

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

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Center	D. Hawkins

Guidance for Industry: Preparing a Claim of Categorical Exclusion or an Environmental Assessment for Submission to the Center for Food Safety and Applied Nutrition; Availability

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: Preparing a Claim of Categorical Exclusion or an Environmental Assessment for Submission to the Center for Food Safety and Applied Nutrition" (the guidance). This guidance provides information to industry on how to prepare a claim of categorical exclusion or an environmental assessment (EA) for submission to the Center for Food Safety and Applied Nutrition (CFSAN) in notifications for food contact substances, food additive petitions, color additive petitions, requests for exemption from regulation as a food additive, generally recognized as safe (GRAS) petitions, and petitions for certain food labeling regulations.

DATES: This guidance document is final upon the date of publication. Submit written or electronic comments concerning this guidance document at any time.

ADDRESSES: Submit written requests for single copies of the guidance document to the Office of Food Additive Safety (HFS-265), Center for Food Safety and

Applied Nutrition, Food and Drug Administration, 5100 Paint Branch Pkwy., College Park, MD 20740. Include a self-addressed adhesive label to assist that office in processing your request. 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.fda.gov/dockets/ecomments>. To ensure a timelier processing of comments, FDA is no longer accepting comments submitted to the agency by e-mail. See the **SUPPLEMENTARY INFORMATION** section for electronic access to the guidance document.

FOR FURTHER INFORMATION CONTACT: Layla I. Batarseh, Center for Food Safety and Applied Nutrition (HFS-246), 5100 Paint Branch Pkwy., College Park, MD, 20740-3835, 301-436-1296, FAX 301-436-2973, or e-mail:

layla.batarseh@fda.hhs.gov.

SUPPLEMENTARY INFORMATION:

I. Background

As an integral part of its decision-making process, FDA is obligated under the National Environmental Policy Act of 1969 (NEPA) to consider the environmental impact of its actions, including allowing notifications for food contact substances to become effective and approving food additive petitions, color additive petitions, GRAS affirmation petitions, requests for exemption from regulation as a food additive, and actions on certain food labeling citizen petitions, nutrient content claims petitions, and health claims petitions. In 1997, FDA amended its regulations in 21 CFR part 25 to provide for categorical exclusions for additional classes of actions that do not individually or cumulatively have a significant effect on the human environment (62 FR 40570, July 29, 1997). As a result of that rulemaking, FDA no longer routinely

requires submission of information about the manufacturing and production of FDA-regulated articles. FDA also has eliminated the previously required EA and abbreviated EA formats from the amended regulations. Instead, FDA is providing this guidance that contains sample formats to help industry submit a claim of categorical exclusion or an EA to CFSAN. This guidance document identifies, interprets, and clarifies existing requirements imposed by statute and regulation, consistent with the Council on Environmental Quality regulations (40 CFR 1507.3). It consists of recommendations that do not themselves create requirements; rather, they are explanatory guidance for FDA's own procedures in order to ensure full compliance with the purposes and provisions of NEPA.

This guidance provides information to assist in the preparation of claims of categorical exclusion and EAs for submission to CFSAN. The following topics are covered in this guidance: (1) What types of industry-initiated actions are subject to a claim of categorical exclusion, (2) What must a claim of categorical exclusion include by regulation, (3) What is an EA, (4) When is an EA required by regulation and what format should be used, (5) What are extraordinary circumstances, and (6) What suggestions does CFSAN have for preparing an EA? Although CFSAN encourages industry to use the EA formats described in this guidance because standardized documentation submitted by industry increases the efficiency of the review process, alternative approaches may be used if these approaches satisfy the requirements of the applicable statutes and regulations.

In the **Federal Register** of September 17, 2003 (68 FR 54462), FDA announced the availability of a draft guidance document entitled "Guidance for Industry: Preparing a Claim of Categorical Exclusion or an Environmental

Assessment for Submission to the Center for Food Safety and Applied Nutrition.” The agency solicited public comments on the draft guidance document. FDA did not receive any comments and is finalizing the draft guidance without revision, except for those revisions necessary to update certain contact information.

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 document represents FDA’s current thinking on the preparation of a claim of categorical exclusion or an EA for submission to CFSAN. It does not create or confer any rights for or on any person and does not operate to bind FDA or the public. You may use an alternative approach if such approach satisfies the requirements of the applicable statutes and regulations. If you want to discuss an alternative approach, contact the FDA staff responsible for implementing this guidance (see **FOR FURTHER INFORMATION CONTACT**).

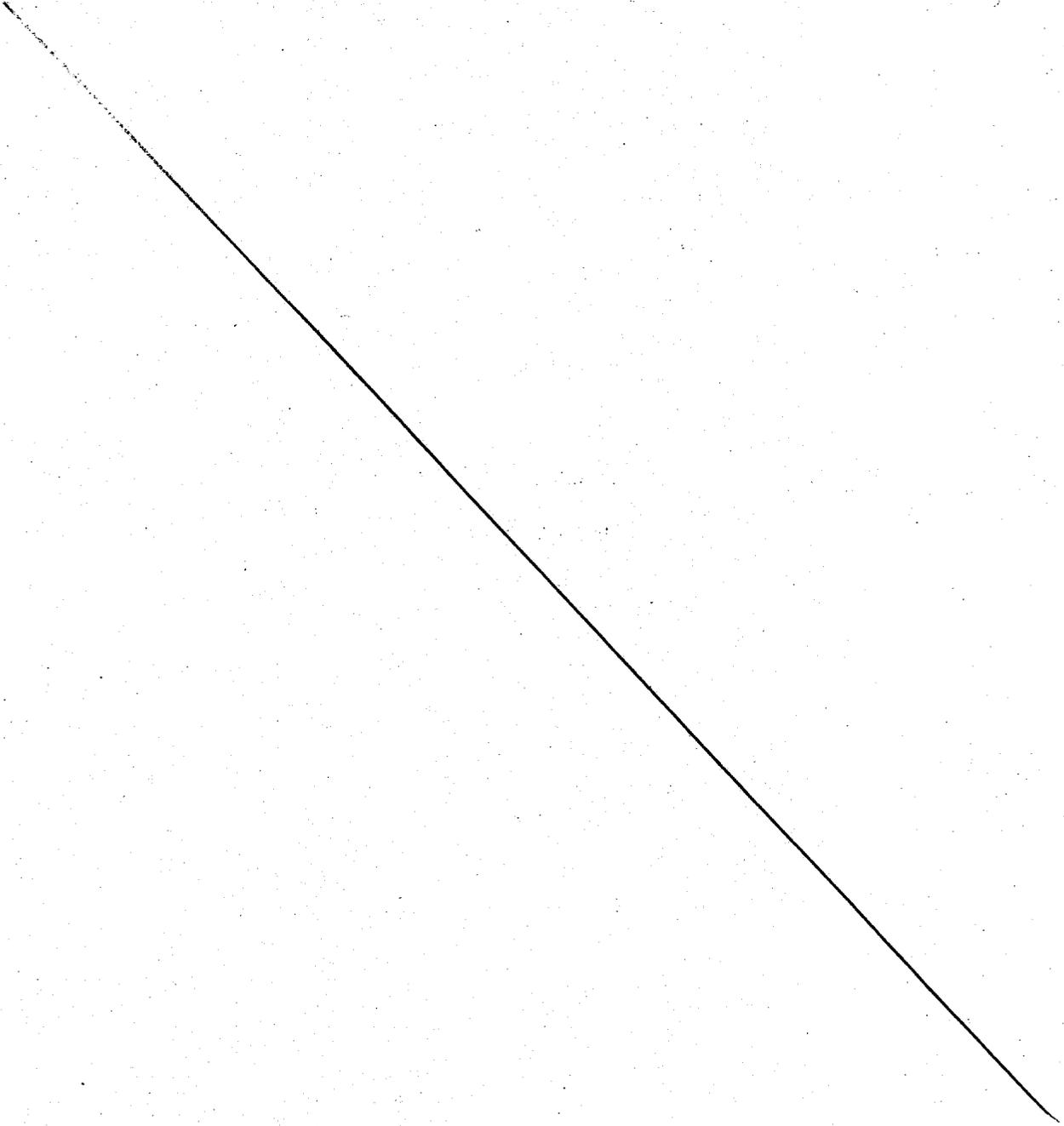
II. Paperwork Reduction Act of 1995

This guidance contains information collection provisions that 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 collection of information in this guidance was approved under OMB control number 0910–0541.

III. Comments

Interested persons may submit to the Division of Dockets Management (see **ADDRESSES**) written or electronic comments regarding this guidance at any time. 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. The guidance document and received comments

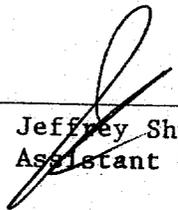
may be seen in the Division of Dockets Management between 9 a.m. and 4 p.m., Monday through Friday.



IV. Electronic Access

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

Dated: 5/10/06
May 10, 2006.



Jeffrey Shuren,
Assistant Commissioner for Policy.

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