

Dated: March 22, 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. 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.

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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.