submitting the application, applicants are providing the certification and need not mail back the certification with the application.

Applicant must also understand that they will be held accountable for the smoking prohibition included within Pub. L. 103–227, Part C Environmental Tobacco Smoke (also known as the Pro-Children's Act of 1994). A copy of the **Federal Register** notice which implements the smoking prohibition is included with the forms. By signing and submitting the application, applicants are providing the certification and need not mail back the certification with the application. Copies of these assurances/certifications can be obtained from the ADD Web site (*http://www.acf.dhhs.gov/programs/add*) or by contacting Carla R. Brown, ADD, 370 L'Enfant Promenade SW., Washington, DC 20447, (202) 690–8332. These forms can be reproduced, as necessary.

E. Checklist for a Complete Application

The checklist below is for your use to ensure that your application package has been properly prepared.

—One original, signed and dated application, plus two copies.
—Application is from an organization that is eligible under the eligibility requirements defined in Part IV under Program Description and Requirements.

Application length does not exceed 25 pages, unless otherwise specified in the priority area description.

A complete application consists of the following items in this order:

—Application for Federal Assistance (SF 424, REV 4–92);
—A completed SPOC certification with the date of SPOC contact entered in line 16, page 1 of the SF 424 if applicable.
—Budget Information—Non-Construction Programs (SF 424A, REV 4–92);
—Budget justification for Section B—Budget Categories;
—Proof of designation as lead agency;
—Table of Contents;
—Letter from the Internal Revenue Service, *etc.* to prove non-profit status, if necessary;
—Copy of the applicant's approved indirect cost rate agreement, if appropriate;
—Project Description (See Part III, Section E);
—Any appendices/attachments;
—Assurances—Non-Construction Programs (Standard Form 424B, REV 4–92);
—Certification Regarding Lobbying;
—Certification of Protection of Human Subjects, if necessary; and
—Certification of the Pro-Children Act of 1994 (Environmental Tobacco Smoke), signature on the application represents certification.

F. The Application Package

Each application package must include an original and two copies of the complete application. Each copy should be stapled securely (front and back if necessary) in the upper left-hand corner. All pages of the narrative (including charts, tables, maps, exhibits, *etc.*) must be sequentially numbered, beginning with page one. In order to facilitate handling, please do not use covers, binders or tabs. Do not include extraneous materials as attachments, such as agency promotion brochures, slides, tapes, film clips, minutes of meetings, survey instruments or articles of incorporation.

Applicants have the option of omitting from the application copies (not the original) of specific salary rates or amounts for individuals specified in the application budget and Social Security Numbers, if otherwise required for individuals. The copies may include summary salary information.

Reporting Requirements

The Grantees are required to file the Financial Status Report (SF–269) semi-annually and the Program Performance Reports quarterly. Funds issued under these awards must be accounted for, and reported upon, separately from all other grant activities. The official receipt point for all reports and correspondence is the Grants Officer, Administration for Children and Families, Office of Grants Management, 370 L'Enfant Promenade, SW., 8th Floor, Washington, DC 20447–0002, telephone: (202) 401–2344. An original and one copy of each report shall be submitted 30 days of the end of each reporting period directly to the Office of Grants Management.

A final Financial Status Report and Program Performance Report shall be due 90 days after the project expiration date or termination of Federal budget support.

G. Paperwork Reduction Act of 1995 (Pub. L. 104–13)

The Uniform Project Description information collection within this announcement is approved under the Uniform Project Description (0970–0139), Expiration Date 12/31/2003.

Public reporting burden for this collection of information is estimated to average 10 hours per response, including the time for reviewing instructions, gathering and maintaining the data needed, and reviewing the collection of information.

An agency may not conduct or sponsor, and a person is not required to respond to, a collection of information unless it displays a currently valid OMB control number.

Dated: July 25, 2003.

Patricia Morrissey,

Commissioner, Administration on Developmental Disabilities.

[FR Doc. 03–19905 Filed 8–4–03; 8:45 am]

BILLING CODE 4184–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. 2002N–0511]

Thomas Ronald Theodore; Debarment Order

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is issuing an order under the Federal Food, Drug, and Cosmetic Act (the act) permanently debarring Mr. Thomas Ronald Theodore from providing services in any capacity to a person that has an approved or pending drug product application including, but not limited to, a biologics license application. FDA bases this order on a finding that Mr. Theodore was convicted of a felony under Federal law for conduct relating to the regulation of a drug product under the act. After being given notice of the proposed permanent debarment and his opportunity to request a hearing within the timeframe prescribed by regulation, Mr. Theodore failed to request a hearing. Mr. Theodore's failure to request a hearing constitutes a waiver of his right to a hearing concerning this action.

DATES: This order is effective August 5, 2003.

ADDRESSES: Submit applications for termination of debarment to the Division of Dockets Management (HFA–305), Food and Drug Administration, 5630 Fishers Lane, rm. 1061, Rockville, MD 20852.

FOR FURTHER INFORMATION CONTACT: Kathleen Swisher, Center for Biologics Evaluation and Research (HFM–17), Food and Drug Administration, 1401 Rockville Pike, Rockville, MD 20852–1448, 301–827–6210.

SUPPLEMENTARY INFORMATION:

I. Background

On March 1, 2002, the U.S. District Court for the District of Massachusetts

entered judgment against Mr. Theodore for nine counts of mail fraud, Federal felony offenses under 18 U.S.C. 1341. Mr. Theodore devised a scheme and artifice to defraud and to obtain money and property by means of false and fraudulent pretenses and representations. Mr. Theodore illegally arranged to ship an unapproved new drug identified as ''LK–200'' that had been manufactured in Woburn, MA, to the Bahamas, and then arranged to have the drug shipped from the Bahamas to pharmacists, physicians, and patients in the United States.

As a result of this conviction, FDA sent to Mr. Theodore by certified mail on December 17, 2002, a notice proposing to permanently debar Mr. Theodore from providing services in any capacity to a person that has an approved or pending drug product application including, but not limited to, a biologics license application. The proposal also offered Mr. Theodore an opportunity for a hearing on the proposal. The proposal was based on a finding, under section 306(a)(2)(B) and (c)(2)(A)(ii) of the act (21 U.S.C. 335a(a)(2)(B) and (c)(2)(A)(ii)), that Mr. Theodore was convicted of a felony under Federal law for conduct relating to the regulation of a drug product. Mr. Theodore was provided 30 days to file objections and request a hearing. On January 3, 2003, FDA received from Mr. Theodore a response to the proposal to debar and notice of opportunity for hearing. Mr. Theodore did not request a hearing. Mr. Theodore argued that, although he was convicted of all felony counts, an appeal is pending. However, this argument fails under the applicability of conviction provision of section 306(l)(1)(A) of the act (21 U.S.C. 335a(l)(1)(A)). This law states that a person is considered to have been convicted of a criminal offense when a judgment of conviction has been entered against the person by a Federal or State court, regardless of whether there is an appeal pending. Therefore, Mr. Theodore's failure to request a hearing constitutes a waiver of his opportunity for a hearing and a waiver of any contentions concerning his debarment. In the event that the convictions that served as the basis for Mr. Theodore's debarment are reversed on appeal, the order of debarment shall be withdrawn. (See section 306(d)(3)(B)(i) of the act (21 U.S.C. 335a(d)(3)(B)(i)).)

II. Findings and Order

Therefore, the Director, Center for Biologics Evaluation and Research, under section 306(a)(2)(B) of the act (21 U.S.C. 335a(a)(2)(B)), and under authority delegated to the Director (21 CFR 5.34(a)), finds that Mr. Theodore has been convicted of a felony under Federal law for conduct relating to the regulation of a drug product.

As a result of the foregoing finding, Mr. Theodore is permanently debarred from providing services in any capacity to a person with an approved or pending drug product application. A drug product means a drug, including a biological product, subject to regulation under sections 505, 512, or 802 of the act (21 U.S.C. 355, 360b, or 382), or under section 351 of the Public Health Service Act (42 U.S.C. 262). Any person with an approved or pending drug product application including, but not limited to, a biologics license application, who knowingly employs or retains as a consultant or contractor, or otherwise uses the services of Mr. Theodore, in any capacity, during Mr. Theodore's permanent debarment, will be subject to civil money penalties (section 307(a)(6) of the act (21 U.S.C. 335b(a)(6))). If Mr. Theodore, during his permanent debarment, provides services in any capacity to a person with an approved or pending drug product application including, but not limited to, a biologics license application, Mr. Theodore will be subject to civil money penalties (section 307(a)(7) of the act (21 U.S.C. 335b(a)(7))). In addition, FDA will not accept or review any abbreviated new drug applications submitted by or with the assistance of Mr. Theodore during Mr. Theodore's permanent debarment.

Any application by Mr. Theodore for termination of debarment under section 306(d)(4) of the act should be identified with Docket No. 2002N–0511 and sent to the Division of Dockets Management (see **ADDRESSES**). All such submissions are to be filed in four copies (§ 10.20(a) (21 CFR 10.20(a))). The public availability of information in these submissions is governed by § 10.20(j). Publicly available submissions may be seen in the Division of Dockets Management between 9 a.m. and 4 p.m., Monday through Friday (§ 10.20(j)(1)).

Dated: July 23, 2003.

Mark Elengold,

Deputy Director for Operations, Center for Biologics Evaluation and Research.

[FR Doc. 03–19806 Filed 8–4–03; 8:45 am]

BILLING CODE 4160–01–S

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, and First District Association jointly to market test romano cheese for manufacturing that deviates from the U.S. standard of identity for romano cheese (21 CFR 133.183). The purpose of the temporary permit is to allow the co-applicants 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 test product is introduced or caused to be introduced into interstate commerce, but not later than November 3, 2003.

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 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; and First District Association, 101 South Swift Ave., Litchfield, MN 55355.

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 (21 CFR 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