

or reverse distributor shall do as follows:

\* \* \* \* \*

■ 9. Section 1304.22 is amended by revising paragraph (b) and adding new paragraph (e) to read as follows:

**§ 1304.22 Records for manufacturers, distributors, dispensers, researchers, importers, and exporters.**

\* \* \* \* \*

(b) *Records for distributors.* Except as provided in paragraph (e) of this section, each person registered or authorized to distribute controlled substances shall maintain records with the same information required of manufacturers pursuant to paragraphs (a)(2)(i), (ii), (iv), (v), (vii), (viii) and (ix) of this section.

\* \* \* \* \*

(e) *Records for reverse distributors.* Each person registered to distribute controlled substances as a reverse distributor shall maintain records with the following information for each controlled substance:

(1) For each controlled substance in bulk form the following:

(i) The name of the controlled substance.

(ii) The total quantity of the controlled substance to the nearest metric unit weight consistent with unit size.

(iii) The quantity received from other persons, including the date and quantity of each receipt and the name, address, and registration number of the other person from whom the controlled substance was received.

(iv) The quantity returned to the original manufacturer of the controlled substance or the manufacturer's agent, including the date of and quantity of each distribution and the name, address and registration number of the manufacturer or manufacturer's agent to whom the controlled substance was distributed.

(v) The quantity disposed of including the date and manner of disposal and the signatures of two responsible employees of the registrant who witnessed the disposal.

(2) For each controlled substance in finished form the following:

(i) The name of the substance.

(ii) Each finished form (e.g., 10-milligram tablet or 10-milligram concentration per fluid ounce or milliliter) and the number of units or volume of finished form in each commercial container (e.g., 100-tablet bottle or 3-milliliter vial).

(iii) The number of commercial containers of each such finished form received from other persons, including

the date of and number of containers in each receipt and the name, address, and registration number of the person from whom the containers were received.

(iv) The number of commercial containers of each such finished form distributed back to the original manufacturer of the substance or the manufacturer's agent, including the date of and number of containers in each distribution and the name, address, and registration number of the manufacturer or manufacturer's agent to whom the containers were distributed.

(v) The number of units or volume of finished forms and/or commercial containers disposed of including the date and manner of disposal, the quantity of the substance in finished form disposed, and the signatures of two responsible employees of the registrant who witnessed the disposal.

■ 10. Section 1304.33 is amended by revising paragraph (c) to read as follows:

**§ 1304.33 Reports to ARCOS.**

\* \* \* \* \*

(c) *Persons reporting.* For controlled substances in Schedules I, II or narcotic controlled substances in Schedule III, each person who is registered to manufacture in bulk or dosage form, or to package, repackage, label or relabel, and each person who is registered to distribute, including each person who is registered to reverse 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.

\* \* \* \* \*

**PART 1305—ORDER FORMS**

■ 11. The authority citation for part 1305 continues to read as follows:

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

■ 12. Section 1305.08 is amended by revising paragraph (b) to read as follows:

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

\* \* \* \* \*

(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/she obtained the

substance, to the manufacturer of the substance, or to a registered reverse distributor pursuant to the order form of the latter person;

\* \* \* \* \*

**PART 1307—MISCELLANEOUS**

■ 13. The authority citation for part 1307 continues to read as follows:

**Authority:** 21 U.S.C. 821, 822(d), 871(b), unless otherwise noted.

■ 14. Section 1307.11 is revised to read as follows:

**§ 1307.11 Distribution by dispenser to another practitioner or reverse distributor.**

(a) A practitioner who is registered to dispense a controlled substance may distribute (without being registered to distribute) a quantity of such substance to—

(1) Another practitioner for the purpose of general dispensing by the practitioner to patients, provided that—

(i) The practitioner to whom the controlled substance is to be distributed is registered under the Act to dispense that controlled substance;

(ii) The distribution is recorded by the distributing practitioner in accordance with § 1304.22(c) of this chapter and by the receiving practitioner in accordance with § 1304.22(c) of this chapter;

(iii) If the substance is listed in Schedule I or II, an order form is used as required in part 1305 of this chapter; and

(iv) The total number of dosage units of all controlled substances distributed by the practitioner pursuant to this section and § 1301.25 of this chapter during each calendar year in which the practitioner is registered to dispense does not exceed 5 percent of the total number of dosage units of all controlled substances distributed and dispensed by the practitioner during the same calendar year.

(2) A reverse distributor who is registered to receive such controlled substances.

(b) If, during any calendar year in which the practitioner is registered to dispense, the practitioner has reason to believe that the total number of dosage units of all controlled substances which will be distributed by him pursuant to paragraph (a)(1) of this section and § 1301.25 of this chapter will exceed 5 percent of this total number of dosage units of all controlled substances distributed and dispensed by him during that calendar year, the practitioner shall obtain a registration to distribute controlled substances.

■ 15. Section 1307.12 is amended by revising the title and revising paragraph (a) to read as follows: