



U.S. Customs and Border Protection

Our Mission

We are the guardians of our Nation's borders.

We are America's frontline.

We safeguard the American homeland at and beyond our borders.

We protect the American public against terrorists and the instruments of terror.

We steadfastly enforce the laws of the United States while fostering our nation's economic security through lawful international trade and travel.

We serve the American public with vigilance, integrity and professionalism.

U.S. Customs and Border Protection and the Food and Drug Administration

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U.S. Customs and
Border Protection

FDA Indicators in the HTS

INDICATORS

- FD0 – FDA Data Not Allowed
- FD1 – FDA Data **May Be** Required 801(a)
- FD2 – FDA Data **Required** 801(a)
- FD3 – Prior Notice Data **May Be** Required 801(m)
- FD4 – Prior Notice Data **Required** 801(m)
- None – But FD2 is Allowed Voluntarily

801 (a)

- Sec. 801.1 Medical devices; name and place of business of manufacturer, packer or distributor.
 - (a) The label of a device in package form shall specify conspicuously the name and place of business of the manufacturer, packer, or distributor.

801 (m)

The Public Health Security and Bioterrorism Preparedness and Response Act of 2002 (Bioterrorism Act), section 307, added section 801 (m) to the Federal Food, Drug, and Cosmetic Act (the Act) to require that FDA receive prior notice for food imported or offered for import into the United States. Section 801(m) also provides that if an article of food arrives at the port of arrival with inadequate prior notice (e.g., no prior notice, inaccurate prior notice, or untimely prior notice), the food is subject to refusal of admission under section 801(m)(l) of the Act and may not be delivered to the importer, owner, or consignee. If an article of food is refused under section 801 (m)(1) of the Act, unless CBP concurrence is obtained for export and the article is immediately exported from the port of arrival under CBP supervision, it must be held within the port of entry for the article unless directed by CBP or FDA.

FDO

- When FDA codes a tariff number FDO they are stating that they **do not** want FDA data on this tariff number
- ABI will not allow FDA data to be sent
- If the filer attempts to send data they will get an error message:
 - **VGU FDA 701:FDA NOTIFY NOT REQUIRED**

FD1

- Tariff number is general enough that a product may or may not be subject to FDA
- If it **does not** qualify
 - Filer sends a “Disclaim”
 - Code of “FD0” sent with the OA record
- If it **does** qualify
 - Filer sends a full “FDA Data Sheet”
 - includes an OA through FD05 record
- If the Filer **does not** send anything they will get a reject:
 - VNA FD 701: FORM MAY BE REQUIRED

FD2

- This indicator requires the filer to send a full FDA data set.
- If the filer does not they will receive a reject:
 - VNB FD 701: FORM REQUIRED
- If the filer tries to disclaim they will receive a reject:
 - VF3 OGA DISCLAIMER NOT ALLOWED

FD3

- The Product **May Be** subject to Prior Notice and regular FDA

Here is where it gets a little tricky

- It **May Be** subject to **Neither** regular FDA nor Prior Notice
 - The filer sends a FD0 “disclaim”
- It **May Be** subject to regular FDA **But** Not Prior Notice
 - The Filer sends and Affirmation of Compliance PND for “Prior Notice Disclaim”
 - Full FDA data for the regular FDA
- It **May Be** subject to Prior Notice
 - The filer sends regular and Prior Notice data
- If the filer sends nothing they will get a reject:
 - FDP REQ'D PRIOR NOTICE NOT SUBMITTED



FD4

- This indicator means that both Prior Notice and Regular FDA data is **Required**
- If the filer sends nothing or only regular FDA data is sent they will receive a reject:
 - FDP REQ'D PRIOR NOTICE NOT SUBMITTED

No Indicator (Voluntary)

- Filers can send FDA 801 (a) data voluntarily

FDA Indicators

- Once all information is entered correctly you should receive any one of the following:

May Proceed

Examine

Pending Review

FDA'S IMPORT REFUSAL

19 CFR 12.1

- Sec. 12.1 Cooperation with certain agencies; joint regulations.
(a) Federal Food, Drug, and Cosmetic Act. The importation into the United States of food, drugs, devices, and cosmetics as defined in section 201 (f), (g), (h), and (i) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 321 (f), (g), (h), (i)) is governed by section 801 of the Act, as amended (21 U.S.C. 381) and regulations issued under authority of section 701(b) of the Act (21 U.S.C. 371(b)) by the Secretary of Health and Human Services and the Secretary of the Treasury (21 CFR 1.83 through 1.99).

19 CFR

- 12.1 – 12.5 – Food import procedures
 - 12.1(a) Cooperation w/certain agencies; joint regulations; Federal Food, Drug and Cosmetic Act
 - 12.3 Release under bond; liquidated damages
- 141.113(c) – Recall of merchandise released from Customs and Border Protection custody
- 145.57 – Regulations of other agencies
- 159.55 – Possible prohibited food, drugs or other articles
 - (a) Suspension of liquidation
 - (b) Allowance of exportation or destruction

When CBP Receives a Refusal

- FDA faxes to CBP the “Notice of FDA Action” listing the refused line/merchandise
- Import specialist queries status of the entry
- If entry is set to liquidate, entry must be retrieved and unset
- Notice to Redeliver (CBP Form 4647) must be issued w/in 30 days of FDA refusal date
- Add/update NOTE screen in ACS
- If merchandise is not redelivered w/in 30 days, import specialist initiates liquidated damages against importer

Redelivery

- If the merchandise owner does not comply with the notice of refusal and does not export, destroy or bring the merchandise into compliance through relabelling or reconditioning w/in 90 days of the date of refusal, CBP requests redelivery.
- CBP enforces statutes and regulations for other agencies through the redelivery process. See 19 CFR 141.113
- Failure to redeliver results in the assessment of liquidated damages.

CBP Form 4647

1. FROM		DEPARTMENT OF HOMELAND SECURITY U.S. Customs and Border Protection	
2. NAME OF CONTACT PERSON		NOTICE TO MARK AND/OR NOTICE TO REDELIVER 19 CFR 134.51, 134.52, 141.113	
3. TELEPHONE NUMBER			
4. TO (Importer of Record Name and Address)			
		5. PORT OF ENTRY 6. ENTRY NO. 7. DATE OF ENTRY 8. BROKER OR IMPORTER FILE NO.	
SECTION I (To be completed by CBP) The merchandise described below is in violation of statute(s)/regulation(s) as indicated, and cannot be allowed into the commerce of the United States until brought into conformity as noted below in Section II. If it is not brought into conformity, collected, reported, or destroyed (prior U.S. Customs and Border Protection supervision within 30 days from the date of this notice or the time specified by another government agency having jurisdiction over the importation, liquidated damages and/or criminal/civil penalties shall apply).			
9. STATUTE(S)/REGULATION(S) VIOLATED: <input type="checkbox"/> 19 U.S.C. 1581 (Section 301, Tariff Act of 1930) (Country of Origin Marking Violation) <input type="checkbox"/> OTHER NAMELY:			
10	11	12	13
DESCRIPTION OF MERCHANDISE	QUANTITY	IDENTIFYING MARKS AND NUMBERS	SHIPPER/MANUFACTURER
14. <input type="checkbox"/> Merchandise must be brought into compliance as specified below or returned to CBP custody within 30 days of this Notice or other time specified. ACTION REQUIRED OF IMPORTER: <input type="checkbox"/> Marking or other corrective action must be done under CBP supervision. <input type="checkbox"/> CBP supervision of marking or other corrective action not required. After all merchandise has been brought into conformity with all applicable regulations, complete the certification below and return copy to CBP. <input type="checkbox"/> with <input type="checkbox"/> without a sample. WARNING: All merchandise must be retained until you are notified by CBP that corrective action is acceptable. <input type="checkbox"/> Merchandise must be redelivered to CBP within 30 days from the date of this Notice or other time specified.			
15. REMARKS/INSTRUCTIONS/OTHER ACTION REQUIRED OF IMPORTER			
16. SIGNATURE OF CBP OFFICER		17. DATE	
SECTION III - IMPORTER CERTIFICATION (To be completed by Importer/Authorized Agent) IMPORTER: Appropriate form must be completed, signed, and dated before acceptance by CBP.			
<input type="checkbox"/> MERCHANDISE TO BE <input type="checkbox"/> EXPORTED <input type="checkbox"/> DESTROYED UNDER CBP SUPERVISION <input type="checkbox"/> CERTIFY THAT ALL MERCHANDISE HAS BEEN MARKED TO PERMIT RE-ENTRY TO THE COUNTRY OF ORIGIN AS REQUIRED BY 19 U.S.C. 1304, OR OTHERWISE MARKED IN ACCORDANCE WITH OTHER STATUTES/REGULATIONS.			
PLACE	DATE	TIME	SAMPLE <input type="checkbox"/> IS <input type="checkbox"/> IS NOT SUBMITTED HEREIN. MERCHANDISE AND ORIGINAL CONTAINER(S) MUST BE IN CONTACT AND AVAILABLE FOR CBP INSPECTION AT INDICATED PLACE AND TIME NUMBER.
I (WE) GUARANTEE THE PAYMENT OF ALL EXPENSES INCIDENT TO THE ABOVE ACTION.			
SIGNATURE OF IMPORTER OR AUTHORIZED AGENT		TELEPHONE	DATE
SECTION IV (To be completed by CBP) <input type="checkbox"/> MERCHANDISE EXCEPTED FROM MARKING UNDER <input type="checkbox"/> MERCHANDISE HAS BEEN LEGALLY MARKED OR OTHERWISE BROUGHT INTO CONFORMITY WITH OTHER STATUTES/REGULATION(S) <input type="checkbox"/> UNDER CBP SUPERVISION <input type="checkbox"/> CERTIFICATION ACCEPTED. <input type="checkbox"/> MERCHANDISE WAS <input type="checkbox"/> EXPORTED <input type="checkbox"/> DESTROYED UNDER CBP SUPERVISION <input type="checkbox"/> OTHER, NAMELY:			
SIGNATURE OF CBP OFFICER		DATE	
X		X	

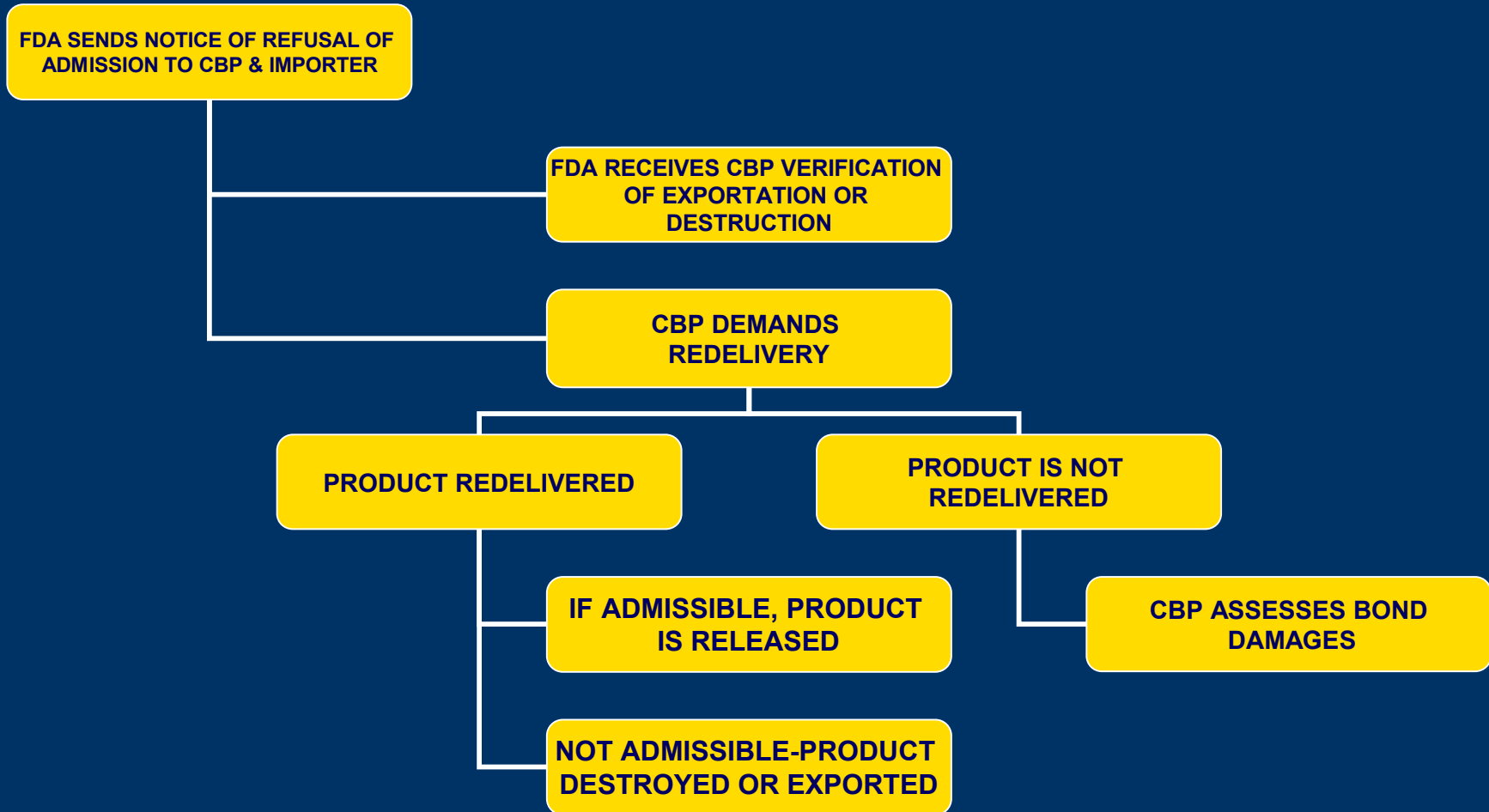
CBP Form 4647 (08/08)

CBP Form 4647

Section II, Block 15: REMARKS/INSTRUCTIONS/OTHER ACTION
REQUIRED OF IMPORTER

“Merchandise has been refused admission by the FDA on 6/15/2009 and must be either exported or destroyed under Customs supervision or redelivered to Customs custody for the purpose of exportation or destruction within 90 days of the noted date of issuance of the FDA Notice of Refusal of Admission. If merchandise has already been exported, destroyed or released by the FDA, please furnish proof to the office identified in Block 1.”

REFUSAL PROCESS



Liquidated Damages Penalty

Liquidated Damages Penalty

- If a liquidated damage penalty is assessed you have not redelivered the merchandise to CBP's custody.



Redelivery Violation

- 19 CFR 141.113
- Recall of merchandise released from customs and border protection custody
- (c) Food , drugs, devices, and cosmetics

Failure to comply with a demand for redelivery

- Will result in the assessment of liquidated damages equal to three times the value of the merchandise involved unless the port director has prescribed a bond equal to the domestic value of the merchandise pursuant to §12.3(b) of this Chapter.

**Notice or Penalty or Liquidated
Damages Incurred and Demand for
Payment**

(19USC1618, 19USC 1623)

CBP Form 5955A

DEPARTMENT OF HOMELAND SECURITY U.S. Customs and Border Protection		Case Number
NOTICE OF PENALTY OR LIQUIDATED DAMAGES INCURRED AND DEMAND FOR PAYMENT 19 USC 1618, 19 USC 1623		Port Name and Code
		Investigation File No.
TO: []		
DEMAND IS HEREBY MADE FOR PAYMENT OF \$ _____, representing <input type="checkbox"/> Penalties or <input type="checkbox"/> Liquidated Damages assessed against you for violation of law or regulation, or breach of bond, as set forth below:		
LAW OR REGULATION VIOLATED		BOND BREACHED
DESCRIPTION OF BOND (if any)	Case Number	Amount \$
Name and Address of Principal or Surety		Law
Name and Address of Party or State		Case File Number (if any)
If you wish there are extenuating circumstances, you have the right to object to the above action. Your petition should explain why you should not be penalized for the cited violation. Write this petition as a letter or in legal form; submit in _____ (duplicate) _____ (triplicate), addressed to the Commissioner of Customs and Border Protection, and forward to the PP&F Officer at:		
Unless the amount herein demanded is paid or a petition for relief is filed with the PP & F Office within the indicated time limit, further action will be taken in connection with your bond or the matter will be referred to the United States Attorney.		TIME LIMIT FOR PAYMENT OR FILING PETITION FOR RELIEF (Days from the date of this Notice)
Signature	Date	File
By _____		
CBP Form 5955A (08/07)		

What is on the form?

- Case Number
- Port Name and Code
- Investigation File No.
- To (the address if the violator)

Demand is hereby made for payment of \$_____,
representing () penalties or () liquidated damages assessed
against you for violation of law or regulation, or breach of
bond, as set forth below: (*narrative*)

What is on the form?

- Law or regulation violated
- Bond breached
- Description of bond (if any)
- Form number
- Amount
- Date
- Name and address of principal on bond
- Name and address of surety on bond

What is on the form?

- If you feel there are extenuating circumstances, you have the right to object to the above action. Your petition should explain why you should not be penalized for the cited violation. Write the petition as a letter or legal form; submit in (duplicate) (triplicate), addressed to the Commissioner of Customs and Border Protection, and forward to the PP&F Officer at:
 - *6747 Engle Road*
 - *Middleburg Heights, Ohio 44130*

What is on the form?

- Unless the amount herein demanded is paid or a petition for relief is filed with the FP&F Officer within the indicated time limit, further action will be taken in connection with your bond or the matter will be referred to the United States Attorney.
- TIME LIMIT FOR PAYMENT OR FILING PETITION FOR RELIEF (days from the date of this notice)
- Signature Title Date

Exception

- Merchandise entered under chapter 98 subchapter XIII
- The liquidated damages to be assessed on merchandise entered under chapter 98 is set forth in 10.39(d)(3) of this chapter

Chapter 98, Subchapter XIII,

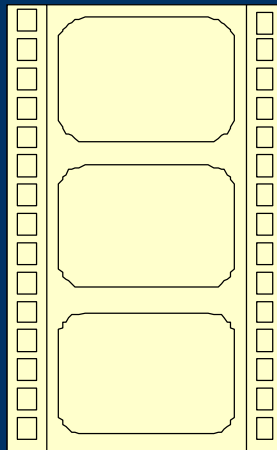
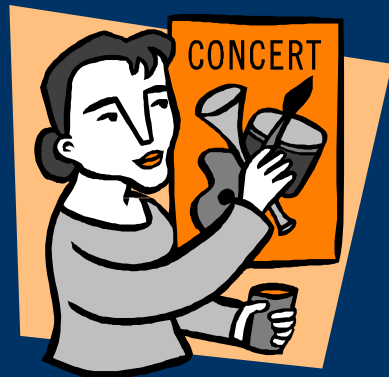
- **§ 10.104 Temporary importation entries for United States Government agencies.**
- The entry of articles brought into the United States temporarily by an agency or office of the United States Government and claimed to be exempt from duty under Chapter 98, Subchapter XIII, Heading 9813, Harmonized Tariff Schedule of the United States (HTSUS)

CFR 10.39(d)(3)

- Liquidated damages in an amount equal to double the estimated duties on the merchandise not returned shall be demanded.
- Except that in the case of samples solely for use in taking orders

Merchandise covered

- Motion picture advertising films



Merchandise covered

- Professional equipment



Merchandise covered

- Tools of trade and
- Repair components for professional equipment and tools of trade

Your Neighborhood FDA

- The network of field offices is generally the first point of contact for the public and regulated manufacturers. The employees in these offices focus on inspection and surveillance, laboratory work, and public and industry education.
- The FDA staff who work in the greater Washington, D.C. are focus on product review and regulatory policy.

FDA Contacts

- **Cincinnati District, (CIN-DO), 6751 Steger Dr., Cincinnati, OH 45237-3097** Main Number/Emergency (after hours)
Answering Service (513) 679-2700

- **Detroit District, (DET-DO), 300 River Place, Suite 5900, Detroit, MI 48207** Main Number: (313) 393-8100/Emergency (after hours)
Answering Service (313) 343-5120

CBP Contacts

Commodity Specialist Team 314 @ 440-891-3824

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Lisa Olsen, Import Specialist

Mark C. Marrano, Import Specialist

Edward P. Wachovec, Supervisory Import Specialist