

1995, 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: October 4, 1995.

Betty L. Jones,

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

[FR Doc. 95-25886 Filed 10-18-95; 8:45 am]

BILLING CODE 4160-01-F

[Docket No. 95N-0335]

**Drug Export; Atrovent® (Ipratropium Bromide) Nasal Spray 0.06%, 15 Milliliter (mL)**

**AGENCY:** Food and Drug Administration, HHS.

**ACTION:** Notice.

**SUMMARY:** The Food and Drug Administration (FDA) is announcing that Boehringer Ingelheim Pharmaceuticals Inc., has filed an application requesting approval for the export of the human drug Atrovent® (ipratropium bromide) Nasal Spray 0.06%, 15 mL to Canada.

**ADDRESSES:** Relevant information on this application may be directed to the Dockets Management Branch (HFA-305), Food and Drug Administration, rm. 1-23, 12420 Parklawn Dr., 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 Boehringer Ingelheim Pharmaceuticals Inc., 900 Ridgebury Rd., Ridgefield, CT 06877, has filed an application requesting approval for the export of the human drug Atrovent® (ipratropium bromide) Nasal Spray 0.06%, 15 mL to Canada. This drug product is used for the symptomatic relief of rhinorrhea associated with allergic or nonallergic perennial rhinitis. The application was received and filed in the Center for Drug Evaluation and Research on September 28, 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 October 30, 1995, 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: October 5, 1995.

Betty L. Jones,

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

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**Health Resources and Services Administration**

**Agency Forms Undergoing Paperwork Reduction Act Review**

Periodically, the Health Resources and Services Administration (HRSA) will publish a list of information collection requests under review, in compliance with the Paperwork Reduction Act (44 U.S.C. Chapter 35). To request a copy of these documents, call the HRSA Reports Clearance Office on (301)-443-1129.

The following request has been submitted to the Office of Management and Budget for review under the Paperwork Reduction Act.

1. Study of Physicians' Educational Preparation for Practice in Managed Care Settings—New—A mail survey will be conducted of primary care physicians and medical directors in managed care organizations to assess their views of the adequacy of their preparation for practice in that setting. The survey of physicians will be limited to those who graduated between 1986 and 1990. The information will be used by the Bureau of Health Professions to formulate recommendations for curriculum changes. Because this is a mail survey, automated collection techniques will not be used. Burden estimates are as follows:

	No. of re-spond-ents	No. of re-sponses per re-spond-ent	Avg. bur-den/re-sponse	Total hours of bur-den
Eligible Physicians/ Medical Directors .....	1915	1	.25 hours .	479
Ineligible Physicians/ Medical Directors .....	200	1	.07 hours .	14
Estimated Total Annual Burden: 493 hours.				

Written comments and recommendations concerning the

proposed information collections should be sent within 30 days of this

notice to: Allison Eydt, Human Resources and Housing Branch, Office