C. Regulatory Flexibility Act

20. The Regulatory Flexibility Act of 1980 (RFA) [21] generally requires a description and analysis of final rules that will have significant economic impact on a substantial number of small entities. The Commission is not required to make such an analysis if proposed regulations would not have such an effect.[22] Most companies regulated by the Commission do not fall within the RFA's definition of a small entity.[23]

21. The rule proposed herein should have no significant negative impact on those entities, be they large or small, subject to the Commission's regulatory jurisdiction under the NGA. Most companies to which the rules proposed herein, if finalized, would apply, do not fall within the RFA's definition of small entities. In addition, the proposed rule is only triggered if more than one affiliate of the same entity participates in an open season for pipeline capacity in which the pipeline may allocate capacity on a *pro rata* basis, and each affiliate does not have an independent business reason for submitting a bid. Therefore, the rule would only affect a limited number of small entities. The rules proposed herein, if finalized, will not have a significant economic effect on these small entities because the rule does not impose any reporting or recordkeeping requirements. Therefore, the Commission certifies that the proposed rules will not have a significant economic effect on a substantial number of small entities.

D. Comment Procedures

22. The Commission invites interested persons to submit comments on the matters and issues proposed in this notice to be adopted, including any related matters or alternative proposals that commenters may wish to discuss. Comments are due 45 days from publication in the **Federal Register**. Comments must refer to Docket No. RM11–15–000, and must include the commenter's name, the organization they represent, if applicable, and their address in their comments.

23. The Commission encourages comments to be filed electronically via the eFiling link on the Commission's Web site at *http://www.ferc.gov.* The Commission accepts most standard word processing formats. Documents created electronically using word processing software should be filed in native applications or print-to-PDF format and not in a scanned format. Commenters filing electronically do not need to make a paper filing.

24. Commenters that are not able to file comments electronically must mail or hand deliver an original copy of their comments to: Federal Energy Regulatory Commission, Secretary of the Commission, 888 First Street, NE., Washington, DC 20426.

25. All comments will be placed in the Commission's public files and may be viewed, printed, or downloaded remotely as described in the Document Availability section below. Commenters on this proposal are not required to serve copies of their comments on other commenters.

E. Document Availability

26. In addition to publishing the full text of this document in the **Federal Register**, the Commission provides all interested persons an opportunity to view and/or print the contents of this document via the Internet through FERC's Home Page (*http://www.ferc.gov*) and in FERC's Public Reference Room during normal business hours (8:30 a.m. to 5 p.m. Eastern time) at 888 First Street, NE., Room 2A, Washington, DC 20426.

27. From FERC's Home Page on the Internet, this information is available on eLibrary. The full text of this document is available on eLibrary in PDF and Microsoft Word format for viewing, printing, and/or downloading. To access this document in eLibrary, type the docket number excluding the last three digits of this document in the docket number field.

28. User assistance is available for eLibrary and the FERC's Web site during normal business hours from FERC Online Support at (202) 502–6652 (toll free at 1–866–208–3676) or e-mail at *ferconlinesupport@ferc.gov,* or the Public Reference Room at (202) 502–8371, TTY (202)502–8659. E-mail the Public Reference Room at *public.referenceroom@ferc.gov.*

List of Subjects in 18 CFR Part 284

Continental shelf, Natural gas, Reporting and recordkeeping requirements.

By direction of the Commission.

Kimberly D. Bose,

Secretary.

In consideration of the foregoing, the Commission proposes to amend part 284, Chapter I, Title 18, Code of Federal Regulations, to read as follows:

PART 284—CERTAIN SALES AND TRANSPORTATION OF NATURAL GAS UNDER THE NATURAL GAS POLICY ACT OF 1978 AND RELATED AUTHORITIES

1. The authority citation for part 284 continues to read as follows:

Authority: 15 U.S.C. 717–717w, 3301–3432; 42 U.S.C. 7101–7352; 43 U.S.C. 1331–1356.

2. Section 284.15 is added to read as follows.

§ 284.15 Bidding by affiliates in open seasons for pipeline capacity.

(a) Multiple affiliates of the same entity may not participate in an open season for pipeline capacity conducted by any interstate pipeline providing service under subparts B and G of this part, in which the pipeline may allocate capacity on a *pro rata* basis, unless each affiliate has an independent business reason for submitting a bid.

(b) If more than one affiliate of the same entity participates in an open season subject to paragraph (a) of this section, none of those affiliates may release any capacity obtained in that open season to any affiliate, or otherwise allow any affiliate effectively to obtain the use of the allocated capacity.

(c) For purposes of this section, an affiliate is any person that satisfies the definition of affiliate in §§ 358.3(a)(1) and (3) of this chapter with respect to another entity participating in an open season subject to paragraph (a) of this section.

[FR Doc. 2011–8915 Filed 4–12–11; 8:45 am]

BILLING CODE 6717–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

21 CFR Parts 16, 312, 511, and 812

[Docket No. FDA–2011–N–0079]

RIN 0910–AG49

Disqualification of a Clinical Investigator

AGENCY: Food and Drug Administration, HHS.

ACTION: Proposed rule.

SUMMARY: The Food and Drug Administration (FDA) is proposing to amend the regulations to expand the scope of clinical investigator disqualification. Under this proposal, when the Commissioner of Food and Drugs determines that an investigator is

[21] 5 U.S.C. 601–612 (2006).

[22] 5 U.S.C. 605(b) (2006).

[23] 5 U.S.C. 601(3) (citing section 3 of the Small Business Act, 15 U.S.C. 623 (2006)). Section 3 defines a "small-business concern" as a business which is independently owned and operated and which is not dominant in its field of operation.

ineligible to receive certain test articles (drugs, devices, or new animal drugs), the investigator also will be ineligible to conduct any clinical investigation that supports an application for a research or marketing permit for products regulated by FDA. This proposal is based in part upon recommendations from the Government Accountability Office, and is intended to help ensure adequate protection of research subjects and the quality and integrity of data submitted to FDA. FDA also is amending the list of regulatory provisions under which an informal regulatory hearing is available by changing the scope of certain provisions and adding regulatory provisions that were inadvertently omitted.

DATES: Submit either electronic or written comments on the proposed rule by July 12, 2011. See section VII of this document for the proposed effective date of a final rule based on this document.

ADDRESSES: You may submit comments, identified by Docket No. FDA–2011–N–0079 and/or RIN number 0910–AG49, by any of the following methods:

Electronic Submissions

Submit electronic comments in the following way:

- *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.

Instructions: All submissions received must include the Agency name and Docket No. FDA–2011–N–0079 and Regulatory Information Number (RIN) for this rulemaking. All comments received may 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.

FOR FURTHER INFORMATION CONTACT: Kathleen E. Pfaender, Office of Good Clinical Practice, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 32, rm. 5129, Silver Spring, MD 20993, 301–796–8340.

SUPPLEMENTARY INFORMATION:

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I. Introduction

Under current regulations, a clinical investigator disqualified by the Commissioner of Food and Drugs (the Commissioner) is ineligible to receive a particular type of FDA-regulated test article only; *i.e.,* drugs (including biologics) in § 312.70 (21 CFR 312.70); new animal drugs in § 511.1(c) (21 CFR 511.1(c)); or devices in § 812.119 (21 CFR 812.119). The proposed rulemaking will amend §§ 312.70, 511.1(c), and 812.119 to provide that when the Commissioner determines that a clinical investigator is ineligible to receive the test article under that provision (*e.g.,* drugs in § 312.70), the clinical investigator also will be ineligible to conduct any clinical investigation that supports an application for a research or marketing permit for products regulated by FDA, including drugs, biologics, devices, new animal drugs, foods, including dietary supplements, that bear a nutrient content claim or a health claim, infant formulas, food and color additives, and tobacco products.

Other proposed revisions are intended to clarify and harmonize the clinical investigator disqualification regulations in parts 312, 511, and 812 (21 CFR parts 312, 511, and 812). FDA proposes this rulemaking to help protect the rights and safety of subjects involved in FDA-regulated investigations and to help ensure the reliability and integrity of the data used to support marketing of products regulated by FDA.

II. Background

FDA inspects the records of a clinical investigator to evaluate the quality and integrity of clinical data used to support applications under review by FDA and to evaluate whether protections are afforded to participating research subjects, where required. FDA may consider disqualification of a clinical investigator when FDA has information that an investigator has repeatedly or deliberately failed to comply with applicable requirements for the conduct of clinical investigations, or has repeatedly or deliberately submitted to FDA or to the sponsor false information in any required report.

Disqualification of an investigator is initiated by the appropriate FDA Center depending upon the particular type of test article under study by the investigator in the clinical investigation. For example, the Center for Devices and Radiological Health may pursue disqualification of a clinical investigator who conducted a device study and allegedly violated the regulations. The regulations provide the investigator, who is subject to disqualification, an opportunity to be heard and explain the matter(s) complained of; *i.e.,* explain the alleged violation(s). If the explanation offered is not accepted by the Center, the investigator will be given an opportunity for an informal regulatory hearing under part 16 (21 CFR part 16). After evaluating all available information, including any explanation presented by the investigator, the Commissioner issues a Commissioner's decision regarding the eligibility of the investigator to receive a particular type of test article. When disqualified by a Commissioner's decision, the investigator is no longer eligible to receive the particular type of test article (drugs, devices, or new animal drugs) under study when the violations occurred. Under current regulations, an

investigator disqualified by a Commissioner's decision as ineligible to receive investigational devices, for example, may still be eligible to receive investigational drugs (including biologics), because the regulations do not specifically prohibit such an investigator from receiving other types of test articles.

In September 2009, the Government Accountability Office (GAO) released a final report on FDA's oversight of clinical investigators (Ref. 1). In that report, the GAO recommended, among other things, that FDA extend disqualification by a Commissioner's decision to include ineligibility to receive drugs, biologics, and medical devices. The GAO noted that FDA's disqualification regulations are included in separate sets of regulations and, as a result, the regulations as currently written limit the types of test articles to which disqualification applies and consequently, limits FDA's oversight of clinical investigators (Ref. 1 at page 40, under "FDA's Regulations Allow Disqualified Clinical Investigators to Conduct Trials for Other Medical Products"). The GAO elaborated, comparing disqualifications that resulted from a Commissioner's decision with those resulting from a consent agreement between FDA and the investigator. That is, a consent agreement may contain "more extensive restrictions by disqualifying the investigator from receiving any FDA-regulated investigational products (including drugs, biologics, devices, animal drugs, and food additives)" (Ref. 1 at page 41). The GAO concluded that it is critical for FDA to take action and to have the authority to take action to prevent clinical investigators who engaged in serious misconduct from doing so again, whether in research that involves drugs, biologics, or devices (Ref. 1 at page 42).

In past investigator disqualification actions, there is little, if any, evidence that an investigator disqualified from receiving one type of test article (*e.g.,* drugs) later conducted a clinical investigation studying a different type of test article (*e.g.,* devices). Even so, FDA agrees with the GAO's recommendation and its underlying rationale to expand the scope of articles covered when an investigator is disqualified by a Commissioner's decision. This proposed action of explicitly extending a disqualified investigator's ineligibility to receive any FDA-regulated test article would help to reduce the risk of additional violations in other FDA-regulated investigations and thus, would help to ensure the integrity of clinical trial data and help reduce the risk to human subjects who participate in FDA-regulated investigations. This proposed rule may also lead to improved public confidence in the clinical data supporting FDA decisions.

We therefore propose that a clinical investigator disqualified by a Commissioner's decision will be ineligible to receive any test article under the disqualification regulations in parts 312, 511, or 812, and, in addition, the investigator will be ineligible to conduct any clinical investigation that supports an application for a research or marketing permit for products regulated by FDA. Those products include drugs, biologics, devices, new animal drugs, foods, including dietary supplements, that bear a nutrient content claim or a health claim, infant formulas, food and color additives, and tobacco products. To effect this change, FDA proposes to amend the current regulations in §§ 312.70, 511.1(c), and 812.119.

III. Description of the Proposed Rule

To harmonize the headings for the clinical investigator disqualification regulations in parts 312, 511, and 812, FDA proposes to change the heading in § 511.1(c) to match those currently in §§ 312.70 and 812.119. Therefore, we propose to change the heading in § 511.1(c) from "Withdrawal of eligibility to receive investigational-use new animal drugs" to "Disqualification of a clinical investigator". This revision will help to identify the investigator disqualification regulations pertaining to new animal drugs.

A. Disqualification Proceedings (§§ 312.70(a), 511.1(c)(1), and 812.119(a))

FDA proposes to revise the provisions currently in §§ 312.70(a), 511.1(c)(1), and 812.119(a), to clarify, simplify, and to harmonize those provisions. Also, for consistency with other proposed changes to the disqualification regulations, FDA proposes to change the scope of the question addressed during a part 16 hearing, should the investigator request and be granted an informal regulatory hearing.

1. Proposed Revisions to § 312.70(a)

- To harmonize the provisions in § 312.70(a) with those currently in § 812.119(a), we propose to add "repeatedly or deliberately" before the reference to submitting false information in any required report. The addition of "repeatedly or deliberately" before "submitted to FDA or to the sponsor false information in any required report," codifies FDA's current policies and makes consistent the clinical investigator disqualification regulations.
- To harmonize the provisions in § 312.70(a) with those currently in § 812.119(a), we propose to add a provision for accepting an investigator's explanation concerning the alleged misconduct. That is, if the investigator offers an explanation in writing or during an informal conference and the explanation is accepted by the applicable Center, the Center will discontinue pursuit of the disqualification proceeding. This proposed revision clarifies FDA's current policies and makes consistent the clinical investigator disqualification regulations.
- To simplify the regulations, we propose to change "Center for Drug Evaluation and Research or the Center for Biologics Evaluation and Research" to "applicable Center" after "If an explanation is offered but not accepted by the * * *".
- We propose to add "of this chapter" after "the investigator will be given an opportunity for a regulatory hearing under part 16 * * *", for clarity and to harmonize § 312.70(a) with the provisions currently in § 812.119(a).
- Regarding the question of whether the investigator is entitled to receive test articles, we propose to change "entitled" to "eligible" because "eligible" is the correct term for this provision.
- We propose to change the scope of the question addressed during a part 16 hearing, should the investigator request and be granted an informal hearing, from whether the investigator is eligible to receive "investigational new drugs" to whether the investigator is eligible to receive "test articles under this part and eligible to conduct any clinical investigation that supports an application for a research or marketing permit for products regulated by FDA". Those FDA-regulated products include drugs, biologics, devices, new animal drugs, foods, including dietary supplements, that bear a nutrient content claim or a health claim, infant formulas, food and color additives, and tobacco products.

2. Proposed Revisions to § 511.1(c)(1)

- To harmonize the investigator disqualification regulations, we propose to change the first words in the first sentence in § 511.1(c)(1) from "Whenever the Food and Drug Administration" to "If FDA".
- Although already applicable, we propose to add explicit provisions in § 511.1(c)(1), consistent with the current regulations in § 312.70(a), that a clinical investigator includes a sponsor-investigator. Because sponsor-

investigators must meet an investigator's regulatory responsibilities as well as a sponsor's, FDA has consistently considered sponsor-investigators to be subject to the clinical investigator disqualification provisions in studies of drugs, animal drugs, and devices.[1]

- To harmonize the provisions in § 511.1(c)(1) with the provisions currently in § 812.119(a), we propose to add "repeatedly or deliberately" before the reference to submitting false information in any required report. The addition of "repeatedly or deliberately" codifies FDA's current policies and makes consistent the clinical investigator disqualification regulations.
- To make the investigator disqualification regulations consistent, we propose to change the wording of the first sentence in § 511.1(c)(1) to read as follows, "If FDA has information indicating that an investigator (including a sponsor-investigator) has repeatedly or deliberately failed to comply with the conditions of these exempting regulations or has repeatedly or deliberately submitted to FDA or to the sponsor false information in any required report, the Center for Veterinary Medicine will furnish the investigator written notice of the matter complained of and offer the investigator an opportunity to explain the matter in writing, or, at the option of the investigator, in an informal conference." For this first sentence, this proposal removes the reference to "in general terms" concerning the Center's written notice of the matter to the investigator. This proposal also replaces offering "him" with offering "the investigator" an opportunity to explain. At the end of this first sentence, the wording is changed from "in an informal conference and/or in writing" to "in writing, or, at the option of the investigator, in an informal conference."
- To harmonize the provisions in § 511.1(c)(1) with those currently in § 812.119(a), we propose to add a provision for accepting an investigator's explanation concerning the alleged misconduct. That is, if the investigator offers an explanation in writing or during an informal conference and the explanation is accepted by the affected Center, the Center will discontinue pursuit of the disqualification proceeding. This proposed revision clarifies FDA's current policies and makes consistent the clinical investigator disqualification regulations.
- For consistency with the regulations currently in §§ 312.70(a) and 812.119(a), we propose to change in the second sentence in § 511.1(c)(1) (the third sentence in this proposal), "shall have" to "will be given", and remove after "an opportunity for a regulatory hearing * * *" the clause, "before the Food and Drug Administration pursuant to * * *" Also, in this sentence, we propose to change the term "entitled" to the term "eligible".
- We propose to change the scope of the question addressed during a part 16 hearing, should the investigator request and be granted an informal hearing, from whether the investigator is eligible to receive "investigational new animal drugs" to whether the investigator is eligible to receive "test articles under this part and eligible to conduct any clinical investigation that supports an application for a research or marketing permit for products regulated by FDA". Those FDA-regulated products include drugs, biologics, devices, new animal drugs, foods, including dietary supplements, that bear a nutrient content claim or a health claim, infant formulas, food and color additives, and tobacco products.

3. Proposed Revisions to § 812.119(a)

- Although already applicable, we propose to add explicit provisions in § 812.119(a), consistent with the current regulations in § 312.70(a), that a clinical investigator includes a sponsor-investigator. Because sponsor-investigators must meet an investigator's regulatory responsibilities as well as a sponsor's, FDA has consistently considered sponsor-investigators to be subject to the clinical investigator disqualification provisions in studies of drugs, animal drugs, and devices.[2]
- To harmonize the provisions in § 812.119(a) with those currently in § 312.70(a), we propose to change after repeatedly or deliberately submitted "false information either to the sponsor of the investigation or * * *", to read instead, "to FDA or to the sponsor false information in any required report, * * *"
- To harmonize the provisions in § 812.119(a) with those currently in § 312.70(a), we propose to change the matter "under complaint" to the matter "complained of".
- For clarity and consistency with our current procedures and the proposed changes to §§ 312.70(a) and 511.1(c)(1), we propose to change the language in § 812.119(a) from "the disqualification process will be terminated" to "the Center will discontinue pursuit of the disqualification proceeding."
- For consistency with the proposed revisions to §§ 312.70(a) and 511.1(c)(1), we propose to add "applicable" before "Center" to read, "If an explanation is offered but not accepted by the applicable Center".
- Regarding the question of whether the investigator is entitled to receive test articles, we propose to change the term "entitled" to "eligible".
- We propose to change the scope of the question addressed during a part 16 hearing, should the investigator request and be granted an informal hearing, from whether the investigator is eligible to receive investigational devices to whether the investigator is eligible to receive "test articles under this part and eligible to conduct any clinical investigation that supports an application for a research or marketing permit for products regulated by FDA". Those FDA-regulated products include drugs, biologics, devices, new animal drugs, foods, including dietary supplements, that bear a nutrient content claim or a health claim, infant formulas, food and color additives, and tobacco products.

In summary, the proposed harmonized provisions in §§ 312.70(a), 511.1(c)(1), and 812.119(a) provide that when FDA has information indicating that a clinical investigator, including a sponsor-investigator, has repeatedly or deliberately failed to comply with the relevant regulatory requirements or has repeatedly or deliberately submitted to FDA or to the sponsor of the investigation false information in any required report, the applicable FDA Center notifies the investigator in writing of the alleged violations. This written notice offers the investigator an opportunity to explain the matter in writing, or, at the option of the investigator, during an informal conference. If the investigator offers an explanation that is accepted by the applicable Center, that Center will discontinue pursuit of the disqualification proceeding. If, however, the investigator offers an explanation not accepted by the applicable Center, the investigator will be offered an opportunity to request an informal regulatory hearing [3] under part 16 [4] on the question of whether the investigator is eligible to receive test articles under

[1] See, for example, the final rule at 62 FR 46875, September 5, 1997; clarifying FDA's authority to reach sponsor-investigators under the regulations for disqualification of a clinical investigator.

[2] See, for example, the final rule at 62 FR 46875, September 5, 1997; clarifying FDA's authority to reach sponsor-investigators under the regulations for disqualification of a clinical investigator.

[3] FDA issues to the investigator a "Notice of Opportunity for Hearing". The investigator must show that there is a genuine and substantial issue of fact that warrants a hearing (§ 16.26(a)).

[4] See part 16, subpart D—Procedures for Regulatory Hearing.

the applicable part and eligible to conduct any clinical investigation that supports an application for a research or marketing permit for products regulated by FDA. Those FDA-regulated products include drugs, biologics, devices, new animal drugs, foods, including dietary supplements, that bear a nutrient content claim or a health claim, infant formulas, food and color additives, and tobacco products.

B. Ineligibility To Receive Any Test Article (§§ 312.70(b), 511.1(c)(2), and 812.119(b))

1. Proposed Revisions to § 312.70(b)

- For consistency, we propose to refer to "repeatedly or deliberately" in the same order throughout the provision.
- For clarity, we propose to move after "submitted" the clause, "to FDA or to the sponsor". Therefore, the proposed provision reads, "or has repeatedly or deliberately submitted to FDA or to the sponsor false information in any required report, * * *".
- We propose to add a notification to the reviewing institutional review board(s) (IRB(s)) about the investigator's disqualification. This proposed change will harmonize § 312.70(b) with FDA's current procedures along with those provisions currently in § 812.119(b). IRBs play a significant role in ensuring that clinical investigators meet the applicable statutory and regulatory requirements.[5] We therefore propose to add this provision in § 312.70(b) to help ensure that any reviewing IRB is aware of the clinical investigator's disqualification.
- We propose to change "entitled" to "eligible".
- FDA proposes to harmonize the disqualification regulations by changing the investigator's ineligibility from receiving "investigational drugs" to ineligibility to receive "test articles under this part." We are also proposing that an investigator disqualified by a Commissioner's decision also will be ineligible to conduct any clinical investigation that supports an application for a research or marketing permit for products regulated by FDA, including drugs, biologics, devices, new animal drugs, foods, including dietary supplements, that bear a nutrient content claim or a health claim, infant formulas, food and color additives, and tobacco products.
- For clarity and consistency with our procedures, we propose to add an explicit reference concerning notification by FDA about the investigator's disqualification. That is, the investigator and sponsor will be notified about the basis for the disqualification determination. The notification to the sponsor, for example, will provide a statement of the basis for disqualification such as a list of the investigator's violations, and also include instructions concerning ongoing studies and any approved products containing the investigator's data.
- For consistency with our procedures, we propose to add that the reviewing IRB(s) also will be notified about the basis for the disqualification determination.

2. Proposed Revisions to § 511.1(c)(2)

- To harmonize the investigator disqualification regulations in § 511.1(c)(2) with those currently in §§ 312.70(b) and 812.119(b), we propose to change the first word "If" in § 511.1(c)(2) to read instead, "After evaluating all available information, including any explanation presented by the investigator, if the Commissioner determines that * * *".
- We propose to change the term "section" to "subchapter". The disqualification action is pursuant to the investigator's failure to comply with the conditions of the exempting regulations in subchapter E (21 CFR chapter I, subchapter E)—Animal drugs, feeds, and related products. Therefore, we propose "this subchapter" is the applicable and correct term as opposed to the narrower reference currently in § 511.1(c)(2) to "this section".
- For clarity and to harmonize § 511.1(c)(2) with the proposed investigator disqualification regulations in §§ 312.70(b) and 812.119(b), we propose to move and modify the clause "to the sponsor of an investigation" and add "to FDA" and "in any required report", to read, "or has repeatedly or deliberately submitted to FDA or to the sponsor false information in any required report, * * *".
- For clarity and to harmonize the investigator disqualification regulations, we propose to change "he" to "the investigator".
- We propose to change "entitled" to "eligible".
- FDA proposes to harmonize the disqualification regulations by changing the investigator's ineligibility from receiving "investigational use new animal drugs" to ineligibility to receive "test articles under this part." We are also proposing that an investigator disqualified by a Commissioner's decision also will be ineligible to conduct any clinical investigation that supports an application for a research or marketing permit for products regulated by FDA, including drugs, biologics, devices, new animal drugs, foods, including dietary supplements, that bear a nutrient content claim or a health claim, infant formulas, food and color additives, and tobacco products.
- For clarity and consistency with our procedures, we propose to add an explicit reference concerning notification by FDA about the investigator's disqualification. That is, the investigator and sponsor will be notified about the basis for the disqualification determination. The notification to the sponsor, for example, will provide a statement of the basis for disqualification such as a list of the investigator's violations, and also include instructions concerning ongoing studies and any approved products containing the investigator's data.

3. Proposed Revisions to § 812.119(b)

- For consistency, we propose to refer to "repeatedly or deliberately" in the same order throughout the provision.
- For clarity and to harmonize § 812.119(b) with the proposed investigator disqualification regulations in §§ 312.70(b) and 511.1(c)(2), we propose to move and modify the clause "to the sponsor of an investigation", add "to FDA", and remove "either", to read, "or has repeatedly or deliberately submitted to FDA or to the sponsor false information in any required report, * * *".
- We propose to change "entitled" to "eligible".
- FDA proposes to harmonize the disqualification regulations by changing the investigator's ineligibility from receiving "investigational devices" to ineligibility to receive "test articles under this part." We are also proposing that an investigator disqualified by a Commissioner's decision also will be ineligible to conduct any clinical investigation that supports an application for a research or marketing permit for products regulated by FDA, including drugs, biologics, devices, new animal drugs, foods, including dietary supplements, that bear a nutrient content claim or a health claim, infant formulas, food and color additives, and tobacco products.
- For clarity and consistency with our procedures, we propose to add an explicit reference concerning notification by FDA about the investigator's disqualification. That is, the investigator, sponsor, and reviewing IRB(s) will be notified about the basis for the disqualification determination. The notification to the sponsor, for example, will provide a statement of the basis for disqualification such as a list of the investigator's violations, and also include instructions concerning ongoing

[5] 63 FR 55873 at 55874, October 19, 1998.

studies and any approved or cleared products containing the investigator's data.

Therefore, as proposed, an investigator determined to be ineligible to receive test articles under one part of FDA's regulations also would be ineligible to conduct any clinical investigation that supports an application for a research or marketing permit for products regulated by FDA, including drugs, biologics, devices, new animal drugs, foods, including dietary supplements, that bear a nutrient content claim or a health claim, infant formulas, food and color additives, and tobacco products. This proposal is consistent with the underlying rationale for disqualifying a clinical investigator, which is to preserve the integrity of study data and to help ensure the safety, rights, and welfare of study subjects. As proposed, those principles would apply to all test articles and studies; an investigator who is determined to have repeatedly or deliberately violated the regulations while conducting a study of a particular type of test article sufficient to warrant disqualification would thus be ineligible to receive any FDA-regulated test article or conduct any clinical investigation that supports an application for a research or marketing permit for products regulated by FDA.

C. Disqualified Investigator's Data in Applications and Submissions to FDA (§§ 312.70(c), 511.1(c)(3), and 812.119(c))

1. Proposed Revisions to § 312.70(c)

Currently, § 312.70(c) provides, "Each IND and each approved application submitted under part 314 containing data reported by an investigator who has been determined to be ineligible to receive investigational drugs will be examined to determine whether the investigator has submitted unreliable data that are essential to the continuation of the investigation or essential to the approval of any marketing application." FDA proposes to revise the current regulations in § 312.70(c) to clarify the applicability of this provision, update this provision consistent with §§ 312.70(b), 511.1(c)(2), and 812.119(b) of this proposal, and to harmonize the disqualification regulations in §§ 312.70(c), 511.1(c)(3), and 812.119(c). Therefore, we propose to amend § 312.70(c) to change "Each IND and each approved application submitted under part 314" to "Each application or submission to FDA under the provisions of this chapter". The "provisions of this chapter" refers to chapter I and includes INDs and approved applications submitted under part 314. Also, we propose to change "drugs" to "FDA-regulated test articles"; "continuation of the investigation" to "continuation of any investigation"; and add after "essential to the approval of any marketing application" the phrase "essential to the continued marketing of an FDA-regulated product."

2. Proposed Revisions to § 511.1(c)(3)

Currently, § 511.1(c)(3) provides, "Each 'Notice of Claimed Investigational Exemption for a New Animal Drug' and each approved new animal drug application containing data reported by an investigator who has been determined to be ineligible to receive investigational-use new animal drugs will be examined to determine whether he has submitted unreliable data that are essential to the continuation of the investigation or essential to the approval of any new animal drug application." FDA proposes to revise the current regulations in § 511.1(c)(3) to clarify the applicability of this provision, update this provision consistent with §§ 312.70(b), 511.1(c)(2), and 812.119(b) of this proposal, and to harmonize the disqualification regulations in §§ 312.70(c), 511.1(c)(3), and 812.119(c). Therefore, we propose to revise § 511.1(c)(3) to provide, "Each application or submission to FDA under the provisions of this chapter and containing data reported by an investigator who has been determined to be ineligible to receive FDA-regulated test articles will be examined to determine whether the investigator has submitted unreliable data that are essential to the continuation of any investigation or essential to the approval of any marketing application, or essential to the continued marketing of an FDA-regulated product." The "provisions of this chapter" refers to chapter I and includes a notice of claimed investigational exemption for a new animal drug and an approved new animal drug application.

3. Proposed Revisions to § 812.119(c)

Currently, § 812.119(c) provides, "Each investigational device exemption (IDE) and each cleared or approved application submitted under this part, subpart E of part 807 of this chapter, or part 814 of this chapter containing data reported by an investigator who has been determined to be ineligible to receive investigational devices will be examined to determine whether the investigator has submitted unreliable data that are essential to the continuation of the investigation or essential to the approval or clearance of any marketing application." FDA proposes to revise the current regulations in § 812.119(c) to clarify the applicability of this provision, update this provision consistent with §§ 312.70(b), 511.1(c)(2), and 812.119(b) of this proposal, and to harmonize the disqualification regulations in §§ 312.70(c), 511.1(c)(3), and 812.119(c). Therefore, we propose to revise § 812.119(c) to provide, "Each application or submission to FDA under the provisions of this chapter and containing data reported by an investigator who has been determined to be ineligible to receive FDA-regulated test articles will be examined to determine whether the investigator has submitted unreliable data that are essential to the continuation of any investigation or essential to the clearance or approval of any marketing application, or essential to the continued marketing of an FDA-regulated product." The "provisions of this chapter" refers to chapter I and includes investigational device exemptions (IDEs), and cleared or approved applications submitted under part 812; 21 CFR part 807, subpart E; or part 814 (21 CFR part 814).

D. Disqualified Investigator's Data in Applications and Submissions to FDA—Sponsor Notification, Opportunities, and Responsibilities (§§ 312.70(d), 511.1(c)(4), and 812.119(d))

1. Proposed Revisions to § 312.70(d)

- In accordance with FDA's procedures and for consistency with the provisions currently in § 812.119(d), we propose to add "and the reviewing IRB(s)" after "shall terminate the IND immediately and notify the sponsor * * *".
- We propose to change "determination" to "termination". This correction is consistent with the regulations currently in §§ 511.1(c)(4) and 312.44 and, therefore, will harmonize and clarify the regulations. This proposal provides, "If a danger to the public health exists * * * the Commissioner shall terminate the IND immediately and notify the sponsor and the reviewing IRB(s) of the termination."
- We propose to add a new sentence at the end of § 312.70(d), to clarify and emphasize the sponsor's responsibilities under this provision. That is, we propose to add that when the Commissioner determines that an investigation may not be considered in support of a research or marketing application, or a notification or petition submission, this determination does not relieve the sponsor of any obligation under any other applicable regulation to submit to FDA the results of the investigation.

2. Proposed Revisions to § 511.1(c)(4)

- For the purpose of plain language and for consistency with the current and proposed investigator disqualification regulations, FDA proposes to make corrections to § 511.1(c)(4):
  - Change "he shall first" to "the Commissioner will",
  - Change "before the Food and Drug Administration pursuant to" to "before FDA under",
  - Remove "on whether the exemption should be terminated",
  - Change "he" to "the Commissioner",
  - Change "forthwith" to "immediately",
  - Change "event" to "case",
  - Change "the Food and Drug Administration pursuant to" to "FDA under", and
  - Remove "(see 42 FR 15075, March 22, 1977)".
- We propose to add a new sentence at the end of § 511.1(c)(4), to clarify and emphasize the sponsor's responsibilities under this provision. That is, we propose to add that when the Commissioner determines that an investigation may not be considered in support of a research or marketing application, or a notification or petition submission, this determination does not relieve the sponsor of any obligation under any other applicable regulation to submit to FDA the results of the investigation.

3. Proposed Revisions to § 812.119(d)

- We propose to change "determination" to "termination". This correction is consistent with the regulations currently in § 511.1(c)(4) and therefore will harmonize and clarify the regulations. Also, we propose to add "(s)" at the end of "IRB" because there might be more than one reviewing IRB, to provide that "the Commissioner shall terminate the IDE immediately and notify the sponsor and the reviewing IRB(s) of the termination."
- We propose to add a new sentence at the end of § 812.119(d). As proposed for §§ 312.70(d) and 511.1(c)(4), we propose to add that when the Commissioner determines that an investigation may not be considered in support of a research or marketing application, or a notification or petition submission, this determination does not relieve the sponsor of any obligation under any other applicable regulation to submit to FDA the results of the investigation.

E. Disqualified Investigator's Data in Applications and Submissions to FDA—Withdrawal of Product Approval (§§ 312.70(e), 511.1(c)(5), and 812.119(e))

1. Proposed Revisions to § 312.70(e)

The current investigator disqualification regulations provide that if the Commissioner determines, after the unreliable data submitted by the investigator are eliminated from consideration, that the continued approval of the drug product for which the data were submitted cannot be justified, the Commissioner will proceed to withdraw approval of the drug product in accordance with the applicable provisions of the Federal Food, Drug, and Cosmetic Act as amended (the FD&C Act). We also note that the Commissioner would revoke any biologics license approved under the Public Health Service Act. To harmonize the investigator disqualification regulations in §§ 312.70(e), 511.1(c)(5), and 812.119(e), we propose to remove the reference to "drug". To keep the investigator disqualification regulations consistent, this proposal also changes the reference to the applicable provisions of the FD&C Act to a reference to the applicable provisions of the relevant statutes.

2. Proposed Revisions to § 511.1(c)(5)

The current investigator disqualification regulations in § 511.1(c)(5) provide that if the Commissioner determines, after the unreliable data submitted by the investigator are eliminated from consideration, that the "data remaining are such that a new animal drug application would not have been approved, he will proceed to withdraw approval of the application in accordance with section 512(e) of the act." This proposal does not change the meaning of this provision, however, for simplicity and to keep the investigator disqualification regulations consistent, we propose changes to harmonize the investigator disqualification regulations, as follows:

- Change the "data remaining are such that a new animal drug application would not have been approved" to "continued approval of the product for which the data were submitted cannot be justified",
- Change "he" to "the Commissioner",
- Change "application" to "product", and
- Change "in accordance with section 512(e) of the act" to "in accordance with the applicable provisions of the relevant statutes".

3. Proposed Revisions to § 812.119(e)

The current investigator disqualification regulations provide that if the Commissioner determines, after the unreliable data submitted by the investigator are eliminated from consideration, that the continued clearance or approval of the marketing application for which the data were submitted cannot be justified, the Commissioner will proceed to withdraw approval or rescind clearance of the medical device in accordance with the applicable provisions of the FD&C Act. We propose to harmonize and simplify the provisions in §§ 312.70(e), 511.1(c)(5), and 812.119(e). Therefore, in § 812.119(e), we propose to change "marketing application" and "medical device" to "product" and change "in accordance with the applicable provisions of the act" to "in accordance with the applicable provisions of the relevant statutes". Also, we propose to change the order of "withdraw approval or rescind clearance" to "rescind clearance or withdraw approval" to match respectively the order at the beginning of the sentence.

F. Other Proceedings

Although not explicit in the proposed codified, the disqualification of an investigator is independent of, and neither in lieu of nor a precondition to, other proceedings or actions authorized by the FD&C Act. That is, at any time, FDA may, through the Department of Justice, institute any appropriate judicial proceedings (civil or criminal) and any other appropriate regulatory action, in addition to or in lieu of, and before, at the time of, or after, disqualification. Also, FDA may refer pertinent matters to another Federal, State, or local government agency for any action determined appropriate by that agency.

G. Reinstatement (§§ 312.70(f), 511.1(c)(6), and 812.119(f))

FDA proposes minor revisions to the regulations currently in §§ 312.70(f), 511.1(c)(6), and 812.119(f), to make the investigator disqualification regulations consistent. This proposal changes the references to an investigator who has been determined to be ineligible to receive "investigational drugs", "investigational-use new animal drugs", and "investigational devices" currently in those provisions to, instead, reference an investigator who has been determined to be ineligible under the appropriate paragraph in the relevant section (*e.g.,* in proposed § 312.70(f), "an investigator who has been determined to be ineligible under paragraph (b) of

[§ 312.70] may be reinstated as eligible * * *"). This proposal also changes the current references to "parts 50 and 56" and to "the provisions of this part" in §§ 312.70(f) and 812.119(f), and the reference to "the exempting regulations in this section" in § 511.1(c)(6), to "the applicable provisions of this chapter" (*i.e.,* chapter I). We also added, for consistency with the proposed changes to §§ 312.70(b), 511.1(c)(2), and 812.119(b), the phrase, "and will conduct any clinical investigation that supports an application for a research or marketing permit for products regulated by FDA". We therefore propose that an investigator who has been determined to be ineligible under §§ 312.70(b), 511.1(c)(2), or 812.119(b), may be reinstated as eligible when the Commissioner determines that the investigator has presented adequate assurances that the investigator will employ all test articles, and will conduct any clinical investigation that supports an application for a research or marketing permit for products regulated by FDA, solely in compliance with the applicable provisions of chapter I.

H. Part 511 Definitions (§ 511.3)

FDA proposes to amend part 511 by adding a new section that provides definitions for a contract research organization, investigator, sponsor, and sponsor-investigator. We propose to add those definitions to harmonize part 511 with other regulations for the disqualification of a clinical investigator.

IV. Regulatory Hearing Before the Food and Drug Administration

We propose to add to 16.1(b)(2) an entry for 812.119 and to revise the entries for 312.70 and 511.1(c)(1). Also, the list of regulatory provisions under which a part 16 regulatory hearing is available (§ 16.1(b)(2)) is incomplete. The provisions for § 58.204(b) (21 CFR 58.204(b)), relating to disqualifying a testing facility, and § 822.7(a)(3) (21 CFR 822.7(a)(3)), relating to an order to conduct postmarket surveillance of a medical device under section 522 of the FD&C Act (21 U.S.C. 360l), were inadvertently omitted. We, therefore, propose to amend part 16 by adding those provisions.

V. 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.

VI. Legal Authority

The disqualification of a clinical investigator is a remedial measure. The purpose of disqualifying investigators who violate the regulations is to preserve the integrity of data needed to assess the safety and effectiveness of an FDA-regulated product before the product is made available to the public, and to protect the safety of study subjects during the conduct of a clinical investigation and patient safety after the approval or clearance of a marketing application.

Although the concept of disqualification is not explicitly mentioned in the FD&C Act, FDA has the authority to disqualify clinical investigators who violate FDA's regulations. The Supreme Court in *Weinberger* v. *Bentex Pharmaceuticals, Inc.,* 412 U.S. 645, 653 (1973) has recognized that FDA has authority that "is implicit in the regulatory scheme, not spelled out in *haec verba*" in the statute. As stated in *Morrow* v. *Clayton,* 326 F.2d 36, 44 (10th Cir. 1963):

[I]t is a fundamental principle of administrative law that the powers of an administrative agency are not limited to those expressly granted by the statutes, but include, also, all of the powers that may fairly be implied therefrom.

See *Mourning* v. *Family Publications Service, Inc.,* 411 U.S. 356 (1973), and *National Petroleum Refiners Association* v. *FTC,* 482 F.2d 672 (DC Cir. 1973). See also *Weinberger* v. *Hynson, Westcott & Dunning, Inc.,* 412 U.S. 609 (1973); *National Nutritional Foods Association* v. *Weinberger,* 512 F.2d 688, *cert denied,* 423 U.S. 827 (1975); *United States* v. *Nova Scotia Food Products Corp.,* 568 F.2d 240, 246–248 (2d Cir. 1977); *American Frozen Food Institute* v. *Mathews* 413 F.Supp. 548 (D.D.C. 1976) *aff'd per curiam,* 555 F.2d 1059 (DC Cir. 1977); *National Confectioners Association* v. *Califano,* 569 F.2d 690 (DC Cir. 1978); and *National Association of Pharmaceutical Manufacturers* v. *FDA,* 637 F.2d 877 (2d Cir. 1981).

"[R]egulatory acts should be given a practical construction, and one which will enable the agency to perform the duties required of it by Congress." *Federal Deposit Ins. Corp.* v. *Sumner Fin. Corp.,* 451 F.2d 898, 904 (5th Cir. 1971). Congressional inaction on proposed legislation that would state expressly an agency's authority to act does not support an inference that the agency lacks implicit authority to act under existing legislation. *Red Lion Broadcasting Co.* v. *FCC,* 395 U.S. 367, 381–382 n. 11 (1969). See also *Leist* v. *Simplot,* 638 F.2d 283, 318 (2d Cir. 1980), *affirmed sub nom. Merrill Lynch, Pierce, Fenner & Smith* v. *Curran,* 456 U.S. 353 (1982). The Supreme Court has often recognized "the construction of a statute by those charged with its administration is entitled to substantial deference." *United States* v. *Rutherford,* 442 U.S. 544 (1979). *Board of Governors of FRS* v. *First Lincolnwood,* 439 U.S. 234, 248, 99 S.Ct. 505, 513, 58 L.Ed.2d 484 (1978) (the Court's conclusion "is influenced by the principle that courts should defer to an agency's construction of its own statutory mandate, *Red Lion Broadcasting Co.* v. *FCC,* 395 U.S. at 381; *Commissioner* v. *Sternberger's Estate,* 348 U.S. 187, 199 (1955), particularly when that construction accords with well established congressional goals." 439 U.S. at 251); *Bayside Enterprises, Inc.* v. *NLRB,* 429 U.S. 298, 304, 97 S.Ct. 576, 581, 50 L.Ed.2d 494 (1977); *Udall* v. *Tallman,* 380 U.S. 1, 16, 85 S.Ct. 792, 801, 13 L.Ed.2d 616 (1965).

Under section 701(a) of the FD&C Act (21 U.S.C. 371(a)), the Commissioner is empowered to promulgate regulations for the efficient enforcement of the FD&C Act. Regulations issued by the Commissioner under section 701(a) for determining whether a clinical investigation of a drug intended for human use, among other things, was scientifically reliable and valid to support approval of a new drug, have been upheld by the Supreme Court (*Weinberger* v. *Hynson, Westcott & Dunning, Inc.*); see also *Upjohn Co.* v. *Finch,* 422 F.2nd 944 (6th Cir. 1970); and *Pharmaceutical Manufacturers Association* v. *Richardson,* 318 F.Supp. 301 (D.Del. 1970)).

Furthermore, sections 505(i), 512(j) and 520(g) of the FD&C Act regarding clinical investigations that require prior FDA authorization direct the Commissioner to promulgate regulations to protect the public health in the course of those investigations. Also, sections 505(i)(1), 512(j), and 520(g)(2)(A) of the FD&C Act require that investigations be conducted by "experts qualified by scientific training and experience." An investigator who repeatedly or deliberately violates the regulations or who repeatedly or deliberately submits false information would not be considered a qualified expert with the experience required to conduct investigations of FDA-regulated articles. Among other stated objectives, the proposed rulemaking is intended to fulfill those mandates.

The Commissioner therefore concludes that legal authority to promulgate those regulations regarding clinical investigators exists under sections 505(i), 512(j), 520(g) and 701(a)

of the FD&C Act, as essential to protection of the public health and safety and to enforcement of the agency's responsibilities under sections 409, 502, 503, 505, 506, 510, 512, 513, 514, 515, 518, 519, 520 and 801 of the FD&C Act (21 U.S.C. 348, 352, 353, 355, 356, 360, 360b, 360c, 360d, 360e, 360h, 360i, 360j and 381), as well as the responsibilities of FDA under section 351 of the Public Health Service Act (42 U.S.C. 262).

VII. Proposed Implementation Plan

FDA proposes that any final rule that may issue based on this proposal become effective 30 days after the date of publication of the final rule in the **Federal Register**.

VIII. Analysis of Impacts

FDA has examined the impacts of the proposed rule under Executive Order 12866 and the Regulatory Flexibility Act (5 U.S.C. 601–612), and the Unfunded Mandates Reform Act of 1995 (Pub. L. 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 a 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 a rule on small entities. Because this proposed rule does not impose new requirements on any entity and therefore has no associated compliance costs, the Agency proposes to certify that the final rule will not 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 $135 million, using the most current (2009) 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.

A. Objective

The objective of the proposed rule is to strengthen the process for ensuring the reliability and integrity of the clinical trial data supporting FDA decision-making on product applications and to help ensure the adequate protection of research subjects participating in FDA-regulated clinical investigations. Specifically, this rule would expand the scope of FDA's disqualification actions so that a disqualified clinical investigator is ineligible to receive any FDA-regulated test article. That is, an investigator determined to be ineligible to receive test articles under parts 312, 511 or 812, will be ineligible to conduct any clinical investigation that supports an application for a research or marketing permit for products regulated by FDA, including drugs, biologics, devices, new animal drugs, foods, including dietary supplements, that bear a nutrient content claim or a health claim, infant formulas, food and color additives, and tobacco products. This action would help reduce the risk to human subjects who participate in FDA-regulated clinical investigations by explicitly extending a disqualified investigator's ineligibility to receive any FDA-regulated test article. In addition, the proposed rulemaking would establish uniform language across the several existing regulations that address investigator disqualification.

B. Background

In 2009, the GAO conducted a study of FDA's oversight of clinical investigators who conduct research involving new drugs, biologics and medical devices, "Oversight of Clinical Investigators—Action Needed To Improve Timeliness and Enhance Scope of FDA's Debarment and Disqualification Processes for Medical Product Investigators" (Ref 1.). Among its findings, the GAO recommended that FDA amend its regulations to ensure that those clinical investigators who have engaged in misconduct sufficient to warrant disqualification for one type of investigational medical product are not able to serve as clinical investigators for other types of medical products.

Currently, FDA regulations provide authority to disqualify researchers conducting clinical investigations of medical products when FDA determines that the investigators have not followed the rules intended to protect study subjects, or who have submitted false information. The actions to disqualify clinical investigators are initiated because FDA has evidence that the clinical investigator repeatedly or deliberately violated FDA's regulations governing the proper conduct of clinical investigations. However, the regulatory language may allow a disqualified investigator to participate in clinical investigations as long as the investigational products studied are different from the product involved in the disqualification.

C. Baseline

To develop a baseline of the disqualification actions that would be affected by this proposed rule, FDA's Office of Good Clinical Practice reviewed all FDA disqualification actions over a 10-year period, 1998–2007. This time-period was selected to provide a data set large enough to analyze and to allow sufficient elapsed time from initiation to final action to characterize completed actions. Over this 10-year period, FDA has initiated a total of about 60 disqualification actions, or an average of 6 per year. Of those 60 disqualification actions, 5 percent of the investigators were not disqualified. Approximately 75 percent of clinical investigators entered into a consent agreement or a restricted agreement that restricts their ability to investigate other FDA-regulated products, *i.e.,* products different from the one in the study (or studies) that led to disqualification. A small number of clinical investigators, about 20 percent of the disqualification actions, were ultimately disqualified following a Commissioner's decision. In those matters, FDA does not have regulatory authority to prohibit those investigators, who are disqualified by a Commissioner's decision, from conducting investigations involving other FDA-regulated articles. We have little, if any, evidence that any of the investigators to date who have been disqualified via a Commissioner's decision have conducted investigations with other types of FDA-regulated test articles. Nonetheless, the agency agrees with GAO's recommendation that FDA have in place uniform and enforceable regulatory requirements to prevent clinical investigations in other product areas by disqualified clinical investigators.

D. Costs of the Proposed Rule

We estimate that there may be an average of about 1 or 2 matters per year of clinical investigators who are ultimately disqualified via a Commissioner's decision. Because the majority of disqualification actions are concluded by consent agreements that specifically preclude the investigator from investigating other FDA-regulated articles and current practices already

reduce the risk of such occurrences, we do not expect that this proposed rule would impose additional costs. Past disqualification actions show little, if any, evidence that an investigator disqualified from receiving one type of test article later conducted a clinical investigation studying a different type of test article. Nonetheless, based in part on GAO recommendations, we find that explicit regulatory language is needed to ensure that a disqualified investigator cannot conduct a clinical investigation with any FDA-regulated test article.

FDA would realize cost savings if there are future disqualification matters involving clinical investigators who are already disqualified and then conduct additional research in another FDA-regulated product area. There would be no need to bring a second action because the first disqualification would prohibit research by the disqualified investigator with any test article. We cannot estimate the amount of savings, but the legal costs avoided would be considerable for each additional product area.

E. Benefit

The proposed rule would help ensure that disqualified investigators cannot receive any FDA-regulated article, *i.e.,* disqualified investigators will be ineligible to conduct any clinical investigation that supports an application for a research or marketing permit for products regulated by FDA, including drugs, biologics, devices, new animal drugs, foods, including dietary supplements, that bear a nutrient content claim or a health claim, infant formulas, food and color additives, and tobacco products. Explicitly expanding a disqualified investigator's ineligibility to receive any FDA-regulated test article would help to reduce the risk of additional violations in other FDA-regulated investigations and would help to ensure the integrity of clinical trial data. This action would help reduce the risk to human subjects who participate in FDA-regulated investigations. This proposed rule may also lead to improved public confidence in the clinical data supporting FDA decisions.

F. Alternatives

This proposed rule constitutes a minor change to existing regulations to ensure that FDA has the clear regulatory authority it needs to protect human subjects from exposure to research conducted by disqualified clinical investigators. We considered not expanding the scope of FDA's disqualification actions to include the ineligibility of a disqualified clinical investigator to receive any FDA-regulated test article. However, this would not meet the objective of helping to ensure the adequate protection of human subjects in clinical investigations or helping to ensure the reliability and integrity of the clinical trial data supporting FDA decision-making on product applications. There are no other viable alternatives.

G. Small Business Impact

The clinical research community, including clinical investigators, is composed of many large and small business entities. Clinical investigators may be associated with government and academic research institutions, contract research organizations, site-management organizations, or independent researchers. Investigational product research is often sponsored by FDA-regulated firms that seek to bring a new product to market.

The proposed rule is not expected to have a significant economic impact on a substantial number of small entities as previously discussed in this document. As stated above in this section of this document, we do not expect that the proposed rule would impose additional new costs. This proposed rule is expected to affect an average of about 1 to 2 clinical investigators per year. Affected investigators are disqualified because FDA has evidence that the clinical investigator repeatedly or deliberately violated FDA's regulations governing the proper conduct of clinical investigations. FDA is not imposing any additional requirements for the conduct of clinical investigations used to support marketing applications. It is clarifying its regulatory authority over disqualified investigators. Under this proposed rule a disqualified investigator would explicitly be ineligible to conduct any studies of FDA-regulated articles. We have little, if any, evidence that a disqualified investigator has conducted a clinical investigation studying a different type of test article.

For the reasons stated above, we propose to certify that this proposed rule would not have a significant economic impact on a substantial number of small entities.

IX. Paperwork Reduction Act of 1995

This proposed rule contains no new collections of information. Therefore, clearance by the Office of Management and Budget under the Paperwork Reduction Act of 1995 is not required.

The information collection in § 312.70 pertaining to the disqualification of a clinical investigator and an investigator's opportunity to respond to FDA is approved under the investigational new drug regulations, OMB control number 0910–0014; expiration date August 31, 2011.[6] The notification of IRB(s) in proposed § 312.70 is approved under OMB control number 0910–0130—Protection of Human Subjects; Recordkeeping Requirements for Institutional Review Boards (IRBs); expiration date December 31, 2010 (renewal pending at OMB).[7] The information collection in § 511.1(c) pertaining to the disqualification of a clinical investigator and an investigator's opportunity to respond to FDA is approved under the new animal drugs for investigational use regulations OMB control number 0910–0117; expiration date August 31, 2011.[8] The information collection in § 812.119 pertaining to the disqualification of a clinical investigator and an investigator's opportunity to respond to FDA is approved under the investigational device exemptions reports and records in part 812, OMB control number 0910–0078; expiration date February 28, 2013.[9] In addition, INDs and new drug applications are approved under OMB control number 0910–0416; animal drug applications, 21 CFR part 514 are approved under OMB control number 0910–0032; premarket notification submissions, 510(k), subpart E are approved under OMB control number 0910–0120; and premarket approvals of medical devices, part 814, are approved under OMB control number 0910–0231.

X. 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, if finalized, would not contain policies that would 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 tentatively concludes 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.

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[6] See *http://www.reginfo.gov/public/do/PRAViewICR?ref_nbr=200905-0910-005* (accessed on February 4, 2011).

[7] See *http://www.reginfo.gov/public/do/PRAViewICR?ref_nbr=200711-0910-003* (accessed on February 4, 2011).

[8] See *http://www.reginfo.gov/public/do/PRAViewICR?ref_nbr=200806-0910-005* (accessed on February 4, 2011).

[9] See *http://www.reginfo.gov/public/do/PRAViewICR?ref_nbr=201001-0910-010* (accessed on February 4, 2011).

XI. Request for Comments

Interested persons may submit to the Division of Dockets Management (see **ADDRESSES**) either electronic or written comments regarding this document. It is only necessary to send one set of comments. It is no longer necessary to send two copies of mailed comments. Identify comments 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.

XII. References

The following reference has been placed on display in the Division of Dockets Management, Food and Drug Administration, 5630 Fishers Lane, rm. 1061, Rockville, MD 20857 and may be seen by interested persons between 9 a.m. and 4 p.m., Monday through Friday. We have verified the Web site address, but we are not responsible for any subsequent changes to the Web site after this document publishes in the **Federal Register**.

1. GAO Report to Congressional Requesters—Oversight of Clinical Investigators, Action Needed to Improve Timeliness and Enhance Scope of FDA's Debarment and Disqualification Processes for Medical Product Investigators; GAO–09–807. See *http://www.gao.gov/new.items/d09807.pdf* (accessed on February 4, 2011).

List of Subjects

21 CFR Part 16

Administrative practice and procedure.

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 812

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

Therefore, under the Federal Food, Drug, and Cosmetic Act and under authority delegated to the Commissioner of Food and Drugs, it is proposed that 21 CFR parts 16, 312, 511, 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.

2. Section 16.1 is amended in paragraph (b)(2) by adding in numerical sequence entries for "§ 58.204(b)", "§ 812.119", and "§ 822.7(a)(3)" and by revising the entries for "§ 312.70" and "§ 511.1(c)(1)" to read as follows:

§ 16.1 Scope.

* * * * *

(b) * * *

(2) * * *

§ 58.204(b), relating to disqualifying a testing facility.

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§ 312.70, relating to whether an investigator is eligible to receive test articles under part 312 of this chapter and eligible to conduct any clinical investigation that supports an application for a research or marketing permit for products regulated by FDA, including drugs, biologics, devices, new animal drugs, foods, including dietary supplements, that bear a nutrient content claim or a health claim, infant formulas, food and color additives, and tobacco products.

* * * * *

§ 511.1(c)(1), relating to whether an investigator is eligible to receive test articles under part 511 of this chapter and eligible to conduct any clinical investigation that supports an application for a research or marketing permit for products regulated by FDA including drugs, biologics, devices, new animal drugs, foods, including dietary supplements, that bear a nutrient content claim or a health claim, infant formulas, food and color additives, and tobacco products.

* * * * *

§ 812.119, relating to whether an investigator is eligible to receive test articles under part 812 of this chapter and eligible to conduct any clinical investigation that supports an application for a research or marketing permit for products regulated by FDA including drugs, biologics, devices, new animal drugs, foods, including dietary supplements, that bear a nutrient content claim or a health claim, infant formulas, food and color additives, and tobacco products.

* * * * *

§ 822.7(a)(3), relating to an order to conduct postmarket surveillance of a medical device under section 522 of the act.

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PART 312—INVESTIGATIONAL NEW DRUG APPLICATION

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

Authority: 21 U.S.C. 321, 331, 351, 352, 353, 355, 360bbb, 371; 42 U.S.C. 262.

4. Section 312.70 is revised to read as follows:

§ 312.70 Disqualification of a clinical investigator.

(a) If FDA has information indicating that an investigator (including a sponsor-investigator) has repeatedly or deliberately failed to comply with the requirements of this part, part 50 of this chapter, or part 56 of this chapter, or has repeatedly or deliberately submitted to FDA or to the sponsor false information in any required report, the Center for Drug Evaluation and Research or the Center for Biologics Evaluation and Research will furnish the investigator written notice of the matter complained of and offer the investigator an opportunity to explain the matter in writing, or, at the option of the investigator, in an informal conference. If an explanation is offered and accepted by the applicable Center, the Center will discontinue pursuit of the disqualification proceeding. If an explanation is offered but not accepted by the applicable Center, the investigator will be given an opportunity for a regulatory hearing under part 16 of this chapter on the question of whether the investigator is eligible to receive test articles under this part and eligible to conduct any clinical investigation that supports an application for a research or marketing permit for products regulated by FDA.

(b) After evaluating all available information, including any explanation presented by the investigator, if the Commissioner determines that the investigator has repeatedly or deliberately failed to comply with the requirements of this part, part 50 of this chapter, or part 56 of this chapter, or has repeatedly or deliberately submitted to FDA or to the sponsor false information in any required report, the Commissioner will notify the investigator, the sponsor of any investigation in which the investigator has been named as a participant, and the reviewing institutional review board (IRB(s)) that the investigator is not eligible to receive test articles under this part. The notification to the investigator, sponsor, and IRB(s) will provide a statement of the basis for such

determination. The notification also will explain that an investigator determined to be ineligible to receive test articles under this part will be ineligible to conduct any clinical investigation that supports an application for a research or marketing permit for products regulated by FDA, including drugs, biologics, devices, new animal drugs, foods, including dietary supplements, that bear a nutrient content claim or a health claim, infant formulas, food and color additives, and tobacco products.

(c) Each application or submission to FDA under the provisions of this chapter and containing data reported by an investigator who has been determined to be ineligible to receive FDA-regulated test articles will be examined to determine whether the investigator has submitted unreliable data that are essential to the continuation of any investigation or essential to the approval of any marketing application, or essential to the continued marketing of an FDA-regulated product.

(d) If the Commissioner determines, after the unreliable data submitted by the investigator are eliminated from consideration, that the data remaining are inadequate to support a conclusion that it is reasonably safe to continue the investigation, the Commissioner will notify the sponsor who shall have an opportunity for a regulatory hearing under part 16 of this chapter. If a danger to the public health exists, however, the Commissioner shall terminate the IND immediately and notify the sponsor and the reviewing IRB(s) of the termination. In such case, the sponsor shall have an opportunity for a regulatory hearing before FDA under part 16 of this chapter on the question of whether the IND should be reinstated. The determination that an investigation may not be considered in support of a research or marketing application or a notification or petition submission does not, however, relieve the sponsor of any obligation under any other applicable regulation to submit to FDA the results of the investigation.

(e) If the Commissioner determines, after the unreliable data submitted by the investigator are eliminated from consideration, that the continued approval of the product for which the data were submitted cannot be justified, the Commissioner will proceed to withdraw approval of the product in accordance with the applicable provisions of the relevant statutes.

(f) An investigator who has been determined to be ineligible under paragraph (b) of this section may be reinstated as eligible when the Commissioner determines that the investigator has presented adequate assurances that the investigator will employ all test articles, and will conduct any clinical investigation that supports an application for a research or marketing permit for products regulated by FDA, solely in compliance with the applicable provisions of this chapter.

PART 511—NEW ANIMAL DRUGS FOR INVESTIGATIONAL USE

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

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

6. Section 511.1 is amended by revising paragraph (c) to read as follows:

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

* * * * *

(c) *Disqualification of a clinical investigator.* (1) If FDA has information indicating that an investigator (including a sponsor-investigator) has repeatedly or deliberately failed to comply with the conditions of these exempting regulations or has repeatedly or deliberately submitted to FDA or to the sponsor false information in any required report, the Center for Veterinary Medicine will furnish the investigator written notice of the matter complained of and offer the investigator an opportunity to explain the matter in writing, or, at the option of the investigator, in an informal conference. If an explanation is offered and accepted by the Center for Veterinary Medicine, the Center will discontinue pursuit of the disqualification proceeding. If an explanation is offered but not accepted by the Center for Veterinary Medicine, the investigator will be given an opportunity for a regulatory hearing under part 16 of this chapter on the question of whether the investigator is eligible to receive test articles under this part and eligible to conduct any clinical investigation that supports an application for a research or marketing permit for products regulated by FDA.

(2) After evaluating all available information, including any explanation presented by the investigator, if the Commissioner determines that the investigator has repeatedly or deliberately failed to comply with the conditions of the exempting regulations in this subchapter, or has repeatedly or deliberately submitted to FDA or to the sponsor false information in any required report, the Commissioner will notify the investigator and the sponsor of any investigation in which the investigator has been named as a participant that the investigator is not eligible to receive test articles under this part. The notification to the investigator and sponsor will provide a statement of the basis for such determination. The notification also will explain that an investigator determined to be ineligible to receive test articles under this part will be ineligible to conduct any clinical investigation that supports an application for a research or marketing permit for products regulated by FDA, including drugs, biologics, devices, new animal drugs, foods, including dietary supplements, that bear a nutrient content claim or a health claim, infant formulas, food and color additives, and tobacco products.

(3) Each application or submission to FDA under the provisions of this chapter and containing data reported by an investigator who has been determined to be ineligible to receive FDA-regulated test articles will be examined to determine whether the investigator has submitted unreliable data that are essential to the continuation of any investigation or essential to the approval of any marketing application, or essential to the continued marketing of an FDA-regulated product.

(4) If the Commissioner determines, after the unreliable data submitted by the investigator are eliminated from consideration, that the data remaining are inadequate to support a conclusion that it is reasonably safe to continue the investigation, the Commissioner will notify the sponsor who shall have an opportunity for a regulatory hearing under part 16 of this chapter. If a danger to the public health exists, however, the Commissioner shall terminate the exemption immediately and notify the sponsor of the termination. In such case, the sponsor shall have an opportunity for a regulatory hearing before FDA under part 16 of this chapter on the question of whether the exemption should be reinstated. The determination that an investigation may not be considered in support of a research or marketing application or a notification or petition submission does not, however, relieve the sponsor of any obligation under any other applicable regulation to submit to FDA the results of the investigation.

(5) If the Commissioner determines, after the unreliable data submitted by the investigator are eliminated from consideration, that the continued approval of the product for which the data were submitted cannot be justified, the Commissioner will proceed to withdraw approval of the product in accordance with the applicable provisions of the relevant statutes.

(6) An investigator who has been determined to be ineligible under paragraph (c)(2) of this section may be reinstated as eligible when the Commissioner determines that the investigator has presented adequate assurances that the investigator will employ all test articles, and will conduct any clinical investigation that supports an application for a research or marketing permit for products regulated by FDA, solely in compliance with the applicable provisions of this chapter.

* * * * *

7. Part 511 is amended by adding § 511.3 to read as follows:

§ 511.3 Definitions.

As used in this part:

Contract research organization means a person that assumes, as an independent contractor with the sponsor, one or more of the obligations of a sponsor, *e.g.,* design of a protocol, selection or monitoring of investigations, evaluation of reports, and preparation of materials to be submitted to FDA.

Investigator means an individual who actually conducts a clinical investigation (*i.e.,* under whose immediate direction the drug is administered or dispensed to a subject). In the event an investigation is conducted by a team of individuals, the investigator is the responsible leader of the team. "Subinvestigator" includes any other individual member of that team.

Sponsor means a person who takes responsibility for and initiates a clinical investigation. The sponsor may be an individual or pharmaceutical company, governmental agency, academic institution, private organization, or other organization. The sponsor does not actually conduct the investigation unless the sponsor is a sponsor-investigator. A person other than an individual that uses one or more of its own employees to conduct an investigation that it has initiated is a sponsor, not a sponsor-investigator, and the employees are investigators.

Sponsor-investigator means an individual who both initiates and conducts an investigation, and under whose immediate direction the investigational drug is administered or dispensed. The term does not include any person other than an individual. The requirements applicable to a sponsor-investigator under this part include both those applicable to an investigator and a sponsor.

PART 812—INVESTIGATIONAL DEVICE EXEMPTIONS

8. 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.

9. Section 812.119 is revised to read as follows:

§ 812.119 Disqualification of a clinical investigator.

(a) If FDA has information indicating that an investigator (including a sponsor-investigator) has repeatedly or deliberately failed to comply with the requirements of this part, part 50 of this chapter, or part 56 of this chapter, or has repeatedly or deliberately submitted to FDA or to the sponsor false information in any required report, the Center for Devices and Radiological Health, the Center for Biologics Evaluation and Research, or the Center for Drug Evaluation and Research will furnish the investigator written notice of the matter complained of and offer the investigator an opportunity to explain the matter in writing, or, at the option of the investigator, in an informal conference. If an explanation is offered and accepted by the applicable Center, the Center will discontinue pursuit of the disqualification proceeding. If an explanation is offered but not accepted by the applicable Center, the investigator will be given an opportunity for a regulatory hearing under part 16 of this chapter on the question of whether the investigator is eligible to receive test articles under this part and eligible to conduct any clinical investigation that supports an application for a research or marketing permit for products regulated by FDA.

(b) After evaluating all available information, including any explanation presented by the investigator, if the Commissioner determines that the investigator has repeatedly or deliberately failed to comply with the requirements of this part, part 50 of this chapter, or part 56 of this chapter, or has repeatedly or deliberately submitted to FDA or to the sponsor false information in any required report, the Commissioner will notify the investigator, the sponsor of any investigation in which the investigator has been named as a participant, and the reviewing IRB(s) that the investigator is not eligible to receive test articles under this part. The notification to the investigator, sponsor, and IRB(s) will provide a statement of the basis for such determination. The notification also will explain that an investigator determined to be ineligible to receive test articles under this part will be ineligible to conduct any clinical investigation that supports an application for a research or marketing permit for products regulated by FDA, including drugs, biologics, devices, new animal drugs, foods, including dietary supplements, that bear a nutrient content claim or a health claim, infant formulas, food and color additives, and tobacco products.

(c) Each application or submission to FDA under the provisions of this chapter and containing data reported by an investigator who has been determined to be ineligible to receive FDA-regulated test articles will be examined to determine whether the investigator has submitted unreliable data that are essential to the continuation of any investigation or essential to the clearance or approval of any marketing application, or essential to the continued marketing of an FDA-regulated product.

(d) If the Commissioner determines, after the unreliable data submitted by the investigator are eliminated from consideration, that the data remaining are inadequate to support a conclusion that it is reasonably safe to continue the investigation, the Commissioner will notify the sponsor who shall have an opportunity for a regulatory hearing under part 16 of this chapter. If a danger to the public health exists, however, the Commissioner shall terminate the IDE immediately and notify the sponsor and the reviewing IRB(s) of the termination. In such case, the sponsor shall have an opportunity for a regulatory hearing before FDA under part 16 of this chapter on the question of whether the IDE should be reinstated. The determination that an investigation may not be considered in support of a research or marketing application or a notification or petition submission does not, however, relieve the sponsor of any obligation under any other applicable regulation to submit to FDA the results of the investigation.

(e) If the Commissioner determines, after the unreliable data submitted by the investigator are eliminated from consideration, that the continued clearance or approval of the product for which the data were submitted cannot be justified, the Commissioner will proceed to rescind clearance or withdraw approval of the product in accordance with the applicable provisions of the relevant statutes.

(f) An investigator who has been determined to be ineligible under paragraph (b) of this section may be reinstated as eligible when the Commissioner determines that the

investigator has presented adequate assurances that the investigator will employ all test articles, and will conduct any clinical investigation that supports an application for a research or marketing permit for products regulated by FDA, solely in compliance with the applicable provisions of this chapter.

Dated: April 7, 2011.

David Dorsey,

Acting Deputy Commissioner for Policy, Planning and Budget.

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

21 CFR Chapter I

[Docket No. FDA–2011–N–0251]

FDA Food Safety Modernization Act: Focus on Preventive Controls for Facilities; Public Meeting

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice of public meeting; request for comment.

SUMMARY: The Food and Drug Administration (FDA) is announcing a public meeting entitled "FDA Food Safety Modernization Act: Focus on Preventive Controls for Facilities." The purpose of the public meeting is to provide interested persons an opportunity to discuss implementation of the preventive controls for facilities provisions of the recently enacted FDA Food Safety Modernization Act (FSMA). FDA is seeking information on preventive controls used by facilities to identify and address hazards associated with specific types of food and specific processes. The public will have an opportunity to provide information and share views that will inform the development of guidance and regulations on preventive controls for food facilities that manufacture, process, pack or hold human food or animal food and feed (including pet food).

DATES: See "How to Participate in the Meeting" in the **SUPPLEMENTARY INFORMATION** section of this document.

FOR FURTHER INFORMATION CONTACT: Patricia M. Kuntze, Office of External Affairs, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 32, rm. 5322, Silver Spring, MD 20993, 301–796–8641, *Patricia.Kuntze@fda.hhs.gov.*

SUPPLEMENTARY INFORMATION:

I. Background

FSMA (Pub. L. 111–353) amends the Federal Food, Drug, and Cosmetic Act (the FD&C Act) to establish the foundation for a modernized, prevention-based food safety system and gives FDA for the first time a legislative mandate to require comprehensive, science-based preventive controls across the food supply.

In particular, section 103 of FSMA requires the owner, operator, or agent in charge of a facility that is required to register under section 415 of the FD&C Act (21 U.S.C. 350d) to take certain preventive actions, including to evaluate the hazards that could affect food manufactured, processed, packed, or held by the facility, and to identify and implement preventive controls to significantly minimize or prevent the occurrence of such hazards. FDA is required to develop regulations to establish science-based standards for conducting a hazard analysis, documenting hazards, implementing preventive controls, and documenting their implementation.

In addition, FDA is required to issue guidance with respect to hazard analysis and preventive controls. Given the diversity of registered facilities and regulated foods, FDA will use the guidance to assist the food and feed industries in complying with the preventive controls regulations, when they are finalized. FDA will leverage, where appropriate, best practices for hazards and controls identified by industry for specific types of food and feed and specific methods in manufacturing, processing, packing, and holding food and feed. FDA is interested in making appropriate best practices publicly available. FDA is particularly interested in preventive control practices that are applicable and practical for small and very small businesses to implement.

II. Purpose and Format of the Meeting

If you wish to attend and/or present at the meeting scheduled for April 20, 2011, please register by e-mail at *http://www.blsmeetings.net/FDAPreventiveControls* by April 15, 2011. FDA is holding the public meeting on section 103 of FSMA to receive input from the public to inform the development of the regulations and guidance identified previously in this document. FDA will also consider input it has received previously through its engagement of stakeholders as part of the process to examine and update current good manufacturing practice requirements and to develop an animal feed safety system.

In general, the meeting format will include introductory presentations by FDA. Listening to our stakeholders is the primary purpose of this meeting. In order to meet this goal, FDA will provide multiple opportunities for individuals to actively express their views by making presentations at the meeting, participating in a total of three 75-minute break-out sessions on the provisions discussed at the meeting, and submitting written comments to the docket within 30 days after this meeting. (Participants can select up to three of the following five break-out sessions: Preventive Controls Guidance, On-Farm Manufacturing and Small Business, Product Testing and Environmental Monitoring, Training and Technical Assistance, and Preventive Controls and the Relationship to cGMPs.) There will be an interactive Webcast; see section III of this document, "How to Participate in the Meeting." In order to provide Webcast participants with information before and after the meeting, we request attendees provide their name, their affiliation, and email when registering.

III. How To Participate in the Meeting

Stakeholders will have an opportunity to provide oral comments. Due to limited space and time, FDA encourages all persons who wish to attend the meeting, including those requesting an opportunity to make an oral presentation during the time allotted for public comment at the meeting, to register in advance and to provide the specific topic or issue to be addressed and the approximate desired length of their presentation. Depending on the number of requests for such oral presentations, there may be a need to limit the time of each oral presentation (*e.g.,* 3 minutes each). If time permits, individuals or organizations that did not register in advance may be granted the opportunity for such an oral presentation. FDA would like to maximize the number of stakeholders who make a presentation at the meeting and will do our best to accommodate all persons who wish to make a presentation or express their views at the meeting. FDA anticipates that there will be several opportunities to speak in break-out sessions and an interactive Webcast will also be available for stakeholders who are not onsite.

FDA encourages persons and groups who have similar interests to consolidate their information for presentation through a single representative. After reviewing the presentation requests, FDA will notify each participant before the meeting of the amount of time available and the