8 January 2019

PART 1304 - RECORDS AND REPORTS OF REGISTRANTS

REPORTS

§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 UN Reporting and Quota Section, Diversion Control Division, 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;
- (3) Actual quantity shipped;
- (4) Assay (percent) of cocaine alkaloid and
- (5) Total cocaine alkaloid content.

(d) Upon importation of coca leaves, samples will be selected and assays made by the importing manufacturer in accordance with recognized chemical procedures. These assays shall form the basis of accounting for such coca leaves, which shall be accounted for in terms of their cocaine alkaloid content or equivalency or their total anhydrous coca alkaloid content. Where final assay data is not determined at the time of submission, 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.

(e) Where factory procedure is such that partial withdrawals of medicinal coca leaves are made from individual containers, there shall be attached to the container a stock record card on which shall be kept a complete record of withdrawals therefrom.

(f) 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

https://www.deadiversion.usdoj.gov/21cfr/cfr/1304/1304_32.htm

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specified end-product, it must no longer be accounted for as precursor stocks available for conversion or use, but rather as end-product in-process inventories.

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