

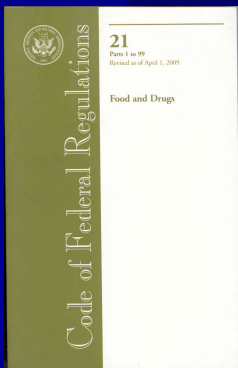
FDA District Actions

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Disclaimer

Code of Federal Regulations title 21 sec 10.85

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Entry Reviewer's Possible actions

- May Proceed
- Request docs
- Set up Field Exam
- Incomplete Entry return to Filer
- Send to Compliance Officer with a recommendation
 - Detention Without Physical Examination
 - Detention

Field Exam

- No Violations, no reason to sample
 - IB release
- No Violation, sample
 - Send sample to lab (case is referred to compliance when lab results are complete)
- Violation
 - Refer to Compliance
- Goods not available
 - Refer to Compliance

Field Exam:

Goods not available

- If the Compliance officer feels that the situation needs it, the Cincinnati district will request that Customs demand redelivery. See Federal Food, Drug, and Cosmetic Act SEC . 801(a) [21 USC §381(a)]

Compliance Officer Possible Actions with detention request

- Release
- Refer to other agency
- Release with Comment
 - **NOTE:** Sometimes the entry will be detained and released on the same notice
- Detain
 - Detain
 - Detain without Physical Examination

Detention

- FDA must provide the reason for the detention with a response date, ten days (excluding Saturdays, Sundays, and holidays)
- The Importer has until the response date to overcome the appearance of a violation

Ways to Respond to a Detention

- Phone
- Mail
- Email
- In person

Responses to a Detention

- Provide evidence that the product is not violative
- Request to Recondition: FDA 766
 - **APPLICATION FOR AUTHORIZATION TO RELABEL OR TO PERFORM OTHER ACTION OF THE FEDERAL FOOD, DRUG, AND COSMETIC ACT AND OTHER RELATED ACTS**
- Request an extension if more time is needed
- Request refusal to destroy or export

Extension

- The response period may be extended at the request of the respondent if it is made within the 10-day time-frame shown in the "Notice of Detention and Hearing," and the requestor provides a reasonable basis for extension.

Extension

- Not for indefinite or excessively long periods
- In order to obtain or prepare evidence pertaining to the specific charges of the detention.
- extensions should only be granted if some type of resolution is actively being pursued.

FDA 766

- If the goods are going to be Processed, please submit a FDA 766
- FDA must approve the 766
- There must be a good and sufficient bond ("CBP redeliver bond") by the owner or consignee (see 21 USC 381(b))

FDA 766: Outcomes

- Recondition successful
 - For parts reconditioned a notice "Originally Detained and Now Released."
 - Parts not reconditioned will be "Refused" and must be destroyed, or re-exported under FDA or CBP supervision
- Recondition Fails
 - Refusal

When will a Notice of Refusal of Admission be issued: (1 of 3)

- 1. A response to a Notice of Detention and Hearing is not received within the specified ten day time frame (excluding Saturdays, Sundays, and holidays) and an extension of time for responding has not been granted. (Additional time may be noted due to circumstances affecting district operations).
- 2. Efforts to relabel or recondition the detained shipment pursuant to an approved application (Form FD-766) have failed.

When will a Notice of Refusal of Admission be issued: (2 of 3)

- 3. When a detained shipment has been reconditioned pursuant to an approved application (Form FD-766), and we have agreed to the exportation of the reject material, a Notice of Refusal of Admission is issued covering the rejects.
- 4. After a hearing relative to the validity of the charges for detention, the hearing officer rules that the charges are valid and a Form FD-766 has not been submitted.

When will a Notice of Refusal of Admission be issued: (3 of 3)

- 5. If the importer requests permission to export or destroy, FDA will refuse prior to the response date

Rescind Refusal

- FDA will only rescind a refusal, if FDA made an error
 - Refused prior to Response date with no request
 - Notice of detention was never provided

Please Note

Failure of an importer or filer to respond to a detention notice or to not request an extension prior to the response date is not an FDA error. The refusal will stand see "Regulatory Procedures Manual" March 2009, Chapter 9 "Import Operations And Actions" sect. 9-9 "Notice of Refusal of Admission"

Refusal types

- Refuse Inform after export
 - FDA would like a copy of the 7512 or 3499 destruction notice from Customs
- Refuse Inform before export
 - FDA will witness destruction or export

Questions