

manufacture in bulk or dosage form, or to package, repack, label or relabel, and each person who is registered to distribute shall report acquisition/distribution transactions. In addition to reporting acquisition/distribution transactions, each person who is registered to manufacture controlled substances in bulk or dosage form shall report manufacturing transactions on controlled substances in Schedules I and II, each narcotic controlled substance listed in Schedules III, IV, and V, and on each psychotropic controlled substance listed in Schedules III and IV as identified in paragraph (d) of this section.

(d) *Substances covered.* (1) Manufacturing and acquisition/distribution transaction reports shall include data on each controlled substance listed in Schedules I and II and on each narcotic controlled substance listed in Schedule III (but not on any material, compound, mixture or preparation containing a quantity of a substance having a stimulant effect on the central nervous system, which material, compound, mixture or preparation is listed in Schedule III or on any narcotic controlled substance listed in Schedule V). Additionally, reports on manufacturing transactions shall include the following psychotropic controlled substances listed in Schedules III and IV:

- (i) Schedule III
  - (A) Benzphetamine;
  - (B) Cyclobarbital;
  - (C) Methyprylon; and
  - (D) Phendimetrazine.
- (ii) Schedule IV
  - (A) Barbital;
  - (B) Diethylpropion (Amfepramone);
  - (C) Ethchlorvynol;
  - (D) Ethinamate;
  - (E) Lefetamine (SPA);
  - (F) Mazindol;
  - (G) Meprobamate;
  - (H) Methylphenobarbital;
  - (I) Phenobarbital;
  - (J) Phentermine; and
  - (K) Pipradrol.

(2) Data shall be presented in such a manner as to identify the particular form, strength, and trade name, if any, of the product containing the controlled substance for which the report is being made. For this purpose, persons filing reports shall utilize the Na-

tional Drug Code Number assigned to the product under the National Drug Code System of the Food and Drug Administration.

(e) *Transactions reported.* Acquisition/distribution transaction reports shall provide data on each acquisition to inventory (identifying whether it is, e.g., by purchase or transfer, return from a customer, or supply by the Federal Government) and each reduction from inventory (identifying whether it is, e.g., by sale or transfer, theft, destruction or seizure by Government agencies). Manufacturing reports shall provide data on material manufactured, manufacture from other material, use in manufacturing other material and use in producing dosage forms.

(f) *Exceptions.* A registered institutional practitioner who repackages or relabels exclusively for distribution or who distributes exclusively to (for dispensing by) agents, employees, or affiliated institutional practitioners of the registrant may be exempted from filing reports under this section by applying to the ARCOS Unit of the Administration.

(Approved by the Office of Management and Budget under control number 1117-0003)

[62 FR 13962, Mar. 24, 1997]

## PART 1305—ORDER FORMS

Sec.

- 1305.01 Scope of part 1305.
- 1305.02 Definitions.
- 1305.03 Distributions requiring order forms.
- 1305.04 Persons entitled to obtain and execute order forms.
- 1305.05 Procedure for obtaining order forms.
- 1305.06 Procedure for executing order forms.
- 1305.07 Power of attorney.
- 1305.08 Persons entitled to fill order forms.
- 1305.09 Procedure for filling order forms.
- 1305.10 Procedure for endorsing order forms.
- 1305.11 Unaccepted and defective order forms.
- 1305.12 Lost and stolen order forms.
- 1305.13 Preservation of order forms.
- 1305.14 Return of unused order forms.
- 1305.15 Cancellation and voiding of order forms.
- 1305.16 Special procedure for filling certain order forms.

AUTHORITY: 21 U.S.C. 821, 828, 871(b), unless otherwise noted.

SOURCE: 36 FR 7796, Apr. 24, 1971, unless otherwise noted. Redesignated at 38 FR 26609, Sept. 24, 1973.

**§ 1305.01 Scope of part 1305.**

Procedures governing the issuance, use, and preservation of order forms pursuant to section 1308 of the Act (21 U.S.C. 828) are set forth generally by that section and specifically by the sections of this part.

**§ 1305.02 Definitions.**

Any term contained in this part shall have the definition set forth in section 102 of the Act (21 U.S.C. 802) or part 1300 of this chapter.

[62 FR 13963, Mar. 24, 1997]

**§ 1305.03 Distributions requiring order forms.**

An order form (DEA Form 222) is required for each distribution of a Schedule I or II controlled substance except to persons exempted from registration under part 1301 of this chapter; which are exported from the United States in conformity with the Act; or for delivery to a registered analytical laboratory, or its agent approved by DEA.

[62 FR 13963, Mar. 24, 1997]

**§ 1305.04 Persons entitled to obtain and execute order forms.**

(a) Order forms may be obtained only by persons who are registered under section 303 of the Act (21 U.S.C. 823) to handle controlled substances listed in Schedules I and II, and by persons who are registered under section 1008 of the Act (21 U.S.C. 958) to export such substances. Persons not registered to handle controlled substances listed in Schedule I or II and persons registered only to import controlled substances listed in any schedule are not entitled to obtain order forms.

(b) An order form may be executed only on behalf of the registrant named thereon and only if his/her registration as to the substances being purchased has not expired or been revoked or suspended.

[36 FR 7796, Apr. 24, 1971. Redesignated at 38 FR 26609, Sept. 24, 1973, as amended at 62 FR 13964, Mar. 24, 1997]

**§ 1305.05 Procedure for obtaining order forms.**

(a) Order Forms are issued in mailing envelopes containing either seven or fourteen forms, each form containing an original duplicate and triplicate copy (respectively, Copy 1, Copy 2, and Copy 3). A limit, which is based on the business activity of the registrant, will be imposed on the number of order forms which will be furnished on any requisition unless additional forms are specifically requested and a reasonable need for such additional forms is shown.

(b) Any person applying for a registration which would entitle him/her to obtain order forms may requisition such forms by so indicating on the application form; order forms will be supplied upon the registration of the applicant. Any person holding a registration entitling him/her to obtain order forms may requisition such forms for the first time by contacting any Division Office or the Registration Unit of the Administration. Any person already holding order forms may requisition additional forms on DEA Form 222a which is mailed to a registrant approximately 30 days after each shipment of order forms to that registrant or by contacting any Division Office or the Registration Unit of the Administration. All requisition forms (DEA Form 222a) shall be submitted to the Registration Unit, Drug Enforcement Administration, Department of Justice, Post Office Box 28083, Central Station, Washington, DC 20005.

(c) Each requisition shall show the name, address, and registration number of the registrant and the number of books of order forms desired. Each requisition shall be signed and dated by the same person who signed the most recent application for registration or for reregistration, or by any person authorized to obtain and execute order forms by a power of attorney pursuant to § 1305.07.

(d) Order forms will be serially numbered and issued with the name, address and registration number of the registrant, the authorized activity and schedules of the registrant. This information cannot be altered or changed by the registrant; any errors must be corrected by the Registration Unit of

the Administration by returning the forms with notification of the error.

[36 FR 7796, Apr. 24, 1971, as amended at 36 FR 18732, Sept. 21, 1971. Redesignated at 38 FR 26609, Sept. 24, 1973, and amended at 51 FR 5319, Feb. 13, 1986; 53 FR 4963, Feb. 19, 1988; 62 FR 13964, Mar. 24, 1997]

**§ 1305.06 Procedure for executing order forms.**

(a) Order forms shall be prepared and executed by the purchaser simultaneously in triplicate by means of interleaved carbon sheets which are part of the DEA Form 222. Order forms shall be prepared by use of a typewriter, pen, or indelible pencil.

(b) Only one item shall be entered on each numbered line. An item shall consist of one or more commercial or bulk containers of the same finished or bulk form and quantity of the same substance. The number of lines completed shall be noted on that form at the bottom of the form, in the space provided. Order forms for carfentanil, etorphine hydrochloride, and diprenorphine shall contain only these substances.

(c) The name and address of the supplier from whom the controlled substances are being ordered shall be entered on the form. Only one supplier may be listed on any form.

(d) Each order form shall be signed and dated by a person authorized to sign an application for registration. The name of the purchaser, if different from the individual signing the order form, shall also be inserted in the signature space. Unexecuted order forms may be kept and may be executed at a location other than the registered location printed on the form, provided that all unexecuted forms are delivered promptly to the registered location upon an inspection of such location by any officer authorized to make inspections, or to enforce, any Federal, State, or local law regarding controlled substances.

[62 FR 13963, Mar. 24, 1997]

**§ 1305.07 Power of attorney.**

Any purchaser may authorize one or more individuals, whether or not located at the registered location of the purchaser, to obtain and execute order forms on his/her behalf by executing a power of attorney for each such indi-

vidual. The power of attorney shall be signed by the same person who signed the most recent application for registration or reregistration and by the individual being authorized to obtain and execute order forms. The power of attorney shall be filed with the executed order forms of the purchaser, and shall be retained for the same period as any order form bearing the signature of the attorney. The power of attorney shall be available for inspection together with other order form records. Any power of attorney may be revoked at any time by executing a notice of revocation, signed by the person who signed (or was authorized to sign) the power of attorney or by a successor, whoever signed the most recent application for registration or reregistration, and filing it with the power of attorney being revoked. The form for the power of attorney and notice of revocation shall be similar to the following:

Power of Attorney for DEA Order Forms

\_\_\_\_\_ (Name of registrant)  
\_\_\_\_\_ (Address of registrant)  
\_\_\_\_\_ (DEA registration number)

I, \_\_\_\_\_ (name of person granting power), the undersigned, who is authorized to sign the current application for registration of the above-named registrant under the Controlled Substances Act or Controlled Substances Import and Export Act, have made, constituted, and appointed, and by these presents, do make, constitute, and appoint \_\_\_\_\_ (name of attorney-in-fact), my true and lawful attorney for me in my name, place, and stead, to execute applications for books of official order forms and to sign such order forms in requisition for Schedule I and II controlled substances, in accordance with section 308 of the Controlled Substances Act (21 U.S.C. 828) and part 1305 of Title 21 of the Code of Federal Regulations. I hereby ratify and confirm all that said attorney shall lawfully do or cause to be done by virtue hereof.

\_\_\_\_\_  
(Signature of person granting power)

I, \_\_\_\_\_ (name of attorney-in-fact), hereby affirm that I am the person named herein as attorney-in-fact and that the signature affixed hereto is my signature.

\_\_\_\_\_  
(Signature of attorney-in-fact)

Witnesses:

- 1. \_\_\_\_\_.
- 2. \_\_\_\_\_.

Signed and dated on the \_\_\_\_ day of \_\_\_\_\_, (year), at \_\_\_\_\_.

## Notice of Revocation

The foregoing power of attorney is hereby revoked by the undersigned, who is authorized to sign the current application for registration of the above-named registrant under the Controlled Substances Act of the Controlled Substances Import and Export Act. Written notice of this revocation has been given to the attorney-in-fact \_\_\_\_\_ this same day.

\_\_\_\_\_  
(Signature of person revoking power)

Witnesses:

1. \_\_\_\_\_

2. \_\_\_\_\_

Signed and dated on the \_\_\_\_ day of \_\_\_\_\_, (year), at \_\_\_\_\_.

[62 FR 13963, Mar. 24, 1997]

**§ 1305.08 Persons entitled to fill order forms.**

An order form may be filled only by a person registered as a manufacturer or distributor of controlled substances listed in Schedule I or II under section 303 of the Act (21 U.S.C. 823) or as an importer of such substances under section 1008 of the Act (21 U.S.C. 958), except for the following:

(a) A person registered to dispense such substances under section 303 of the Act, or to export such substances under section 1008 of the Act, if he/she is discontinuing business or if his/her registration is expiring without reregistration, may dispose of any controlled substances listed in Schedule I or II in his/her possession pursuant to order forms in accordance with § 1307.14 of this chapter;

(b) A person who has obtained any controlled substance in Schedule I or II by order form may return such substance, or portion thereof, to the person from whom he obtained the substance or the manufacturer of the substance pursuant to the order form of the latter person;

(c) A person registered to dispense such substances may distribute such substances to another dispenser pursuant to, and only in the circumstances described in, § 1307.11 of this chapter; and

(d) A person registered or authorized to conduct chemical analysis or research with controlled substances may distribute a controlled substance listed in Schedule I or II to another person registered or authorized to conduct

chemical analysis, instructional activities, or research with such substances pursuant to the order form of the latter person, if such distribution is for the purpose of furthering such chemical analysis, instructional activities, or research.

(e) A person registered as a compounder of narcotic substances for use at off-site locations in conjunction with a narcotic treatment program at the compounding location, who is authorized to handle Schedule II narcotics, is authorized to fill order forms for distribution of narcotic drugs to off-site narcotic treatment programs only.

[36 FR 7796, Apr. 24, 1971, as amended at 36 FR 13386, July 21, 1971; 36 FR 18732, Sept. 21, 1971; 37 FR 15921, Aug. 8, 1972. Redesignated at 38 FR 26609, Sept. 24, 1973]

EDITORIAL NOTE: For FEDERAL REGISTER citations affecting § 1305.08, see the List of CFR Sections Affected in the Finding Aids section of this volume.

**§ 1305.09 Procedure for filling order forms.**

(a) The purchaser shall submit Copy 1 and Copy 2 of the order form to the supplier, and retain Copy 3 in his own files.

(b) The supplier shall fill the order, if possible and if he/she desires to do so, and record on Copies 1 and 2 the number of commercial or bulk containers furnished on each item and the date on which such containers are shipped to the purchaser. If an order cannot be filled in its entirety, it may be filled in part and the balance supplied by additional shipments within 60 days following the date of the order form. No order form shall be valid more than 60 days after its execution by the purchaser, except as specified in paragraph (f) of this section.

(c) The controlled substances shall only be shipped to the purchaser and at the location printed by the Administration on the order form, except as specified in paragraph (f) of this section.

(d) The supplier shall retain Copy 1 of the order form for his/her own files and forward Copy 2 to the Special Agent in Charge of the Drug Enforcement Administration in the area in which the

supplier is located. Copy 2 shall be forwarded at the close of the month during which the order is filled; if an order is filled by partial shipments, Copy 2 shall be forwarded at the close of the month during which the final shipment is made or during which the 60-day validity period expires.

(e) The purchaser shall record on Copy 3 of the order form the number of commercial or bulk containers furnished on each item and the dates on which such containers are received by the purchaser.

(f) Order forms submitted by registered procurement officers of the Defense Personnel Support Center of Defense Supply Agency for delivery to armed services establishments within the United States may be shipped to locations other than the location printed on the order form, and in partial shipments at different times not to exceed six months from the date of the order, as designated by the procurement officer when submitting the order.

[36 FR 7796, Apr. 24, 1971, as amended at 36 FR 18732, Sept. 21, 1971. Redesignated at 38 FR 26609, Sept. 24, 1973, and amended at 47 FR 41735, Sept. 22, 1982; 62 FR 13964, Mar. 24, 1997]

**§ 1305.10 Procedure for endorsing order forms.**

(a) An order form made out to any supplier who cannot fill all or a part of the order within the time limitation set forth in § 1305.09 may be endorsed to another supplier for filling. The endorsement shall be made only by the supplier to whom the order form was first made, shall state (in the spaces provided on the reverse sides of Copies 1 and 2 of the order form) the name and address of the second supplier, and shall be signed by a person authorized to obtain and execute order forms on behalf of the first supplier. The first supplier may not fill any part of an order on an endorsed form. The second supplier shall fill the order, if possible and if he/she desires to do so, in accordance with § 1305.09 (b), (c), and (d), including shipping all substances directly to the purchaser.

(b) Distributions made on endorsed order forms shall be reported by the second supplier in the same manner as all other distributions except that

where the name of the supplier is requested on the reporting form, the second supplier shall record the name, address and registration number of the first supplier.

[36 FR 7796, Apr. 24, 1971. Redesignated at 38 FR 26609, Sept. 24, 1973, as amended at 62 FR 13964, Mar. 24, 1997]

**§ 1305.11 Unaccepted and defective order forms.**

(a) No order form shall be filled if it:

- (1) Is not complete, legible, or properly prepared, executed, or endorsed; or
- (2) Shows any alteration, erasure, or change of any description.

(b) If an order form cannot be filled for any reason under this section, the supplier shall return Copies 1 and 2 to the purchaser with a statement as to the reason (e.g., illegible or altered). A supplier may for any reason refuse to accept any order and if a supplier refuses to accept the order, a statement that the order is not accepted shall be sufficient for purposes of this paragraph.

(c) When received by the purchaser, Copies 1 and 2 of the order form and the statement shall be attached to Copy 3 and retained in the files of the purchaser in accordance with § 1305.13. A defective order form may not be corrected; it must be replaced by a new order form in order for the order to be filled.

**§ 1305.12 Lost and stolen order forms.**

(a) If a purchaser ascertains that an unfilled order form has been lost, he shall execute another in triplicate and a statement containing the serial number and date of the lost form, and stating that the goods covered by the first order form were not received through loss of that order form. Copy 3 of the second form and a copy of the statement shall be retained with Copy 3 of the order form first executed. A copy of the statement shall be attached to Copies 1 and 2 of the second order form sent to the supplier. If the first order form is subsequently received by the supplier to whom it was directed, the supplier shall mark upon the face thereof "Not accepted" and return Copies 1 and 2 to the purchaser, who shall attach it to Copy 3 and the statement.

(b) Whenever any used or unused order forms are stolen or lost (otherwise than in the course of transmission) by any purchaser or supplier, he/she shall immediately upon discovery of such theft or loss, report the same to the Special Agent in Charge of the Drug Enforcement Administration in the Divisional Office responsible for the area in which the registrant is located, stating the serial number of each form stolen or lost. If the theft or loss includes any original order forms received from purchasers and the supplier is unable to state the serial numbers of such order forms, he/she shall report the date or approximate date of receipt thereof and the names and addresses of the purchasers. If an entire book of order forms is lost or stolen, and the purchaser is unable to state the serial numbers of the order forms contained therein, he/she shall report, in lieu of the numbers of the forms contained in such book, the date or approximate date of issuance thereof. If any unused order form reported stolen or lost is subsequently recovered or found, the Special Agent in Charge of the Drug Enforcement Administration in the Divisional Office responsible for the area in which the registrant is located shall immediately be notified.

[36 FR 7796, Apr. 24, 1971, as amended at 36 FR 13386, July 21, 1971. Redesignated at 38 FR 26609, Sept. 24, 1973, and amended at 51 FR 5319, Feb. 13, 1986; 62 FR 13964, Mar. 24, 1997]

#### **§ 1305.13 Preservation of order forms.**

(a) The purchaser shall retain Copy 3 of each order form which has been filled. He/She shall also retain in his files all copies of each unaccepted or defective order form and each statement attached thereto.

(b) The supplier shall retain Copy 1 of each order form which he/she has filled.

(c) Order forms must be maintained separately from all other records of the registrant. Order forms are required to be kept available for inspection for a period of 2 years. If a purchaser has several registered locations, he/she must retain Copy 3 of the executed order forms and any attached statements or other related documents (not including unexecuted order forms which may be kept elsewhere pursuant

to § 1305.06(d)) at the registered location printed on the order form.

(d) The supplier of carfentanil etorphine hydrochloride and diprenorphine shall maintain order forms for these substances separately from all other order forms and records required to be maintained by the registrant.

[36 FR 7796, Apr. 24, 1971. Redesignated at 38 FR 26609, Sept. 24, 1973, and amended at 39 FR 17839, May 21, 1974; 54 FR 33674, Aug. 16, 1989; 62 FR 13964, Mar. 24, 1997]

#### **§ 1305.14 Return of unused order forms.**

If the registration of any purchaser terminates (because the purchaser dies, ceases legal existence, discontinues business or professional practice, or changes his name or address as shown on his registration) or is suspended or revoked pursuant to § 1301.36 of this chapter as to all controlled substances listed in Schedules I and II for which he/she is registered, he/she shall return all unused order forms for such substance to the nearest office of the Administration.

[36 FR 7796, Apr. 24, 1971, as amended at 36 FR 18732, Sept. 21, 1971. Redesignated at 38 FR 26609, Sept. 24, 1973, as amended at 62 FR 13964, Mar. 24, 1997]

#### **§ 1305.15 Cancellation and voiding of order forms.**

(a) A purchaser may cancel part or all of an order on an order form by notifying the supplier in writing of such cancellation. The supplier shall indicate the cancellation on Copies 1 and 2 of the order form by drawing a line through the canceled items and printing "canceled" in the space provided for number of items shipped.

(b) A supplier may void part or all of an order on an order form by notifying the purchaser in writing of such voiding. The supplier shall indicate the voiding in the manner prescribed for cancellation in paragraph (a) of this section.

(c) No cancellation or voiding permitted by this section shall affect in any way contract rights of either the purchaser or the supplier.

[36 FR 7796, Apr. 24, 1971, as amended at 36 FR 13386, July 21, 1971. Redesignated at 38 FR 26609, Sept. 24, 1973]

**§ 1305.16 Special procedure for filling certain order forms.**

(a) The purchaser of carfentanil etorphine hydrochloride or diprenorphine shall submit copy 1 and 2 of the order form to the supplier and retain copy 3 in his own files.

(b) The supplier, if he/she determines that the purchaser is a veterinarian engaged in zoo and exotic animal practice, wildlife management programs and/or research and authorized by the Administrator to handle these substances shall fill the order in accordance with the procedures set forth in § 1305.09 except that:

(1) Order forms for carfentanil etorphine hydrochloride and diprenorphine shall only contain these substances in reasonable quantities and

(2) The substances shall only be shipped to the purchaser at the location printed by the Administration upon the order form under secure conditions using substantial packaging material with no markings on the outside which would indicate the content.

[39 FR 17839, May 21, 1974, as amended at 54 FR 33674, Aug. 16, 1989; 62 FR 13964, Mar. 24, 1997]

**PART 1306—PRESCRIPTIONS**

GENERAL INFORMATION

- Sec.
- 1306.01 Scope of part 1306.
- 1306.02 Definitions.
- 1306.03 Persons entitled to issue prescriptions.
- 1306.04 Purpose of issue of prescription.
- 1306.05 Manner of issuance of prescriptions.
- 1306.06 Persons entitled to fill prescriptions.
- 1306.07 Administering or dispensing of narcotic drugs.

CONTROLLED SUBSTANCES LISTED IN SCHEDULE II

- 1306.11 Requirement of prescription.
- 1306.12 Refilling prescriptions.
- 1306.13 Partial filling of prescriptions.
- 1306.14 Labeling of substances and filling of prescriptions.

CONTROLLED SUBSTANCES LISTED IN SCHEDULES III, IV, AND V

- 1306.21 Requirement of prescription.
- 1306.22 Refilling of prescriptions.
- 1306.23 Partial filling of prescriptions.
- 1306.24 Labeling of substances and filling of prescriptions.

1306.25 Transfer between pharmacies of prescription information for Schedules III, IV, and V controlled substances for refill purposes.

1306.26 Dispensing without prescription.

AUTHORITY: 21 U.S.C. 821, 829, 871(b), unless otherwise noted.

SOURCE: 36 FR 7799, Apr. 24, 1971; 36 FR 13386, July 21, 1971, unless otherwise noted. Redesignated at 38 FR 26609, Sept. 24, 1973.

GENERAL INFORMATION

**§ 1306.01 Scope of part 1306.**

Rules governing the issuance, filling and filing of prescriptions pursuant to section 309 of the Act (21 U.S.C. 829) are set forth generally in that section and specifically by the sections of this part.

**§ 1306.02 Definitions.**

Any term contained in this part shall have the definition set forth in section 102 of the Act (21 U.S.C. 802) or part 1300 of this chapter.

[62 FR 13964, Mar. 24, 1997]

**§ 1306.03 Persons entitled to issue prescriptions.**

(a) A prescription for a controlled substance may be issued only by an individual practitioner who is:

(1) authorized to prescribe controlled substances by the jurisdiction in which he is licensed to practice his profession and

(2) either registered or exempted from registration pursuant to §§ 1301.22(c) and 1301.23 of this chapter.

(b) A prescription issued by an individual practitioner may be communicated to a pharmacist by an employee or agent of the individual practitioner.

[36 FR 7799, Apr. 24, 1971, as amended at 36 FR 18732, Sept. 21, 1971. Redesignated at 38 FR 26609, Sept. 24, 1973, as amended at 62 FR 13966, Mar. 24, 1997]

**§ 1306.04 Purpose of issue of prescription.**

(a) A prescription for a controlled substance to be effective must be issued for a legitimate medical purpose by an individual practitioner acting in the usual course of his professional practice. The responsibility for the proper prescribing and dispensing of