertake to investigate and document research misconduct, including promptly taking custody of all records and evidence, performing an inventory of these items, and sequestering them, as well as taking custody of additional records and evidence discovered during the course of a research misconduct proceeding. FDA's proposed rule on falsification would not require extensive investigation, documentation, and recordkeeping, but rather would simply require reporting of known or potential data falsification when a sponsor becomes aware of information indicating that such activity may have occurred. This would impose a substantially lesser burden than that created by the PHS rule.

*Description of Respondents*: Persons and businesses, including small businesses and manufacturers.

[5] 2004 National Industry-Specific Occupational Employment and Wage Estimates, US Department of Labor, Bureau of Labor Statistics (*www.bls.gov/oes/current/naics4_325400.htm*); compliance officer wage rate for pharmaceutical and medicine manufacturing (NAICS 325400) plus a 30-percent increase for benefits.

TABLE 1.—ESTIMATED ANNUAL REPORTING BURDEN[1]

| 21 CFR Section | No. of Respondents | Annual Frequency per Response | Total Annual Responses | Hours per Response | Total Hours |
|---|---|---|---|---|---|
| 58.11(a) | 3 | 1 | 3 | 5 | 15 |
| 71.1(k) | 1 | 1 | 1 | 5 | 5 |
| 101.69(p) | 0 | 0 | 0 | 0 | 0 |
| 101.70(k) | 0 | 0 | 0 | 0 | 0 |
| 170.101(f) | 1 | 1 | 1 | 5 | 5 |
| 171.1(o) | 1 | 1 | 1 | 5 | 5 |
| 190.6(g) | 0 | 0 | 0 | 0 | 0 |
| 312.56(e) | 50 | 1 | 50 | 5 | 250 |
| 511.1(c)(1) | 2 | 1 | 2 | 5 | 10 |
| 571.1(l) | 0 | 0 | 0 | 0 | 0 |
| 812.46(d) | 15 | 1 | 15 | 5 | 75 |
| Total | 73 | 7 | 73 | 35 | 365 |

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

In compliance with the Paperwork Reduction Act of 1995 (44 U.S.C. 3507(d)), the agency has submitted the information collection provisions of this proposed rule to OMB for review. Interested persons are requested to send comments regarding this information collection to the Office of Information and Regulatory Affairs, OMB (see **ADDRESSES**).

Before this proposed rule becomes final, FDA will publish a notice in the **Federal Register** announcing OMB's decision to approve, modify, or disapprove the information collection provisions in the final rule. An agency may not conduct or sponsor, and a person is not required to respond to, a collection of information unless the information collection displays a current OMB control number.

## VIII. Federalism

FDA has analyzed this proposed rule in accordance with the principles set forth in Executive Order 13132. FDA has determined that the proposed 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, the agency has concluded that the proposed 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.

## IX. Request for Comments

In addition to requesting general comments on the proposed rule, FDA has also identified several specific issues on which it invites public comment. The public comments will help FDA decide whether additional revisions to the proposed regulations are needed. The issues are as follows:

(1) We welcome comments concerning the definition of "falsification of data."

(2) The proposed rule states that the information should be reported to FDA "promptly," but no later than 45 calendar days after the sponsor becomes aware of the information. We believe that 45 calendar days would provide a sponsor a reasonable amount of time to review the information to determine if it must be reported to FDA. However, we welcome comments on whether this timeframe is appropriate.

(3) Although we have not proposed to amend regulations related to marketing applications (i.e., parts 314, 514, 807, and 814), we invite comments as to whether we should amend these regulations to require applicants to report possible falsification of data.

(4) We invite comments on whether the proposed rule should specify an evidentiary standard or threshold, such as a certain form or quantity of information that a sponsor must be aware of before the sponsor would be required to report possible falsification of data.

(5) We invite comments on whether we should include additional descriptions of what we consider "errors" (beyond the listing of examples such as typographical errors and transposed numbers or characters) that sponsors would not be required to report.

(6) We invite comments on the information that should be provided to FDA when a sponsor reports possible falsification of data, as well as on whether the regulations should specify what information must be reported.

Interested persons may submit to the Division of Dockets Management (see **ADDRESSES**) written or electronic comments on this proposal. Submit a single copy of electronic comments or two paper copies of any mailed comments, except that individuals may submit one paper copy. Comments are to be identified with the docket number found in brackets in the heading of this document. Received comments may be seen in the Division of Dockets Management between 9 a.m. and 4 p.m., Monday through Friday.

## List of Subjects

*21 CFR Part 16*

Administrative practice and procedure.

*21 CFR Part 58*

Laboratories, Reporting and recordkeeping requirements.

*21 CFR Part 71*

Administrative practice and procedure, Color additives, Confidential business information, Cosmetics, Drugs,

Reporting and recordkeeping requirements.

*21 CFR Part 101*

Food labeling, Nutrition, Reporting and recordkeeping requirements.

*21 CFR Part 170*

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

*21 CFR Part 171*

Administrative practice and procedure, Food additives.

*21 CFR Part 190*

Dietary foods, Foods, Food additives, Reporting and recordkeeping requirements.

*21 CFR Part 312*

Drugs, Exports, Imports, Investigations, Labeling, Medical research, Reporting and recordkeeping requirements, Safety.

*21 CFR Part 511*

Animal drugs, Medical research, Reporting and recordkeeping requirements.

*21 CFR Part 571*

Administrative practice and procedure, Animal feeds, Animal foods, Food additives.

*21 CFR Part 812*

Health records, Medical devices, Medical research, Reporting and recordkeeping requirements.

Therefore, under the Federal Food, Drug, and Cosmetic Act and the Public Health Service Act, and under authority delegated to the Commissioner of Food and Drugs, it is proposed that 21 CFR parts 16, 58, 71, 101, 170, 171, 190, 312, 511, 571, and 812 be amended as follows:

## PART 16—REGULATORY HEARING BEFORE THE FOOD AND DRUG ADMINISTRATION

1. The authority citation for 21 CFR part 16 continues to read as follows:

**Authority:** 15 U.S.C. 1451–1461; 21 U.S.C. 141–149, 321–394, 467f, 679, 821, 1034; 28 U.S.C. 2112; 42 U.S.C. 201–262, 263b, 364.

### § 16.1 [Amended]

2. Section 16.1 is amended in paragraph (b)(2) by removing "511.1(c)(1)" and adding in its place "511.1(d)(1)" and by removing the phrase "511.1(c)(4) and (d)" and adding in its place the phrase "511.1(d)(4) and (e)".

## PART 58—GOOD LABORATORY PRACTICE FOR NONCLINICAL LABORATORY STUDIES

3. The authority citation for 21 CFR part 58 continues to read as follows:

**Authority:** 21 U.S.C. 342, 346, 346a, 348, 351, 352, 353, 355, 360, 360b–360f, 360h–360j, 371, 379e, 381; 42 U.S.C. 216, 262, 263b–263n.

4. Section 58.11 is added to subpart A to read as follows:

### § 58.11 Reporting falsification of data.

(a) When a sponsor becomes aware of information indicating that any person has, or may have, engaged in the falsification of data in the course of reporting study results, or in the course of proposing, designing, performing, recording, supervising, or reviewing studies conducted by or on behalf of a sponsor or relied on by a sponsor involving studies subject to this part, the sponsor must report this information to FDA. A sponsor must report this information regardless of whether the sponsor has evidence as to the intent of the person who has, or may have, falsified data. The sponsor must report this information to FDA promptly, but no later than 45 calendar days after the sponsor becomes aware of the information. For the purpose of this section only, the following definitions apply:

(1) *Falsification of data* means creating, altering, recording, or omitting data in such a way that the data do not represent what actually occurred. Examples of falsification of data include, but are not limited to, the following:

(i) Creating data that were never obtained (e.g., making up data or results and recording or reporting them; reporting enrollment in a study of a subject who did not exist; forging the signature on an informed consent form);

(ii) Altering data by replacing original data with something different that does not accurately reflect study conduct or results (e.g., changing a laboratory measurement to a less extreme deviation from normal);

(iii) Recording or obtaining data from a specimen, sample, or test whose origin is not accurately described or in a way that does not accurately reflect the data (e.g., changing the date of a specimen, sample, or test; adding a substance not called for in the study to a specimen or sample; identifying a specimen, sample, or test as coming from a specific subject when it came from a source other than the subject);

(iv) Omitting data that were obtained and would be appropriate for recording based on study design and conduct (e.g., not recording exclusionary medical history or prohibited concomitant medications or treatments; omitting data so that a statistical analysis yields a result that would not have been obtained had all data been analyzed).

(2) The term *data* includes, but is not limited to, individual facts, tests, specimens, samples, results, statistics, items of information, or statements made by individuals.

(b) Sponsors should not report errors (e.g., typographical errors, transposed numbers or characters) to FDA under this section.

5. Section 58.217 is transferred to subpart A and redesignated as § 58.12 and newly redesignated § 58.12 is revised to read as follows:

### § 58.12 Suspension or termination of a testing facility by a sponsor.

Termination of a testing facility by a sponsor is independent of, and neither in lieu of nor a precondition to, proceedings or actions authorized by subpart K of this part. If a sponsor terminates or suspends a testing facility from further participation in a nonclinical laboratory study that is being conducted as part of any application for a research or marketing permit that has been submitted to any Center of the Food and Drug Administration (whether approved or not), the sponsor must notify that center in writing within 15 working days of the action; the notice must include a statement of the reasons for such action. Suspension or termination of a testing facility by a sponsor does not relieve it of any obligation under any other applicable regulation to submit the results of the study to the Food and Drug Administration.

## PART 71—COLOR ADDITIVE PETITIONS

6. The authority citation for 21 CFR part 71 continues to read as follows:

**Authority:** 21 U.S.C. 321, 342, 348, 351, 355, 360, 360b–360f, 360h–360j, 361, 371, 379e, 381; 42 U.S.C. 216, 262.

7. Section 71.1 is amended by adding paragraph (k) to read as follows:

### § 71.1 Petitions.

* * * * *

(k)(1) When a petitioner becomes aware of information indicating that any person has, or may have, engaged in the falsification of data in the course of reporting study results, or in the course of proposing, designing, performing, recording, supervising, or reviewing studies conducted by or on behalf of a petitioner, relied on by a petitioner, or otherwise cited in a petition under this

part, the petitioner must report this information to the Center for Food Safety and Applied Nutrition (Center). A petitioner must report this information regardless of whether the petitioner has evidence as to the intent of the person who has, or may have, falsified data. The petitioner must report this information to the Center promptly, but no later than 45 calendar days after the petitioner becomes aware of the information. For the purpose of this section only, the following definitions apply:

(i) *Falsification of data* means creating, altering, recording, or omitting data in such a way that the data do not represent what actually occurred. Examples of falsification of data include, but are not limited to, the following:

(A) Creating data that were never obtained (e.g., making up data or results and recording or reporting them; reporting enrollment in a study of a subject who did not exist; forging the signature on an informed consent form);

(B) Altering data by replacing original data with something different that does not accurately reflect study conduct or results (e.g., changing a laboratory measurement to a less extreme deviation from normal);

(C) Recording or obtaining data from a specimen, sample, or test whose origin is not accurately described or in a way that does not accurately reflect the data (e.g., changing the date of a specimen, sample, or test; adding a substance not called for in the study to a specimen or sample; identifying a specimen, sample, or test as coming from a specific subject when it came from a source other than the subject);

(D) Omitting data that were obtained and would be appropriate for recording based on study design and conduct (e.g., not recording exclusionary medical history or prohibited concomitant medications or treatments; omitting data so that a statistical analysis yields a result that would not have been obtained had all data been analyzed).

(ii) The term *data* includes, but is not limited to, individual facts, tests, specimens, samples, results, statistics, items of information, or statements made by individuals.

(2) Petitioners should not report errors (e.g., typographical errors, transposed numbers or characters) to FDA under paragraph (k) of this section.

## PART 101—FOOD LABELING

8. The authority citation for 21 CFR part 101 continues to read as follows:

**Authority:** 15 U.S.C. 1453, 1454, 1455; 21 U.S.C. 321, 331, 342, 343, 348, 371; 42 U.S.C. 243, 264, 271.

9. Section 101.69 is amended by adding paragraph (p) to read as follows:

### § 101.69 Petitions for nutrient content claims.

* * * * *

(p)(1) When a petitioner becomes aware of information indicating that any person has, or may have, engaged in the falsification of data in the course of reporting study results, or in the course of proposing, designing, performing, recording, supervising, or reviewing studies conducted by or on behalf of a petitioner, relied on by a petitioner, or otherwise cited in a petition under this part, the petitioner must report this information to the Center for Food Safety and Applied Nutrition (Center). A petitioner must report this information regardless of whether the petitioner has evidence as to the intent of the person who has, or may have, falsified data. The petitioner must report this information to the Center promptly, but no later than 45 calendar days after the petitioner becomes aware of the information. For the purpose of this section only, the following definitions apply:

(i) *Falsification of data* means creating, altering, recording, or omitting data in such a way that the data do not represent what actually occurred. Examples of falsification of data include, but are not limited to, the following:

(A) Creating data that were never obtained (e.g., making up data or results and recording or reporting them; reporting enrollment in a study of a subject who did not exist; forging the signature on an informed consent form);

(B) Altering data by replacing original data with something different that does not accurately reflect study conduct or results (e.g., changing a laboratory measurement to a less extreme deviation from normal);

(C) Recording or obtaining data from a specimen, sample, or test whose origin is not accurately described or in a way that does not accurately reflect the data (e.g., changing the date of a specimen, sample, or test; adding a substance not called for in the study to a specimen or sample; identifying a specimen, sample, or test as coming from a specific subject when it came from a source other than the subject);

(D) Omitting data that were obtained and would be appropriate for recording based on study design and conduct (e.g., not recording exclusionary medical history or prohibited concomitant medications or treatments; omitting data so that a statistical analysis yields a result that would not have been obtained had all data been analyzed).

(ii) The term *data* includes, but is not limited to, individual facts, tests, specimens, samples, results, statistics, items of information, or statements made by individuals.

(2) Petitioners should not report errors (e.g., typographical errors, transposed numbers or characters) to FDA under paragraph (p) of this section.

10. Section 101.70 is amended by adding paragraph (k) to read as follows:

### § 101.70 Petitions for health claims.

* * * * *

(k)(1) When a petitioner becomes aware of information indicating that any person has, or may have, engaged in the falsification of data in the course of reporting study results, or in the course of proposing, designing, performing, recording, supervising, or reviewing studies conducted by or on behalf of a petitioner, relied on by a petitioner, or otherwise cited in a petition under this part, the petitioner must report this information to the Center for Food Safety and Applied Nutrition (Center). A petitioner must report this information regardless of whether the petitioner has evidence as to the intent of the person who has, or may have, falsified data. The petitioner must report this information to the Center promptly, but no later than 45 calendar days after the petitioner becomes aware of the information. For the purpose of this section only, the following definitions apply:

(i) *Falsification of data* means creating, altering, recording, or omitting data in such a way that the data do not represent what actually occurred. Examples of falsification of data include, but are not limited to, the following:

(A) Creating data that were never obtained (e.g., making up data or results and recording or reporting them; reporting enrollment in a study of a subject who did not exist; forging the signature on an informed consent form);

(B) Altering data by replacing original data with something different that does not accurately reflect study conduct or results (e.g., changing a laboratory measurement to a less extreme deviation from normal);

(C) Recording or obtaining data from a specimen, sample, or test whose origin is not accurately described or in a way that does not accurately reflect the data (e.g., changing the date of a specimen, sample, or test; adding a substance not called for in the study to a specimen or sample; identifying a specimen, sample, or test as coming from a specific subject

when it came from a source other than the subject);

(D) Omitting data that were obtained and would be appropriate for recording based on study design and conduct (e.g., not recording exclusionary medical history or prohibited concomitant medications or treatments; omitting data so that a statistical analysis yields a result that would not have been obtained had all data been analyzed).

(ii) The term *data* includes, but is not limited to, individual facts, tests, specimens, samples, results, statistics, items of information, or statements made by individuals.

(2) Petitioners should not report errors (e.g., typographical errors, transposed numbers or characters) to FDA under paragraph (k) of this section.

## PART 170—FOOD ADDITIVES

11. The authority citation for 21 CFR part 170 continues to read as follows:

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

12. Section 170.101 is amended by adding paragraph (f) to read as follows:

### § 170.101 Information in a premarket notification for a food contact substance (FCN).

* * * * *

(f)(1) When a manufacturer or supplier who submits a FCN becomes aware of information indicating that any person has, or may have, engaged in the falsification of data in the course of reporting study results, or in the course of proposing, designing, performing, recording, supervising, or reviewing studies conducted by or on behalf of a manufacturer or supplier, relied on by a manufacturer or supplier, or otherwise cited in the notification under this part, the manufacturer or supplier must report this information to the Center for Food Safety and Applied Nutrition (Center). A manufacturer or supplier must report this information regardless of whether the manufacturer or supplier has evidence as to the intent of the person who has, or may have, falsified data. The manufacturer or supplier must report this information to the Center promptly, but no later than 45 calendar days after the manufacturer or supplier becomes aware of the information. For the purpose of this section only, the following definitions apply:

(i) *Falsification of data* means creating, altering, recording, or omitting data in such a way that the data do not represent what actually occurred. Examples of falsification of data include, but are not limited to, the following:

(A) Creating data that were never obtained (e.g., making up data or results and recording or reporting them; reporting enrollment in a study of a subject who did not exist; forging the signature on an informed consent form);

(B) Altering data by replacing original data with something different that does not accurately reflect study conduct or results (e.g., changing a laboratory measurement to a less extreme deviation from normal);

(C) Recording or obtaining data from a specimen, sample, or test whose origin is not accurately described or in a way that does not accurately reflect the data (e.g., changing the date of a specimen, sample, or test; adding a substance not called for in the study to a specimen or sample; identifying a specimen, sample, or test as coming from a specific subject when it came from a source other than the subject);

(D) Omitting data that were obtained and would be appropriate for recording based on study design and conduct (e.g., not recording exclusionary medical history or prohibited concomitant medications or treatments; omitting data so that a statistical analysis yields a result that would not have been obtained had all data been analyzed).

(ii) The term *data* includes, but is not limited to, individual facts, tests, specimens, samples, results, statistics, items of information, or statements made by individuals.

(2) Manufacturers or suppliers should not report errors (e.g., typographical errors, transposed numbers or characters) to FDA under paragraph (f) of this section.

## PART 171—FOOD ADDITIVE PETITIONS

13. The authority citation for 21 CFR part 171 continues to read as follows:

**Authority:** 21 U.S.C. 321, 342, 348, 371.

14. Section 171.1 is amended by adding paragraph (o) to read as follows:

### § 171.1 Petitions.

* * * * *

(o)(1) When a petitioner becomes aware of information indicating that any person has, or may have, engaged in the falsification of data in the course of reporting study results, or in the course of proposing, designing, performing, recording, supervising, or reviewing studies conducted by or on behalf of a petitioner, relied on by a petitioner, or otherwise cited in the petition under this part, the petitioner must report this information to the Center for Food Safety and Applied Nutrition (Center). A petitioner must report this information regardless of whether the petitioner has evidence as to the intent of the person who has, or may have, falsified data. The petitioner must report this information to the Center promptly, but no later than 45 calendar days after the petitioner becomes aware of the information. For the purpose of this section only, the following definitions apply:

(i) *Falsification of data* means creating, altering, recording, or omitting data in such a way that the data do not represent what actually occurred. Examples of falsification of data include, but are not limited to, the following:

(A) Creating data that were never obtained (e.g., making up data or results and recording or reporting them; reporting enrollment in a study of a subject who did not exist; forging the signature on an informed consent form);

(B) Altering data by replacing original data with something different that does not accurately reflect study conduct or results (e.g., changing a laboratory measurement to a less extreme deviation from normal);

(C) Recording or obtaining data from a specimen, sample, or test whose origin is not accurately described or in a way that does not accurately reflect the data (e.g., changing the date of a specimen, sample, or test; adding a substance not called for in the study to a specimen or sample; identifying a specimen, sample, or test as coming from a specific subject when it came from a source other than the subject);

(D) Omitting data that were obtained and would be appropriate for recording based on study design and conduct (e.g., not recording exclusionary medical history or prohibited concomitant medications or treatments; omitting data so that a statistical analysis yields a result that would not have been obtained had all data been analyzed).

(ii) The term *data* includes, but is not limited to, individual facts, tests, specimens, samples, results, statistics, items of information, or statements made by individuals.

(2) Petitioners should not report errors (e.g., typographical errors, transposed numbers or characters) to FDA under paragraph (o) of this section.

## PART 190—DIETARY SUPPLEMENTS

15. The authority citation for 21 CFR part 190 is revised to read as follows:

**Authority:** 21 U.S.C. 321(ff), 331, 342, 350(b), 371.

16. Section 190.6 is amended by adding paragraph (g) to read as follows:

**§ 190.6 Requirement for premarket notification.**

* * * * *

(g)(1) When a manufacturer or distributor who submits a notification becomes aware of information indicating that any person has, or may have, engaged in the falsification of data in the course of reporting study results, or in the course of proposing, designing, performing, recording, supervising, or reviewing studies conducted by or on behalf of a manufacturer or distributor, relied on by a manufacturer or distributor, or otherwise cited in the petition under this part, the manufacturer or distributor must report this information to the Center for Food Safety and Applied Nutrition (Center). A manufacturer or distributor must report this information regardless of whether the manufacturer or distributor has evidence as to the intent of the person who has, or may have, falsified data. The manufacturer or distributor must report this information to the Center promptly, but no later than 45 calendar days after the manufacturer or distributor becomes aware of the information. For the purpose of this section only, the following definitions apply:

(i) *Falsification of data* means creating, altering, recording, or omitting data in such a way that the data do not represent what actually occurred. Examples of falsification of data include, but are not limited to, the following:

(A) Creating data that were never obtained (e.g., making up data or results and recording or reporting them; reporting enrollment in a study of a subject who did not exist; forging the signature on an informed consent form);

(B) Altering data by replacing original data with something different that does not accurately reflect study conduct or results (e.g., changing a laboratory measurement to a less extreme deviation from normal);

(C) Recording or obtaining data from a specimen, sample, or test whose origin is not accurately described or in a way that does not accurately reflect the data (e.g., changing the date of a specimen, sample, or test; adding a substance not called for in the study to a specimen or sample; identifying a specimen, sample, or test as coming from a specific subject when it came from a source other than the subject);

(D) Omitting data that were obtained and would be appropriate for recording based on study design and conduct (e.g., not recording exclusionary medical history or prohibited concomitant medications or treatments; omitting data so that a statistical analysis yields a result that would not have been obtained had all data been analyzed).

(ii) The term *data* includes, but is not limited to, individual facts, tests, specimens, samples, results, statistics, items of information, or statements made by individuals.

(2) Manufacturers or distributors should not report errors (e.g., typographical errors, transposed numbers or characters) to FDA under paragraph (g) of this section.

## PART 312—INVESTIGATIONAL NEW DRUG APPLICATION

17. The authority citation for 21 CFR part 312 continues to read as follows:

**Authority:** 21 U.S.C. 321, 331, 351, 352, 353, 355, 356, 371, 381, 382, 383, 393; 42 U.S.C. 262.

18. Section 312.56 is amended by revising the section heading and by adding new paragraph (e) to read as follows:

**§ 312.56 Review of ongoing investigations; reporting falsification of data.**

* * * * *

(e)(1) When a sponsor becomes aware of information indicating that any person has, or may have, engaged in the falsification of data in the course of reporting study results, or in the course of proposing, designing, performing, recording, supervising, or reviewing studies conducted by or on behalf of a sponsor or relied on by a sponsor involving studies subject to this part, the sponsor must report this information to the Center for Drug Evaluation and Research (Center). A sponsor must report this information regardless of whether the sponsor has evidence as to the intent of the person who has, or may have, falsified data. The sponsor must report this information to the Center promptly, but no later than 45 calendar days after the sponsor becomes aware of the information. For the purpose of this section only, the following definitions apply:

(i) *Falsification of data* means creating, altering, recording, or omitting data in such a way that the data do not represent what actually occurred. Examples of falsification of data include, but are not limited to, the following:

(A) Creating data that were never obtained (e.g., making up data or results and recording or reporting them; reporting enrollment in a study of a subject who did not exist; forging the signature on an informed consent form);

(B) Altering data by replacing original data with something different that does not accurately reflect study conduct or results (e.g., changing a laboratory measurement to a less extreme deviation from normal);

(C) Recording or obtaining data from a specimen, sample, or test whose origin is not accurately described or in a way that does not accurately reflect the data (e.g., changing the date of a specimen, sample, or test; adding a substance not called for in the study to a specimen or sample; identifying a specimen, sample, or test as coming from a specific subject when it came from a source other than the subject);

(D) Omitting data that were obtained and would be appropriate for recording based on study design and conduct (e.g., not recording exclusionary medical history or prohibited concomitant medications or treatments; omitting data so that a statistical analysis yields a result that would not have been obtained had all data been analyzed).

(ii) The term *data* includes, but is not limited to, individual facts, tests, specimens, samples, results, statistics, items of information, or statements made by individuals.

(2) Sponsors should not report errors (e.g., typographical errors, transposed numbers or characters) to FDA under paragraph (e) of this section.

## PART 511—NEW ANIMAL DRUGS FOR INVESTIGATIONAL USE

19. The authority citation for 21 CFR part 511 continues to read as follows:

**Authority:** 21 U.S.C. 321, 351, 352, 353, 360b, 371.

20. Section 511.1 is amended by redesignating paragraphs (c), (d), (e), (f), and (g) as paragraphs (d), (e), (f), (g), and (h), respectively, and by adding new paragraph (c) to read as follows:

**§ 511.1 New animal drugs for investigational use exempt from section 512(a) of the act.**

* * * * *

(c) *Reporting falsification of data.* (1) When a sponsor becomes aware of information indicating that any person has, or may have, engaged in the falsification of data in the course of reporting study results, or in the course of proposing, designing, performing, recording, supervising, or reviewing studies conducted by or on behalf of a sponsor or relied on by a sponsor, the sponsor must report this information to the Center for Veterinary Medicine (Center). A sponsor must report this information regardless of whether the sponsor has evidence as to the intent of the person who has, or may have, falsified data. The sponsor must report this information to the Center promptly, but no later than 45 calendar days after the sponsor becomes aware of the

information. For the purpose of this paragraph only, the following definitions apply:

(i) *Falsification of data* means creating, altering, recording, or omitting data in such a way that the data do not represent what actually occurred. Examples of falsification of data include, but are not limited to, the following:

(A) Creating data that were never obtained (e.g., making up data or results and recording or reporting them; reporting enrollment in a study of a subject who did not exist; forging the signature on an informed consent form);

(B) Altering data by replacing original data with something different that does not accurately reflect study conduct or results (e.g., changing a laboratory measurement to a less extreme deviation from normal);

(C) Recording or obtaining data from a specimen, sample, or test whose origin is not accurately described or in a way that does not accurately reflect the data (e.g., changing the date of a specimen, sample, or test; adding a substance not called for in the study to a specimen or sample; identifying a specimen, sample, or test as coming from a specific subject when it came from a source other than the subject);

(D) Omitting data that were obtained and would be appropriate for recording based on study design and conduct (e.g., not recording exclusionary medical history or prohibited concomitant medications or treatments; omitting data so that a statistical analysis yields a result that would not have been obtained had all data been analyzed).

(ii) The term *data* includes, but is not limited to, individual facts, tests, specimens, samples, results, statistics, items of information, or statements made by individuals.

(2) Sponsors should not report errors (e.g., typographical errors, transposed numbers or characters) to FDA under paragraph (c) of this section.

* * * * *

## PART 571—FOOD ADDITIVE PETITIONS

21. The authority citation for 21 CFR part 571 continues to read as follows:

**Authority:** 21 U.S.C. 321, 342, 348, 371; 42 U.S.C. 241.

22. Section 571.1 is amended by adding paragraph (l) to read as follows:

### § 571.1 Petitions.

* * * * *

(l)(1) When a petitioner becomes aware of information indicating that any person has, or may have, engaged in the falsification of data in the course of reporting study results, or in the course of proposing, designing, performing, recording, supervising, or reviewing studies conducted by or on behalf of the petitioner, relied on by the petitioner, or otherwise cited in the petition under this part, the petitioner must report this information to the Center for Food Safety and Applied Nutrition (Center). A petitioner must report this information regardless of whether the petitioner has evidence as to the intent of the person who has, or may have, falsified data. The petitioner must report this information to the Center promptly, but no later than 45 calendar days after the petitioner becomes aware of the information. For the purpose of this section only, the following definitions apply:

(i) *Falsification of data* means creating, altering, recording, or omitting data in such a way that the data do not represent what actually occurred. Examples of falsification of data include, but are not limited to, the following:

(A) Creating data that were never obtained (e.g., making up data or results and recording or reporting them; reporting enrollment in a study of a subject who did not exist; forging the signature on an informed consent form);

(B) Altering data by replacing original data with something different that does not accurately reflect study conduct or results (e.g., changing a laboratory measurement to a less extreme deviation from normal);

(C) Recording or obtaining data from a specimen, sample, or test whose origin is not accurately described or in a way that does not accurately reflect the data (e.g., changing the date of a specimen, sample, or test; adding a substance not called for in the study to a specimen or sample; identifying a specimen, sample, or test as coming from a specific subject when it came from a source other than the subject);

(D) Omitting data that were obtained and would be appropriate for recording based on study design and conduct (e.g., not recording exclusionary medical history or prohibited concomitant medications or treatments; omitting data so that a statistical analysis yields a result that would not have been obtained had all data been analyzed).

(ii) The term *data* includes, but is not limited to, individual facts, tests, specimens, samples, results, statistics, items of information, or statements made by individuals.

(2) Petitioners should not report errors (e.g., typographical errors, transposed numbers or characters) to FDA under paragraph (l) of this section.

## PART 812—INVESTIGATIONAL DEVICE EXEMPTIONS

23. The authority citation for 21 CFR part 812 continues to read as follows:

**Authority:** 21 U.S.C. 331, 351, 352, 353, 355, 360, 360c–360f, 360h–360j, 371, 372, 374, 379e, 381, 382, 383; 42 U.S.C. 216, 241, 262, 263b–263n.

24. Section 812.2 is amended by revising paragraph (c) introductory text to read as follows:

### § 812.2 Applicability.

* * * * *

(c) *Exempted investigations.* This part, with the exception of §§ 812.46(d) and 812.119, does not apply to investigations of the following categories of devices:

* * * * *

25. Section 812.46 is amended by adding paragraph (d) to read as follows:

### § 812.46 Monitoring investigations.

* * * * *

(d) *Falsification.* (1) When a sponsor becomes aware of information indicating that any person has, or may have, engaged in the falsification of data in the course of reporting study results, or in the course of proposing, designing, performing, recording, supervising, or reviewing studies conducted by or on behalf of a sponsor or relied on by a sponsor involving studies subject to this part, the sponsor must report this information to FDA. A sponsor must report this information regardless of whether the sponsor has evidence as to the intent of the person who has, or may have, falsified data. The sponsor must report this information to FDA promptly, but no later than 45 calendar days after the sponsor becomes aware of the information. Such reports should be submitted to the Center with jurisdiction over the product or clinical trial. For studies involving devices regulated by the Center for Devices and Radiological Health (CDRH), reports should be submitted to the Division of Bioresearch Monitoring (HFZ–310), Office of Compliance, Center for Devices and Radiological Health, Food and Drug Administration. For studies involving products regulated by the Center for Biologics Evaluation and Research (CBER), reports should be submitted to the Division of Inspections and Surveillance (HFM–650), Office of Compliance and Biologics Quality, Center for Biologics Evaluation and Research, Food and Drug Administration. For the purpose of this section only, the following definitions apply:

(i) *Falsification of data* means creating, altering, recording, or omitting

data in such a way that the data do not represent what actually occurred. Examples of falsification of data include, but are not limited to, the following:

(A) Creating data that were never obtained (e.g., making up data or results and recording or reporting them; reporting enrollment in a study of a subject who did not exist; forging the signature on an informed consent form);

(B) Altering data by replacing original data with something different that does not accurately reflect study conduct or results (e.g., changing a laboratory measurement to a less extreme deviation from normal);

(C) Recording or obtaining data from a specimen, sample, or test whose origin is not accurately described or in a way that does not accurately reflect the data (e.g., changing the date of a specimen, sample, or test; adding a substance not called for in the study to a specimen or sample; identifying a specimen, sample, or test as coming from a specific subject when it came from a source other than the subject);

(D) Omitting data that were obtained and would be appropriate for recording based on study design and conduct (e.g., not recording exclusionary medical history or prohibited concomitant medications or treatments; omitting data so that a statistical analysis yields a result that would not have been obtained had all data been analyzed).

(ii) The term *data* includes, but is not limited to, individual facts, tests, specimens, samples, results, statistics, items of information, or statements made by individuals.

(2) Sponsors should not report errors (e.g., typographical errors, transposed numbers or characters) to FDA under paragraph (d) of this section.

Dated: February 12, 2010.

**Leslie Kux,**

*Acting Assistant Commissioner for Policy.*

[FR Doc. 2010–3123 Filed 2–18–10; 8:45 am]

**BILLING CODE 4160–01–S**

## POSTAL REGULATORY COMMISSION

### 39 CFR Part 3050

**[Docket No. RM2010–8; Order No. 406]**

### Periodic Reporting

**AGENCY:** Postal Regulatory Commission.

**ACTION:** Advance notice of proposed rulemaking; availability of rulemaking petition.

**SUMMARY:** The Commission is noticing a Postal Service petition proposing a change in transportation cost system sampling. The proposal involves distributing rail costs using inter-BMC highway distribution factors. This notice briefly describes the Postal Service's rationale for proposing this change and addresses procedural steps associated with the petition.

**DATES:** Comments are due: February 24, 2010.

**ADDRESSES:** Submit comments electronically via the Commission's Filing Online system at *http://www.prc.gov*. Commenters who cannot submit their views electronically should contact the person identified in **FOR FURTHER INFORMATION CONTACT** by telephone for advice on alternatives to electronic filing.

**FOR FURTHER INFORMATION CONTACT:** Stephen L. Sharfman, General Counsel, 202–789–6820 or *stephen.sharfman@prc.gov.*

**SUPPLEMENTARY INFORMATION:**

**Table of Contents**



**I. Background**

On February 9, 2010, the Postal Service filed a petition to initiate an informal rulemaking proceeding to consider a change in the analytical methods approved for use in periodic reporting.[1] The Postal Service labels its proposal "Proposal One" because it intends that it relate to the FY 2010 rather than the FY 2009 compliance reporting cycle. Proposal One seeks authorization from the Commission to immediately eliminate the rail portion of the Transportation Cost System (TRACS) sampling, and proposes instead to distribute rail costs using the Inter-BC highway distribution factors.

The Postal Service states that as part of a realignment of its transportation and distribution systems, it is shifting much of its transportation needs from rail to truck. Because rail costs are rapidly dwindling, it proposes to eliminate TRACS rail sampling, and to use the TRACS inter-BMC distribtion in place of the Rail distribution key in Cost Segment 14. Table 1 of the supporting material accompanying the Petition (Proposal One) shows that Freight Rail and Rail Plant Load costs are expected to decline by 75 percent from FY 2009 to FY 2010, when they will amount to less than $15 million. *Id.,* Proposal One, at 1. Table 2 shows that substituting the inter-BMC distribution key for the Rail distribution key in FY 2009 would have had a small impact on the share of Segment 14 costs borne by each market dominant product. *Id.* at 2. The Postal Service comments that the impact will be *de minimis* in FY 2010 when Rail costs will make up a much smaller share of Segment 14 costs. The Postal Service states its desire to make the change before Quarter 3 of FY 2010 makes more efficient use of its data collection resources. *Id.*

**II. Procedural Matters**

The Commission sets February 24, 2010 as the due date for public comments. The Commission will determine the need for reply comments after reviewing the initial comments received.

Kenneth Moeller is designated as the Public Representative to represent the interests of the general public in this proceeding.

**III. Ordering Paragraphs**

*It is ordered:*

1. The Petition of the United States Postal Service Requesting Initiation of a Proceeding to Consider a Proposed Change in Analytic Principles (Proposal One), filed February 9, 2010, is granted.

2. The Commission establishes Docket No. RM2010–8 to consider the matters raised by the Postal Service's Petition.

3. Interested persons may submit comments on Proposal One no later than February 24, 2010.

4. Pursuant to 39 U.S.C. 505, Kenneth Moeller is appointed to serve as the Public Representative representing the interests of the general public.

5. The Secretary shall arrange for publication of this notice in the **Federal Register.**

By the Commission.

**Shoshana M. Grove,**

*Secretary.*

[FR Doc. 2010–3225 Filed 2–18–E8; 8:45 am]

**BILLING CODE 7710–FW–S**

[1] Petition of the United States Postal Service Requesting Initiation of a Proceeding to Consider a Proposed Change in Analytic Principles (Proposal One), February 9, 2010 (Petition).

## ENVIRONMENTAL PROTECTION AGENCY

### 40 CFR Parts 80, 85, and 86

**[EPA–HQ–OAR–2010–0052; FRL–9113–8]**

**RIN 2060–AI23; 2060–AQ12**

### Tier 2 Light-Duty Vehicle and Light-Duty Truck Emission Standards and Gasoline Sulfur Control Requirements (Section 610 Review)

**AGENCY:** Environmental Protection Agency (EPA).