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; Extension of Temporary Permit

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice; extension of temporary permit.

SUMMARY: The Food and Drug Administration (FDA) is announcing the extension of a temporary permit issued to Kraft Foods, Inc., to market test products designated as ''100% Grated Parmesan Cheese'' that deviate from the U.S. standards of identity for parmesan cheese and grated cheese. The extension will allow the permit holder to continue to collect data on consumer acceptance of the products while the agency takes action on a petition to amend the standard of identity for parmesan cheese that was submitted by the permit holder.

DATES: The new expiration date of the permit will be either the effective date of a final rule amending the standard of identity for parmesan cheese that may result from the permit holder's petition or 30 days after denial of the petition, whichever the case may be.

FOR FURTHER INFORMATION CONTACT: Loretta A. Carey, Center for Food Safety and Applied Nutrition (HFS–822), Food and Drug Administration, 200 C St. SW., Washington, DC 20204, 202–205–4168.

SUPPLEMENTARY INFORMATION: In accordance with 21 CFR 130.17, FDA issued a temporary permit to Kraft Foods, Inc., Three Lakes Dr., Northfield, IL 60093–2753, to market test products identified as ''parmesan cheese'' that deviate from the U.S. standards of identity for parmesan cheese (21 CFR 133.165) and grated cheeses (21 CFR 133.146) (see 64 FR 16743, April 6, 1999). The agency issued the permit to facilitate market testing of foods deviating from the requirements of the standard of identity for parmesan cheese issued under section 401 of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 341). The permit covers limited interstate market testing of products identified as ''parmesan cheese'' that deviate from the standardized parmesan cheese products described in 21 CFR part 133 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 standard with the exception of this deviation.

On August 28, 2000, Kraft Foods, Inc. requested that its temporary permit be extended to allow for additional time for the market testing of its products under the permit in order to gain additional information in support of its petition. The petition requests FDA to amend the standard of identity for parmesan cheese to change the curing time from 10 months to 6 months.

The agency finds that it is in the interest of consumers to issue an extension of the time period for the market testing of products identified as parmesan cheese to gain information on consumer expectation and acceptance. FDA is inviting interested persons to participate in the market test under the conditions that apply to Kraft Foods (e.g., the composition of the test product), except that a different condition for the designated area of distribution may apply. Any person who wishes to participate in the extended market test must notify, in writing, the Director, Division of Standards and Labeling Regulations, Office of Nutritional Products, Labeling and Dietary Supplements, Center for Food Safety and Applied Nutrition (HFS–820), Food and Drug Administration, 200 C St. SW., Washington, DC 20204. The notification must include a description of the test products to be distributed, a justification statement for the amount requested, the area of distribution, and the labeling that will be used for the test product (i.e., a draft label for each size of container and each brand of product to be market tested). The information panel of the label must bear nutrition labeling in accordance with 21 CFR 101.9. Each of the ingredients used in the food must be declared on the label as required by the applicable sections of 21 CFR part 101.

Therefore, under the provisions of 21 CFR 130.17(i), FDA is extending the temporary permit granted to Kraft Foods, Inc., Three Lakes Dr., Northfield, IL 60093–2753 to provide for continued market testing on an annual basis of 86 million pounds. The test products will bear the name ''100% Grated Parmesan Cheese.'' FDA is extending the expiration date of the permit so that the permit expires either on the effective date of a final rule amending the standard of identity for parmesan cheese that may result from the permit holder's petition or 30 days after denial of the petition, whichever the case may be. All other conditions and terms of this permit remain the same.

Dated: December 12, 2000.

Christine J. Lewis,

Director, Office of Nutritional Products Labeling and Dietary Supplements, Center for Food Safety and Applied Nutrition.

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

Veterinary Antimicrobial Decision Support System

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) Center for Veterinary Medicine (CVM) announces that funds may be available to support an unsolicited grant application submitted by Iowa State University. The applicant has requested funds to develop a web-based, peer-reviewed antimicrobial decision support system centered on therapeutic applications that will allow food animal veterinary practitioners to utilize all available information in the construction of antimicrobial regimens.

FOR FURTHER INFORMATION CONTACT:

Regarding the administrative and financial management aspects of this notice: Peggy L. Jones, Division of Contracts and Procurement Management (HFA–520), Food and Drug Administration, 5600 Fishers Lane, rm. 2129, Rockville, MD 20857, 301–827–7160. Correspondence hand-carried or commercially delivered should be addressed to 5630 Fishers Lane (HFA–520), rm. 2129, Rockville, MD 20857.

Regarding the programmatic aspects of this notice: David B. Batson, Office of Research, Center for Veterinary Medicine (HFV–502), Food and Drug Administration, 8401 Muirkirk Rd., Laurel, MD 20708, 301–827–8021.

SUPPLEMENTARY INFORMATION:

I. Purpose of the Project

The specific aims of the project are as follows: (1) Perform extensive literature searches to identify pharmacokinetic, pharmacodynamic, clinical trial, antimicrobial pathogen susceptibility, regulatory, food safety, and approval process information pertinent to the veterinary antimicrobial decision support system (VADS); (2) develop and apply standard operating procedures for