substance users in a narcotic treatment program shall maintain records with the following information for each narcotic controlled substance:

(1) Name of substance;

(2) Strength of substance;

(3) Dosage form;

(4) Date dispensed;

(5) Adequate identification of patient (consumer);

(6) Amount consumed;

(7) Amount and dosage form taken home by patient; and

(8) Dispenser's initials.

(b) The records required by paragraph (a) of this section will be maintained in a dispensing log at the narcotic treatment program site and will be maintained in compliance with § 1304.22 without reference to § 1304.03.

(c) All sites which compound a bulk narcotic solution from bulk narcotic powder to liquid for on-site use must keep a separate batch record of the compounding.

(d) Records of identity, diagnosis, prognosis, or treatment of any patients which are maintained in connection with the performance of a narcotic treatment program shall be confidential, except that such records may be disclosed for purposes and under the circumstances authorized by part 310 and 42 CFR part 2.

[39 FR 37985, Oct. 25, 1974. Redesignated and amended at 62 FR 13961, Mar. 24, 1997]

§ 1304.25 Records for treatment programs which compound narcotics for treatment programs and other locations.

Each person registered or authorized by § 1301.22 of this chapter to compound narcotic drugs for off-site use in a narcotic treatment program shall maintain records which include the following information for each narcotic drug:

(a) For each narcotic controlled substance in bulk form to be used in, or capable of use in, or being used in, the compounding of the same or other non-controlled substances in finished form:

(1) The name of the substance;

(2) The quantity compounded in bulk form by the registrant, including the date, quantity and batch or other identifying number of each batch compounded;

(3) 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 substance was received;

(4) The quantity imported directly by the registrant (under a registration as an importer) for use in compounding by him, including the date, quantity and import permit or declaration number of each importation;

(5) The quantity used to compound the same substance in finished form, including:

(i) The date and batch or other identifying number of each compounding;

(ii) The quantity used in the compound;

(iii) The finished form (e.g., 10-milligram tablets or 10-milligram concentration per fluid ounce or milliliter;

(iv) The number of units of finished form compounded;

(v) The quantity used in quality control;

(vi) The quantity lost during compounding and the causes therefore, if known;

(vii) The total quantity of the substance contained in the finished form;

(viii) The theoretical and actual yields; and

(ix) Such other information as is necessary to account for all controlled substances used in the compounding process;

(6) The quantity used to manufacture other controlled and non-controlled substances; including the name of each substance manufactured and the information required in paragraph (a)(5) of this section;

(7) The quantity distributed in bulk form to other programs, including the date and quantity of each distribution and the name, address and registration number of each program to whom a distribution was made;

(8) The quantity exported directly by the registrant (under a registration as an exporter), including the date, quantity, and export permit or declaration number of each exploration; and

(9) The quantity disposed of by destruction, including the reason, date and manner of destruction. All other destruction of narcotic controlled substances will comply with § 1307.22.

(b) For each narcotic controlled substance in finished form:

(1) The name of the substance;

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

(3) The number of containers of each such commercial finished form compounded from bulk form by the registrant, including the information required pursuant to paragraph (a)(5) of this section;

(4) The number of units of finished forms and/or commercial containers received from other persons, including the date of and number of units and/or commercial containers in each receipt and the name, address and registration number of the person from whom the units were received;

(5) The number of units of finished forms and/or commercial containers imported directly by the person (under a registration or authorization to import), including the date of, the number of units and/or commercial containers in, and the import permit or declaration number for, each importation;

(6) The number of units and/or commercial containers compounded by the registrant from units in finished form received from others or imported, including:

(i) The date and batch or other identifying number of each compounding;

(ii) The operation performed (e.g., repackaging or relabeling);

(iii) The number of units of finished form used in the compound, the number compounded and the number lost during compounding, with the causes for such losses, if known; and

(iv) Such other information as is necessary to account for all controlled substances used in the compounding process;

(7) The number of containers distributed to other programs, including the date, the number of containers in each distribution, and the name, address and registration number of the program to whom the containers were distributed;

(8) The number of commercial containers exported directly by the registrant (under a registration as an exporter), including the date, number of containers and export permit or declaration number for each exportation; and

(9) The number of units of finished forms and/or commercial containers destroyed in any manner by the registrant, including the reason, the date and manner of destruction. All other destruction of narcotic controlled substances will comply with § 1307.22.

[39 FR 37985, Oct. 25, 1974. Redesignated at 62 FR 13961, Mar. 24, 1997]

REPORTS

§ 1304.31 Reports from manufacturers importing narcotic raw material.

(a) Every manufacturer which imports or manufactures from narcotic raw material (opium, poppy straw, and concentrate of poppy straw) shall submit information which accounts for the importation and for all manufacturing operations performed between importation and the production in bulk or finished marketable products, standardized in accordance with the U.S. Pharmacopeia, National Formulary or other recognized medical standards. Reports shall be signed by the authorized official and submitted quarterly on company letterhead to the Drug Enforcement Administration, Drug and Chemical Evaluation Section, Washington, D.C. 20537, on or before the 15th day of the month immediately following the period for which it is submitted.

(b) The following information shall be submitted for each type of narcotic raw material (quantities are expressed as grams of anhydrous morphine alkaloid):

(1) Beginning inventory;

(2) Gains on reweighing;

(3) Imports;

(4) Other receipts;

(5) Quantity put into process;

(6) Losses on reweighing;

(7) Other dispositions and

(8) Ending inventory.

(c) The following information shall be submitted for each narcotic raw material derivative including morphine, codeine, thebaine, oxycodone, hydrocodone, medicinal opium, manufacturing opium, crude alkaloids and