Dated: April 26, 1999.

Laura M. Tarantino,

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

[FR Doc. 99–11309 Filed 05–05–99; 8:45 am]

BILLING CODE 4160–01–F

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 currrent 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]

BILLING CODE 4160–01–F

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

those effects, to examples of testing that might be considered as part of the overall safety evaluation of finished devices or constituent materials.

FDA published a notice of availability of the original draft guidance in the **Federal Register** of March 18, 1997 (62 FR 12832). Comments were received from 28 respondents, including medical device manufacturers, industry trade groups, and individuals. These comments were reviewed by the CDRH Immunotoxicology Working Group. Based on these comments, the draft guidance was revised to include additional didactic and technical information. The revised draft guidance was reviewed by a group of regulatory reviewers as well as senior CDRH management to obtain the final version of ''Immunotoxicity Testing Guidance.''

II. Significance of Guidance

This guidance represents the agency's current thinking on immunotoxicity testing of medical devices and constituents. 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 applicable statute, regulations, or both.

The agency has adopted good guidance practices (GGP's), which set forth the agency's policies and procedures for the development, issuance, and use of guidance documents (62 FR 8961, February 27, 1997). This guidance is issued as a Level 1 guidance consistent with GGP's.

III. Electronic Access

In order to receive ''Immunotoxicity Testing Guidance'' via your fax machine, call the CDRH Facts-On-Demand system at 800–899–0381 or 301–827–0111 from a touch-tone telephone. At the first voice prompt press 1 to access DSMA Facts, at second voice prompt press 2, and then enter the document number (635) followed by the pound sign (#). Then follow the remaining voice prompts to complete your request.

Persons interested in obtaining a copy of the guidance may also do so using the World Wide Web (WWW). CDRH maintains an entry on the WWW for easy access to information including text, graphics, and files that may be downloaded to a personal computer with access to the WWW. Updated on a regular basis, the CDRH home page includes ''Immunotoxicity Testing Guidance,'' device safety alerts, **Federal Register** reprints, information on premarket submissions (including lists of approved applications and manufacturers' addresses), small manufacturers' assistance, information on video conferencing and electronic submissions, mammography matters, and other device-oriented information. The CDRH home page may be accessed at ''http://www.fda.gov/cdrh''. The ''Immunotoxicity Testing Guidance'' document will be available at ''http://www.fda.gov/cdrh/ost/ostggp/immunotox.html''.

IV. Comments

Interested persons may, at any time, submit written comments regarding this guidance to the contact person listed previously. Such comments will be considered when determining whether to amend the current guidance.

Dated: April 28, 1999.

Linda S. Kahan,

Deputy Director for Regulations Policy, Center for Devices and Radiological Health.

[FR Doc. 99–11345 Filed 5–5–99; 8:45 am]

BILLING CODE 4160–01–F

DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

National Cancer Institute; Notice of Closed Meeting

Pursuant to section 10(d) of the Federal Advisory Committee Act, as amended (5 U.S.C. Appendix 2), notice is hereby given of the following meeting.

The meeting will be closed to the public in accordance with the provisions set forth in sections 552b(c)(4) and 552b(c)(6), Title 5 U.S.C., as amended. The grant applications and the discussions could disclose confidential trade secrets or commercial property such as patentable material, and personal information concerning individuals associated with the grant applications, the disclosure of which would constitute a clearly unwarranted invasion of personal privacy.

Name of Committee: National Cancer Institute Initial Review Group Subcommittee C—Basic & Preclinical.

Date: June 11, 1999.

Time: 1:30 PM to 4:30 PM.

Agenda: To review and evaluate grant applications.

Place: 6130 Executive Blvd. 6th Floor, Rockville, MD 20852, (Telephone Conference Call).

Contact Person: Florence E. Farber, Ph.D., Executive Secretary, Office of Advisory Activities, Division of Extramural Activities, National Cancer Institute, National Institutes of Health, 6130 Executive Boulevard, EPN 609, Rockville, MD 20892, 301/496–2378.

(Catalogue of Federal Domestic Assistance Program Nos. 93.392, Cancer Construction; 93.393, Cancer Cause and Prevention Research; 93.394, Cancer Detection and Diagnosis Research; 93.395, Cancer Treatment Research; 93.396, Cancer Biology Research; 93.397, Cancer Centers Support; 93.398, Cancer Research Manpower; 93.399, Cancer Control, National Institutes of Health, HHS)

Dated: April 30, 1999.

LaVerne Y. Stringfield,

Committee Management Officer, NIH.

[FR Doc. 99–11430 Filed 5–5–99; 8:45 am]

BILLING CODE 4140–01–M

DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

National Cancer Institute; Notice of Closed Meeting

Pursuant to section 10(d) of the Federal Advisory Committee Act, as amended (5 U.S.C. Appendix 2), notice is hereby given of the following meeting.

The meeting will be closed to the public in accordance with the provisions set forth in sections 552b(c)(4) and 552b(c)(6), title 5 U.S.C., as amended. The grant applications and the discussions could disclose confidential trade secrets or commercial property such as patentable material, and personal information concerning individuals associated with the grant applications, the disclosure of which would constitute a clearly unwarranted invasion of personal privacy.

Name of Committee: National Cancer Institute Initial Review Group Subcommittee H—Clinical Groups.

Date: June 7–8, 1999.

Time: 8:00 AM to 5:00 PM.

Agenda: To review and evaluate grant applications.

Place: Holiday Inn—Silver Spring, 8777 Georgia Avenue, Silver Spring, MD 20910.

Contact Person: Deborah R. Jaffe, PHD, Grants Review Branch, Division of Extramural Activities, National Cancer Institute, National Institutes of Health, 6130 Executive Boulevard, Rockville, MD 20892, (301) 496–7221.

(Catalogue of Federal Domestic Assistance Program Nos. 93.392, Cancer Construction; 93.393, Cancer Cause and Prevention Research; 93.394, Cancer Detection and Diagnosis Research; 93.395, Cancer Treatment Research; 93.396, Cancer Biology Research; 93.397, Cancer Centers Support; 93.398, Cancer Research Manpower; 93.399, Cancer Control, National Institutes of Health, HHS)

Dated: April 30, 1999.

LaVerne Y. Stringfield,

Committee Management Officer, NIH.

[FR Doc. 99–11431 Filed 5–5–99; 8:45 am]

BILLING CODE 4140–01–M