

United States Code Annotated [Currentness](#)

Title 21. Food and Drugs ([Refs & Annos](#))

▣ [Chapter 13](#). Drug Abuse Prevention and Control ([Refs & Annos](#))

▣ [Subchapter II](#). Import and Export ([Refs & Annos](#))

→ § 958. **Registration requirements**

(a) Applicants to import or export controlled substances in schedule I or II

The Attorney General shall register an applicant to import or export a controlled substance in schedule I or II if he determines that such registration is consistent with the public interest and with United States obligations under international treaties, conventions, or protocols in effect on May 1, 1971. In determining the public interest, the factors enumerated in [paragraph \(1\)](#) through [\(6\) of section 823\(a\)](#) of this title shall be considered.

(b) Activity limited to specified substances

Registration granted under this section shall not entitle a registrant to import or export controlled substances other than specified in the registration.

(c) Applicants to import controlled substances in schedule III, IV, or V or to export controlled substances in schedule III or IV; applicants to import or export list I chemicals

(1) The Attorney General shall register an applicant to import a controlled substance in schedule III, IV, or V or to export a controlled substance in schedule III or IV, unless he determines that the issuance of such registration is inconsistent with the public interest. In determining the public interest, the factors enumerated in [paragraphs \(1\)](#) through [\(6\) of section 823\(d\)](#) of this title shall be considered.

(2)(A) The Attorney General shall register an applicant to import or export a list I chemical unless the Attorney General determines that registration of the applicant is inconsistent with the public interest. Registration under this subsection shall not be required for the import or export of a drug product that is exempted under [section 802\(39\)\(A\)\(iv\)](#) of this title.

(B) In determining the public interest for the purposes of subparagraph (A), the Attorney General shall consider the factors specified in [section 823\(h\)](#) of this title.

(d) Denial of application

(1) The Attorney General may deny an application for registration under subsection (a) of this section if he is unable to determine that such registration is consistent with the public interest (as defined in subsection (a) of this section) and with the United States obligations under international treaties, conventions, or protocols in effect on May 1, 1971.

(2) The Attorney General may deny an application for registration under subsection (c) of this section, or revoke or suspend a registration under subsection (a) or (c) of this section, if he determines that such registration is inconsistent with the public interest (as defined in subsection (a) or (c) of this section) or with the United States obligations under international treaties, conventions, or protocols in effect on May 1, 1971.

(3) The Attorney General may limit the revocation or suspension of a registration to the particular controlled substance, or substances, or list I chemical or chemicals, with respect to which grounds for revocation or suspension exist.

(4) Before taking action pursuant to this subsection, the Attorney General shall serve upon the applicant or registrant an order to show cause as to why the registration should not be denied, revoked, or suspended. The order to show cause shall contain a statement of the basis thereof and shall call upon the applicant or registrant to appear before the Attorney General, or his designee, at a time and place stated in the order, but in no event less than thirty days after the date of receipt of the order. Proceedings to deny, revoke, or suspend shall be conducted pursuant to this subsection in accordance with subchapter II of chapter 5 of Title 5. Such proceedings shall be independent of, and not in lieu of, criminal prosecutions or other proceedings under this subchapter or any other law of the United States.

(5) The Attorney General may, in his discretion, suspend any registration simultaneously with the institution of proceedings under this subsection, in cases where he finds that there is an imminent danger to the public health and safety. Such suspension shall continue in effect until the conclusion of such proceedings, including judicial review thereof, unless sooner withdrawn by the Attorney General or dissolved by a court of competent jurisdiction.

(6) In the event that the Attorney General suspends or revokes a registration granted under this section, all controlled substances or list I chemicals owned or possessed by the registrant pursuant to such registration at the time of suspension or the effective date of the revocation order, as the case may be, may, in the discretion of the Attorney General, be seized or placed under seal. No disposition may be made of any controlled substances or list I chemicals under seal until the time for taking an appeal has elapsed or until all appeals have been concluded, except that a court, upon application therefor, may at any time order the sale of perishable controlled substances or list I chemicals. Any such order shall require the deposit of the proceeds of the sale with the court. Upon a revocation order becoming final, all such controlled substances or list I chemicals (or proceeds of the sale thereof which have been deposited with the court) shall be forfeited to the United States; and the Attorney General shall dispose of such controlled substances or list I chemicals in accordance with [section 881\(e\)](#) of this title.

(e) Registration period

No registration shall be issued under this subchapter for a period in excess of one year. Unless the regulations of the Attorney General otherwise provide, [sections 822\(f\)](#), [825](#), [827](#), and [830](#) of this title shall apply to persons registered under this section to the same extent such sections apply to persons registered under [section 823](#) of this title.

(f) Rules and regulations

The Attorney General is authorized to promulgate rules and regulations and to charge reasonable fees relating to the registration and control of importers and exporters of controlled substances or listed chemicals.

(g) Scope of authorized activity

Persons registered by the Attorney General under this section to import or export controlled substances or list I chemicals may import or export (and for the purpose of so importing or exporting, may possess) such substances to the extent authorized by their registration and in conformity with the other provisions of this subchapter and subchapter I of this chapter.

(h) Separate registrations for each principal place of business

A separate registration shall be required at each principal place of business where the applicant imports or exports controlled substances or list I chemicals.

(i) Emergency situations

Except in emergency situations as described in [section 952\(a\)\(2\)\(A\)](#) of this title, prior to issuing a registration under this section to a bulk manufacturer of a controlled substance in schedule I or II, and prior to issuing a regulation under [section 952\(a\)](#) of this title authorizing the importation of such a substance, the Attorney General shall give manufacturers holding registrations for the bulk manufacture of the substance an opportunity for a hearing.

CREDIT(S)

(Pub.L. 91-513, Title III, § 1008, Oct. 27, 1970, 84 Stat. 1289; [Pub.L. 98-473, Title II, §§ 524](#), 525, Oct. 12, 1984, 98 Stat. 2076; [Pub.L. 99-570, Title I, § 1866\(d\)](#), Oct. 27, 1986, 100 Stat. 3207-55; [Pub.L. 103-200](#), § 3(f), Dec. 17, 1993, 107 Stat. 2337; [Pub.L. 108-447](#), Div. B, Title VI, § 633(c), Dec. 8, 2004, 118 Stat. 2922.)

HISTORICAL AND STATUTORY NOTES

Revision Notes and Legislative Reports

1970 Acts. House Report No. 91-1444 and Conference Report No. 91-1603, see 1970 U.S. Code Cong. and Adm. News, p. 4566.

1984 Acts. House Report No. 98-1030 and [House Conference Report No. 98-1159](#), see 1984 U.S. Code Cong. and Adm. News, p. 3182.

1986 Acts. Statement by President, see 1986 U.S. Code Cong. and Adm. News, p. 5393.

1993 Acts. House Report No. 103-379, see 1993 U.S. Code Cong. and Adm. News, p. 2983.

2004 Acts. House Conference Report No. 108-792, see 2004 U.S. Code Cong. and Adm. News, p. 2577.

Statement by President, see 2004 U.S. Code Cong. and Adm. News, p. S46.

References in Text

Schedules I, II, III, IV, and V, referred to in subsecs. (a), (c), and (i) are set out in section 812(c) of this title.

This subchapter, referred to in subsecs. (d)(4) and (g), was in the original “this title” meaning Title III of Pub.L. 91-513, Oct. 27, 1970, 84 Stat. 1285. Part A of Title III comprises this subchapter. For classification of Part B, consisting of sections 1101 to 1105 of Title III of Pub.L. 91-513, see Tables.

Codifications

In subsec. (a) “May 1, 1971” was substituted for “effective date of this section” and in subsec. (d)(1) and (2) “May 1, 1971” was substituted for “effective date of this part”.

Amendment by section 663(c) of Pub.L. 108-447, Div. B, Title VI, was executed to subsec. (f) of this section, which is section 1008(f) of the Controlled Substances Import and Export Act, as the probable intent of Congress despite directory language purporting to amend “Section 1088(f) of the Controlled Substances Import and Export Act”.

Amendments

2004 Amendments. Subsec. (f). Pub.L. 108-447, Div. B, § 633(c), inserted “and control” following “the registration”, and struck out “list I chemicals under this section.” and inserted “listed chemicals.”

1993 Amendments. Subsec. (c)(1). Pub.L. 103-200, § 3(f)(1)(A), designated existing provision of subsec. (c) as par. (1).

Subsec. (c)(2). Pub.L. 103-200, § 3(f)(1)(B), added par. (2).

Subsec. (d)(3). Pub.L. 103-200, § 3(f)(2)(A), inserted “or list I chemical or chemicals,” following “substances,”.

Subsec. (d)(6). Pub.L. 103-200, § 3(f)(2)(B), inserted “or list I chemicals” following “controlled substances” whenever appearing.

Subsec. (e). Pub.L. 103-200, § 3(f)(3), substituted “827, and 830 of this title” for “and 827 of this title”.

Subsec. (f). Pub.L. 103-200, § 3(f)(4), inserted “or list I chemicals” following “controlled substances”.

Subsec. (g). Pub.L. 103-200, § 3(f)(4), inserted “or list I chemicals” following “controlled substances”.

Subsec. (h). Pub.L. 103-200, § 3(f)(4), inserted “or list I chemicals” following “controlled substances”.

1986 Amendments. Subsec. (e). Pub.L. 99-570, § 1866(d), substituted “sections” for “section” preceding “822(f)”.

1984 Amendments. Subsec. (b). Pub.L. 98-473, § 524, substituted “Registration granted under this section shall not entitle a registrant to import or export controlled substances other than specified in the registration.” for “Registration granted under subsection (a) of this section shall not entitle a registrant to import or export controlled substances in schedule I or II other than those specified in the registration.”

Subsec. (d). Pub.L. 98-473, § 525, redesignated former subsec. (d) as (e).

Pub.L. 98-473, § 525(1), added subsec. (d).

Subsec. (e). Pub.L. 98-473, § 525, redesignated former subsec. (d) as (e). Former subsec. (e) was redesignated (f).

Pub.L. 98-473, § 525(2), struck out reference to section 824 of this title.

Subsecs. (f) to (i). Pub.L. 98-473, § 525, redesignated former subsecs. (e) to (h) as (f) to (i), respectively.

Effective and Applicability Provisions

1993 Acts. Amendment to this section by Pub.L. 103-200 to take effect on the date that is 120 days after the date of enactment of Pub.L. 103-200, which was approved Dec. 17, 1993, see section 11 of Pub.L. 103-200, set out as a note under section 802 of this title.

1970 Acts. Section effective the first day of the seventh calendar month that begins after the day immediately preceding Oct. 27, 1970, see section 1105(a) of Pub.L. 91-513, set out as a note under section 951 of this title.

CODE OF FEDERAL REGULATIONS

Administrative policies, practices, and procedures, see [21 CFR § 1316.01 et seq.](#)

Controlled drugs, warnings, see [21 CFR § 290.5 et seq.](#)

Labeling and packaging requirements, see [21 CFR § 1302.01 et seq.](#)

Recordkeeping and reporting requirements, see [21 CFR § 1304.01 et seq.](#)

LIBRARY REFERENCES

American Digest System

Customs Duties  [14](#)  22.

RESEARCH REFERENCES

ALR Library

[19 ALR, Fed. 736](#), Administrative Inspections and Warrants Under § 510 of Comprehensive Drug Abuse Prevention & Control Act of 1970 ([21 U.S.C.A. § 880](#)).

Encyclopedias

[Am. Jur. 2d Drugs and Controlled Substances § 99](#), Registration; Permits.

[Am. Jur. 2d Drugs and Controlled Substances § 150](#), Possession, Generally.

Forms

[Federal Procedural Forms § 31:268](#), Denial of Application--Necessity of Order to Show Cause.

[Federal Procedural Forms § 31:275](#), Provisions Governing Hearings.

Treatises and Practice Aids

[Federal Procedure, Lawyers Edition § 35:669](#), Grant of Certificate of Registration.

[Federal Procedure, Lawyers Edition § 35:672](#), Order to Show Cause Why Registration Should Not be Denied.

[Federal Procedure, Lawyers Edition § 35:683](#), Provisions Governing Hearings.

[Federal Procedure, Lawyers Edition § 35:688](#), Burden of Proof.

[Federal Procedure, Lawyers Edition § 35:717](#), Necessity of Order to Show Cause Prior to Suspension or Revocation; Contents and Service of Order.

[Federal Procedure, Lawyers Edition § 37:1293](#), Opportunity for Hearing.

[Federal Procedure, Lawyers Edition § 37:1294](#), Issuance or Denial of Registration.

[Federal Procedure, Lawyers Edition § 37:1295](#), Suspension or Revocation of Registration.

[Federal Procedure, Lawyers Edition § 37:1331](#), Seizure and Forfeiture--In Connection With Suspension or Revocation of Penalty.

21 U.S.C.A. § 958, 21 USCA § 958

Current through P.L. 111-112 (excluding P.L. 111-84) approved 11-30-09

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