

NOTICE



NOTIFICATION OF REPORTS FOR REGULATED MACHINE IMPORT/EXPORT/DOMESTIC TRANSFER (RETURN INFORMATION)

The Drug Enforcement Administration (DEA) issues this notice to inform businesses and individuals (i.e. regulated persons) of the requirements for reporting the importation, exportation, or domestic transfer of tableting and encapsulating machines (regulated machines), including providing return information (also known as actual date of shipment) under the Controlled Substances Act (CSA).

According to the CSA ([21 U.S.C. § 830\(a\)\(1\)](#)):

- Each regulated person who engages in a regulated transaction involving a listed chemical, a tableting machine, or an encapsulating machine shall keep a record of the transaction as specified by [21 C.F.R. § 1310.04](#) and file reports as specified by [21 C.F.R. § 1310.05](#). ([21 C.F.R. § 1310.03\(a\)](#)).
- It is the duty of each regulated person who engages in a regulated transaction to identify the other party to the transaction. It is the duty of such other parties to present proof of identity to the regulated person. For sales to individuals or cash purchases, documents and other evidence of proof must consist of at least a signature, driver's license, and one other form of identification. ([21 C.F.R. § 1310.07\(a\), \(d\)](#)).
- Each regulated person must orally report any domestic regulated transaction involving a regulated machine to the Special Agent in Charge of the DEA Divisional Office where the regulated person is located. The regulated person also must file a report of the transaction (on DEA Form 452) with the Administration through the DEA Diversion Control Division secure network application within 15 calendar days after the order has been shipped by the seller. ([21 C.F.R. § 1310.05\(b\)\(2\)](#)).
- Similarly, each regulated person who imports or exports a regulated machine must submit a DEA Form 452 at least 15 calendar days before the anticipated arrival at the port of entry or port of export. [21 C.F.R. 1310.05\(c\) \(1\)](#).
- Once machines are received by the importer, domestic transaction reporting requirements commence. Distributions of tableting and encapsulating machines from the importer to their customers must be reported as domestic regulated transactions in accordance with [21 C.F.R. § 1310.05\(b\)\(2\)](#).
- Within 30 calendar days after actual receipt of a tableting or encapsulating machine, or within 10 calendar days after receipt of a written request by the Administration to the importer, whichever is sooner, the importer must file a report with the Administration (on DEA Form 452) specifying the particulars of the transaction utilizing the DEA Diversion Control Division secure network application. ([21 C.F.R. § 1310.06\(h\)](#)).

For further information, please consult [21 CFR §§ 1310.05](#), [1310.06](#), and [1310.07](#).

The Drug Enforcement Administration thanks you for your cooperation in this matter.

For more information, please visit: DEAdiversion.usdoj.gov under reporting of Regulated Machines

To report suspicious regulated machine activity, please email: RegulatedMachines@dea.gov

For additional questions, please email: Tableting-EncapsuleMachine@dea.gov