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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BILLING CODE 4184–01–P

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,