

Applied Nutrition (HFS-820), Food and Drug Administration, 5100 Paint Branch Pkwy., College Park, MD 20740, 301-436-2371.

**SUPPLEMENTARY INFORMATION:** In accordance with § 130.17 (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 jointly to Kerry, Inc., 352 East Grand Ave., Beloit, WI 53511; Eau Galle Cheese Factory, N6765 State Hwy., Durand, WI 54736; First District Association, 101 South Swift Ave., Litchfield, MN 55355; and Mullins Cheese, Inc., 598 Seagull Dr., Mosinee, WI 54455.

The permit covers limited interstate marketing tests of products identified as "Romano cheese for manufacturing made from cow's milk." These products may deviate from the U.S. standard of identity for romano cheese (§ 133.183) in two ways. First, the product is formulated using an enzyme technology that fully cures the cheese in 2 months rather than 5 months and, second, the product is intended only for further manufacturing into food ingredients. Except for these two deviations, the test product meets all the requirements of the standard. The purpose of the temporary permit is to allow the coapplicants to measure consumer acceptance of the product, identify mass production problems, and assess commercial feasibility.

FDA previously issued a temporary permit jointly to Kerry, Inc., Eau Galle Cheese Factory, and First District Association to market test this product, i.e., romano cheese for manufacturing made from cow's milk (68 FR 46198, August 5, 2003). In accordance with the provisions of § 130.17(b), the permit required the permit holders to introduce or cause the introduction of the test product into interstate commerce no later than November 5, 2003. Because the permit holders did not introduce or cause the introduction of the test product into interstate commerce within the assigned time period, that permit was terminated.

The current permit provides for the temporary marketing of a total of 9 million pounds (4.1 million kilograms) of the test product. The test product will be manufactured by Eau Galle Cheese Factory, N6765 State Hwy., Durand, WI 54736; First District Association, 101 South Swift Ave., Litchfield, MN 55355; and Mullins Cheese, Inc., 598 Seagull Dr., Mosinee, WI 54455. The test

product then will be shipped to Kerry, Inc., plants in Wisconsin and Minnesota, where it will be further manufactured into food ingredients. The food ingredients will be distributed by Kerry, Inc., throughout the United States. Each of the ingredients used in the test product must be declared on the labels of the test product as required by the applicable sections of 21 CFR part 101. The permit is effective for 15 months, beginning on the date the permit holders introduced or caused the introduction of the product into interstate commerce, but not later than September 8, 2004.

Dated: May 25, 2004.

**Laura Tarantino,**

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

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**BILLING CODE 4160-01-S**

## DEPARTMENT OF HEALTH AND HUMAN SERVICES

### Food and Drug Administration

[Docket No. 2002D-0237]

#### International Conference on Harmonisation; Evaluation of Stability Data; Availability

**AGENCY:** Food and Drug Administration, HHS.

**ACTION:** Notice.

**SUMMARY:** The Food and Drug Administration (FDA) is announcing the availability of a guidance entitled "Q1E Evaluation of Stability Data." The guidance was prepared under the auspices of the International Conference on Harmonisation of Technical Requirements for Registration of Pharmaceuticals for Human Use (ICH). This guidance is a supplement to an ICH guidance entitled "Q1A(R2) Stability Testing of New Drug Substances and Products," which was revised from Q1A(R) and published in the **Federal Register** of November 21, 2003 (68 FR 65717). It is intended to provide guidance on how to use stability data, generated in accordance with the principles outlined in Q1A(R2), to propose a retest period for the drug substance and a shelf life for the drug product.

**DATES:** The guidance is effective June 8, 2004. Submit written or electronic comments at any time.

**ADDRESSES:** Submit written comments on the guidance to the Division of Dockets Management (HFA-305), Food and Drug Administration, 5630 Fishers

Lane, rm. 1061, Rockville, MD 20852. Submit electronic comments to <http://www.fda.gov/dockets/ecomments>. Submit written requests for single copies of the guidance to the Division of Drug Information (HFD-240), Center for Drug Evaluation and Research, Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857, or the Office of Communication, Training, and Manufacturers Assistance (HFMA-40), Center for Biologics Evaluation and Research, Food and Drug Administration, 1401 Rockville Pike, Rockville, MD 20852-1448, 301-827-3844. Send two self-addressed adhesive labels to assist the office in processing your requests. Requests and comments should be identified with the docket number found in brackets in the heading of this document. See the **SUPPLEMENTARY INFORMATION** section for electronic access to the guidance.

#### FOR FURTHER INFORMATION CONTACT:

*Regarding the guidance:* Chi-wan

Chen, Center for Drug Evaluation and Research (HFD-830), Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857, 301-827-2001; or Andrew Shrake, Center for Biologics Evaluation and Research (HFM-345), Food and Drug Administration, 1401 Rockville Pike, Rockville, MD 20852-1148, 301-402-4635.

*Regarding the ICH:* Janet Showalter, Office of International Programs (HFG-1), Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857, 301-827-0864.

#### SUPPLEMENTARY INFORMATION:

##### I. Background

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, Labour, 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, Health Canada's Health Products and Food Branch, and the European Free Trade Area.

In the **Federal Register** of June 14, 2002 (67 FR 40949), FDA published a draft tripartite guidance entitled "Evaluation of Stability Data." The notice gave interested persons an opportunity to submit comments by August 1, 2002.

After consideration of the comments received and revisions to the guidance, a final draft of the guidance was submitted to the ICH Steering Committee and endorsed by the three participating regulatory agencies in February 2003.

This guidance complements an ICH guidance entitled "Q1A(R2) Stability Testing of New Drug Substances and Products," which was revised from Q1A(R) and published in the **Federal Register** of November 21, 2003. The guidance is intended to provide recommendations on how to use stability data, generated in accordance with the principles outlined in Q1A(R2), to propose a retest period for the drug substance and a shelf life for the drug product.

The recommendations on the evaluation and statistical analysis of stability data provided in Q1A(R2) are brief in nature and limited in scope. Although Q1A(R2) states that regression

analysis is an acceptable approach to analyzing quantitative stability data for retest period or shelf life estimation and recommends that a statistical test for batch poolability be performed using a level of significance of 0.25, it includes few details. In addition, Q1A(R2) does not cover situations where multiple factors are involved in a full- or reduced-design study. This guidance provides a clear explanation of the expectations when proposing a retest period or shelf life and storage conditions based on the evaluation of stability data for both quantitative and qualitative test attributes. It outlines recommendations for establishing a retest period or shelf life based on stability data from single or multifactor and full- or reduced-design studies. The guidance further describes when and how limited extrapolation can be undertaken to propose a retest period or shelf life beyond the observed range of data from the long-term storage condition.

This guidance represents the agency's current thinking on this topic. 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 requirements of the applicable statutes and regulations.

**II. Comments**

Interested persons may submit to the Division of Dockets Management (see **ADDRESSES**) written or electronic comments on the guidance. Submit a single copy of electronic comments or two paper copies of any mailed comments, except that individuals may submit one paper copy. Comments are to be identified with the docket number found in brackets in the heading of this document. The guidance and received comments may be seen in the Division of Dockets Management between 9 a.m. and 4 p.m., Monday through Friday.

**III. Electronic Access**

Persons with access to the Internet may obtain the document at <http://www.fda.gov/ohrms/dockets/default.htm>, <http://www.fda.gov/cder/guidance/index.htm>, or <http://www.fda.gov/cber/publications.htm>.

Dated: May 29, 2004.

**Jeffrey Shuren,**

*Assistant Commissioner for Policy.*

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**DEPARTMENT OF HEALTH AND HUMAN SERVICES**

**Health Resources and Services Administration**

**Agency Information Collection Activities: Submission for OMB Review; Comment Request**

Periodically, the Health Resources and Services Administration (HRSA) publishes abstracts of information collection requests under review by the Office of Management and Budget, in compliance with the Paperwork Reduction Act of 1995 (44 U.S.C. chapter 35). To request a copy of the clearance requests submitted to OMB for review, call the HRSA Reports Clearance Office on (301) 443-1129.

The following request has been submitted to the Office of Management and Budget for review under the Paperwork Reduction Act of 1995:

**Proposed Project: Data System for Organ Procurement and Transplantation Network (42 CFR Part 121, OMB No. 0915-0184): Revision**

The operation of the Organ Procurement and Transplantation Network (OPTN) necessitates certain recordkeeping and reporting requirements in order to perform the functions related to organ transplantation under contract to HHS. This is a request for an extension of the current record keeping and reporting requirements associated with the OPTN. These data will be used by HRSA in monitoring the contracts for the OPTN and the Scientific Registry of Transplant Recipients (SRTR) and in carrying out other statutory responsibilities. Information is needed to match donor organs with recipients, to monitor compliance of member organizations with OPTN rules and requirements, and to ensure that all qualified entities are accepted for membership in the OPTN.

**ESTIMATED ANNUAL REPORTING AND RECORD KEEPING BURDEN**

Section and activity	Number of respondents	Responses per respondent	Total responses	Hours per response	Total burden hours
121.3(b)(2) OPTN membership and application requirements for OPOs, hospitals, and histocompatibility laboratories .....	30	1	30	40	1,200