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.

[FR Doc. E9–862 Filed 1–15–09; 8:45 am]

BILLING CODE 4160–01–S

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

would not make sense in a particular context.

The guidance states that a certification body should immediately notify FDA and the establishment it is certifying if an auditor finds or discovers a situation in which there is a reasonable probability that the food or feed from the audited establishment will cause serious adverse health consequences or death to humans or animals. We believe that such reporting is appropriate. Although the certification body is not a regulatory entity, we believe it would help protect public health for such circumstances to be reported to FDA so that we can investigate the situation. The guidance also notes that an establishment that receives this information may be subject to the requirement imposed by section 1005 of the Food and Drug Administration Amendments Act of 2007 to report certain information to FDA via an electronic portal.

The guidance states that while FDA may provide incentives for participation, neither establishments nor certifying bodies are under an obligation to participate. FDA does not intend to target uncertified establishments or products for inspection or sampling, for example, based solely on their lack of certification.

One comment raised a concern regarding the ability of a foreign Government to serve as a certification body. As in the draft guidance, the guidance states that foreign Governments may be certification bodies. More specifically, the definition of certification body states that it could be a Federal, State, local, or foreign Government agency, as well as a non-Government entity that is independent of the businesses it certifies and free from conflicts of interest.

This 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 voluntary third-party certification programs for foods and feeds. 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.

II. Comments

Interested persons may submit to the Division of Dockets Management (see **ADDRESSES**) written or electronic comments regarding the guidance. 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 the brackets in the heading of this document. A copy of the guidance and received comments are available for public examination in the Division of Dockets Management between 9 a.m. and 4 p.m., Monday through Friday.

Please note that on January 15, 2008, the FDA Division of Dockets Management Web site transitioned to the Federal Dockets Management System (FDMS). FDMS is a Government-wide, electronic docket management system. Electronic comments or submissions will be accepted by FDA only through FDMS at*http://www.regulations.gov*.

III. Electronic Access

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

Dated: January 12, 2009.

Jeffrey Shuren,

Associate Commissioner for Policy and Planning.

[FR Doc. E9–861 Filed 1–15–09; 8:45 am]

BILLING CODE 4160–01–S

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2007–D–0371 (formerly Docket No. 2007D–0125)]

Guidance for Industry: Evidence-Based Review System for the Scientific Evaluation of Health Claims

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is announcing the availability of a guidance document entitled ''Guidance for Industry: Evidence-Based Review System for the Scientific Evaluation of Health Claims.'' This guidance outlines the agency's approach to the review of the scientific evidence for health claims that meet the significant scientific agreement standard (SSA) and qualified health claims. Elsewhere in this issue of the **Federal Register**, FDA is announcing the withdrawal of the guidance documents entitled ''Guidance for Industry and FDA: Interim Evidence-Based Ranking System for Scientific Data'' and ''Guidance for Industry: Significant Scientific Agreement in the Review of Health Claims for Conventional Foods and Dietary Supplements.''

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

ADDRESSES: Submit written requests for single copies of the guidance to the Office of Nutrition, Labeling, and Dietary Supplements, Center for Food Safety and Applied Nutrition, (HFS–830), Food and Drug Administration, 5100 Paint Branch Pkwy., College Park, MD 20740. Send two self-addressed adhesive labels 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 on the guidance to *http://www.regulations.gov*. See the **SUPPLEMENTARY INFORMATION** section for electronic access to the guidance.

FOR FURTHER INFORMATION CONTACT: Paula R. Trumbo, Center for Food Safety and Applied Nutrition (HFS–830), Food and Drug Administration, 5100 Paint Branch Pkwy., College Park, MD 20740, 301–436–1191.

SUPPLEMENTARY INFORMATION:

I. Background

In the **Federal Register** of July 9, 2007 (72 FR 37246), FDA announced the availability of a draft guidance entitled ''Guidance for Industry: Evidence-Based Review System for the Scientific Evaluation of Health Claims.'' The agency considered received comments as it finalized this guidance. The primary purpose of this guidance is to provide a description of the scientific evaluation process that FDA uses in determining the strength of the relationship of a substance to decreasing the risk of a disease or health-related condition.

FDA is issuing this guidance document as a level 1 guidance consistent with FDA's good guidance practices regulation (21 CFR 10.115). This guidance represents the agency's current thinking on the evaluation of scientific evidence for health claims. It does not create or confer any rights for or on any person and does not operate to bind FDA or the public. An alternate approach may be used if such approach satisfies the requirements of the applicable statutes and regulations.

II. 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