

on the Internet. The address for the CDC homepage is: <http://www.cdc.gov>.

Potential applicants may obtain a copy of Healthy People 2000 (Full Report, Stock No. 017-001-00474-0) or Healthy People 2000 (Summary Report, Stock No. 017-001-00473-1) referenced in the **Introduction** section through the Superintendent of Documents, Government Printing Office, Washington, DC 20402-9325, telephone (202) 512-1800.

The National Occupational Research Agenda: copies of this publication may be obtained from the National Institute for Occupational Safety and Health, Publications Office, 4676 Columbia Parkway, Cincinnati, OH 45226-1998 or telephone 1-800-356-4674, and is available through the NIOSH Home Page; <http://www.cdc.gov/niosh/nora.html>.

NORA Priority Research Areas

Disease and Injury

- Allergic and Irritant Dermatitis
- Asthma and Chronic Obstructive Pulmonary Disease
- Fertility and Pregnancy Abnormalities
- Hearing Loss
- Infectious Diseases
- Low Back Disorders
- Musculoskeletal Disorders of the Upper Extremities
- Traumatic Injuries

Work Environment and Workforce

- Emerging Technologies
- Indoor Environment
- Mixed Exposures
- Organization of Work
- Special Populations at Risk

Research Tools and Approaches

- Cancer Research Methods
- Control Technology and Personal Protective Equipment
- Exposure Assessment Methods
- Health Services Research
- Intervention Effectiveness Research
- Risk Assessment Methods
- Social and Economic Consequences of Workplace Illness and Injury
- Surveillance Research Methods

Dated: June 4, 1997.

Diane D. Porter,

Acting Director, National Institute for Occupational Safety and Health, Centers for Disease Control and Prevention (CDC).

[FR Doc. 97-15180 Filed 6-10-97; 8:45 am]

BILLING CODE 4163-19-P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. 97N-0212]

Agency Information Collection Activities: Proposed Collection; Comment Request; Extension

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is announcing an opportunity for public comment on the proposed collection of certain information by the agency. Under the Paperwork Reduction Act of 1995 (the PRA), Federal agencies are required to publish notice in the **Federal Register** concerning each proposed collection of information, including each proposed extension of an existing collection of information, and to allow 60 days for public comment in response to the notice. This notice solicits comments on the electronic collection of data by FDA regarding FDA-regulated products of foreign origin that are being offered for import into the United States.

DATES: Submit written comments on the collection of information by August 11, 1997.

ADDRESSES: Submit written comments on the collection of information to the Dockets Management Branch (HFA-305), Food and Drug Administration, 12420 Parklawn Dr., rm. 1-23, Rockville, MD 20857. All comments should be identified with the docket number found in brackets in the heading of this document.

FOR FURTHER INFORMATION CONTACT: Margaret R. Wolff, Office of Information Resources Management (HFA-250), Food and Drug Administration, 5600 Fishers Lane, rm. 16B-19, Rockville, MD 20857, 301-827-1223.

SUPPLEMENTARY INFORMATION: Under the PRA (44 U.S.C. 3501-3520), Federal agencies must obtain approval from the Office of Management and Budget (OMB) for each collection of information they conduct or sponsor. "Collection of information" is defined in 44 U.S.C. 3502(3) and 5 CFR 1320.3(c) and includes agency requests or requirements that members of the public submit reports, keep records, or provide information to a third party. Section 3506(c)(2)(A) of the PRA (44 U.S.C. 3506(c)(2)(A)) requires Federal agencies to provide a 60-day notice in the **Federal Register** concerning each proposed collection of information, including each proposed extension of an

existing collection of information, before submitting the collection to OMB for approval. To comply with this requirement, FDA is publishing notice of the proposed collection of information listed below.

With respect to the following collection of information, FDA invites comments on: (1) Whether the proposed collection of information is necessary for the proper performance of FDA's functions, including whether the information will have practical utility; (2) the accuracy of FDA's estimate of the burden of the proposed collection of information, including the validity of the methodology and assumptions used; (3) ways to enhance the quality, utility, and clarity of the information to be collected; and (4) ways to minimize the burden of the collection of information on respondents, including through the use of automated collection techniques, when appropriate, and other forms of information technology.

Importer's Entry Notice—(OMB Control Number 0910-0046)—Extension

Section 801 of the Federal Food, Drug, and Cosmetic Act (the act) (21 U.S.C. 381) charges FDA with the following responsibilities: (1) Assuring that foreign-origin FDA-regulated foods, drugs, cosmetics, medical devices, and radiological health products offered for import into the United States meet the same requirements of the act as do domestic products; and (2) preventing shipments from entering the country if they are not in compliance.

The information collected by FDA consists of the following: (1) Product code, an alpha-numeric series of characters that identifies each product FDA regulates; (2) FDA country of origin, the country where the FDA-registered or FDA-responsible firm is located; (3) FDA manufacturer, the party who manufactured, grew, assembled, or otherwise processed the goods (if more than one, the last party who substantially transformed the product); (4) shipper, the party responsible for packing, consolidating, or arranging the shipment of the goods to their final destination; (5) quantity and value of the shipment; and (6) if appropriate, affirmation of compliance, a code that conveys specific FDA information, such as registration number, foreign government certification, etc. This information is collected electronically by the entry filer via the U.S. Customs Service's Automated Commercial System at the same time he/she files an entry for import with the U.S. Customs Service. FDA uses the information to make admissibility decisions about

FDA-regulated products offered for import into the United States.

FDA estimates the burden of this collection of information as follows:

ESTIMATED ANNUAL REPORTING BURDEN

No. of Respondents	Annual Frequency per Response	Total Annual Responses	Hours per Response	Total Hours
2,505	1,212.54	3,037,426	0.07 h	229,693

There are no capital costs or operating and maintenance costs associated with this collection.

The source of the estimate for the number of respondents is the number of importers who submitted entry data for foreign-origin FDA-regulated products in 1996. The estimated reporting burden is based on information obtained by contacting several past respondents.

Dated: June 3, 1997.

William K. Hubbard,
Associate Commissioner for Policy
Coordination.

[FR Doc. 97-15168 Filed 6-10-97; 8:45 am]

BILLING CODE 4160-01-F

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. 97G-0219]

Beatrice Foods, Inc.; Withdrawal of GRAS Affirmation Petition

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is announcing the withdrawal, without prejudice to a future filing, of a petition (GRASP 5G0047) proposing that the use of magnesium caseinate for use as an ingredient for making cheese alternate products which can be blended with natural cheese or used alone as a total substitute for cheese be affirmed as generally recognized as safe (GRAS).

FOR FURTHER INFORMATION CONTACT: Rudolph Harris, Center for Food Safety and Applied Nutrition (HFS-206), Food and Drug Administration, 200 C St. SW., Washington, DC 20204, 202-418-3090.

SUPPLEMENTARY INFORMATION: In a notice published in the **Federal Register** of February 4, 1975 (40 FR 5180), FDA announced that a petition (GRASP 5G0047) had been filed by Beatrice Foods Co., Inc., 1526 South State St., Chicago, IL 60605. This petition proposed that the use of magnesium caseinate for use as an ingredient for making cheese alternate products which can be blended with natural cheese or used alone as a total substitute for cheese is GRAS.

Beatrice Foods Co., Inc., of Chicago, the submitter of the original GRAS affirmation petition no longer exists. Beatrice Cheese Inc., 770 North Springdale Rd., Waukesha, WI, 53180, which was formerly part of Beatrice Foods Co., Inc., indicated that the proposed use had been abandoned and acknowledged that the agency should close the petition file and withdraw the petition. Therefore, the agency is announcing that it considers this petition to be withdrawn, without prejudice to a future filing, in accordance with 21 CFR 171.7.

Dated: May 12, 1997.

Alan M. Rulis,
Director, Office of Premarket Approval,
Center for Food Safety and Applied Nutrition.
[FR Doc. 97-15313 Filed 6-10-97; 8:45 am]
BILLING CODE 4160-01-F

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. 97M-0186]

Millenium Medical Supply, Inc.; Premarket Approval of Needle-Ease™ 2501

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is announcing its approval of the application submitted by Louise N. Howe of the law firm HALE and DORR, as the U.S. Representative on behalf of Millenium Medical Supply, Inc., Ontario, Canada, for premarket approval, under the Federal Food, Drug, and Cosmetic Act (the act), of Needle-Ease™ 2501. FDA's Center for Devices and Radiological Health (CDRH) notified the applicant, by letter of March 6, 1997, of the approval of the application.

DATES: Petitions for administrative review by July 11, 1997.

ADDRESSES: Written requests for copies of the summary of safety and effectiveness data and petitions for administrative review to the Dockets

Management Branch (HFA-305), Food and Drug Administration, 12420 Parklawn Dr., rm. 1-23, Rockville, MD 20857.

FOR FURTHER INFORMATION CONTACT: Chiu S. Lin, Center for Devices and Radiological Health (HFZ-480), Food and Drug Administration, 9200 Corporate Blvd., Rockville, MD 20850, 301-443-8913.

SUPPLEMENTARY INFORMATION: On December 6, 1996, Louise N. Howe of the law firm HALE and DORR, as the U.S. Representative on behalf of Millenium Medical Supply, Inc., Ontario, Canada, N3T 5M1, submitted to CDRH an application for premarket approval of Needle-Ease™ 2501. This device is a sharps needle destruction device that is intended for home use by diabetics to reduce the incidence of needlesticks by the incineration of 28-30 gauge needles, 29 and 30 gauge diabetic "pen tips," and 23-26 gauge diabetic lancets.

In accordance with the provisions of section 515(c)(2) of the act (21 U.S.C. 360e(c)(2)) as amended by the Safe Medical Devices Act of 1990, this premarket approval application (PMA) was not referred to the General Hospital and Personal Use Devices Panel of the Medical Devices Advisory Committee, an FDA advisory committee, for review and recommendation because the information in the PMA substantially duplicates information previously reviewed by this panel. On March 6, 1997, CDRH approved the application by a letter to the applicant from the Director of the Office of Device Evaluation, CDRH.

A summary of the safety and effectiveness data on which CDRH based its approval is on file in the Dockets Management Branch (address above) and is available from that office upon written request. Requests should be identified with the name of the device and the docket number found in brackets in the heading of this document.

Opportunity For Administrative Review

Section 515(d)(3) of the act authorizes any interested person to petition, under