

package, which may include additional information to support a request to participate in certain fast-track programs. As with the request for fast-track designation, the agency expects that most sponsors or applicants will have gathered such information to meet existing requirements under the act, the PHS Act, or implementing regulations, such as descriptions of clinical safety and efficacy trials not conducted under an IND (i.e., foreign studies), and information to support a request for accelerated approval. If information has been previously submitted to FDA under an OMB approved collection of information, the discussion of such information in a fast-track premeeting package may be summarized. Consequently, FDA anticipates that the additional collection of information attributed solely to the guidance will be minimal.

Section 506(c) of the act requires a collection of information before an applicant may be permitted to submit to FDA portions of an application for review. Under this provision of the fast-track statute, a sponsor must submit clinical data sufficient for the agency to determine, after preliminary evaluation, that a fast-track product may be effective. Section 506(c) of the act also requires that an applicant provide a schedule for the submission of information necessary to make the

application complete before FDA can commence its review. The guidance will not provide for any new collection of information regarding the submission of portions of an application that is not required under section 506(c) of the act or any other provision of the act. All forms that will be referred to in the guidance have valid OMB control numbers. These forms include: FDA Form 1571 (OMB Control No. 0910-0104, expires December 31, 1999); FDA Form 356h (OMB Control No. 0910-0338, expires April 30, 2000); and FDA Form 3397 (OMB Control No. 0910-0297, expires April 30, 2001). Respondents to this information collection are sponsors and applicants that seek fast-track designation under section 506 of the act. The agency estimates that the aggregate annual number of respondents submitting requests for fast-track designation to the Center for Biologics Evaluation and Research (CBER) and the Center for Drug Evaluation and Research (CDER) will be approximately 60. To obtain this estimate, FDA extrapolated from the number of requests for fast-track designation actually received by CBER and CDER in a 6-month period since November 21, 1997, the date of enactment of FDAMA. Within this time period, CBER received 9 requests, and CDER received 20 requests. FDA estimates that the number of hours

needed to prepare a request for fast-track designation may generally range between 40 and 80 hours per request, depending on the complexity of each request, with an average of 60 hours per request, as indicated in Table 1 of this document. Not all requests for fast-track designation may meet the statutory standard. The agency estimates that approximately 90 percent of all annual requests, approximately 54 respondents, for fast-track designation would be granted. Of those respondents who receive fast-track designation for a product, FDA expects that all will submit a premeeting package and that a premeeting package would generally need more preparation time than needed for a designation request because the issues may be more complex and the data may need to be more developed. FDA estimates that the preparation hours may generally range between 80 and 120 hours, with an average of 100 hours per package, as indicated in Table 1 of this document. The hour burden estimates contained in Table 1 of this document are for information collections requests in the guidance only and do not include burden estimates for statutory requirements specifically mandated by the act, the PHS Act, or implementing regulations. FDA estimates the burden of this collection of information as follows:

TABLE 1.—ESTIMATED ANNUAL REPORTING BURDEN<sup>1</sup>

	No. of Respondents	Annual Frequency per Response	Total Annual Responses	Hours per Response	Total Hours
Designation Request .....	60	1	60	60	3,600
Premeeting Packages ....	54	1	54	100	5,400
Totals .....	114		114		9,000

<sup>1</sup> There are no capital costs or operating and maintenance costs associated with this collection of information.

Dated: April 29, 1999.

**William K. Hubbard,**

*Associate Commissioner for Policy Coordination.*

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## DEPARTMENT OF HEALTH AND HUMAN SERVICES

### Food and Drug Administration

[Docket No. 99F-1170]

#### Ciba Specialty Chemicals Corp.; Filing of Food Additive Petition

**AGENCY:** Food and Drug Administration, HHS.

**ACTION:** Notice.

**SUMMARY:** The Food and Drug Administration (FDA) is announcing that Ciba Specialty Chemicals Corp. has filed a petition proposing that the food additive regulations be amended to provide for the safe use of 2-methyl-4,6-bis-[(octylthio)methyl] phenol as a stabilizer for repeat use rubber articles.

**FOR FURTHER INFORMATION CONTACT:** Mark A. Hepp, Center for Food Safety and Applied Nutrition (HFS-215), Food and Drug Administration, 200 C St. SW., Washington, DC 20204, 202-418-3098.

**SUPPLEMENTARY INFORMATION:** Under the Federal Food, Drug, and Cosmetic Act (sec. 409(b)(5) (21 U.S.C. 348(b)(5))), notice is given that a food additive petition (FAP 9B4660) has been filed by Ciba Specialty Chemicals Corp., 540 White Plains Rd., P.O. Box 2005,

Tarrytown, NY 10591-9005. The petition proposes to amend the food additive regulations in § 178.2010 *Antioxidants and/or stabilizers for polymers* (21 CFR 178.2010) to provide for the safe use of 2-methyl-4,6-bis-[(octylthio)methyl] phenol as a stabilizer for repeat use rubber articles.

The agency has determined under 21 CFR 25.32(i) that this action is of a type that does not individually or cumulatively have a significant effect on the human environment. Therefore, neither an environmental assessment nor an environmental impact statement is required.

Dated: April 26, 1999.

**Laura M. Tarantino,**

*Acting Director, Office of Premarket Approval, Center for Food Safety and Applied Nutrition.*

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## DEPARTMENT OF HEALTH AND HUMAN SERVICES

### Food and Drug Administration

[Docket No. 99P-1041]

#### **Salad Dressing Deviating From Identity Standard; Temporary Permit for Market Testing**

**AGENCY:** Food and Drug Administration, HHS.

**ACTION:** Notice.

**SUMMARY:** The Food and Drug Administration (FDA) is announcing that a temporary permit has been issued to Kraft Foods, Inc., to market test a product designated as "salad dressing" that deviates from the U.S. standard of identity for salad dressing. The purpose of the temporary permit is to allow the applicant to measure consumer acceptance of the product, identify mass production problems, and assess commercial feasibility, in support of a petition to amend the standard of identity for salad dressing.

**DATES:** This permit is effective for 15 months, beginning on the date the food is introduced or caused to be introduced into interstate commerce, but not later than August 4, 1999.

**FOR FURTHER INFORMATION CONTACT:** Loretta A. Carey, Center for Food Safety and Applied Nutrition (HFS-158), Food and Drug Administration, 200 C St. SW., Washington, DC 20204, 202-205-5099.

**SUPPLEMENTARY INFORMATION:** In accordance with 21 CFR 130.17 concerning temporary permits to facilitate market testing of foods deviating from the requirements of the standards of identity issued under section 401 of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 341), FDA is giving notice that a temporary permit has been issued to Kraft Foods, Inc., Three Lakes Dr., Northfield, IL 60093-2753.

The permit covers limited interstate marketing tests of products identified as "salad dressing" that deviate from the U.S. standard of identity for salad dressing (21 CFR 169.150) by adding potassium sorbate, phosphoric acid, and lactic acid, which are not permitted under the current standard, and by reducing the amount of egg below the

amount required by the current standard and adding polysorbate 60 and propylene glycol alginate, which are not permitted under the current standard, as safe and suitable emulsifiers other than egg. In all other respects, the test product will conform to the standard for salad dressing. The test product meets all the requirements of the standard with the exception of the reduced amount of egg level in the product and the addition of potassium sorbate, phosphoric acid, lactic acid, polysorbate 60, and propylene glycol alginate. Because test preferences vary by area, along with social and environmental differences, the purpose of this permit is to test the product throughout the United States.

Under this temporary permit, the salad dressing will be test marketed as "salad dressing."

This permit provides for the temporary marketing of approximately 390 million pounds of product during the entire 15-month period. The test product will be manufactured by Kraft Foods, Inc., at 2340 Forest Lane, Garland, TX 75040; 1701 West Bradley Ave., Champaign, IL 61821; and 7352 Industrial Blvd., Allentown, PA 18106. The product will be distributed throughout the United States.

The information panel of the labels will bear nutrition labeling in accordance with 21 CFR 101.9. Each of the ingredients used in the food must be declared on the labels as required by the applicable sections of 21 CFR part 101. This permit is effective for 15 months, beginning on the date the food is introduced or caused to be introduced into interstate commerce, but not later than August 4, 1999.

Dated: April 27, 1999.

**Kenneth J. Falci,**

*Acting Director, Office of Food Labeling, Center for Food Safety and Applied Nutrition.*

[FR Doc. 99-11346 Filed 5-5-99; 8:45 am]

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## DEPARTMENT OF HEALTH AND HUMAN SERVICES

### Food and Drug Administration

[Docket No. 97D-0024]

#### **Immunotoxicity Testing Guidance; Availability**

**AGENCY:** Food and Drug Administration, HHS.

**ACTION:** Notice.

**SUMMARY:** The Food and Drug Administration (FDA) is announcing the availability of the guidance entitled "Immunotoxicity Testing Guidance."

This guidance is intended to provide FDA reviewers and manufacturers with a coherent strategy for assessing whether testing for potential adverse effects involving medical devices or constituent materials and the immune system is needed. The guidance is also intended to aid in developing a systematic approach to such testing.

**DATES:** Written comments may be submitted at any time.

**ADDRESSES:** Submit written requests for single copies on a 3.5" diskette of the guidance entitled "Immunotoxicity Testing Guidance" to the Division of Small Manufacturers Assistance (HFZ-220), Center for Devices and Radiological Health (CDRH), Food and Drug Administration, 1350 Piccard Dr., Rockville, MD 20850. Send two self-addressed adhesive labels to assist that office in processing your request, or fax your request to 301-443-8818. See the **SUPPLEMENTARY INFORMATION** section for information on electronic access to the guidance.

Submit written comments on the "Immunotoxicity Testing Guidance" to the contact person listed below.

**FOR FURTHER INFORMATION CONTACT:** John J. Langone, Center for Devices and Radiological Health (HFZ-113), Food and Drug Administration, 12709 Twinbrook Pkwy., Rockville, MD 20852, 301-443-2911.

#### **SUPPLEMENTARY INFORMATION:**

##### **I. Background**

In May 1995, FDA adopted the General Program Memorandum G95-1, an FDA-modified version of International Standard ISO-10993, entitled "Biological Evaluation of Medical Devices—Part 1: Evaluation and Testing." It was pointed out that in addition to the general guidance for toxicity testing contained in that document, additional guidance might be needed for evaluation of specific organ or system toxicity. As a result, the Office of Device Evaluation, CDRH, developed the "Immunotoxicity Testing Guidance" to deal specifically with testing for adverse effects of medical devices or constituent materials on the immune system. The guidance is intended to ensure a consistent and scientifically sound approach to the overall evaluation of product safety.

In addition to explanatory text, the guidance contains: (1) A flowchart to determine if immunotoxicity testing is recommended, and (2) three tables that lead sequentially from potential immunological effects, to potential responses commonly associated with