

21 USC 814: Removal of exemption of certain drugs

Text contains those laws in effect on March 29, 2017

From Title 21-FOOD AND DRUGS

CHAPTER 13-DRUG ABUSE PREVENTION AND CONTROL

SUBCHAPTER I-CONTROL AND ENFORCEMENT

Part B-Authority To Control; Standards and Schedules

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§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), 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) 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), 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) 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) 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-

- (A) the Attorney General has evidence that, applying the factors described in subsection (b) to the drug product, the drug product is being diverted; and
- (B) the Attorney General so notifies the applicant.

(4) Amendment and modification

A regulation reinstating an exemption under paragraph (1) may be modified or revoked with respect to a particular drug product upon a finding that-

- (A) applying the factors described in subsection (b) to the drug product, the drug product is being diverted; or
- (B) there is a significant change in the data that led to the issuance of the regulation.

(Pub. L. 91-513, title II, §204, as added Pub. L. 103-200, §2(b)(1), Dec. 17, 1993, 107 Stat. 2334 ; amended Pub. L. 104-237, title IV, §401(c), Oct. 3, 1996, 110 Stat. 3108 ; Pub. L. 109-177, title VII, §712(a)(2), Mar. 9, 2006, 120 Stat. 263 .)

AMENDMENTS

2006-Subsec. (e). Pub. L. 109-177 struck out subsec. (e). Text read as follows: "Pursuant to subsection (d) (1) of this section, the Attorney General shall by regulation reinstate the exemption with respect to a particular ephedrine, pseudoephedrine, or phenylpropanolamine drug product if the Attorney General determines that the drug product is manufactured and distributed in a manner that prevents diversion. In making this determination the Attorney General shall consider the factors listed in subsection (d)(2) of this section. Any regulation issued pursuant to this subsection may be amended or revoked based on the factors listed in subsection (d)(4) of this section."

1996-Subsec. (e). Pub. L. 104-237 added subsec. (e).

EFFECTIVE DATE OF 1996 AMENDMENT

Amendment by Pub. L. 104-237 not applicable to sale of any pseudoephedrine or phenylpropanolamine product prior to 12 months after Oct. 3, 1996, except that, on application of manufacturer of particular drug product, Attorney General may exercise sole and judicially unreviewable discretion to extend such effective date up to additional 6 months, see section 401(g) of Pub. L. 104-237, set out as a note under section 802 of this title.

EFFECTIVE DATE

Section effective on date that is 120 days after Dec. 17, 1993, see section 11 of Pub. L. 103-200, set out as an Effective Date of 1993 Amendment note under section 802 of this title.