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]

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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