Human Services where this Act or the amendments made by this Act so provide, promulgate any interim rules necessary for the implementation of this Act or the amendments made by this Act, prior to its effective date [see Effective Date of 2008 Amendment note above].''

Pub. L. 98–509, title III, § 301(b), Oct. 19, 1984, 98 Stat. 2364, provided that: ''The Secretary of Health and Human Services shall, within ninety days of the date of the enactment of this Act [Oct. 19, 1984], promulgate regulations for the administration of section 102(28) of the Controlled Substances Act [21 U.S.C. 802(29)] as amended by subsection (a) and shall include in the first report submitted under section 505(b) [503(b)] of the Public Health Service Act [former 42 U.S.C. 290aa–2(b)] after the expiration of such ninety days the findings of the Secretary with respect to the effect of the amendment made by subsection (a).''

CONSTRUCTION OF 2008 AMENDMENT

Pub. L. 110–425, § 4, Oct. 15, 2008, 122 Stat. 4834, provided that: ''Nothing in this Act [see Short Title of 2008 Amendment note set out under section 801 of this title] or the amendments made by this Act shall be construed as authorizing, prohibiting, or limiting the use of electronic prescriptions for controlled substances.''

PRESERVATION OF STATE AUTHORITY TO REGULATE SCHEDULED LISTED CHEMICALS

Pub. L. 109–177, title VII, § 711(g), Mar. 9, 2006, 120 Stat. 263, provided that: ''This section [amending this section and sections 830, 841, 842, and 844 of this title and enacting provisions set out as notes under sections 830 and 844 of this title] and the amendments made by this section may not be construed as having any legal effect on section 708 of the Controlled Substances Act [21 U.S.C. 903] as applied to the regulation of scheduled listed chemicals (as defined in section 102(45) of such Act [21 U.S.C. 802(45)]).''

REPORT ON DIVERSION OF ORDINARY, OVER-THE-COUNTER PSEUDOEPHEDRINE AND PHENYLPROPANOLAMINE PRODUCTS

Pub. L. 106–310, div. B, title XXXVI, § 3642, Oct. 17, 2000, 114 Stat. 1237, provided that:

''(a) STUDY.—The Attorney General shall conduct a study of the use of ordinary, over-the-counter pseudoephedrine and phenylpropanolamine products in the clandestine production of illicit drugs. Sources of data for the study shall include the following:

''(1) Information from Federal, State, and local clandestine laboratory seizures and related investigations identifying the source, type, or brand of drug products being utilized and how they were obtained for the illicit production of methamphetamine and amphetamine.

''(2) Information submitted voluntarily from the pharmaceutical and retail industries involved in the manufacture, distribution, and sale of drug products containing ephedrine, pseudoephedrine, and phenylpropanolamine, including information on changes in the pattern, volume, or both, of sales of ordinary, over-the-counter pseudoephedrine and phenylpropanolamine products.

''(b) REPORT.—

''(1) REQUIREMENT.—Not later than 1 year after the date of the enactment of this Act [Oct. 17, 2000], the Attorney General shall submit to Congress a report on the study conducted under subsection (a).

''(2) ELEMENTS.—The report shall include—

''(A) the findings of the Attorney General as a result of the study; and

''(B) such recommendations on the need to establish additional measures to prevent diversion of ordinary, over-the-counter pseudoephedrine and phenylpropanolamine (such as a threshold on ordinary, over-the-counter pseudoephedrine and phenylpropanolamine products) as the Attorney General considers appropriate.

''(3) MATTERS CONSIDERED.—In preparing the report, the Attorney General shall consider the comments and recommendations including the comments on the Attorney General's proposed findings and recommendations, of State and local law enforcement and regulatory officials and of representatives of the industry described in subsection (a)(2).

''(c) REGULATION OF RETAIL SALES.—

''(1) IN GENERAL.—Notwithstanding section 401(d) of the Comprehensive Methamphetamine Control Act of 1996 [Pub. L. 104–237] (21 U.S.C. 802 note) and subject to paragraph (2), the Attorney General shall establish by regulation a single-transaction limit of not less than 24 grams of ordinary, over-the-counter pseudoephedrine or phenylpropanolamine (as the case may be) for retail distributors, if the Attorney General finds, in the report under subsection (b), that—

''(A) there is a significant number of instances (as set forth in paragraph (3)(A) of such section 401(d) for purposes of such section) where ordinary, over-the-counter pseudoephedrine products, phenylpropanolamine products, or both such products that were purchased from retail distributors were widely used in the clandestine production of illicit drugs; and

''(B) the best practical method of preventing such use is the establishment of single-transaction limits for retail distributors of either or both of such products.

''(2) DUE PROCESS.—The Attorney General shall establish the single-transaction limit under paragraph (1) only after notice, comment, and an informal hearing.''

REGULATION OF RETAIL SALES OF CERTAIN PRECURSOR CHEMICALS; EFFECT ON THRESHOLDS; COMBINATION EPHEDRINE PRODUCTS

Pub. L. 104–237, title IV, § 401(d)–(f), Oct. 3, 1996, 110 Stat. 3108, which authorized the Attorney General to establish a single-transaction limit of 24 grams for pseudoephedrine, phenylpropanolamine, and combination ephedrine products for retail distributors, was repealed by Pub. L. 109–177, title VII, § 712(b), Mar. 9, 2006, 120 Stat. 264.

EXEMPTION FOR SUBSTANCES IN PARAGRAPH (41)

Pub. L. 101–647, title XIX, § 1903, Nov. 29, 1990, 104 Stat. 4853, as amended by Pub. L. 108–358, § 2(c), Oct. 22, 2004, 118 Stat. 1663, provided that:

''(a) DRUGS FOR TREATMENT OF RARE DISEASES.—If the Attorney General finds that a drug listed in paragraph (41) of section 102 of the Controlled Substances Act (as added by section 2 [1902] of this Act) is—

''(1) approved by the Food and Drug Administration as an accepted treatment for a rare disease or condition, as defined in section 526 of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 360bb); and

''(2) does not have a significant potential for abuse, the Attorney General may exempt such drug from any production regulations otherwise issued under the Controlled Substances Act as may be necessary to ensure adequate supplies of such drug for medical purposes.

''(b) DATE OF ISSUANCE OF REGULATIONS.—The Attorney General shall issue regulations implementing this section not later than 45 days after the date of enactment of this Act [Nov. 29, 1990], except that the regulations required under section 3(a) [former 1903(a)] shall be issued not later than 180 days after the date of enactment of this Act.''

§ 803. Repealed. Pub. L. 95–137, § 1(b), Oct. 18, 1977, 91 Stat. 1169

Section, Pub. L. 91–513, title II, § 103, Oct. 27, 1970, 84 Stat. 1245, authorized Bureau of Narcotics and Dangerous Drugs to add, during fiscal year 1971, 300 agents, together with necessary supporting personnel, and provided for appropriations of $6,000,000 to carry out such addition.

PART B—AUTHORITY TO CONTROL; STANDARDS AND SCHEDULES

§ 811. Authority and criteria for classification of substances

(a) Rules and regulations of Attorney General; hearing

The Attorney General shall apply the provisions of this subchapter to the controlled substances listed in the schedules established by section 812 of this title and to any other drug or other substance added to such schedules under this subchapter. Except as provided in subsections (d) and (e) of this section, the Attorney General may by rule—

(1) add to such a schedule or transfer between such schedules any drug or other substance if he—

(A) finds that such drug or other substance has a potential for abuse, and

(B) makes with respect to such drug or other substance the findings prescribed by subsection (b) of section 812 of this title for the schedule in which such drug is to be placed; or

(2) remove any drug or other substance from the schedules if he finds that the drug or other substance does not meet the requirements for inclusion in any schedule.

Rules of the Attorney General under this subsection shall be made on the record after opportunity for a hearing pursuant to the rulemaking procedures prescribed by subchapter II of chapter 5 of title 5. Proceedings for the issuance, amendment, or repeal of such rules may be initiated by the Attorney General (1) on his own motion, (2) at the request of the Secretary, or (3) on the petition of any interested party.

(b) Evaluation of drugs and other substances

The Attorney General shall, before initiating proceedings under subsection (a) of this section to control a drug or other substance or to remove a drug or other substance entirely from the schedules, and after gathering the necessary data, request from the Secretary a scientific and medical evaluation, and his recommendations, as to whether such drug or other substance should be so controlled or removed as a controlled substance. In making such evaluation and recommendations, the Secretary shall consider the factors listed in paragraphs (2), (3), (6), (7), and (8) of subsection (c) of this section and any scientific or medical considerations involved in paragraphs (1), (4), and (5) of such subsection. The recommendations of the Secretary shall include recommendations with respect to the appropriate schedule, if any, under which such drug or other substance should be listed. The evaluation and the recommendations of the Secretary shall be made in writing and submitted to the Attorney General within a reasonable time. The recommendations of the Secretary to the Attorney General shall be binding on the Attorney General as to such scientific and medical matters, and if the Secretary recommends that a drug or other substance not be controlled, the Attorney General shall not control the drug or other substance. If the Attorney General determines that these facts and all other relevant data constitute substantial evidence of potential for abuse such as to warrant control or substantial evidence that the drug or other substance should be removed entirely from the schedules, he shall initiate proceedings for control or removal, as the case may be, under subsection (a) of this section.

(c) Factors determinative of control or removal from schedules

In making any finding under subsection (a) of this section or under subsection (b) of section 812 of this title, the Attorney General shall consider the following factors with respect to each drug or other substance proposed to be controlled or removed from the schedules:

(1) Its actual or relative potential for abuse.

(2) Scientific evidence of its pharmacological effect, if known.

(3) The state of current scientific knowledge regarding the drug or other substance.

(4) Its history and current pattern of abuse.

(5) The scope, duration, and significance of abuse.

(6) What, if any, risk there is to the public health.

(7) Its psychic or physiological dependence liability.

(8) Whether the substance is an immediate precursor of a substance already controlled under this subchapter.

(d) International treaties, conventions, and protocols requiring control; procedures respecting changes in drug schedules of Convention on Psychotropic Substances

(1) If control is required by United States obligations under international treaties, conventions, or protocols in effect on October 27, 1970, the Attorney General shall issue an order controlling such drug under the schedule he deems most appropriate to carry out such obligations, without regard to the findings required by subsection (a) of this section or section 812(b) of this title and without regard to the procedures prescribed by subsections (a) and (b) of this section.

(2)(A) Whenever the Secretary of State receives notification from the Secretary-General of the United Nations that information has been transmitted by or to the World Health Organization, pursuant to article 2 of the Convention on Psychotropic Substances, which may justify adding a drug or other substance to one of the schedules of the Convention, transferring a drug or substance from one schedule to another, or deleting it from the schedules, the Secretary of State shall immediately transmit the notice to the Secretary of Health and Human Services who shall publish it in the Federal Register and provide opportunity to interested persons to submit to him comments respecting the scientific and medical evaluations which he is to prepare respecting such drug or substance. The Secretary of Health and Human Services shall prepare for transmission through the Secretary of State to the World Health Organization such medical and scientific evaluations as may be appropriate regarding the possible action that could be proposed by the World Health Organization respecting the drug or substance with respect to which a notice was transmitted under this subparagraph.