



2023 DEA Supply Chain Conference

Diversions Control Division

Houston, Texas

Tableting & Encapsulating Machines

May 2-4, 2023



The contents of this document do not have the force and effect of law and are not meant to bind the public or DEA in any way. This document is intended only to provide clarity to the public regarding existing requirements under the law or agency policies.





- **Definitions**
- **Tableting & Encapsulating Machines**
- **Laws, Regulations, and Reporting Requirements**
- **Reports for Regulated Machines**
- **DEA Form 452 – Reports of Regulated Machines**
- **Required Recordkeeping**
- **Proof of Identification**
- **Seizure and Release of Regulated Machines**
- **Contacts**





- **Title 21 United States Code (USC) Controlled Substances Act (CSA)**
- **§802 Definitions**
- **Regulated Person:**
 - (38) The term "regulated person" means a person who manufactures, distributes, imports, or exports a listed chemical, a tableting machine, or an encapsulating machine or who acts as a broker or trader for an international transaction involving a listed chemical, a tableting machine, or an encapsulating machine.**
- **Regulated Transaction:**
 - (39) The term "regulated transaction" means —**
 - (B) a distribution, importation, or exportation of a tableting machine or encapsulating machine.**



Tableting & Encapsulating Machines



Manual



Desktop (Model TDP)



Floor

Tableting Machine means any manual, semi-automatic, or fully automatic equipment which may be used for the compaction or molding of powdered or granular solids, or semi-solid material, to produce coherent solid tablets. Title 21 C.F.R. 1300.02



Tableting & Encapsulating Machines



Manual



Desktop (Model TDP)



Floor

Encapsulating Machine means any manual, semi-automatic, or fully automatic equipment which may be used to fill shells or capsules with any powdered, granular, or semi-solid material, or liquid material. Title 21 C.F.R. 1300.02





- **The Controlled Substances Act (CSA) and its implementing regulations provide for limited controls on tableting or encapsulating machines.**
- **Title 21 C.F.R. 1310.05(b)(2) 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.**
- **Domestic Transfer: Oral notification must be made to the field office where the regulated person is located when the order is placed, and a DEA form 452 must be filed *within 15 calendar days* after the shipment of the machine to the purchaser.**





- **Title 21 C.F.R. 1310.05(c)** Each regulated person who imports or exports a tableting machine, must file a report of such importation or exportation on DEA Form 452 with the Administration through the DEA Diversion Control Division secure network application.
- **Importation**: DEA form 452 must be filed online ***at least 15 calendar days prior*** to the anticipated arrival date by the importer.
- **Exportation**: DEA form 452 must be filed online ***at least 15 calendar days prior*** to the anticipated shipping date by the exporter.





- **The purpose of the DEA Form 452 is to notify the DEA, rather than to indicate an approval, or disapproval, as specified by the law.**
- **Importers, exporters, distributors, manufacturers, and purchasers of tableting and encapsulating machines are “regulated persons.” 21 U.S.C. 802.**
- **According to 21 C.F.R 1310.04(a), regulated persons must maintain records of transactions for a period of two years.**
- **Regulated persons are not subject to the same stringent inspection requirements as a DEA registrant.**



Reports for Regulated Machines



U.S. DEPARTMENT OF JUSTICE ★ DRUG ENFORCEMENT ADMINISTRATION
DIVERSION CONTROL DIVISION

HOME REGISTRATION REPORTING RESOURCES ABOUT US

REPORTING > Reports Required by 21 CFR > Reports for Regulated Machines - DEA Form 452

Reports for Regulated Machines - DEA Form 452

Get Email Updates:

Regulated Machines Online

DEA Form 452 - Import, Export, or Domestic Transactions of Tableting and Encapsulating Machines

Reference Guides:

- [Registering/Creating a Company User Account](#) (PDF)
- [Completing a DEA Form 452 for Import](#) (PDF)
- [Completing a DEA Form 452 for Export](#) (PDF)
- [Completing a DEA Form 452 for Domestic Transfer](#) (PDF)

ARCOS
BCM Online
Chemical Import/Export Declarations
CSOS (Controlled Substances Ordering System)
Theft/Loss Reporting
Import/Export
Medical Missions
Quotas
Registrant Record of Controlled Substances Destroyed
Regulated Machines (Tableting and Encapsulating)
Reports Required by 21 CFR
SORS
Submit a Tip to DEA
Year-End Reports

DEA Form 452 - Reports for Regulated Machines



Purpose: The purpose of this form is to report all domestic, imports, and exports transactions of tableting and encapsulating machines to DEA.

To DEA: A DEA Form 452 *at least* **15 days prior** to the import or export and within **15 days after** a domestic transaction.

From DEA: The Transaction Identification Number.



DEA Form 452 - Reports for Regulated Machines



Drug Enforcement Administration Reports for Regulated Machines

Web Tracking No.:

Federal Regulations require a regulated person to submit a detailed report of any Import or Export of tableting or encapsulating machines. A tableting machine or encapsulating machine may not be imported or exported until a DEA transaction identification has been filed by the Administration. Federal regulations require a regulated person to submit a detailed report of all domestic regulated transactions in a tableting machine or encapsulating machine.

1. Type of Request: ORIGINAL AMENDED WITHDRAWAL OMB Approval No. 1117-0024 Expiration Date: 11/30/2022

2. Type of Submission: ORIGINAL AMENDED WITHDRAWAL

3. Purpose Need: Medical Commercial Scientific Other (please describe):

4. Proposed Date of Import: _____
Anticipated Port of Entry: _____

DEA Transaction ID: _____

5. Regulated Person: (Business Name, Business Address): _____

6. Broker/Forwarding Agent: (Business Name, Business Address): _____

Registration Number (required if registered):
POC Name:
Email address:
Business Phone:

Country:
POC Name:
Email address:
Business Phone:

7. Consignor: (Business Name, Business Address): _____

Country: CHINA
POC Name:
Email address:
Business Phone:

E-SIGNATURE OF AUTHORIZED INDIVIDUAL: _____

DATE: _____

PRIVACY ACT INFORMATION
AUTHORITY: Section 301 of the Controlled Substances Act of 1970 (PL 91-513).
PURPOSE: Report of Regulated Machines.
ROUTINE USES: The Controlled Substances Act authorizes the production of special reports required for statistical and analytical purposes. Disclosures of information from this system are made to the following categories of users for the purposes stated:
A. Other Federal law enforcement and regulatory agencies for law enforcement and regulatory purposes.
B. State and local law enforcement and regulatory agencies for law enforcement and regulatory purposes.
EFFECT: Failure to report may result in penalties under Section 402 and 403 of the Controlled Substances Act.
Under the Paperwork Reduction Act, a person is not required to respond to a collection of information unless it displays a currently valid OMB control number.

Public reporting burden for this collection of information is estimated to average 15 minutes per response for imports, exports, and domestic transactions, and 5 minutes per response for Return Declarations, including the time for reviewing instructions, searching existing data sources, gathering and maintaining the data needed, and completing and reviewing the collection of information. Send comments regarding this burden estimate or any other aspect of this collection of information, including suggestions for reducing this burden, to the Drug Enforcement Administration, Attn: Federal Register Representative/ODW, 8701 Morrisette Drive, Springfield, VA 22152; and to the Office of Management and Budget, Paperwork Reduction Project No. 1117-0024, Washington, D.C. 20503.
Freedom of Information: Please prominently identify any confidential business information per 28 CFR 16.8(c) and Exemption 4 of the Freedom of Information Act (FOIA). In the event DEA receives a FOIA request to obtain such information, DEA will give written notice to the registrant to obtain such information. DEA will give written notice to the registrant to allow an opportunity to object prior to the release of information.

8. Description of Each Machine		DEA Transaction ID:
Machine Type: <input type="checkbox"/> Encapsulating <input type="checkbox"/> Tableting Serial #: _____ Make: _____ Model: _____ <input type="checkbox"/> Electric <input type="checkbox"/> Manual Description: _____	Machine Type: <input type="checkbox"/> Encapsulating <input type="checkbox"/> Tableting Serial #: _____ Make: _____ Model: _____ <input type="checkbox"/> Electric <input type="checkbox"/> Manual Description: _____	Machine Type: <input type="checkbox"/> Encapsulating <input type="checkbox"/> Tableting Serial #: _____ Make: _____ Model: _____ <input type="checkbox"/> Electric <input type="checkbox"/> Manual Description: _____
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§1310.04 Maintenance of records.

(a) Every record required to be kept subject to §1310.03 for a List I chemical, *a tableting machine, or an encapsulating machine* shall be kept by the regulated person for 2 years after the date of the transaction.





- **Regulated persons must identify the other party to the transaction.**
- **Transactions with a business: Use such methods as checking a telephone directory, credit bureau, Better Business Bureau, or DEA registration number. 21 C.F.R. 1310.07(b).**
- **When transacting business with a new representative of a firm, the regulated person must verify the claimed agency status of the representative. 21 C.F.R. 1310.07(c).**





- **Transactions with an individual or cash purchasers: Required to obtain proof identity such as signature of the purchaser, drivers license, and one other form of identification. 21 C.F.R. 1301.07 (d).**
- **Transactions with a new customer who is not an individual or cash customer, the regulated person shall establish the identity of the authorized purchasing agent or agents and have on file that person's signature, electronic password, or other identification. 21 C.F.R. 1310.07(e).**





- **Failure of the regulated person to comply with the applicable laws and regulations may result in seizure of the shipment by the Customs and Border Protection (CBP) or Drug Enforcement Administration (DEA)**
- **Regulated persons will need to coordinate with DEA field offices and/or CBP in order to release detained machines**





Encapsulating/Tableting Machine

Tablet-EncapsuleMachine@dea.gov

Thank you

