

16, 1997. In publishing the final order in the Federal Register, the Attorney General shall publish a copy of the letter that was transmitted by the Secretary of Health and Human Services.

“(B) In the case of gamma hydroxybutyric acid that is contained in a drug product for which an application is approved under section 505 of the Federal Food, Drug, and Cosmetic Act [21 U.S.C. 355] (whether the application involved is approved before, on, or after the date of the enactment of this Act [Feb. 18, 2000]), the final order shall schedule such drug in the same schedule as that recommended by the Secretary of Health and Human Services for authorized formulations of the drug. The recommendation referred to in the preceding sentence is contained in the last sentence of the fourth paragraph of the letter referred to in subparagraph (A) with respect to May 19, 1999.

“(2) FAILURE TO ISSUE ORDER.—If the final order is not issued within the period specified in paragraph (1), gamma hydroxybutyric acid (together with its salts, isomers, and salts of isomers) is deemed to be scheduled under section 202(c) of the Controlled Substances Act [21 U.S.C. 812(c)] in accordance with the policies described in paragraph (1), as if the Attorney General had issued a final order in accordance with such paragraph.”

PLACEMENT OF PIPRADROL AND SPA IN SCHEDULE IV TO CARRY OUT OBLIGATION UNDER CONVENTION ON PSYCHOTROPIC SUBSTANCES

Section 102(c) of Pub. L. 95-633 provided that: “For the purpose of carrying out the minimum United States obligations under paragraph 7 of article 2 of the Convention on Psychotropic Substances, signed at Vienna, Austria, on February 21, 1971, with respect to pipradrol and SPA (also known as (-)-1-dimethylamino-1,2-diphenylethane), the Attorney General shall by order, made without regard to sections 201 and 202 of the Controlled Substances Act [this section and section 811 of this title], place such drugs in schedule IV of such Act [see subsec. (c) of this section].”

Provision of section 102(c) of Pub. L. 95-633, set out above, effective on the date the Convention on Psychotropic Substances enters into force in the United States [July 15, 1980], see section 112 of Pub. L. 95-633, set out as an Effective Date note under section 801a of this title.

§ 813. Treatment of controlled substance analogues

A controlled substance analogue shall, to the extent intended for human consumption, be treated, for the purposes of any Federal law as a controlled substance in schedule I.

(Pub. L. 91-513, title II, §203, as added Pub. L. 99-570, title I, §1202, Oct. 27, 1986, 100 Stat. 3207-13; amended Pub. L. 100-690, title VI, §6470(c), Nov. 18, 1988, 102 Stat. 4378.)

REFERENCES IN TEXT

Schedule I, referred to in text, is set out in section 812(c) of this title.

AMENDMENTS

1988—Pub. L. 100-690 substituted “any Federal law” for “this subchapter and subchapter II of this chapter”.

§ 814. Removal of exemption of certain drugs

(a) Removal of exemption

The Attorney General shall by regulation remove from exemption under section 802(39)(A)(iv) of this title a drug or group of drugs that the Attorney General finds is being diverted to obtain a listed chemical for use in the illicit production of a controlled substance.

(b) Factors to be considered

In removing a drug or group of drugs from exemption under subsection (a) of this section, the Attorney General shall consider, with respect to a drug or group of drugs that is proposed to be removed from exemption—

(1) the scope, duration, and significance of the diversion;

(2) whether the drug or group of drugs is formulated in such a way that it cannot be easily used in the illicit production of a controlled substance; and

(3) whether the listed chemical can be readily recovered from the drug or group of drugs.

(c) Specificity of designation

The Attorney General shall limit the designation of a drug or a group of drugs removed from exemption under subsection (a) of this section to the most particularly identifiable type of drug or group of drugs for which evidence of diversion exists unless there is evidence, based on the pattern of diversion and other relevant factors, that the diversion will not be limited to that particular drug or group of drugs.

(d) Reinstatement of exemption with respect to particular drug products

(1) Reinstatement

On application by a manufacturer of a particular drug product that has been removed from exemption under subsection (a) of this section, the Attorney General shall by regulation reinstate the exemption with respect to that particular drug product if the Attorney General determines that the particular drug product is manufactured and distributed in a manner that prevents diversion.

(2) Factors to be considered

In deciding whether to reinstate the exemption with respect to a particular drug product under paragraph (1), the Attorney General shall consider—

(A) the package sizes and manner of packaging of the drug product;

(B) the manner of distribution and advertising of the drug product;

(C) evidence of diversion of the drug product;

(D) any actions taken by the manufacturer to prevent diversion of the drug product; and

(E) such other factors as are relevant to and consistent with the public health and safety, including the factors described in subsection (b) of this section as applied to the drug product.

(3) Status pending application for reinstatement

A transaction involving a particular drug product that is the subject of a bona fide pending application for reinstatement of exemption filed with the Attorney General not later than 60 days after a regulation removing the exemption is issued pursuant to subsection (a) of this section shall not be considered to be a regulated transaction if the transaction occurs during the pendency of the application and, if the Attorney General denies the application, during the period of 60 days following the date on which the Attorney General denies the application, unless—