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]

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 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.

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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 contract 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.

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Indian Health Service

Proposed Information Collection Activities Available for Public Comment and Recommendations

In accordance with Section 3506(c)(2)(A) of the Paperwork Reduction Act of 1995, the Indian Health Service (IHS) is requesting public comment on the following proposed agency information collection activities. Your comments are invited on: (a) Whether the information collection activity is necessary to carry out an agency function and whether the IHS processes the information collected in a useful and timely fashion; (b) the accuracy of the public burden estimate (this is the amount of time needed for individual respondents to provide the requested information) and the methodology and assumptions used to determine the estimate; (c) ways to enhance the quality, utility, and clarity of the information being collected; and (d) ways to minimize the public burden through the use of automated, electronic, mechanical, or other technological collection techniques or other forms of information technology.

Proposed Activity #1: The IHS Contract Health Service (CHS) seeks (A) approval for a 1 year reinstatement with no change of previously approved information collection activity, 0917–0002, ''Indian Health Service, Hospital, Dental and Other Contract Health Service Reports''; and (B) a 1 year approval for a new CHS form (IHS–843–1A, ''Purchase-Delivery Order for Health Services'') which is currently being pilot tested and is expected to be completed by September 1996.

The 1 year reinstatement of the current CHS forms and the 1 year approval of the new form will provide for a transition and implementation period for the new form and will allow the IHS to provide education and training in the use of the new single form; make any necessary adjustments in the protocol for the use of the new single form; and, make computer programming corrections as may be needed during the implementation period. The IHS-wide implementation of the new form is expected to be completed by the end of fiscal year 1997.

The new streamlined, user friendly CHS form IHS–843–1A combines the three current CHS forms (the IHS 43–1A used for hospital inpatient services, the IHS–57–1A used for dental services, and, the IHS–64–1A used for health care services other than hospital inpatient or dental) into one single form which reduces public response burden. The CHS forms are completed by CHS Providers and used to certify that the health care services request and authorized by the IHS have been performed by the CHS provider(s); process payments for health care services performed by such providers; and serve as a legal document for health and medical care authorized by the IHS and rendered by health care providers under contract with the IHS. The burden estimate for this information collection activity follows:

Information collection activity	Number of respondents	Responses per respondent	Average burden per response (hours)*
IHS–43–1A	580	148	0.17 (10 mins).
IHS–57–1A	532	22	0.42 (25 mins).
IHS–64–1A	7,688	32	0.17 (10 mins).
New form: IHS–843–1A	13.215	41	0.05 (3 mins).
Inpatient Discharge Summary	85,988	1	1.37 (82 mins).

*Burden estimate is based on data provided by the IHS Fiscal Intermediary (FI) contractor and feedback from CHS Providers (respondents) who have completed the forms (current or new) for at least one year. For FY–1994, the FI processed approximately 360,000 forms for some 8,800 respondents; and, the IHS CHS staff processed approximately 180,000 forms for some 4,400 respondents. The number of responses per respondent is based on the average number of forms processed for each Provider.

The inpatient discharge summary was overlooked as an information collection activity in prior approval requests and is added accordingly.

Proposed Activity #2: The IHS Loan Repayment Program (LRP) seeks a 3 year approval for reinstatement with minor change of previously approved information collection activity, 0917–0014, ''Indian Health Service Loan Repayment Program''. The IHS LRP recruits highly qualified health care professionals to meet agency health care staffing needs. The information collection forms used for this activity are contained in the IHS LRP Information and Application Booklet. The booklet provides an overview of the LRP, instructions regarding application procedures and potential employment opportunities, and tear-out application forms. The application form collects the following data from each applicant: Name, address, work and home telephone numbers, education and degree(s) obtained, work experience, and an accounting of financial (tuition) loans to be considered for payback. The instructions and forms contained in the LRP information and application booklet were updated, revised and clarified to improve applicant understanding and ease the response burden. The information collected is used to verify and evaluate applications to determine eligibility for the IHS LRP; award and authorize applicant payments; and, provide statistical program data. The burden estimate for this information collection activity follows: