List of Subjects in 14 CFR Part 23

Aircraft, Aviation safety, Signs and symbols.

■ The authority citation for these special conditions is as follows:

Authority: 49 U.S.C. 106(g), 40113, 44701, 44702, 44704.

The Proposed Special Conditions

■ Accordingly, the Federal Aviation Administration (FAA) proposes the following special conditions as part of the type certification basis for Pilatus Aircraft, Ltd., Model PC–12, PC–12/45, and PC–12/47 airplanes modified by Finnoff Aviation.

1. Installation of Lithium Batteries must show compliance to the following requirements:

(1) Safe cell temperatures and pressures must be maintained during—

i. Normal operations;

ii. Any probable failure conditions of charging or discharging or battery monitoring system;

iii. Any failure of the charging or battery monitoring system not shown to be extremely remote.

(2) The rechargeable lithium battery installation must be designed to preclude explosion or fire in the event of (1)(ii) and (1)(iii) failures.

(3) Design of the rechargeable lithium batteries must preclude the occurrence of self-sustaining, uncontrolled increases in temperature or pressure.

(4) No explosive or toxic gasses emitted by any rechargeable lithium battery in normal operation or as the result of any failure of the battery charging system, monitoring system, or battery installation which is not shown to be extremely remote, may accumulate in hazardous quantities within the airplane.

(5) Installations of rechargeable lithium batteries must meet the requirements of § 23.863(a) through (d) at amendment 23–34.

(6) No corrosive fluids or gases that may escape from any rechargeable lithium battery may damage surrounding structure or any adjacent systems, equipment, electrical wiring, or the airplane in such a way as to cause a major or more severe failure condition, in accordance with § 23.1309(c) at amendment 23–62 and applicable regulatory guidance.

(7) Each rechargeable lithium battery installation must have provisions to prevent any hazardous effect on structure or essential systems that may be caused by the maximum amount of heat the battery can generate during a short circuit of the battery or of its individual cells.

(8) Rechargeable lithium battery installations must have—

i. A system to automatically control the charging rate of the battery to prevent battery overheating and overcharging, or;

ii. A battery temperature sensing and over-temperature warning system with a means for automatically disconnecting the battery from its charging source in the event of an over-temperature condition, or;

iii. A battery failure sensing and warning system with a means for automatically disconnecting the battery from its charging source in the event of battery failure.

(9) Any rechargeable lithium battery installation functionally required for safe operation of the airplane must incorporate a monitoring and warning feature that will provide an indication to the appropriate flight crewmembers whenever the State of Charge (SOC) of the batteries has fallen below levels considered acceptable for dispatch of the airplane.

(10) The Instructions for Continued Airworthiness required by § 23.1529 at amendment 23–26 must contain maintenance requirements to assure that the battery has been sufficiently charged at appropriate intervals specified by the battery manufacturer and the equipment manufacturer that contain the rechargeable lithium battery or rechargeable lithium battery system. This is required to ensure that lithium rechargeable batteries and lithium rechargeable battery systems will not degrade below specified ampere-hour levels sufficient to power the aircraft system. The Instructions for Continued Airworthiness must also contain procedures for the maintenance of replacement batteries in spares storage to prevent the installation of batteries that have degraded charge retention ability or other damage due to prolonged storage at a low state of charge. Replacement batteries must be of the same manufacturer and part number as approved by the FAA.

Note 2: The term ''sufficiently charged'' means that the battery will retain enough of a charge, expressed in ampere-hours, to ensure that the battery cells will not be damaged. A battery cell may be damaged by lowering the charge below a point where there is a reduction in the ability to charge and retain a full charge. This reduction would be greater than the reduction that may result from normal operational degradation.

(11) In showing compliance with the proposed special conditions herein, paragraphs (1) through (8), and the RTCA document, Minimum Operational Performance Standards for Rechargeable Lithium Battery Systems, DO–311, may be used. The list of planned DO–311 tests should be documented in the certification or compliance plan and agreed to by the Denver ACO. Alternate methods of compliance other than DO–311 tests must be coordinated with the directorate and Denver ACO.

Issued in Kansas City, Missouri, on August 18, 2016.

Pat Mullen,

Acting Manager, Small Airplane Directorate, Aircraft Certification Service.

[FR Doc. 2016–20273 Filed 8–23–16; 8:45 am]

BILLING CODE 4910–13–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

21 CFR Parts 16 and 511

[Docket No. FDA–2011–N–0079]

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 for new animal drugs for investigational use to expand the scope of clinical investigator disqualification to include ineligibility to conduct nonclinical laboratory studies. Currently, when the Commissioner of Food and Drugs (the Commissioner) determines that an investigator is ineligible to receive a new animal drug for investigational use, the investigator also is ineligible to conduct any clinical investigation that supports an application for a research or marketing permit for products regulated by FDA. Under this proposal, when the Commissioner determines that an investigator is ineligible to receive a new animal drug for investigational use, the investigator also will be ineligible to conduct any nonclinical study intended to support an application for a research or marketing permit for a new animal drug. This proposal is intended to help ensure adequate protection of animal research subjects and the quality and integrity of data submitted to FDA.

DATES: Submit either electronic or written comments on the proposed rule by November 22, 2016. See section VII of this document for the proposed effective date of a final rule based on this document.

ADDRESSES: You may submit comments as follows:

Electronic Submissions

Submit electronic comments in the following way:

• *Federal eRulemaking Portal: http://www.regulations.gov.* Follow the

instructions for submitting comments. Comments submitted electronically, including attachments, to *http://www.regulations.gov* will be posted to the docket unchanged. Because your comment will be made public, you are solely responsible for ensuring that your comment does not include any confidential information that you or a third party may not wish to be posted, such as medical information, your or anyone else's Social Security number, or confidential business information, such as a manufacturing process. Please note that if you include your name, contact information, or other information that identifies you in the body of your comments, that information will be posted on *http://www.regulations.gov.*

• If you want to submit a comment with confidential information that you do not wish to be made available to the public, submit the comment as a written/paper submission and in the manner detailed (see ''Written/Paper Submissions'' and ''Instructions'').

Written/Paper Submissions

Submit written/paper submissions as follows:

• *Mail/Hand delivery/Courier (for written/paper submissions):* Division of Dockets Management (HFA–305), Food and Drug Administration, 5630 Fishers Lane, Rm. 1061, Rockville, MD 20852.

• For written/paper comments submitted to the Division of Dockets Management, FDA will post your comment, as well as any attachments, except for information submitted, marked and identified, as confidential, if submitted as detailed in ''Instructions.''

Instructions: All submissions received must include the Docket No. FDA–2011–N–0079 for ''Disqualification of a Clinical Investigator.'' Received comments will be placed in the docket and, except for those submitted as ''Confidential Submissions,'' publicly viewable at *http://www.regulations.gov* or at the Division of Dockets Management between 9 a.m. and 4 p.m., Monday through Friday.

• *Confidential Submissions*—To submit a comment with confidential information that you do not wish to be made publicly available, submit your comments only as a written/paper submission. You should submit two copies total. One copy will include the information you claim to be confidential with a heading or cover note that states ''THIS DOCUMENT CONTAINS CONFIDENTIAL INFORMATION.'' The Agency will review this copy, including the claimed confidential information, in its consideration of comments. The second copy, which will have the claimed confidential information redacted/blacked out, will be available for public viewing and posted on *http://www.regulations.gov.* Submit both copies to the Division of Dockets Management. If you do not wish your name and contact information to be made publicly available, you can provide this information on the cover sheet and not in the body of your comments and you must identify this information as ''confidential.'' Any information marked as ''confidential'' will not be disclosed except in accordance with 21 CFR 10.20 and other applicable disclosure law. For more information about FDA's posting of comments to public dockets, see 80 FR 56469, September 18, 2015, or access the information at: *http://www.fda.gov/regulatoryinformation/dockets/default.htm.*

Docket: For access to the docket to read background documents or the electronic and written/paper 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.

Submit written requests for single copies of the guidance to the Policy and Regulations Staff (HFV–6), Center for Veterinary Medicine, Food and Drug Administration, 7519 Standish Pl., Rockville, MD 20855. Send one self-addressed adhesive label to assist that office in processing your requests. See the **SUPPLEMENTARY INFORMATION** section for electronic access to the guidance document.

FOR FURTHER INFORMATION CONTACT: Vernon Toelle, Center for Veterinary Medicine (HFV–230), 7519 Standish Pl., Rockville, MD 20855, 240–402–5637.

SUPPLEMENTARY INFORMATION:

I. Introduction

The current regulations in part 511 (21 CFR part 511) prohibit a disqualified clinical investigator from conducting any clinical investigation that supports an application for a research or marketing permit for products regulated by FDA. We propose to expand the current clinical investigator disqualification regulations in part 511 by providing that a disqualified investigator also is ineligible to conduct any nonclinical laboratory study intended to support an application for a research or marketing permit for a new animal drug. In this document, consistent with our proposal in part 58 (21 CFR part 58) published elsewhere in this issue of the **Federal Register**, the term ''nonclinical laboratory study'' means in vivo or in vitro experiments in which test articles are studied prospectively in test systems under laboratory conditions or in the applicable environment to determine their safety or toxicity or both. The term does not include studies involving human subjects, clinical studies, or clinical investigational use in animals. The term does not include basic exploratory studies carried out to determine whether a test article has any potential utility or basic exploratory studies to determine the physical or chemical characteristics of a test article.

Under current § 511.1(c) (21 CFR 511.1(c)), a clinical investigator disqualified by the Commissioner is ineligible to receive the test article regulated in part 511 (*i.e.,* a new animal drug for investigational use). Also, under the current regulations in § 511.1(c), a disqualified clinical investigator is ineligible to conduct any clinical investigation that supports an application for a research or marketing permit for products regulated by FDA. However, under the current regulations, a disqualified clinical investigator continues to be eligible to conduct a nonclinical laboratory study intended to support an application for a research or marketing permit for a new animal drug.

In order to conclude that a clinical investigator is no longer eligible to receive new animal drugs for investigational use, the Commissioner must find that the investigator repeatedly or deliberately failed to comply with the conditions of the exempting regulations or repeatedly or deliberately submitted to FDA or to the sponsor false information in any required report (§ 511.1(c)(2)). When a clinical investigator is disqualified under part 511, the basis for disqualification typically is the repeated or deliberate submission of false information to FDA or a sponsor in a required report. For new animal drugs, the same clinical investigator could conduct both nonclinical laboratory studies and clinical investigations.

In the new animal drug approval process, nonclinical laboratory studies such as those for target animal safety and human food safety may be essential in determining whether to approve an application for a research or marketing permit for a new animal drug. Therefore, this proposal to expand § 511.1(c) to include nonclinical laboratory studies is intended to help ensure adequate protection of animal research subjects and the quality and integrity of data submitted to FDA for the approval of a new animal drug.

Consistent with the proposed changes to the provisions in part 511, we propose amending the list of regulatory provisions under which a part 16 (21 CFR part 16) informal regulatory hearing is available. In part 16, we propose changing the scope of the relevant provision for part 511 to add ''any nonclinical laboratory study intended to support an application for a research or marketing permit for a new animal drug.''

Concurrent with this proposal, FDA is publishing elsewhere in this issue of the **Federal Register** a related provision in part 58. We propose in § 58.206 (21 CFR 58.206) that a disqualified person under part 58, who is a clinical investigator, would be notified that they are ineligible to receive a test article under part 511. Thus, where this part 511 proposal would make a disqualified clinical investigator ineligible to conduct any nonclinical laboratory study intended to support an application for a research or marketing permit for a new animal drug, the proposal in § 58.206 would make a disqualified person under part 58, who is a clinical investigator, ineligible to receive a test article under part 511. An investigator ineligible to receive a test article under part 511 also would be ineligible to conduct any nonclinical laboratory study intended to support an application for a research or marketing permit for a new animal drug. We propose this action in § 58.206 to help protect the safety and welfare of animal research subjects involved in FDA-regulated nonclinical laboratory studies and clinical investigations, and to help ensure the reliability and integrity of the data submitted to FDA to support FDA decisions concerning new animal drugs.

II. Background

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 (*e.g.,* new animal drug for investigational use) under study by the investigator in the clinical investigation. For example, the Center for Veterinary Medicine (CVM) may pursue disqualification of a clinical investigator who conducted a new animal drug clinical investigation and allegedly submitted to FDA or the sponsor false information in a required report.

The regulations provide the investigator, who is subject to disqualification, an opportunity to be heard and explain the matter complained of, *i.e.,* explain the alleged violations. 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. 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 (*e.g.,* a new animal drug for investigational use). When disqualified by a Commissioner's decision, the investigator is no longer eligible to receive the particular type of test article under study when the violations occurred (*e.g.,* new animal drugs). Also, under current regulations, an investigator disqualified by a Commissioner's decision is ineligible to conduct any clinical investigation that supports an application for a research or marketing permit for products regulated by FDA.

Because CVM regulates drugs for animal use, the study subjects are animals in both nonclinical laboratory studies and clinical investigations intended to support the approval of a new animal drug. Nonclinical laboratory studies such as those for target animal safety and human food safety may be essential in determining whether to approve an application for a research or marketing permit for a new animal drug. For animal drug products regulated by CVM, the same investigator may conduct both nonclinical laboratory studies and clinical investigations. For example, CVM's two most recent clinical investigator disqualification matters involved investigators who were also study directors on nonclinical laboratory studies submitted to CVM in support of applications for a new animal drug. In addition, CVM is aware of multiple persons that conduct both clinical investigations and nonclinical laboratory studies intended to support an application for a research or marketing permit for a new animal drug. Therefore, it is critical for CVM to have the authority to disqualify an investigator from conducting nonclinical laboratory studies when that same investigator is disqualified from conducting clinical investigations, particularly when the basis for disqualification is the repeated or deliberate submission of false information to FDA or the sponsor in a required report.

This proposal to amend part 511 to expand a disqualified investigator's ineligibility to conduct any nonclinical laboratory study intended to support an application for a research or marketing permit for a new animal drug would help to ensure adequate protection of animal research subjects and data integrity. This action also may lead to improved public confidence in the nonclinical and clinical data supporting FDA decisions for new animal drug approvals.

We therefore propose that when the Commissioner determines that a clinical investigator is ineligible to receive the test article under the disqualification regulations in part 511 and is therefore ineligible to conduct any clinical investigation that supports an application for a research or marketing permit for products regulated by FDA, the investigator also would be ineligible to conduct any nonclinical laboratory study intended to support an application for a research or marketing permit for a new animal drug.

To effect this change, FDA proposes to amend the current regulations in § 511.1(c).

III. Description of the Proposed Rule

A. Disqualification Proceedings (§ 511.1(c)(1))

Proposed Revisions to § 511.1(c)(1): 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, also to include whether the investigator is eligible to conduct any nonclinical laboratory study that is intended to support an application for a research or marketing permit for a new animal drug.

B. Ineligibility To Receive Any Test Article (§ 511.1(c)(2))

Proposed Revisions to § 511.1(c)(2): We propose that an investigator disqualified by a Commissioner's decision also will be ineligible to conduct any nonclinical laboratory study that is intended to support an application for a research or marketing permit for a new animal drug.

Therefore, as proposed, an investigator determined to be ineligible to receive a test article under part 511 also would be ineligible to conduct any nonclinical laboratory study intended to support an application for a research or marketing permit for a new animal drug. This proposal expands the scope of the current regulations in § 511.1(c)(2) which states that a disqualified clinical investigator is 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. Reinstatement (§ 511.1(c)(6))

FDA proposes amending § 511.1(c)(6) for consistency with our proposal to add ''any nonclinical laboratory study intended to support an application for a research or marketing permit for a new animal drug'' to the part 511 investigator disqualification regulations. Therefore, for consistency with the proposed changes in § 511.1(c)(2), we propose adding in § 511.1(c)(6) that the investigator has presented adequate assurances that the investigator will conduct any nonclinical laboratory study intended to support an application for a research or marketing permit for a new animal drug solely in compliance with the applicable provisions of chapter I.

IV. Regulatory Hearing before the Food and Drug Administration

We propose to revise § 16.1(b)(2) to amend the entry for § 511.1(c)(1) to add ''any nonclinical laboratory study intended to support an application for a research or marketing permit for a new animal drug'' to be consistent with the other proposed amendments in this rulemaking.

V. Environmental Impact

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

VI. Legal Authority

Under section 701(a) of the FD&C Act (21 U.S.C. 371(a)), FDA is authorized to issue regulations for the efficient enforcement of the FD&C Act. Section 512(j) of the FD&C Act (21 U.S.C. 355(j)) authorizes FDA to issue regulations for exempting from the operation of section 512 of the FD&C Act new animal drugs intended solely for investigational use by experts qualified by scientific training and experience to investigate the safety and effectiveness of animal drugs. An investigator who repeatedly or deliberately violates the regulations or who repeatedly or deliberately submits to FDA or the sponsor false information in a required report would not be considered a qualified expert with the experience required to conduct nonclinical laboratory studies intended to support an application for a research or marketing permit for a new animal drug. This proposed rulemaking would disqualify a clinical investigator from conducting nonclinical laboratory studies intended to support an application for a research or marketing permit for a new animal drug when the Commissioner determines that a clinical investigator is ineligible to receive the test article under the disqualification regulations in part 511. FDA's legal authority to promulgate this proposal regarding clinical investigators exists under sections 512(j) 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 201, 501, 502, 503, 512, and 701 of the FD&C Act (21 U.S.C. 321, 351, 352, 353, 360b, and 371).

VII. Proposed Effective Date

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. Preliminary Economic Analysis

FDA has examined the impacts of the proposed rule under Executive Order 12866, Executive Order 13563, the Regulatory Flexibility Act (5 U.S.C. 601–612), and the Unfunded Mandates Reform Act of 1995 (Pub. L. 104–4). Executive Orders 12866 and 13563 direct 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 Executive Order 12866.

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 $144 million, using the most current (2014) 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.

This proposed rule seeks to expand the scope in part 511 of disqualification of a clinical investigator to include ineligibility to conduct nonclinical laboratory studies. A final rule (77 FR 25353), published on April 30, 2012, prevents a disqualified investigator from conducting any clinical investigation, and therefore applies explicitly to clinical investigations. However, the rule is silent on nonclinical laboratory studies. Thus, under the current regulation in part 511, a disqualified investigator could conduct a nonclinical laboratory study intended to support an application for a research or marketing permit for a new animal drug. Because the reason typically for disqualification in part 511 is the repeated or deliberate submission of false information to FDA or a sponsor in a required report, preventing a disqualified clinical investigator from performing both nonclinical laboratory studies and clinical investigations is essential to adequate protection of animal research subjects and data integrity.

The Agency would not incur additional costs by expanding the scope in part 511 for disqualification of a clinical investigator. Similarly, we do not expect that industry would incur additional costs because the proposed rule would not require sponsors to perform additional tasks. For instance, upon disqualification, the respective investigator's name is posted on FDA's Web page, and this helps mitigate the employment of the investigator for clinical investigations or nonclinical laboratory studies intended to support an application for a research or marketing permit for a new animal drug. Because the typical reason for disqualification in part 511 is the repeated or deliberate submission of false information to FDA or a sponsor in a required report, the benefit of preventing a disqualified clinical investigator from performing both nonclinical laboratory studies and clinical investigations is enhanced protection of animal research subjects and data integrity.

IX. Paperwork Reduction Act

FDA tentatively concludes that this proposed rule contains no collection of information. Therefore, clearance by OMB under the Paperwork Reduction Act of 1995 is not required.

X. Federalism

We have analyzed this proposed rule in accordance with the principles set forth in Executive Order 13132. We have 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.

List of Subjects

21 CFR Part 16

Administrative practice and procedure.

21 CFR Part 511

Animal drugs, 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 parts 16 and 511 be amended as follows:

PART 16—REGULATORY HEARING BEFORE THE FOOD AND DRUG ADMINISTRATION

■ 1. The authority citation for 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. In § 16.1, in paragraph (b)(2), revise the numerically sequenced entry for § 511.1(c)(1) to read as follows:

§ 16.1 Scope.

* * * * *

(b) * * *

(2) * * *

§ 511.1(c)(1), relating to whether an investigator is eligible to receive test articles under part 511 and eligible to conduct:

(i) 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; and

(ii) Any nonclinical laboratory study intended to support an application for a research or marketing permit for a new animal drug.

* * * * *

PART 511—NEW ANIMAL DRUGS FOR INVESTIGATIONAL USE

■ 3. The authority citation for part 511 continues to read as follows:

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

■ 4. In § 511.1, revise the section heading, the last sentences in paragraphs (c)(1) and (2), and revise paragraph (c)(6) to read as follows:

§ 511.1 New animal drugs for investigational use exempt from section 512(a) of the Federal Food, Drug, and Cosmetic Act.

* * * * *

(c) * * *

(1) * * * 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:

(i) Any clinical investigation that supports an application for a research or marketing permit for products regulated by FDA; and

(ii) Any nonclinical laboratory study intended to support an application for a research or marketing permit for a new animal drug.

(2) * * * The notification also will explain that an investigator determined to be ineligible to receive a test article under this part will be ineligible to conduct

(i) 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, and

(ii) Any nonclinical laboratory study intended to support an application for a research or marketing permit for a new animal drug.

* * * * *

(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 and any nonclinical laboratory study intended to support an application for a research or marketing permit for a new animal drug, solely in compliance with the applicable provisions of this chapter.

* * * * *

Dated: August 16, 2016.

Peter Lurie,

Associate Commissioner for Public Health Strategy and Analysis.

[FR Doc. 2016–19876 Filed 8–23–16; 8:45 am]

BILLING CODE 4164–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

21 CFR Part 117

[Docket No. FDA–2016–D–2343]

Hazard Analysis and Risk-Based Preventive Controls for Human Food; Draft Guidance for Industry; Availability

AGENCY: Food and Drug Administration, HHS.

ACTION: Notification of availability.

SUMMARY: The Food and Drug Administration (FDA, we, or Agency) is announcing the availability of a draft guidance for industry entitled ''Hazard Analysis and Risk-Based Preventive Controls for Human Food: Guidance for Industry.'' This draft guidance document includes several chapters of a multi-chapter guidance intended to explain our current thinking on how to comply with the requirements for hazard analysis and risk-based preventive controls under our rule entitled ''Current Good Manufacturing Practice, Hazard Analysis, and Risk-Based Preventive Controls for Human Food.''

DATES: Although you can comment on any guidance at any time (see 21 CFR 10.115(g)(5)), to ensure that we consider your comment on this draft guidance before we issue the final version of the guidance, submit either electronic or written comments on the draft guidance by February 21, 2017.

ADDRESSES: You may submit comments as follows: