produce a final product that is readily comprehensible and usable (4 points); and

Applications will be evaluated based on the extent to which they demonstrate the direct relationship of the project to the applicant organization such as an organizational chart that illustrates the relationship of the project to the current organization; (3 points).

Criterion 5: Budget and Budget Justification (5 Points)

Applications will be evaluated based on the extent to which the applicant presents a budget with reasonable project costs, appropriately allocated across component areas, and sufficient to accomplish the objectives, such as the inclusion of a justification for and documentation of the dollar amount requested.

Applications will be evaluated based upon the extent to which they include a narrative budget justification that describes how the categorical costs are derived and a discussion of the reasonableness and appropriateness of the proposed costs. Line item allocations and justifications are required for Federal funds.

Applicants have the option of omitting the Social Security Numbers and specific salary rates of the proposed project personnel from the two copies submitted with the original applications to ACF. For purposes of the outside review process, applicants may elect to summarize salary information on the copies of their application. All necessary salary information must, however, appear on the signed original application for ACF.

Applications will be evaluated based on the extent to which they discuss and justify the costs of the proposed project as being reasonable and programmatically justified in view of the activities to be conducted and the anticipated results and benefits (3 points); and

Applications will be evaluated based on the extent to which they describe the fiscal control and accounting procedures that will be used to ensure prudent use, proper disbursement, and accurate accounting of funds received under this program announcement; (2 points).

2. Review and Selection Process

Each application submitted under this program announcement will undergo a pre-review to determine that (1) the application was received by the closing date and submitted in accordance with the instructions in this announcement and (2) the applicant is eligible for funding. It is necessary that applicants state specifically which funding announcement they are applying for. Applications will be screened for appropriateness. If applications are found to be inappropriate for the funding announcement in which they are submitted, applicants will be contacted for verbal approval of redirection to a more appropriate priority area. Applications which pass the initial ACF screening will be evaluated and rated by an independent review panel on the basis of specific evaluation criteria. The results of these reviews will assist the Commissioner and ADD program staff in considering competing applications. Reviewers' scores will weigh heavily in funding decisions but will not be the only factors considered. Applications generally will be considered in order of the average scores assigned by reviewers. The evaluation criteria were designed to assess the quality of a proposed project, and to determine the likelihood of its success. The evaluation criteria are closely related and are considered as a whole in judging the overall quality of an application. Points are awarded only to applications which are responsive to the evaluation criteria within the context of this program announcement. Federal reviewers will be used for the review process.

VI. Award Administration Information

1. Award Notices

The successful applicants will be notified through the issuance of a Financial Assistance Award. The Financial Assistance Award will be signed by the Grants Officer and transmitted via postal mail.

Organizations whose applications will not be funded will be notified in writing by the Administration on Developmental Disabilities.

2. Administrative and National Policy Requirements

45 CFR part 74 or 45 CFR part 92.

3. Reporting

Programmatic Reports: Semi-annually.

Financial Reports: Semi-annually.

Special Reporting Requirements: None.

All grantees are required to submit semi-annual program reports; grantees are also required to submit semi-annual expenditure reports using the required financial standard form (SF–269) which is located on the Internet at: *http://forms.psc.gov/forms/sf/SF–269.pdf.* A suggested format for the program report will be sent to all grantees after the awards are made.

VII. Agency Contacts

Program Office Contact: Margaret Schaefer, Administration for Children and Families, Administration on Developmental Disabilities, 370 L'Enfant Promenade, SW., Mail Stop HHH 405–D, Washington, DC 20447, Phone: (202) 690–5962, E-mail: *mschaefer@acf.hhs.gov.*

Grants Management Office Contact: Lois Hodge, Administration for Children and Families, Office of Grants Management, 370 Enfant Promenade, SW., Washington, DC 20447, Telephone (202) 401–2344, E-mail *LHodge@acf.hhs.gov.*

VIII. Other Information

Additional information about this program and its purpose can be located on the following Web sites: *http://www.acf.hhs.gov/programs/add*; *http://www.nass.org.*

Dated: May 27, 2004.

Patricia Morrissey,

Commissioner, Administration on Developmental Disabilities.

[FR Doc. 04–12892 Filed 6–7–04; 8:45 am]

BILLING CODE 4184–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. 2003P–0296]

Romano Cheese for Manufacturing 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 Kerry, Inc., Eau Galle Cheese Factory, First District Association, and Mullins Cheese, Inc., jointly to market test romano cheese for manufacturing that deviates from the U.S. standard of identity for romano cheese § 133.183 (21 CFR 133.183). 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.

DATES: This permit is effective for 15 months, beginning on the date the permit holders introduced or caused the introduction of the test product into interstate commerce, but not later than September 8, 2004.

FOR FURTHER INFORMATION CONTACT: Ritu Nalubola, Center for Food Safety and

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.

[FR Doc. 04–12842 Filed 6–7–04; 8:45 am]

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 (HFM–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