Inc., 900 Ridgebury Rd., P.O. Box 368, Ridgefield, CT 06877, has filed an application requesting conditional approval for the export of the human drug COMBIVENT® (ipratropium bromide and albuterol sulfate) Inhalation Aerosol 20 µg/120 µg/ metered dose to Canada. This product is used as a bronchodilator for the treatment of bronchospasm associated with chronic obstructive pulmonary disease in patients who require more than a single bronchodilator. The application was received and filed in the Center for Drug Evaluation and Research on May 10, 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 26, 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: June 6, 1995.

Betty L. Jones,

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

[FR Doc. 95–14722 Filed 6–14–95; 8:45 am]

BILLING CODE 4160–01–F

[Docket No. 95D–0148]

Guidance for Labeling Reusable Medical Devices for Reprocessing in Health Care Facilities; Draft; Availability

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is announcing the availability of a draft guidance entitled ''Labeling Reusable Medical Devices for Reprocessing in Health Care Facilities: FDA Reviewer Guidance.'' The draft guidance is intended to provide direction to the agency's personnel who are responsible for premarket evaluation of medical devices and to provide criteria for the labeling instructions for reprocessing reusable devices.

DATES: Written comments by August 14, 1995.

ADDRESSES: Submit written requests for single copies of the draft guidance entitled ''Labeling Reusable Medical Devices for Reprocessing in Health Care Facilities: FDA Reviewer Guidance'' to the Division of Small Manufacturers Assistance, Center for Devices and Radiological Health (HFZ–220), Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857, 301–443–0806 (outside MD 1–800–638–2041). Send two self-addressed adhesive labels to assist that office in processing your requests. Submit written comments on the draft guidance to the Dockets Management Branch (HFA–305), Food and Drug Administration, rm. 1–23, 12420 Parklawn Dr., Rockville, MD 20857. Requests and comments should be identified with the docket number found in brackets in the heading of this document. A copy of the draft guidance and received comments are available for public examination in the Dockets Management Branch (address above) between 9 a.m. and 4 p.m., Monday through Friday.

FOR FURTHER INFORMATION CONTACT: Chiu S. Lin, Center for Devices and Radiological Health (HFZ–410), Food and Drug Administration, 9200 Corporate Blvd., Rockville, MD 20850, 301–443–8913.

SUPPLEMENTARY INFORMATION: FDA is announcing the availability of a draft guidance entitled ''Labeling Reusable Medical Devices for Reprocessing in Health Care Facilities: FDA Reviewer Guidance.'' The draft guidance is primarily directed to FDA personnel who are responsible for the evaluation of premarket notification submissions (510(k)'s) and premarket approval (PMA) applications. The draft guidance will also assist persons preparing 510(k)'s and PMA's for submission to FDA.

Under the Federal Food, Drug, and Cosmetic Act, and FDA labeling regulations (21 CFR 801.5), a device is required to bear adequate directions for use. In reprocessing a reusable device (e.g., clean, disinfect, or sterilize), adequate instructions are important in preparing the device for the next patient. The draft guidance provides criteria for the labeling instructions on reprocessing reusable medical devices. The criteria are also applicable to initial processing of single use only and reusable devices that are supplied nonsterile, and reprocessing of certain sterile, single use only implantable devices if they become contaminated before implantation (e.g., orthopedic implants).

The document does not provide in-depth guidance on design and testing factors related to infection control. It is essential that the manufacturer consider infection control requirements during product design and testing to facilitate cleaning and sterilization or disinfection. Design and testing factors are addressed in device specific FDA guidance and FDA's good manufacturing practices guidance.

FDA staff and persons preparing submissions should also refer to the Technical Information Report (TIR), developed by the Association for the Advancement of Medical Instrumentation (AAMI), entitled ''Designing, Testing, and Labeling Reusable Medical Devices for Reprocessing in Health Care Facilities: A Guide for Device Manufacturers,'' AAMI TIR No. 12–1994. The AAMI TIR provides comprehensive technical information for manufacturers and user perspectives on this topic.

Guidances have generally been issued under § 10.90(b) (21 CFR 10.90(b)), which provides for the use of guidances to state procedures or standards of general applicability that are not legal requirements but that are acceptable to FDA. The agency is now in the process of revising § 10.90(b). Therefore, the draft guidance is not being issued under the authority of current § 10.90(b), and it does not create or confer any rights, privileges, or benefits for or on any person, nor does it operate to bind FDA in any way.

Interested persons may, on or before (*insert date 60 days after date of publication in the* **Federal Register**), submit to the Dockets Management Branch (address above) written comments on the draft guidance. 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. The draft guidance and received comments may be seen in the Docket Management Branch between 9 a.m. and 4 p.m., Monday through Friday.

Dated: June 6, 1995.

D.B. Burlington

Director, Center for Devices and Radiological Health.

[FR Doc. 95–14588 Filed 6–14–95; 8:45 am]

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