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 Theodore's debarment are reversed on appeal, the order of debarment shall be withdrawn.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

requirements of the standard. 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.

The 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 at N6765 State Hwy., Durand, WI 54736 and by First District Association at 101 South Swift Ave., Litchfield, MN 55355. 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 food is introduced or caused to be introduced into interstate commerce, but not later than November 3, 2003.

Dated: July 17, 2003.

Christine Taylor,

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

[FR Doc. 03–19805 Filed 8–5–03; 8:45 am]

BILLING CODE 4160–01–S

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

Drug Safety and Risk Management Advisory Committee; Notice of Meeting

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

This notice announces a forthcoming meeting of a public advisory committee of the Food and Drug Administration (FDA). The meeting will be open to the public.

Name of Committee: Drug Safety and Risk Management Advisory Committee.

General Function of the Committee: To provide advice and recommendations to the agency on FDA's regulatory issues.

Date and Time: The meeting will be held on September 19, 2003, from 8 a.m. to 5 p.m.

Location: Holiday Inn, The Ballrooms, 8777 Georgia Ave., Silver Spring, MD.

Contact Person: Shalini Jain, Center for Drug Evaluation and Research (HFD–21), Food and Drug Administration, 5600 Fishers Lane (for express delivery, 5630 Fishers Lane, rm. 1093) Rockville, MD 20857, 301– 827–7001, e-mail at: j*ains@cder.fda.gov*, or FDA Advisory Committee Information Line, 1 800–741–8138 (301–443–0572 in the Washington, DC area), code 12535. Please call the Information Line for up to date information on this meeting. Background materials for this meeting, when available, will be posted on the Web site 1 business day before the meeting at *http://www.fda.gov/ohrms/dockets/ac/acmenu.htm*.

Agenda: The committee will discuss current screening methods to assess sound alike and look alike proprietary drug names, in order to reduce the incidence of medication errors resulting from look-alike and sound-alike names. This advisory committee meeting is in followup to FDA, Institute for Safe Medication Practices, and the Pharmaceutical Research and Manufacturers of America public meeting on the same subject, held on June 26, 2003.

Procedure: Interested persons may present data, information, or views, orally or in writing, on issues pending before the committee. Written submissions may be made to the contact person by September 12, 2003. Oral presentations from the public will be scheduled between approximately 1 p.m. and 2 p.m. Time allotted for each presentation may be limited. Those desiring to make formal oral presentations should notify the contact person before September 12, 2003, and submit a brief statement of the general nature of the evidence or arguments they wish to present, the names and addresses of proposed participants, and an indication of the approximate time requested to make their presentation.

Persons attending FDA's advisory committee meetings are advised that the agency is not responsible for providing access to electrical outlets.

FDA welcomes the attendance of the public at its advisory committee meetings and will make every effort to accommodate persons with physical disabilities or special needs. If you require special accommodations due to a disability, please contact Kimberly Topper at least 7 days in advance of the meeting.

Notice of this meeting is given under the Federal Advisory Committee Act (5 U.S.C. app. 2).

Dated: July 25, 2003.

Peter J. Pitts,

Associate Commissioner for External Relations.

[FR Doc. 03–19807 Filed 8–4–03; 8:45 am]

BILLING CODE 4160–01–S

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. 1991D–0425]

Guideline for the Clinical Evaluation of Analgesic Drugs; Withdrawal of Guidance

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice; withdrawal.

SUMMARY: The Food and Drug Administration (FDA) is announcing the withdrawal of a guidance entitled ''Guideline for the Clinical Evaluation of Analgesic Drugs,'' which was issued on December 1, 1992. The guidance is outdated and no longer reflects FDA's current thinking on development of analgesic drugs. FDA is revising the guidance and will issue a draft for public comment in the future.

DATES: Comments on agency guidances are welcome at any time.

FOR FURTHER INFORMATION CONTACT: Barbara J. Gould, Center for Drug Evaluation and Research (HFD–550), Food and Drug Administration, 5600 Rockville Pike, Rockville, MD 20850, 301–827–2504.

Dated: July 28, 2003.

Jeffrey Shuren,

Assistant Commissioner for Policy.

[FR Doc. 03–19802 Filed 8–4–03; 8:45 am]

BILLING CODE 4160–01–S

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Health Resources and Services Administration

New Annual ''Low-Income'' Levels for Various Health Professions and Nursing Programs Included in Titles VII and VIII of the Public Health Service Act

AGENCY: Health Resources and Services Administration (HRSA), HHS.

ACTION: Notice.

SUMMARY: This notice announces the new ''low-income'' levels for various programs included in titles VII and VIII of the Public Health Service (PHS) Act, which use the U.S. Census Bureau ''low-