

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 Pre-market
Approval, Center for Food Safety and Applied
Nutrition.

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

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[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

October 19, 1995, which shall be considered the filing date for purposes of the act.

Interested persons may submit relevant information on the application to the Dockets Management Branch (address above) in two copies (except that individuals may submit single copies) and identified with the docket number found in brackets in the heading of this document. These submissions may be seen in the Dockets Management Branch between 9 a.m. and 4 p.m., Monday through Friday.

The agency encourages any person who submits relevant information on the application to do so by May 3, 1996, and to provide an additional copy of the submission directly to the contact person identified above, to facilitate consideration of the information during the 30-day review period.

This notice is issued under the Federal Food, Drug, and Cosmetic Act (sec. 802 (21 U.S.C. 382)) and under authority delegated to the Commissioner of Food and Drugs (21 CFR 5.10) and redelegated to the Center for Drug Evaluation and Research (21 CFR 5.44).

Dated: April 5, 1996.

Betty L. Jones,

Deputy Director, Office of Compliance, Center for Drug Evaluation and Research.

[FR Doc. 96-9896 Filed 4-22-96; 8:45 am]

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[Docket No. 96N-0124]

Drug Export; Differin™ (Adapalene) 0.1% Topical Gel

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is announcing that Galderma Laboratories, Inc., has filed an application requesting approval for the export of the human drug Differin™ (Adapalene) 0.1% Topical Gel 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 Galderma Laboratories, Inc., 3000 Alta Mesa Blvd., Forth Worth, TX 76133, has filed an application requesting approval for the export of the human drug Differin™ (Adapalene) 0.1% Topical Gel to Canada. This product is indicated for the topical treatment of acne vulgaris. The application was received and filed in the Center for Drug Evaluation and Research on October 16, 1995, which shall be considered the filing date for purposes of the act.

Interested persons may submit relevant information on the application to the Dockets Management Branch (address above) in two copies (except that individuals may submit single copies) and identified with the docket number found in brackets in the heading of this document. These submissions may be seen in the Dockets Management Branch between 9 a.m. and 4 p.m., Monday through Friday.

The agency encourages any person who submits relevant information on the application to do so by May 3, 1996, and to provide an additional copy of the submission directly to the contact person identified above, to facilitate consideration of the information during the 30-day review period.

This notice is issued under the Federal Food, Drug, and Cosmetic Act (sec. 802 (21 U.S.C. 382)) and under authority delegated to the Commissioner of Food and Drugs (21 CFR 5.10) and redelegated to the Center for Drug Evaluation and Research (21 CFR 5.44).

Dated: April 5, 1996.

Betty L. Jones,

Deputy Director, Office of Compliance, Center for Drug Evaluation and Research.

[FR Doc. 96-9897 Filed 4-22-96; 8:45 am]

BILLING CODE 4160-01-F

[Docket No. 96N-0124]

Drug Export; Differin™ (Adapalene) 0.1% Topical Gel

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is announcing that Galderma Laboratories, Inc., has filed an application requesting approval for the export of the human drug Differin™ (Adapalene) 0.1% Topical Gel 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 Galderma Laboratories, Inc., 3000 Alta Mesa Blvd., Forth Worth, TX 76133, has filed an application requesting approval for the export of the human drug Differin™ (Adapalene) 0.1% Topical Gel to Canada. This product is indicated for the topical treatment of acne vulgaris. The application was received and filed in the Center for Drug Evaluation and Research on October 16, 1995, which shall be considered the filing date for purposes of the act.

Interested persons may submit relevant information on the application