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 As in the draft guidance, the guidance states that foreign Governments may be certification bodies.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

Budget (OMB) under the Paperwork Reduction Act of 1995 (44 U.S.C. 3501–3520). The collections of information in 21 CFR 101.14 and 101.70 have been approved under OMB control no. 0910–0381.

III. 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.

IV. Electronic Access

Persons with access to the Internet may obtain the guidance at *http://www.cfsan.fda.gov/guidance.html*.

V. References

The following references have been placed on display in the Division of Dockets Management (see **ADDRESSES**) and may be seen by interested persons between 9 a.m. and 4 p.m., Monday through Friday. (FDA has verified the Web site address, but FDA is not responsible for any subsequent changes to this Web site after this document publishes in the **Federal Register**.)

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6. Flegal K.M., ''Evaluating Epidemiological Evidence of the Effects of Food and Nutrient Exposures,'' *American Journal of Clinical Nutrition*, 69:1339S–1344S, 1999.

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9. Hord N.G. and J.I. Fenton, ''Context is Everything: Mining the Normal and Preneoplastic Microenvironment for Insights Into the Diet and Cancer Risk Conundrum,'' *Molecular Nutrition and Food Research*, 51:100–106, 2007.

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Dated: January 13, 2009.

Jeffrey Shuren,

Associate Commissioner for Policy and Planning.

[FR Doc. E9–957 Filed 1–15–09; 8:45 am]

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–1999–D–0170] (formerly Docket No. 1999D–5424)

Guidance for Industry: Significant Scientific Agreement in the Review of Health Claims for Conventional Foods and Dietary Supplements; Withdrawal of Guidance

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice; withdrawal.

SUMMARY: The Food and Drug Administration (FDA) is announcing the withdrawal of a guidance entitled ''Guidance for Industry: Significant Scientific Agreement in the Review of Health Claims for Conventional Foods and Dietary Supplements,'' that was issued December 1999.

DATES: The withdrawal is effective January 16, 2009.

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, 301–436–2579.

SUPPLEMENTARY INFORMATION: In a notice published in the **Federal Register** of December 22, 1999 (64 FR 71794), FDA announced the availability of a guidance entitled ''Guidance for Industry: Significant Scientific Agreement in the Review of Health Claims for Conventional Foods and Dietary Supplements.'' This guidance is being withdrawn because it is obsolete.

Dated: January 13, 2009.

Jeffrey Shuren,

Associate Commissioner for Policy and Planning.

[FR Doc. E9–964 Filed 1–15–09; 8:45 am]

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2003–N–0103] (formerly Docket No. 2003N–0069)

Release of Task Force Report; Guidance for Industry and FDA: Interim Evidence-Based Ranking System for Scientific Data; Withdrawal of Guidance

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice; withdrawal.