

By the Commission.

Lois D. Cashell,

Secretary

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DEPARTMENT OF JUSTICE

Drug Enforcement Administration

21 CFR Part 1308

[DEA—127E]

Schedules of Controlled Substances; Extension of Temporary Placement of 4-Bromo-2,5-dimethoxyphenethylamine in Schedule I

AGENCY: Drug Enforcement Administration, Justice.

ACTION: Final rule.

SUMMARY: This final rule is issued by the Deputy Administrator of the Drug Enforcement Administration (DEA) to extend the temporary scheduling of 4-bromo-2,5-dimethoxyphenethylamine (4-bromo-2,5-DMPEA) in Schedule I of the Controlled Substances Act (CSA). The temporary scheduling of 4-bromo-2,5-DMPEA is due to expire on January 6, 1995. This notice will extend the temporary scheduling of 4-bromo-2,5-DMPEA for six months or until rule making proceeding are completed, whichever occurs first.

EFFECTIVE DATE: January 6, 1995.

FOR FURTHER INFORMATION CONTACT: Howard McClain, Jr., Chief, Drug and Chemical Evaluation Section, Drug Enforcement Administration, Washington, DC 20537 Telephone: (202) 307-7183.

SUPPLEMENTARY INFORMATION: On January 6, 1994, the Acting Administrator of the DEA published a final rule in the *Federal Register* (59 FR 671) amending § 1308.11(g) of Title 21 of the Code of Federal Regulations to temporarily place 4-bromo-2,5-DMPEA into Schedule I of the CSA pursuant to the temporary scheduling provisions of 21 U.S.C. 811(g). This final rule, which became effective on the date of publication, was based on findings by the Acting Administrator that the temporary scheduling of 4-bromo-2,5-DMPEA was necessary to avoid an imminent hazard to the public safety. Section 201(h)(2) of the CSA (21 U.S.C. 811(h)(2)) requires that the temporary scheduling of a substance expires at the end of one year from the effective date of the order. However, during the pendency of proceedings under 21 U.S.C. 811(a)(1) with respect to the substance, temporary scheduling of that

substance may be extended for up to six months. Proceedings for the scheduling of a substance under 21 U.S.C. 811(a) may be initiated by the Attorney General (delegated to the Administrator of the DEA pursuant to 28 CFR 0.100 and redelegated to the Deputy Administrator pursuant to 28 CFR 0.104) on his own motion, at the request of the Secretary of Health and Human Services, or on the petition of any interested party. Such proceedings regarding 4-bromo-2,5-DMPEA has been initiated by the Deputy Administrator.

Therefore, the temporary scheduling of 4-bromo-2,5-DMPEA, which is due to expire on January 6, 1995, may be extended until July 6, 1995, or until proceedings initiated in accordance with 21 U.S.C. 811(a) are completed, whichever occurs first. Pursuant to U.S.C. 811(h)(2) the Deputy Administrator hereby orders that the temporary scheduling of 4-bromo-2,5-DMPEA be extended until July 6, 1995, or until the conclusion of scheduling proceedings initiated in accordance with 21 U.S.C. 811(a), whichever occurs first.

The Deputy Administrator of the DEA hereby certifies that extension of the temporary placement of 4-bromo-2,5-DMPEA in Schedule I of the CSA will have no significant impact upon entities whose interests must be considered under the Regulatory Flexibility Act, 5 U.S.C. 601 *et seq.* This action involves the extension of temporary control of a substance with no currently accepted medical use in the United States.

The six month extension of 4-bromo-2,5-DMPEA in Schedule I of the CSA is not a significant regulatory action for the purposes of Executive Order (E.O.) 12866 of September 30, 1993. Drug scheduling matters are not subject to review by the Office of Management and Budget (OMB) pursuant to the provisions of E.O. 12866, § 3(d)(1). This regulation responds to an emergency situation posing no imminent hazard to the public safety and is essential to criminal law enforcement function of the United States.

This action has been analyzed in accordance with the principles and criteria in Executive Order 12612, and it has been determined that this final rule does not have sufficient federalism implications to warrant the preparation of a Federalism Assessment.

Dated: December 9, 1994.

Stephen H. Greene,

Deputy Administrator

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

21 CFR Parts 520 and 556

Animal Drugs, Feeds, and Related Products; Albendazole Suspension

AGENCY: Food and Drug Administration, HHS.

ACTION: Final rule.

SUMMARY: The Food and Drug Administration (FDA) is amending the animal drug regulations to reflect approval of a new animal drug application (NADA) filed by SmithKline Beecham Animal Health Products. The NADA provides for use of albendazole suspension (Valbazen®) as an anthelmintic in sheep. The regulations are also amended to establish a tolerance for albendazole residue in sheep liver.

EFFECTIVE DATE: December 21, 1994.

FOR FURTHER INFORMATION CONTACT: Melanie R. Berson, Center for Veterinary Medicine (HFV-135), Food and Drug Administration, 7500 Standish Pl., Rockville, MD 20855, 301-594-1643.

SUPPLEMENTARY INFORMATION: SmithKline Beecham Animal Health Products, 1600 Paoli Pike, West Chester, PA 19380, filed NADA 140-934, which provides for oral use of a 4.55 percent albendazole suspension (Valbazen®) as an anthelmintic in sheep. It is used for removal and control of: Adult liver flukes; heads and segments of common and fringed tapeworms; adult and fourth stage larvae of certain stomach worms (brown stomach worm, barberpole worm, and small stomach worm); adult and fourth stage larvae of certain intestinal worms (thread-necked intestinal worm, Cooper's worm, bankrupt worm, nodular worm, and large-mouth bowel worm); and adult and larval stages of lungworms.

The NADA is approved as of November 10, 1994, and the regulations are amended in 21 CFR 520.45a to reflect the approval. Additionally the regulations are amended in 21 CFR 556.34 to establish a tolerance for albendazole residue in sheep liver. The basis for approval is discussed in the freedom of information summary.

In accordance with the freedom of information provisions of part 20 (21 CFR part 20) and § 514.11(e)(2)(ii) (21 CFR 514.11(e)(2)(ii)), a summary of safety and effectiveness data and information submitted to support approval of this application may be seen in the Dockets Management Branch (HFA-305), Food and Drug