

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]

§ 1304.26 Additional recordkeeping requirements applicable to drug products containing gamma-hydroxybutyric acid.

In addition to the recordkeeping requirements for dispensers and researchers provided in § 1304.22, practitioners dispensing gamma-hydroxybutyric acid that is manufactured or distributed in accordance with an application under section 505 of the Federal Food, Drug, and Cosmetic Act must maintain and make available for inspection and copying by the Attorney General, all of the following information for each prescription:

(a) Name of the prescribing practitioner.

(b) Prescribing practitioner's Federal and State registration numbers, with the expiration dates of these registrations.

(c) Verification that the prescribing practitioner possesses the appropriate registration to prescribe this controlled substance.

(d) Patient's name and address.

(e) Patient's insurance provider, if available.

[70 FR 293, Jan. 4, 2005]

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 and Chemical Evaluation Section, Drug Enforcement Administration, on or before the 15th day of the month immediately following the period for which it is submitted. See the Table of DEA Mailing Addresses in § 1321.01 of this chapter for the current mailing address.

(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,

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hydrocodone, medicinal opium, manufacturing opium, crude alkaloids and other derivatives (quantities are expressed as grams of anhydrous base or anhydrous morphine alkaloid for manufacturing opium and medicinal opium):

- (1) Beginning inventory;
- (2) Gains on reweighing;
- (3) Quantity extracted from narcotic raw material;
- (4) Quantity produced/manufactured/synthesized;
- (5) Quantity sold;
- (6) Quantity returned to conversion processes for reworking;
- (7) Quantity used for conversion;
- (8) Quantity placed in process;
- (9) Other dispositions;
- (10) Losses on reweighing and
- (11) Ending inventory.

(d) The following information shall be submitted for importation of each narcotic raw material:

- (1) Import permit number;
- (2) Date shipment arrived at the United States port of entry;
- (3) Actual quantity shipped;
- (4) Assay (percent) of morphine, cocaine and thebaine and
- (5) Quantity shipped, expressed as anhydrous morphine alkaloid.

(e) Upon importation of crude opium, samples will be selected and assays made by the importing manufacturer in the manner and according to the method specified in the U.S. Pharmacopoeia. Where final assay data is not determined at the time of rendering report, the report shall be made on the basis of the best data available, subject to adjustment, and the necessary adjusting entries shall be made on the next report.

(f) Where factory procedure is such that partial withdrawals of opium are made from individual containers, there shall be attached to each container a stock record card on which shall be kept a complete record of all withdrawals therefrom.

(g) All in-process inventories should be expressed in terms of end-products and not precursors. Once precursor material has been changed or placed into process for the manufacture of a specified end-product, it must no longer be accounted for as precursor stocks available for conversion or use, but

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rather as end-product in-process inventories.

[62 FR 13961, Mar. 24, 1997, as amended at 75 FR 10677, Mar. 9, 2010]

§ 1304.32 Reports of manufacturers importing coca leaves.

(a) Every manufacturer importing or manufacturing from raw coca leaves shall submit information accounting for the importation and for all manufacturing operations performed between the importation and the manufacture of bulk or finished products standardized in accordance with U.S. Pharmacopoeia, National Formulary, or other recognized standards. The reports shall be submitted quarterly on company letterhead to the Drug and Chemical Evaluation Section, Drug Enforcement Administration, on or before the 15th day of the month immediately following the period for which it is submitted. See the Table of DEA Mailing Addresses in §1321.01 of this chapter for the current mailing address.

(b) The following information shall be submitted for raw coca leaf, ecgonine, ecgonine for conversion or further manufacture, benzoylecgonine, manufacturing coca extracts (list for tinctures and extracts; and others separately), other crude alkaloids and other derivatives (quantities should be reported as grams of actual quantity involved and the cocaine alkaloid content or equivalency):

- (1) Beginning inventory;
- (2) Imports;
- (3) Gains on reweighing;
- (4) Quantity purchased;
- (5) Quantity produced;
- (6) Other receipts;
- (7) Quantity returned to processes for reworking;
- (8) Material used in purification for sale;
- (9) Material used for manufacture or production;
- (10) Losses on reweighing;
- (11) Material used for conversion;
- (12) Other dispositions and
- (13) Ending inventory.

(c) The following information shall be submitted for importation of coca leaves:

- (1) Import permit number;
- (2) Date the shipment arrived at the United States port of entry;