

XV. Implementation Reviews

As part of the terms and conditions of any demonstration proposal that is granted, the Department may require periodic assessments of how the project is being implemented. The Department will review, and when appropriate investigate, documented complaints that a State is failing to comply with requirements specified in the terms and conditions and implementing waivers of any approved demonstration.

XVI. Legal Effect

This notice is intended to inform the public and the States regarding procedures the Department ordinarily will follow in exercising the Secretary's discretionary authority with respect to State demonstration proposals under section 1130. This notice does not create any right or benefit, substantive or procedural, enforceable at law or equity, by any person or entity, against the United States, its agencies or instrumentalities, the States, or any other person.

(Catalog of Federal Domestic Assistance Program Numbers 93.645, Child Services—State Grants; 93.658, Foster Care Maintenance; 93.659, Adoption Assistance)

Dated: June 12, 1995.

Mary Jo Bane,

Assistant Secretary for Children and Families.

Appendix I

This is a list of program ideas that have been suggested by States or others in response to the Department's requests for suggestions. They are listed only as a means of outlining, for States interested in proposing a child welfare waiver demonstration project, the broad range of possible demonstrations that the Department would consider. Whether these sample ideas would be cost-neutral would depend, of course, on how a State proposes to implement them. Similarly, the method of implementation could affect whether a waiver demonstration project would meet the statutory requirement that it not "impair the entitlement of any qualified child or family to benefits under a State" title IV-E Plan.

This list should not be regarded as limiting a State in any way in conceiving demonstration ideas.

- ◆ To meet the need for specialized foster care, and to reduce the amount spent on institutional care, train AFDC recipients or other low income persons to be professional, paid foster parents for specialized foster home placements; ensure appropriate licensing and possibly provide housing subsidies or homeownership assistance to assure the stability of the specialized foster home as a long-term resource.

- ◆ Broaden the use of title IV-E to fund services for children, their parents, and foster families, and to fund preventive services for families at risk, with the expectation that total time in out-of-home care would be

reduced, and in some cases foster placements could be avoided.

- ◆ Provide better services at lower cost by, where appropriate, returning children, especially adolescents, from out-of-State institutional placements. Such a demonstration might include both foster care youth and youth who are in the juvenile justice system. The expectation is that placing them in community-based specialized family foster homes, or community-based group homes, will reduce the total time in out-of-home care.

- ◆ Provide subsidized guardianship or other arrangements which would allow children to stay or be placed in a familial setting that is more cost-effective than continuing them in foster care.

- ◆ For older adolescents in independent living, allow title IV-E funds to be used for the cost of an apartment for a period of time before the youth leaves foster care, and a short period thereafter, to achieve more stable placements for youth.

- ◆ Expand the availability of in-home respite care for foster families, with the expectation that administrative costs, including the costs of recruiting foster families, will be controlled, and more stable placements will result in shortened stays in out-of home care.

- ◆ Provide State-funded parental visitation for parents whose children are in institutional care, including the costs of telephone calls, transportation, and other expenses associated with maintaining or improving contact. The expectation is that more contact between parents/families and children in care can shorten stays in institutional placements.

- ◆ Enter into agreements with private providers to test a managed care concept, with clearly specified and measurable outcomes to be achieved for each family, at a fixed cost negotiated in advance, with the expectation that fiscal incentives would produce a better result with no increase in cost.

- ◆ Enter into agreements with Indian Tribes to permit full access to all aspects of title IV-E funding, with the expectation that services for tribal children and families will improve, while State costs of providing or managing those services will decline.

- ◆ Where court processes are unduly delaying adoptions, enter into agreements with courts to fund adoption-related work as if it were an administrative cost under title IV-E, with the expectation that the courts would then be able to speed adoptions, producing permanency for children earlier, and reducing foster care and case management costs.

- ◆ Seek a waiver of some provision(s) of title IV-A (AFDC), possibly in combination with a title IV-E or IV-B waiver, which might help achieve child welfare objectives. For example, a waiver which allowed a State to continue AFDC payments (in whole or in part) for a period of time, for a family from which the children had been removed, but where reunification is the goal and the loss of AFDC benefits would likely result in

homelessness, thus frustrating reunification efforts.

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Food and Drug Administration

[Docket No. 95N-0165]

Drug Export; COMBIVENT® (Ipratropium Bromide and Albuterol Sulfate) Inhalation Aerosol 20 Micrograms (µg)/120 µg/Metered Dose

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 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.

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 Boehringer Ingelheim Pharmaceuticals,

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.

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[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.

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