Washington, DC 20402–9325, telephone (202) 512–1800.

Dated: April 17, 1996.

Joseph R. Carter,

Acting Associate Director for Management and Operations, Centers for Disease Control and Prevention (CDC).

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BILLING CODE 4163–18–P

Food and Drug Administration

[Docket No. 96N–0066]

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, Federal agencies are required to publish a notice in the Federal Register concerning each proposed collection of information, including each proposed extension of an existing collection of information, and allow 60 days for public comment in response to the notice. This notice solicits comments on reporting and recordkeeping requirements implementing the Federal Import Milk Act.

DATES: Submit written comments on the collections of information by June 24, 1996.

ADDRESSES: Submit written comments on the collections 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: Charity B. Smith, Office of Information Resources Management (HFA–250), Food and Drug Administration, 5600 Fishers Lane, rm. 16B–19, Rockville, MD 20857, 301–827–1686.

SUPPLEMENTARY INFORMATION: Section 3506(c)(2)(A) of the Paperwork Reduction Act of 1995 (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. ''Collection of information'' is defined in 44 U.S.C. 3502(3) and 5 CFR 1320.3(c). 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.

Part 1210 *Regulations Under the Federal Import Milk Act* (21 CFR Part 1210) (OMB Control Number 0910–0212—Extension)

Under the regulations implementing the Federal Import Milk Act (21 U.S.C. 141–149), milk or cream may be imported into the United States only by the holder of a valid import milk permit. Before such permit is issued: (1) All cows from which import milk or cream is produced must be physically examined and found healthy; (2) if the milk or cream is imported raw, all such cows must pass a tuberculin test; (3) the dairy farm and each plant in which the milk or cream is processed or handled must be inspected and found to meet certain sanitary requirements; (4) bacterial counts of the milk at the time of importation must not exceed specified limits; and (5) the temperature of the milk or cream at time of importation must not exceed 50 °F. In addition, the regulations require that dairy farmers and plants maintain pasteurization records (§ 1210.15) and that each container of milk or cream imported into the United States bear a tag with the product type, permit number, and shipper's name and address (§ 1210.22).

FDA estimates the burden of complying with the information collection provisions of these regulations as follows:

Estimated Annual Reporting Burden

Form No.	21 CFR Section	No. of Respondents	Annual Frequency per Response	Total Annual Responses	Hours per Response	Total Hours
FDA 1815/Permits granted on certificates	1210.23	1	1	1	0.5	0.5
FDA 1993/Application of permit	1210.20	1	1	1	0.5	0.5
FDA 1994/Tuberculin test	1210.13	0	0	0	N/A	0
FDA 1995/Physical examination of cows	1210.12	0	0	0	N/A	0
FDA 1996/Sanitary inspection of dairy farms	1210.11	1	300	300	1.5	450
FDA 1997/Sanitary inspections of plants	1210.14	1	1	1	2.0	2.0
Total						453

Estimated Annual Recordkeeping Burden

21 CFR Section	No. of Recordkeepers	Annual Frequency per Recordkeeping	Total Annual Records	Hours per Recordkeeper	Total Hours
21 CFR 1210.15	1	1	1	.05	0.05

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

No burden has been estimated for the tagging requirement in § 1210.22 because the information on the tag is either supplied by FDA (permit number) or is disclosed to third parties as a usual and customary part of the shipper's normal business activities (type of product, shipper's name and address). Under 5 CFR 1320.3(c)(2), the public disclosure of information originally supplied by the Federal government to the recipient for the purpose of disclosure to the public is not a collection of information. Under 5 CFR 1320.3(b)(2)), the time, effort, and financial resources necessary to comply with a collection of information are excluded from the burden estimate if the reporting, recordkeeping, or disclosure activities needed to comply are usual and customary because they would occur in the normal course of activities. No burden has been estimated for Forms FD 1994 and 1995 because they are not currently being used. The Secretary of Health and Human Services has the discretion to allow Form FD 1815, a duly certified statement signed by an accredited official of a foreign government, to be submitted in lieu of Forms FD 1994 and 1995. To date, Form FD–1815 has been submitted in lieu of these forms.

Dated: April 11, 1996.

William K. Hubbard,

Associate Commissioner for Policy Coordination.

[FR Doc. 96–9869 Filed 4–22–96; 8:45 am]

BILLING CODE 4160–01–F

[Docket No. 96F–0107]

Dainippon Ink and Chemicals, Inc.; Filing of Food Additive Petition

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is announcing that Dainippon Ink and Chemicals, Inc., has filed a petition proposing that the food additive regulations be amended to provide for the safe use of aliphatic polyester-polyurethane resin-acid dianhydride adhesive in retortable pouches intended for use in contact with food.

DATES: Written comments on the petitioner's environmental assessment by May 23, 1996.

ADDRESSES: Submit written comments to the Dockets Management Branch (HFA–305), Food and Drug Administration, 12420 Parklawn Dr., rm. 1–23, Rockville, MD 20857.

FOR FURTHER INFORMATION CONTACT: Mark A. Hepp, Center for Food Safety and Applied Nutrition (HFS–216), Food and Drug Administration, 200 C St. SW., Washington, DC 20204, 202–418–3098.

SUPPLEMENTARY INFORMATION: Under the Federal Food, Drug and Cosmetic Act (sec. 409(b)(5) (21 U.S.C. 348(b)(5))), notice is given that a food additive petition (FAP 6B4496) has been filed by Dainippon Ink and Chemicals, Inc., c/o Center for Regulatory Services, 2347 Paddock Lane, Reston, VA 22091. The petition proposes to amend the food additive regulations in § 177.1390 *Laminate structures for use at temperatures of 250° F and above* (21 CFR 177.1390) to permit the safe use of aliphatic polyester-polyurethane resin-acid dianhydride adhesive in retortable pouches intended for use in contact with food.

The potential environmental impact of this action is being reviewed. To encourage public participation consistent with regulations promulgated under the National Environmental Policy Act (40 CFR 1501.4(b)), the agency is placing the environmental assessment submitted with the petition that is the subject of this notice on public display at the Dockets Management Branch (address above) for public review and comment. Interested persons may, on or before May 23, 1996, submit to the Dockets Management Branch (address above) written comments. Two copies of any comments are to be submitted, except that individuals may submit one copy. Comments are to be identified with the docket number found in brackets in the heading of this document. Received comments may be seen in the office above between 9 a.m. and 4 p.m., Monday through Friday. FDA will also place on public display any amendments to, or comments on, the petitioner's environmental assessment without further announcement in the Federal Register. If, based on its review, the agency finds that an environmental impact statement is not required and this petition results in a regulation, the notice of availability of the agency's finding of no significant impact and the evidence supporting that finding will be published with the regulation in the Federal Register in accordance with 21 CFR 25.40(c).

Dated: April 4, 1996.

George H. Pauli,

Acting Director, Office of Premarket Approval, Center for Food Safety and Applied Nutrition.

[FR Doc. 96–9915 Filed 4–22–96; 8:45 am]

BILLING CODE 4160–01–F

[Docket No. 96N–0126]

Drug Export; Migramist™ (dihydroergotamine mesylate, USP) 4 Milligrams(mg)/Milliliters(mL) Nasal Spray

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is announcing that Sandoz Pharmaceuticals Corp. has filed an application requesting conditional approval for the export of the human drug Migramist™ (dihydroergotamine mesylate, USP) 4 mg/mL Nasal Spray to Canada.

ADDRESSES: Relevant information on this application may be directed to the Dockets Management Branch (HFA–305), Food and Drug Administration, 12420 Parklawn Dr., rm. 1–23, Rockville, MD 20857, and to the contact person identified below. Any future inquiries concerning the export of human drugs under the Drug Export Amendments Act of 1986 should also be directed to the contact person.

FOR FURTHER INFORMATION CONTACT: James E. Hamilton, Center for Drug Evaluation and Research (HFD–310), Food and Drug Administration, 7520 Standish Pl., Rockville, MD 20855, 301–594–3150.

SUPPLEMENTARY INFORMATION: The drug export provisions in section 802 of the Federal Food, Drug, and Cosmetic Act (the act) (21 U.S.C. 382) provide that FDA may approve applications for the export of drugs that are not currently approved in the United States. Section 802(b)(3)(B) of the act sets forth the requirements that must be met in an application for approval. Section 802(b)(3)(C) of the act requires that the agency review the application within 30 days of its filing to determine whether the requirements of section 802(b)(3)(B) have been satisfied. Section 802(b)(3)(A) of the act requires that the agency publish a notice in the Federal Register within 10 days of the filing of an application for export to facilitate public participation in its review of the application. To meet this requirement, the agency is providing notice that Sandoz Pharmaceuticals Corp., 59 Rt. 10, East Hanover, NJ 07936–1080, has filed an application requesting conditional approval for the export of the human drug Migramist™ (dihydroergotamine mesylate, USP) 4 mg/mL Nasal Spray to Canada. This product is indicated for the treatment of migraine headaches. The application was received and filed in the Center for Drug Evaluation and Research on