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

evaluating the quality and reliability of information and data for use in developing the VADS system contents; (3) apply the principles of pharmacology in constructing therapeutic regimens for use when approved antimicrobial products are not effective as labeled; (4) design a relational database allowing a user to efficiently search the VADS system for label and extralabel regimens based on therapeutic applications, and to then review regulatory and food safety information applicable to these regimens; and (5) subject the VADS system content to review prior to release and then constantly upgrade the content on the basis of new information and review by users.

II. Eligible Applicants

Assistance may only be provided to Iowa State University because of the following:

1. Iowa State University is the only organization that submitted an unsolicited application for the purpose stated above.

2. The project proposed by the applicant is unique and innovative in that pharmacokinetic, pharmacodynamic, clinical trial, and pathogen susceptibility information will be interpreted by clinical pharmacologists and reviewed by other experts in the appropriate fields prior to inclusion in the system. Users may either use the information as provided or examine the transparent development process used in constructing the system. In addition, by compiling available information to support prudent antimicrobial use, the VADS system will emphasize what information is not available, thereby aiding researchers in targeting research goals.

3. The team assembled to carry out the proposed work is uniquely qualified to achieve the goals of this application. Their combined experience encompasses practice in academic, general, and specialized production medicine settings as well as demonstrated competence in the application of clinical pharmacology and informatics in veterinary medicine. Support for the research team and the VADS system project has already been expressed in the form of start up funding provided by veterinary and producer organizations.

III. Funding

We anticipate that approximately $250,000 may be made available in fiscal year (FY) 2001 to support this project. If funded the award will begin sometime in FY 2001 and will be made for a 12-month budget period within a project period of up to 5 years. Funding estimates may change. Continuation awards within an approved project period will be made on the basis of satisfactory progress as evidenced by required reports and the availability of funds.

Dated: December 22, 2000.

Margaret M. Dotzel,

Associate Commissioner for Policy.

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. 97D–0448]

International Conference on Harmonisation; Guidance on Q6A Specifications: Test Procedures and Acceptance Criteria for New Drug Substances and New Drug Products: Chemical Substances

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is publishing a guidance entitled ''Q6A Specifications: Test Procedures and Acceptance Criteria for New Drug Substances and New Drug Products: Chemical Substances.'' The guidance was prepared under the auspices of the International Conference on Harmonisation of Technical Requirements for Registration of Pharmaceuticals for Human Use (ICH). The guidance describes or provides recommendations concerning the selection of test procedures and the setting and justification of acceptance criteria for new chemical drug substances and new drug products produced from them. The guidance is intended to assist in the establishment of a single set of global specifications for new drug substances and new drug products.

DATES: Submit written comments by March 29, 2001.

ADDRESSES: Submit written comments on the guidance to the Dockets Management Branch (HFA–305), Food and Drug Administration, 5630 Fishers Lane, rm. 1061, Rockville, MD 20852. Copies of the guidance are available from the Drug Information Branch (HFD–210), Center for Drug Evaluation and Research, Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857, 301–827–4573.

FOR FURTHER INFORMATION CONTACT:

Regarding the guidance: Eric B. Sheinin, Center for Drug Evaluation and Research (HFD–003), Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857, 301–594–2847, or Neil D. Goldman, Center for Biologics Evaluation and Research (HFM–20), Food and Drug Administration, 1401 Rockville Pike, Rockville, MD 20852, 301–827–0377.

Regarding the ICH: Janet J. Showalter, Office of Health Affairs (HFY–20), Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857, 301–827–0864.

SUPPLEMENTARY INFORMATION: In recent years, many important initiatives have been undertaken by regulatory authorities and industry associations to promote international harmonization of regulatory requirements. FDA has participated in many meetings designed to enhance harmonization and is committed to seeking scientifically based harmonized technical procedures for pharmaceutical development. One of the goals of harmonization is to identify and then reduce differences in technical requirements for drug development among regulatory agencies.

ICH was organized to provide an opportunity for tripartite harmonization initiatives to be developed with input from both regulatory and industry representatives. FDA also seeks input from consumer representatives and others. ICH is concerned with harmonization of technical requirements for the registration of pharmaceutical products among three regions: The European Union, Japan, and the United States. The six ICH sponsors are the European Commission, the European Federation of Pharmaceutical Industries Associations, the Japanese Ministry of Health and Welfare, the Japanese Pharmaceutical Manufacturers Association, the Centers for Drug Evaluation and Research and Biologics Evaluation and Research, FDA, and the Pharmaceutical Research and Manufacturers of America. The ICH Secretariat, which coordinates the preparation of documentation, is provided by the International Federation of Pharmaceutical Manufacturers Associations (IFPMA).

The ICH Steering Committee includes representatives from each of the ICH sponsors and the IFPMA, as well as observers from the World Health Organization, the Canadian Health Protection Branch, and the European Free Trade Area.

In the **Federal Register** of November 25, 1997 (62 FR 62890), FDA published a draft tripartite guidance entitled ''Q6A Specifications: Test Procedures and