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SUPPLEMENTARY INFORMATION:

I. Background

The National Environmental Policy Act of 1969 (NEPA) requires each Federal agency to assess, as an integral part of its decisionmaking process, the environmental impacts of its actions and requires that the interested and affected public be informed of environmental analyses. As an integral part of its regulatory procedures, FDA is obligated under NEPA to consider the environmental impact of agency 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, certain food labeling citizen petitions, nutrient content claims petitions, and health claims petitions. In 1997, FDA amended its regulations in part 25 (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 and for which, therefore, neither an environmental impact statement nor an EA is required (62 FR 40570, July 29, 1997) (the 1997 rule). As a result of the 1997 rule, FDA no longer routinely requires submission of information about the manufacturing and production of FDA-regulated articles, which information includes a certification of compliance with Federal, State, and local environmental laws. As FDA stated in the 1997 rule (62 FR 40570 at 40585-40586), after reviewing hundreds of EA's, the agency found that articles produced in compliance with applicable emission and occupational safety requirements do not have significant environmental effects, provided that no extraordinary circumstances apply to the production site. FDA also has eliminated the previously required EA and abbreviated EA formats from the amended regulations. Instead, appropriate EA formats are to be presented in guidance documents. FDA believes that guidance documents provide the agency with greater flexibility to interpret requirements under its NEPA procedures in a manner that responds to the evolving nature of environmental science and the needs of industry and interested parties. Such guidance documents, which interpret and clarify existing requirements imposed by statute and regulation and do not themselves create requirements, are not

subject to the notice and comment rulemaking provisions of the Administrative Procedure Act (5 U.S.C. 553) and are consistent with the Council on Environmental Quality regulations (40 CFR 1507.3) that encourage agencies to publish explanatory guidance for their own procedures and to revise them as necessary to ensure full compliance with the purposes and provisions of NEPA.

This draft guidance provides information on how to prepare claims of categorical exclusion and EAs for submission to CFSAN. The following topics are covered in this draft 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? (6) What suggestions does CFSAN have for preparing an EA? Although CFSAN encourages industry to use the EA formats described in this draft 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.

This level 1 draft guidance is being issued consistent with FDA's good guidance practices regulations (21 CFR 10.115). The draft guidance, when finalized, will represent FDA's current thinking on the preparation of a claim of categorical exclusion or an environmental assessment 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 can use an alternative approach if the 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 the guidance. If you cannot identify the appropriate FDA staff, call the appropriate number listed in the title page of the guidance.

II. Paperwork Reduction Act of 1995

Under the Paperwork Reduction Act of 1995 (PRA) (44 U.S.C. 3501-3520), Federal agencies must obtain approval from the Office of Management and Budget (OMB) for each collection of information they conduct or sponsor. "Collection of information" is defined in 44 U.S.C. 3502(3) and 5 CFR 1320.3(c) and includes agency requests or requirements that members of the

public submit reports, keep records, or provide information to a third party. Section 3506(c)(2)(A) of the PRA (44 U.S.C. 3506(c)(2)(A)) requires Federal agencies to provide a 60-day notice in the **Federal Register** concerning each proposed collection of information before submitting the collection to OMB for approval. To comply with this requirement, FDA is publishing notice of the proposed collection of information set forth in this document.

With respect to the following collection of information, FDA invites comments on these topics: (1) Whether the proposed collection of information is necessary for the proper performance of FDA's functions, including whether the information will have practical utility; (2) the accuracy of FDA's estimate of the burden of the proposed collection of information, including the validity of the methodology and assumptions used; (3) ways to enhance the quality, utility, and clarity of the information to be collected; and (4) ways to minimize the burden of the collection of information on respondents, including through the use of automated collection techniques, when appropriate, and other forms of information technology.

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

Description: FDA's regulation in § 25.20 specifies the types of actions related to food additive petitions, color additive petitions, requests for exemption from regulation as a food additive under § 170.39 (21 CFR 170.39), notifications for food contact substances under section 409(h) of the Federal Food, Drug, and Cosmetic Act (the act) (21 U.S.C. 348(h)), GRAS affirmation petitions, and citizen petitions for certain food labeling regulations that require at least the preparation of an EA, unless the action qualifies for a categorical exclusion under § 25.30 or § 25.32. FDA's regulations in part 25 are based upon the requirements of NEPA (42 U.S.C. 4321 *et seq.*). The agency's collection of information on food additives and food-contact substances is based upon the requirements in section 409 of the act. Likewise, section 721 of the act (21 U.S.C. 379(e)) provides for the collection of information on color additives. The submission to FDA by interested parties of a GRAS affirmation petition is voluntary. The information to be submitted with a GRAS affirmation petition is listed in § 170.35 (21 CFR 170.35), including, in § 170.35(c)(1)(viii), the environmental