Dated: January 9, 2009.

Jeffrey Shuren,

Associate Commissioner for Policy and Planning.

[FR Doc. E9–837 Filed 1–15–09; 8:45 am]

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2008–D–0394]

Guidance for Industry on Regulation of Genetically Engineered Animals Containing Heritable recombinant DNA Constructs; Availability

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA or the agency) is announcing the availability of a guidance for industry #187 entitled ''Regulation of Genetically Engineered Animals Containing Heritable recombinant DNA Constructs.'' This guidance is intended to clarify FDA's requirements and recommendations for producers and developers of genetically engineered (GE) animals and their products. The guidance describes how the new animal drug provisions of the Federal Food, Drug, and Cosmetic Act (the act) apply with respect to GE animals, including FDA's intent to exercise enforcement discretion regarding requirements for certain GE animals.

DATES: Submit written or electronic comments on agency guidances at any time.

ADDRESSES: Submit written requests for single copies of the guidance to the Communications Staff (HFV–12), 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. Submit written comments on the guidance to the Division of Dockets Management (HFA–305), Food and Drug Administration, 5630 Fishers Lane, rm. 1061, Rockville, MD 20852. Submit electronic comments to *http://www.regulations.gov*. See the **SUPPLEMENTARY INFORMATION** section for electronic access to the guidance document.

FOR FURTHER INFORMATION CONTACT: Larisa Rudenko, Center for Veterinary Medicine (HFV–100), Food and Drug Administration, 7500 Standish Pl., Rockville, MD 20855, 240–276–8247, e-mail: *larisa.rudenko@hhs.fda.gov.*

SUPPLEMENTARY INFORMATION:

I. Background

In the **Federal Register** of September 19, 2008 (73 FR 54407), FDA published the notice of availability for a draft guidance entitled ''Regulation of Genetically Engineered Animals Containing Heritable rDNA Constructs'' giving interested persons until November 18, 2008, to comment on the draft guidance. FDA received numerous comments on the draft guidance. FDA reviewed and considered all comments and, in response, made several changes. In response to requests for greater transparency, the agency clarified its intent to hold public advisory committee meetings for GE animal-related approvals and its intent to post statements of intent to exercise enforcement discretion over certain GE animals. In response to other comments, FDA clarified the scope of new animal drug application (NADA) approvals for GE animals and clarified its intent to work with other agencies should it receive a request for investigation or approval of a new animal drug in a GE wildlife animal ultimately intended for release into the wild.

The guidance announced in this notice finalizes the draft guidance dated September 19, 2008.

For the purpose of this guidance, FDA defines ''genetically engineered (GE) animals'' as those animals modified by recombinant DNA (rDNA) techniques, including progeny that contain the modification. The term GE animal can refer to both animals with heritable rDNA constructs and animals with non-heritable rDNA constructs (e.g., those modifications intended to be used as gene therapy). Although much of this guidance will be relevant to non-heritable rDNA constructs, and FDA intends to regulate non-heritable constructs in much the same way as described in this guidance for heritable constructs, this guidance only pertains to GE animals containing heritable rDNA constructs. We may issue a separate guidance on the regulation of GE animals bearing non-heritable constructs to discuss when those constructs would be under FDA jurisdiction and the kinds of information that would be relevant for FDA's review. In this guidance, we will use the term ''GE animal'' to refer to GE animals with heritable rDNA constructs. For ease of reference, we sometimes refer to regulation of the article (the rDNA construct) in such GE animals as regulation of the GE animal.

The Center for Veterinary Medicine (''CVM'', ''we'', ''us'', ''our'') has been working on applications submitted by developers of GE animals under the New Animal Drug provisions of the act (21 U.S.C. 321 *et seq.*). This guidance is intended to clarify these requirements and our recommendations for producers and developers (''sponsors,'' ''you'') of GE animals and their products. CVM will work closely with the other Centers at FDA that regulate pharmaceuticals or other medical products derived from biopharm animals to ensure that our oversight is complementary and not unnecessarily duplicative. Developers of GE animals should contact CVM early in the development of their GE animal; developers whose animals are already well under development also should contact CVM. We intend to issue additional guidance to describe more fully how various components of the New Animal Drug provisions of the act apply to biopharm animals and how CVM will implement them, the division of responsibilities between CVM and the other Centers regarding biopharm animals and products derived from them, and, more generally, how CVM and the other Centers will work interactively to regulate biopharm animals and their products. Developers of GE animals should come to CVM early in the process.

II. Significance of Guidance

This level 1 guidance is being issued consistent with FDA's good guidance practices regulation (21 CFR 10.115). The guidance represents the agency's current thinking on the topic. It does not create or confer any rights for or on any person and does not operate to bind FDA or the public. An alternative approach may be used if such approach satisfies the requirements of the applicable statutes and regulations.

III. Paperwork Reduction Act of 1995

This guidance refers to previously approved collections of information found in FDA regulations. These collections of information are subject to review by the Office of Management and Budget (OMB) under the Paperwork Reduction Act of 1995 (44 U.S.C. 3501–3520). The collections of information have been approved under OMB Control Nos. 0910–0032, 0910–0045, 0910–0117, and 0910–0284.

IV. Comments

Interested persons may submit to the Division of Dockets Management (see **ADDRESSES**) written or electronic comments regarding this document. Submit a single copy of electronic comments or two paper copies of any

mailed comments, except that individuals may submit one paper copy. Comments are to be identified with the docket number found in brackets in the heading of this document. Received comments may be seen in the Division of Dockets Management between 9 a.m. and 4 p.m., Monday through Friday. Submit electronic comments to *http://www.regulations.gov*.

V. Electronic Access

Persons with access to the Internet may obtain the guidance at either *http://www.fda.gov/cvm* or *http://www.regulations.gov*.

Dated: January 9, 2009.

Jeffrey Shuren,

Associate Commissioner for Policy and Planning.

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2008–D–0381]

Guidance for Industry on Voluntary Third-Party Certification Programs for Foods and Feeds; Availability

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is announcing the availability of a guidance for industry entitled ''Voluntary Third-Party Certification Programs for Foods and Feeds.'' This guidance describes the general attributes FDA believes a voluntary third-party certification program should have in order to help ensure its certification is a reliable reflection that the foods and feeds (hereinafter foods) from certified establishments meet applicable FDA requirements, as well as other certification criteria.

DATES: Submit written or electronic comments on agency guidance documents at any time.

ADDRESSES: Submit written requests for single copies of the guidance to the Office of Policy, Office of the Commissioner, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 1, rm. 4337, Silver Spring, MD 20993–0002. Send one self-addressed adhesive label to assist that office in processing your requests. The guidance can also be obtained by mail by calling 301–796–4840. Submit written comments on the guidance to the Division of Dockets Management (HFA–305), Food and Drug Administration, 5630 Fishers Lane, rm. 1061, Rockville, MD 20852. Submit electronic comments to *http://www.regulations.gov*. See the **SUPPLEMENTARY INFORMATION** section for electronic access to the guidance document.

FOR FURTHER INFORMATION CONTACT: Sharon Lindan Mayl, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 1, rm. 4337, Silver Spring, MD 20993–0002, 301–796–4840.

SUPPLEMENTARY INFORMATION:

I. Background

FDA is announcing the availability of a guidance for industry entitled ''Voluntary Third-Party Certification Programs for Foods and Feeds.'' This guidance represents FDA's current thinking on the certification process and describes the general attributes FDA believes a voluntary third-party certification program should have in order to provide FDA with confidence in its certification program. If FDA has such confidence, we may choose to recognize the program and provide incentives for establishments to obtain certification by recognized certification programs. Recognition in this context means that FDA has determined that certification may be a reliable reflection that the foods from an establishment certified by that certification body meet applicable FDA requirements, as well as other certification criteria.

This guidance is intended as one of the steps in FDA's future recognition of one or more voluntary third-party certification programs for particular product types. In the future, FDA (we) may issue guidance that addresses third-party certification programs in particular product areas.

This guidance is issued in response to the recommendations contained in the *Action Plan for Import Safety: A Roadmap for Continual Improvement* (Action Plan) issued on November 6, 2007, by the Interagency Working Group on Import Safety (Working Group) established by Executive Order 13439, as well as FDA's Food Protection Plan released on the same date. Both those plans emphasize certification as a way to improve our capacity to verify the safety of products from a growing food establishment inventory, both domestic and foreign.

In the **Federal Register** of April 2, 2008 (73 FR 17989), FDA issued a document requesting comments on the use of third-party certification programs for foods and animal feeds. FDA received approximately 70 comments in response to that document. The comments were generally supportive of the use of third-party certification programs. Many encouraged FDA to recognize such programs as a way to increase participation and improve the safety and security of foods.

On July 10, 2008, we announced the availability of a draft guidance for industry entitled ''Voluntary Third-Party Certification Programs for Foods and Feeds'' (73 FR 39704). In response to the draft guidance, we received 19 comments from a variety of sources, including trade associations, individual companies, standards development organizations, and other domestic and foreign Government agencies. These comments were considered as the guidance was finalized.

Also on July 10, 2008, FDA issued a document announcing a pilot on Voluntary Third-Party Certification Programs for Imported Aquacultured Shrimp (73 FR 39705). We are currently in Phase II of the pilot in which we will conduct onsite audits of selected third-party certification bodies and targeted sampling of imported shrimp products. The goal of the pilot is to gather technical and operational information that will assist FDA in determining its infrastructure needs, as well as the process for evaluating third-party certification programs. Based on our experience with the pilot, we may make additional changes to the guidance being announced in this document.

The guidance makes several changes from the draft guidance. For example, the section on verification that the establishment meets certification criteria no longer includes detailed criteria on specific safety and security systems. Instead, the guidance only recommends that the audit provide the certification body with reasonable assurance that the food or feed is safe and in compliance with certification criteria, which should include FDA requirements. As FDA recognizes third-party certification programs in particular product areas, FDA plans to provide additional guidance on specific certification criteria for those product areas.

In order to help minimize confusion, the guidance uses terminology that is generally consistent with accepted international definitions, such as those used in documents by the International Organization for Standardization (ISO) and the Codex Alimentarius Commission (Codex). There may be some divergence, however, when uses of the terms by these organizations are inconsistent or when use of the internationally accepted terminology