Dated: March 22, 1999.

Laura M. Tarantino,

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

[FR Doc. 99–8442 Filed 4–5–99; 8:45 am]

BILLING CODE 4160–01–F

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. 98P–1121]

Grated Parmesan Cheese 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 ''100% Grated Parmesan Cheese'' that deviates from the U.S. standards of identity for parmesan cheese and grated cheeses. 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 parmesan cheese.

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 July 6, 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 promulgated 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.

The permit covers 86 million pounds of interstate marketing tests products identified as ''grated parmesan cheese'' that deviate from the U.S. standard of identity for parmesan cheese (21 CFR 133.165) and grated cheeses (21 CFR 133.146) in that the product is formulated by using a different enzyme technology that fully cures the cheese in 6 months rather than 10 months. The test product meets all the requirements of the standards with the exception of this deviation. 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 parmesan cheese will be test marketed as grated parmesan cheese. The test product will bear the name ''100% Grated Parmesan Cheese.''

This permit provides for the temporary marketing of 86 million pounds of grated parmesan cheese in retail containers of various sizes. The test product will be manufactured at Kraft Foods, Inc., 10800 Avenue 184, Tulare, CA 93274. The product will then be shipped to Kraft Foods Inc., 1007 Town Line Rd., Wausau, WI 54401, where it is aged, grated, and packaged for distribution. 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 July 6, 1999.

Dated: March 29, 1999.

Kenneth J. Falci,

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

[FR Doc. 99–8440 Filed 4–5–99; 8:45 am]

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. 96G–0096]

The Flax Council of Canada; Withdrawal of GRAS Affirmation Petition

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is announcing the withdrawal, without prejudice to a future filing, of a petition (GRASP 5G0416) proposing to affirm that the use of low linolenic acid flaxseed oil is generally recognized as safe (GRAS) as a food oil.

FOR FURTHER INFORMATION CONTACT: Lawrence J. Lin, Center for Food Safety and Applied Nutrition (HFS–215), Food and Drug Administration, 200 C St. SW., Washington, DC 20204, 202–418–3103.

SUPPLEMENTARY INFORMATION: In a notice published in the **Federal Register** of March 27, 1996 (61 FR 13505), FDA announced that a petition (GRASP 5G0416) had been filed by the Flax Council of Canada, 465–167 Lombard Ave., Winnipeg, MB R3B 0T6, Canada. This petition proposed that the use of low linolenic acid flaxseed oil as a food oil be affirmed as GRAS.

The Flax Council of Canada has now withdrawn the petition without prejudice to a future filing (21 CFR 171.7).

Dated: March 17, 1999.

Eugene C. Coleman,

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

[FR Doc. 99–8443 Filed 4–5–99; 8:45 am]

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. 99D–0557]

''Guidance for Industry: Public Health Issues Posed by the Use of Nonhuman Primate Xenografts in Humans;'' 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: Public Health Issues Posed by the Use of Nonhuman Primate Xenografts in Humans.'' The guidance document is being issued in response to public comments and recent interest among clinical investigators in using nonhuman primate xenografts in the near future. The document is intended to provide guidance on nonhuman primate xenotransplantation in humans.

DATES: Written comments may be submitted at any time, however, comments should be submitted by July 6, 1999, to ensure adequate consideration in preparation of a revised document, if warranted. The agency is soliciting public comment but is implementing this guidance document immediately because of the public health concerns related to the use of live cells, tissues, and organs from nonhuman primate xenografts in humans.

ADDRESSES: Submit written requests for single copies of the guidance document entitled ''Guidance for Industry: Public Health Issues Posed by the Use of Nonhuman Primate Xenografts in Humans'' to the Office of Communication, Training, and Manufacturers Assistance (HFM–40), Center for Biologics Evaluation and Research (CBER), Food and Drug Administration, 1401 Rockville Pike, Rockville, MD 20852–1448. Send one self-addressed adhesive label to assist that office in processing your requests. The guidance document may also be obtained by mail by calling the CBER Voice Information System at 1–800–835–4709 or 301–827–1800, or by fax by calling the FAX Information System at 1–888–CBER–FAX or 301–827–3844. See the **SUPPLEMENTARY INFORMATION** section for electronic access to the guidance document.

Submit written comments on the guidance document to the Dockets Management Branch (HFA–305), Food and Drug Administration, 5630 Fishers Lane, rm. 1061, Rockville, MD 20852.

FOR FURTHER INFORMATION CONTACT: Valerie A. Butler, Center for Biologics Evaluation and Research (HFM–17), Food and Drug Administration, 1401 Rockville Pike, Rockville, MD 20852–1448, 301–827–6210.

SUPPLEMENTARY INFORMATION:

I. Background

FDA is announcing the availability of a guidance document entitled ''Guidance for Industry: Public Health Issues Posed by the Use of Nonhuman Primate Xenografts in Humans.'' The document provides guidance to industry concerning: (1) The potential public health risks posed by nonhuman primate xenografts; (2) the need for further scientific research and evaluation of these risks, particularly infectious agents; and (3) the need for public discussion concerning these issues.

Concerns have arisen in the last few years about the potential infectious disease and public health risks associated with xenotransplantation, particularly nonhuman primate xenotransplantation. For the purpose of this guidance document, xenotransplantation is defined as any procedure that involves the use of live cells, tissues, or organs from a nonhuman animal source transplanted or implanted into a human, or used for ex vivo contact with human body fluids, cells, tissues, or organs that are subsequently given to a human recipient. In addition, defined for the purpose of this document, xenografts include live cells, tissues, or organs from a nonhuman animal source used for xenotransplantation.

In developing the guidance, FDA considered numerous sources of information, including concerns raised in public comments to the ''Draft Public Health Service (PHS) Guideline on Infectious Disease Issues in Xenotransplantation'' (61 FR 49920, September 23, 1996) and concerns voiced by the scientific and lay community at the public workshops on xenotransplantation entitled ''Cross–Species Infectivity and Pathogenesis'' held on July 21 and 22, 1997, and ''Developing U.S. Public Health Service Policy in Xenotransplantation'' held on January 21 and 22, 1998, sponsored by PHS.

The approach outlined in the guidance document has been accepted by the other PHS agencies including the National Institutes of Health, the Centers for Disease Control and Prevention, and the Health Resources and Services Administration, as well as the Department of Health and Human Services Working Group on Xenotransplantation. The agency is aware that other species of animals have been used and are proposed as future sources of xenografts and may pose infectious disease risks. The public health issues raised by xenotransplantation, regardless of source animal species, will continue to receive scientific evaluation and discussion by appropriate Federal agencies and advisory committees.

The guidance document represents the agency's current thinking on the potential public health risks posed by the use of nonhuman primate xenografts in humans, and the consequent need for further scientific evaluation and public discussion of this issue. 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 requirement of the applicable statute, regulations, or both. As with other guidance documents, FDA does not intend this document to be all-inclusive and cautions that not all information may be applicable to all situations. The document is intended to provide information and does not set forth requirements.

II. Comments

The agency notes that measures taken during the production of some nonhuman primate xenografts products, such as extensive preclinical xenotransplant product testing for infectious agents, genetic engineering, enclosure of the product in a semipermeable barrier, and/or the use of well-characterized cell lines which have been handled in a manner to avoid the introduction of new pathogens, could potentially provide greater control of infectious disease risks. The agency specifically solicits comments on the potential for such measures, alone or in combination, to substantially reduce the risks posed by nonhuman primate xenotransplantation. The agency is soliciting public comment but is implementing this guidance document immediately because of the public health concerns related to the use of live cells, tissues and organs from nonhuman primate xenografts in humans.

Interested persons may submit to the Dockets Management Branch (address above) written comments regarding this guidance document. Written comments may be submitted at any time, however, comments should be submitted by July 6, 1999, to ensure adequate consideration in preparation of a revised document, if warranted. Two copies of any comments are to be submitted, except individuals may submit one copy. Comments should be identified with the docket number found in the brackets in the heading of this document. A copy of the guidance document and received comments are available for public examination in the Dockets Management Branch between 9 a.m. and 4 p.m., Monday through Friday.

III. Electronic Access

Persons with access to the Internet may obtain the document using the World Wide Web (WWW). For WWW access, connect to CBER at ''http://www.fda.gov/cber/guidelines.htm''.

Dated: March 30, 1999.

William K. Hubbard,

Acting Deputy Commissioner for Policy.

[FR Doc. 99–8439 Filed 4–5–99; 8:45 am]

BILLING CODE 4160–01–F

DEPARTMENT OF HOUSING AND URBAN DEVELOPMENT

[Docket No. FR–4442–N–09]

Notice Of Proposed Information Collection for Public Comment

AGENCY: Office of the Assistant Secretary for Policy Development and Research, HUD.

ACTION: Notice.

SUMMARY: The proposed information collection requirement described below will be submitted to the Office of Management and Budget (OMB) for