ORTHO™ Antibody to HBsAg ELISA Confirmatory Test is a third generation assay to be used to confirm the presence of Hepatitis B Surface Antigen (HBsAg) in specimens found repeatedly reactive in ORTHO™ Antibody to HBsAg ELISA Test System 3. The application was received and filed in the Center for Biologics Evaluation and Research on May 4, 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 June 12, 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 Biologics Evaluation and Research (21 CFR 5.44).

Dated: May 9, 1995.

**James C. Simmons,**

*Acting Director, Office of Compliance, Center for Biologics Evaluation and Research.*

[FR Doc. 95–13295 Filed 5–31–95; 8:45 am]

BILLING CODE 4160–01–F

**[Docket No. 95N–0143]**

## Drug Export; PEG-L-Asparaginase

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

**ACTION:** Notice.

**SUMMARY:** The Food and Drug Administration (FDA) is announcing that Enzon, Inc., has filed an application requesting approval for the export of the human biological product PEG-L-asparaginase to The Federal Republic of Germany.

**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 biological products under the Drug Export Amendments Act of 1986 should also be directed to the contact person.

**FOR FURTHER INFORMATION CONTACT:** Cathy E. Conn, Center for Biologics Evaluation and Research (HFM–610), Food and Drug Administration, 1401 Rockville Pike, Rockville, MD 20852–1448, 301–594–2006.

**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 human biological products 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 Enzon, Inc., 40 Kingsbridge Rd., Piscataway, NJ 08854, has filed an application requesting approval for the export of the human biological product PEG-L-asparaginase to The Federal Republic of Germany. PEG-L-asparaginase is an antineoplastic combination therapy for reinduction in the case of acute lymphatic leukemia (ALL) in childhood and adulthood in the case of patients with known hypersensitivity to ''native'' L-asparaginase. The application was received and filed in the Center for Biologics Evaluation and Research on May 15, 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 June 12, 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 Biologics Evaluation and Research (21 CFR 5.44).

Dated: May 18, 1995.

**James C. Simmons,**

*Acting Director, Office of Compliance, Center for Biologics Evaluation and Research.*

[FR Doc. 95–13411 Filed 5–31–95; 8:45 am]

BILLING CODE 4160–01–F

**[Docket No. 95N–0142]**

## Drug Export; Caverject Sterile Powder (Alprostadil for Injection) 20 Micrograms per Milliliter (μG/mL) Vials

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

**ACTION:** Notice.

**SUMMARY:** The Food and Drug Administration (FDA) is announcing that The Upjohn Co. has filed an application requesting approval for the export of the human drug CAVERJECT Sterile Powder (Alprostadil for Injection) 20μg/mL vials to Sweden via Belgium.

**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 20857, 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 The Upjohn Co., 7000 Portage Rd., Kalamazoo, MI 49001–0199, has filed an application requesting approval for the export of the human drug CAVERJECT Sterile Powder (Alprostadil for Injection) 20µg/mL vials to Sweden via Belgium. The product is to be used for the treatment of erectile dysfunction. The application was received and filed in the Center for Drug Evaluation and Research on May 5, 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 June 12, 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: May 18, 1995.

**Betty L. Jones,**

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

[FR Doc. 95–13352 Filed 5–31–95; 8:45 am]

**BILLING CODE 4160–01–F**

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**[Docket No. 95N–0124]**

## Medical Devices; Third Party Review of Selected Premarket Notifications; Public Workshop

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

**ACTION:** Notice.

**SUMMARY:** The Food and Drug Administration (FDA) is announcing a public workshop to discuss a proposed pilot program for third party review of selected premarket notifications. The purpose of the workshop is to provide information on the pilot program and to obtain public comments and suggestions that may help FDA refine its plans for third party review of selected premarket notifications. This workshop is one aspect of FDA's efforts in pursuit of the reinventing Government goals of the National Performance Review as well as the promotion and protection of the public health.

**DATES:** The workshop will be held on June 19, 1995, from 9 a.m. to 4:30 p.m. Submit written notices of participation by June 9, 1995. Participants and other persons who want to be heard must be present by 9 a.m. Submit written comments by July 7, 1995. There is no registration fee for this workshop. Interested persons are encouraged to register early because space is limited.

**ADDRESSES:** The workshop will be held at the Doubletree Hotel Rockville (formerly, the Holiday Inn Crowne Plaza), 1750 Rockville Pike, Rockville, MD. A limited number of overnight accommodations have been reserved at the Doubletree Hotel Rockville. Attendees requiring overnight accommodations may contact the hotel at 301–468–1100 and reference FDA meeting group GVL. Reservations will be confirmed at the group rate based on availability.

A registration form for the workshop may be obtained by contacting Sociometrics, Inc., 8300 Colesville Rd., Suite 550, Silver Spring, MD 20910, 301–608–2151 or 1–800–729–0890 (FAX 301–608–3542). Persons with disabilities who require special assistance to attend or participate in the workshop can be accommodated if advance notification is provided. If you have a disability that affects your attendance at, or participation in, this meeting, please contact Ed Rugenstein, Sociometrics, Inc., in writing and identify your needs. The availability of appropriate accommodations cannot be assured unless prior written notification is provided.

Written comments regarding the pilot program may be submitted to the Dockets Management Branch (HFA–305), Food and Drug Administration, rm. 1–23, 12420 Parklawn Dr., Rockville, MD 20857. Those persons who wish to make a presentation must submit a written notice of participation to the Dockets Management Branch (address above), identified with the docket number found in brackets in the heading of this document, including their name, address, telephone number, business affiliation, a brief summary of the presentation, and an estimate of the amount of time required to make their comments. FDA requests that individuals or groups having similar interests consolidate their comments and present them through a single representative. FDA may require joint presentations by persons with common interests.

Transcripts of the workshop will be available from the Freedom of Information Staff (HFI–35), Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857, 301–443–6310 or FAX 301–443–1726.

**FOR FURTHER INFORMATION CONTACT:** Eric J. Rechen, Center for Devices and Radiological Health (HFZ–402), Food and Drug Administration, 9200 Corporate Blvd., Rockville, MD 20850, 301–594–2186, FAX 301–594–2977.

**SUPPLEMENTARY INFORMATION:**

### I. Background

On April 6, 1995, FDA announced a limited pilot program to test the usefulness and practicality of third party review of medical devices. Under the proposed pilot, FDA will designate private sector organizations to review premarket notifications under section 510(k) of the Federal Food, Drug, and Cosmetic Act (the act) (hereinafter referred to as 510(k)'s). This initiative will provide an alternative to FDA review and is one aspect of FDA's efforts in pursuit of the reinventing Government goals of the National Performance Review. FDA expects the pilot program will begin early in fiscal year 1996.

FDA's primary concern remains the promotion and protection of the public health. The proposed pilot will include checks and balances to ensure a high level of quality in the review of 510(k)'s.

### II. Outline of the Proposed Third Party Review Pilot

At this time, FDA has not determined the final form of its pilot third party review process. The initial pilot program will be restricted to third party review, but not clearance, of 510(k)'s. During the pilot, the third party will make a recommendation to FDA. FDA will then make a decision based on the third party's documented review. The purpose of the pilot is to test the feasibility of third party review, including the willingness of qualified third parties to participate, and the quality and timeliness of third party reviews.

Industry participation in the pilot program will be voluntary. An applicant who does not wish to participate will be able to continue to submit 510(k)'s to FDA. The pilot will last 2 years, and will be evaluated by FDA in the second year.

FDA anticipates that the pilot program will be limited to FDA-designated class I and II devices that involve low-to-moderate risk. The pilot