

# Regulations on Tablet Press & Capsule Filling Machine Transactions

An executive order resulted in electronic filing versus paper for the importation and exportation of cargo and hence there was a need by agencies to develop new regulations to implement the order.



Consequently, DEA has developed and amended its regulations. Even end users of the machines will be affected by the regulations when they sell or give away their current machines. They will become a distributor or an exporter.

# AS A RESULT - 1



From	To
Report items, no form	a Form 452
Report on imp/exp day	15 days before
Proposed imp/exp	also verify shipment after the event
Domestic shipment	in addition to a field office alert, submit a Form 452

## AS A RESULT - 2

Be aware that the U.S. port of entry and the U.S. port of export have new definitions.

One must list a reason for an import shipment.

An importer/exporter will need a DEA transaction ID number before entering the shipment data into the ACE system of CBP.

# BACKGROUND

EXECUTIVE ORDER 13659

2/19/2014

# PURPOSE OF THE ORDER

To streamline the export/import process for America's businesses and to require the government-wide utilization of the International Trade Data System (ITDS)

ITDS will be the single window through which businesses will electronically transmit data required by participating agencies for the importation or exportation of cargo.



Businesses will transmit their import and export data to the CBP Automated Commercial Automated Environment (ACE) system

however

The ITDS excludes applications for permits, licenses or certifications

consequently



Because advance notification of the importation or exportation of tablet presses and encapsulating machines is required by DEA, this information must first be transmitted to DEA before being submitted to CBP.

Thus, regulated persons will continue to use the filing process that must be completed in advance of importation or exportation; however, the processes will be electronic rather than paper.

# NOTIFICATION TO DEA IS NOT NEW

(CFR Part 1310.03)

Each regulated person who engages in a regulated transaction involving ... a tableting machine or an encapsulating machine shall keep a record of the transaction ... and file reports ...

The new DEA Form 452 will be accessed, completed and submitted by regulated persons through the DEA Diversion Control Division secure network application. Upon receipt and review, DEA will assign each completed report a transaction identification number (TIN) to indicate it was filed with DEA.

This TIN will be transmitted to the submitter who will then enter this TIN and other information on the transaction into ACE.

DEA will also transmit the submitted data to CBP. ACE will compare the data received from the importer/exporter representative to the record received from DEA and when a match occurs the shipment can proceed.

# IN ADDITION

DEA is now requiring domestic transactions to be entered on the Form 452 on the DEA network application in addition to the current regulations of notifying the DEA field division of the transaction. One may list more than one machine for a single transaction.



# WHY DOMESTIC?

The new electronic domestic reporting will allow DEA to create a streamlined reporting structure of regulated activities applicable to tableting and encapsulating machines.

# New Regulations



Federal Register publications occurred on

9/15/2016, proposed rulemaking

12/30/2016, final rule

1/30/2017, rule currently on hold

with compliance delayed to

7/31/2017

# TOPICS



Definitions (CFR Part 1300.02)

Submission of reports (CFR Part 1310.05)

Report contents (CFR Part 1310.06)

Proof of identity (CFR Part 1310.07)

Maintenance of records (CFR Part 1310.04)

# DEFINITION - 1

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.

## DEFINITION - 2

Encapsulating machine means any manual, semi-automatic, or fully automatic equipment which may be used to fill shells or capsules with any powdered, granular, semi-solid, or liquid material.

## DEFINITION - 3

Regulated person means any individual, corporation, partnership, or other legal entity who manufactures, distributes, imports or exports ... a tableting machine or an encapsulating machine ...

## DEFINITION - 4

Regulated transaction means a distribution, importation, or exportation of a tableting machine or an encapsulating machine ...

# DEFINITION - 5

Port of entry (see CFR 1300.02)

Essentially, in the U.S. where duties are collected



# DEFINITION - 6

Port of export (see CFR: 1300.02) essentially,  
when one conveyance stops at several ports  
before leaving the U.S. (use first port where  
the machines were actually loaded)

or

off loaded from one conveyance to another  
(use last U.S. port for the last conveyance)

# SUBMISSION OF REPORTS - 1

## Domestic transactions - 1

Orally reported to the Special Agent in Charge of the DEA Divisional Office for the area in which the regulated person making the report is located when the order is placed with the seller.

# SUBMISSION OF REPORTS - 2

## Domestic transactions - 2

Regulated person must file a report on Form 452 on the DEA secured network application within fifteen calendar days after the order has been shipped by the seller. One may list more than one machine for a single transaction.

# SUBMISSION OF REPORTS - 3

## Import/Export transactions – 1

File a report on Form 452 on the DEA secured network application at least 15 calendar days before anticipated arrival at the port of entry or port of export. One can report more than one machine on a Form 452 for each shipment.

# SUBMISSION OF REPORTS - 4

## Import/Export transactions - 2

Submit a Form 452 for return information meaning confirmation on the details of the completed importation or exportation

# DOMESTIC REPORT CONTENTS - 1

Type of request: select domestic

Type of Submission: select  
original, amended, or withdrawal

Indicate date of sale

# DOMESTIC REPORT CONTENTS - 2

Regulated person information:

Name/business name of the seller

Address/business address of the seller

Point of contact

Email address

Telephone number

# DOMESTIC REPORT CONTENTS - 3

## Purchaser information:

Name/business name

Address/business address

Point of contact

Telephone number

Email



# DOMESTIC REPORT CONTENTS - 4

For each transaction, a record field exists for

Machine Type: select capsule filler or press

Serial number, if any

Make (mfg.)

Model name and select manual or electric

# DOMESTIC REPORT CONTENTS - 5

Method of transfer (company truck, picked up by customer)

List changes made in identifying information on the machine (e.g. name, brand, model, serial number, etc. )

# DOMESTIC REPORT CONTENTS - 6

Enter a name to represent the E-signature  
of the person that authorized the  
shipment

Indicate the date

# IMPORT REPORT CONTENTS - 1

Type of request: select import

Type of Submission: select

original, amended, or withdrawal

Purpose Need: select

medical, commercial, scientific, or other

# IMPORT REPORT CONTENTS - 2

Provide the anticipated date of arrival at  
the port of entry

Indicate the anticipated port of entry

# IMPORT REPORT CONTENTS - 3

Provide importer information:

Name/business name

Address/business address

Point of contact

Email address

Telephone number

# IMPORT REPORT CONTENTS - 4

Provide broker/forwarding agent data, if any:

Name/business name

Address/business address

Point of contact

Email address

Telephone number

# IMPORT REPORT CONTENTS - 5

Provide consignor information:

Name/business name

Address/business address

Point of contact

Email address

Telephone number



# IMPORT REPORT CONTENTS - 6

For each transaction, a record field exists for

Machine Type: select capsule filler or press

Serial number, if any

Make (mfg.)

Model name and select manual or electric

# IMPORT REPORT CONTENTS - 7

List proposed changes in identifying information on a machine (e.g., name, brand, model, serial number, if any) that will take place after importation

# IMPORT REPORT CONTENTS - 8

Enter a name to represent the E-signature  
of the person that authorized the  
shipment

Indicate the date

Although the Form 452 must be submitted 15 calendar days before the anticipated date of arrival at the port of entry, the importer may proceed with the import as soon as the TIN has been issued for a completed report.

# DENIAL OF RELEASE BY CBP - 1

If a shipment has been denied release, importer must file a Form 452 within five business days describing the event and machine information as indicated in CFR 1310.05(c)(2) and 1310.06(g) in order to obtain a TIN; the original notification will be void.

# DENIAL OF RELEASE BY CBP - 2

One must file an amended Form 452.

One may then proceed with the release of the shipment upon receipt of the TIN for the amendment without regard to the 15 day advance notification.

# IMPORT REPORT RETURN - 1

Within 30 days of receipt, importer must file Form 452 on date and port of release, quantity of machines released, date and quantity of machine(s) that arrived at final destination, changes in identifying information on a machine (e.g. name, brand, model, serial number, if any, etc. ) that will take place after importation.

# IMPORT REPORT RETURN - 2

Provide a description of each machine (make, model, serial number, if any).

Upon receipt and review of this information, DEA will assign a transaction identification number (TIN) to indicate the filing of a completed report.



# EXPORT REPORT CONTENTS - 1

Type of request: select export

Type of Submission: select  
original, amended, or withdrawal

# EXPORT REPORT CONTENTS - 2

Provide the anticipated date of arrival at the port of export, the foreign port and country of entry

# EXPORT REPORT CONTENTS - 3

Provide exporter information:

Name/business name

Address/business address

Point of contact

Email address

Telephone number

# EXPORT REPORT CONTENTS - 4

Provide intermediate consignee data, if any:

Name/business name

Address/business address

Point of contact

Email address

Telephone number

# EXPORT REPORT CONTENTS - 5

Provide consignee information:

Name/business name

Address/business address

Point of contact

Email address

Telephone number

# EXPORT REPORT CONTENTS - 6

Provide export broker data, if applicable:

Name/business name

Address/business address

Point of contact

Email address

Telephone number

# EXPORT REPORT CONTENTS - 7

For each transaction, a record field exists for

Machine Type: select capsule filler or press

Serial number, if any

Make (mfg.)

Model name and select manual or electric

# EXPORT REPORT CONTENTS - 8

Enter a name to represent the E-signature  
of the person that authorized the  
shipment

Indicate the date



Although the Form 452 must be submitted 15 calendar days before the anticipated date of arrival at the port of export, the exporter may proceed with the export as soon as the TIN has been issued for a completed report.

# EXPORT REPORT RETURN

Within 30 days of receipt after machine(s) released at the port of export, exporter must file Form 452 on date released at the port, quantity of machines released, description of each machine (make, model, serial number, if any) and indicate manual or electric machines.

# PROOF OF IDENTITY

Obtain documents to identify the other domestic party

Good faith inquiry to verify the existence and validity of the foreign entity

# MAINTENANCE OF RECORDS

Records retained for two years

Readily retrievable and available for  
inspection by DEA

# KEEP UP TO DATE

(Federal Register Notices)



Go to [www.diversion.usdoj.gov](http://www.diversion.usdoj.gov)

Select RESOURCES near the top of the page

Select Federal Register Notices

Select a year under Rules

Select a topic

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# MAIL ORDER REPORT CONTENTS - 1

## Supplier information:

Name/business name

Address/business address

Point of contact

Email address

Telephone number



# MAIL ORDER REPORT CONTENTS - 2

## Purchaser information:

Name/business name

Address/business address

Point of contact

Telephone number

Email

# MAIL ORDER REPORT CONTENTS - 3

Shipped to information (if different from purchaser):

Name/business name

Address/business address

# MAIL ORDER REPORT CONTENTS - 4

Chemical:

Chemical name

National Drug Code (NDC)

number, if applicable

Total amount shipped

# MAIL ORDER REPORT CONTENTS - 5

Date of shipment

Product name (if a drug product)

Dosage form (if a drug product)  
(e.g. , tablet, liquid)

# MAIL ORDER REPORT CONTENTS - 6

Dosage strength (if a drug product)  
(e.g., 30 mg, 60 mg, per dose etc.)

Number of dosage units (if a drug  
product) (e.g., 100 doses per  
package)

# MAIL ORDER REPORT CONTENTS - 7

Package type (if a drug product)  
(e.g., blister pack, etc.)

Number of packages (if a drug product)

Lot number (if a drug product)