

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