

9307 .01 00117 1252

**Guidance for Industry**  
**And**  
**FDA Employees**  
**Regulatory Procedures Manual**  
**Chapter 9**

**Subchapter:**  
**SECURED STORAGE**

This guidance does not create or confer any rights, privileges, or benefits for, or on, any person and does not operate to bind FDA, U.S. Customs or the public. This guidance is being distributed in accordance with the FDA's policy for Level 2 guidance documents as set out in the agency's Good Guidance Practices, published in the Federal Register of February 27, 1997 (62 FR 8961).

Comments and suggestions regarding this document should be submitted by [date] to Dockets Management Branch (HFA-305), Food and Drug Administration, 12420 Parklawn Dr. rm. 1-23, Rockville, MD 20857. After [date] submit comments to Joseph L. McCallion, Division of Import Operations and Policy (HFC-170) 5600 Fishers Lane, Rockville, MD 20857. For questions regarding this document contact Joseph L. McCallion, (301) 443-6553.

**U.S. Department of Health and Human Services**  
**Food and Drug Administration**  
**Office of Regulatory Affairs**  
**January 2001**

DID\_0002

GDL 1

## REGULATORY PROCEDURES MANUAL - CHAPTER 9

### SUBCHAPTER: SECURED STORAGE

This guidance does not create or confer any rights, privileges, or benefits for, or on, any person and does not operate to bind FDA, U.S. Customs or the public. This guidance is being distributed in accordance with the FDA's policy for Level 2 guidance documents as set out in the agency's Good Guidance Practices, published in the Federal Register of February 27, 1997 (62 FR 8961).

**NOTE:** For the purpose of this subchapter, all references to foods include both human and animal foods.

**PURPOSE:** To prevent distribution of unsafe imported food by requiring unscrupulous importers who repeatedly violate FDA's import rules to store future food imports in secure facilities until FDA has reviewed and released the shipments.

**BACKGROUND:** Importers are normally allowed to post a bond and then take physical possession of imported food products until FDA has made the decision on admissibility. Importers have been advised, however, that they must hold the shipments intact until notified of FDA's decision. Unscrupulous firms often substitute, manipulate, or distribute imported foods prior to FDA's decision. As a result, unsafe foods may be distributed into U.S. commerce and pose a risk to public health and safety.

Customs port directors possess authority to require that products be stored in secure facilities rather than being held by the importer. Importers who have repeatedly distributed imported food prior to FDA release, or have provided the U.S. government with false or misleading information on imported foods, for example, may be required under Customs' authority to store imported product in secure facilities pending release. These facilities most likely will be bonded warehouses or General Order storage facilities.

**GUIDANCE:** Recommend that DIOP request that Customs require secured storage for food offered for entry by firms who have repeatedly distributed imported food prior to FDA release, or have provided the U.S. government with false or misleading information.

**Criteria:**

Districts should recommend that DIOP ask Customs to require secure storage for twelve (12) months when an importer meets any of the following conditions within the previous six (6) months:

- Has provided false or misleading information material to an FDA entry decision; or
- Has substituted food prior to FDA entry decision or after refusal; or,
- Has failed to hold imported foods pending FDA entry decision (twice); or
- Has failed to redeliver refused foods for export or destruction (twice).

**Direct Reference Warning Letters:**

When an importer meets the above criteria, the district should:

Issue a Warning Letter to importers whenever they meet the above criteria. In addition, issue a Warning Letter whenever an importer fails to hold imported food pending FDA entry decision for the first time or fails to redeliver refused goods for export or destruction for the first time.

See attached Model Warning Letters.

**Recommendation and Concurrence Procedures:**

Do not recommend secured storage procedures at the time of issuance of the Warning Letter when the importer has failed to hold or redeliver for the first time.

Do recommend secured storage procedures at the time of issuance of the Warning Letter when the importer has failed to hold or redeliver for the second time, has provided false or misleading information, or has substituted product.

- Submit the recommendation to Division of Import Operations and Policy (HFC-170) with documentation supporting secured storage attached to the recommendation. Documentation should include:
  1. Copy of the Warning Letter(s)
  2. Memorandum of Investigation
  3. Entry documentation, i.e. entry number, invoice, other entry documents
  4. Copy of importer's response to the current and any previous related Warning Letter(s), if available
  5. Verification of importer's name, address, FEI, IRS number or SSN, including all business names and addresses known

See attached Field Recommendation for Secured Storage.

- Upon receipt of a recommendation, DIOP should:
  - review the recommendation package to assure the documentation meets the applicable criteria;
  - request additional information or documentation if necessary;
  - if the recommendation is rejected, notify the district in writing of reason(s) for rejection;
  - upon concurrence, identify any additional firm names or addresses;
  - submit to Customs a recommendation for enforcement of secured storage. The submission should include:
    1. written recommendation, including appropriate time period, endorsed by DIOP, Director, and

2. supporting documentation (items listed above), and
3. a request for a response from Customs, confirming secured storage, time period, and additional identification of the firm, if necessary.

- Customs may respond to DIOP via email.

See attached Headquarters Request for Secured Storage.

- DIOP will maintain a hardcopy of Customs response in the official file
- DIOP will issue an untitled letter to the importer of Customs decision to invoke secured storage and will provide a copy to the recommending district and Customs.

See attached Model Notification letter.

- DIOP will post the identification of the importer and the time period covered by secure storage in Import Alert #99-25, Importers Subject to Secured Storage.

**Entry review and examination procedures for entries offered by importers subject to secured storage:**

- Each importer subject to secured storage will be identified in OASIS. Screening criteria will be entered into OASIS to ensure that subsequent entries will not be issued MAY PROCEED status by system screening. This will result in these entries being individually reviewed by FDA personnel.
- Districts should give high priority to the examination and analysis of products subject to secured storage.
- Notices of FDA detention action for products subject to secured storage should be modified as follows:

DELETE the statement "FDA will not request redelivery for examination or sampling, if the products not released

by FDA are moved, following USCS conditional release to a location within the local metropolitan area or to a location approved by the FDA office at the number below.” And,

REPLACE it with the statement “These products must remain in secured storage until either released by FDA or until removed for supervised exportation or destruction. Customs will not issue a conditional release for this shipment. Controlled removal for reconditioning, relabeling, or testing is allowed only under written approval from FDA.”

- Product may be removed from secured storage only
  - after FDA release, or
  - for controlled and supervised exportation or destruction (Customs should supervise the exportation or destruction unless specifically delegated to FDA), or
  - reconditioning, relabeling, or testing pursuant to written approval by FDA (FD-766 is appropriate authorization for reconditioning or relabeling.)
    - issue written approval to the importer with clear identification of the reason and conditions for removal;
    - written approval should include a time period covering the operation; and
    - provide DIOP and local Customs with a copy of the written approval.
  
- If the district uncovers evidence of additional instances of product substitution, misdeclaration, or submission of misleading information, the evidence should be forwarded to DIOP for consideration for extending the period of secured storage an additional 12 months and additional sanctions if appropriate. See attached Recommendation for Extension of Secured Storage and Headquarters Request for Extension of Secured Storage.

**Review/Revision of existing secured storage:**

- Districts will review activities of each firm subject to secured storage at six month intervals and report any changes in identifying data to DIOP.
- DIOP will review activities of each firm covered by secured storage 11 months after the most recent imposition.
- Based on the district and DIOP reviews, DIOP will contact Customs HQs and recommend necessary changes in the selectivity criteria or removal of the firm from secured storage. DIOP will retain a copy of the communication with Customs and will communicate the final decision to the district. The related Import Alert will be revised accordingly.
- Districts may recommend removal of firms prior to the end of the 12-month period if there is support documenting significant changes in the firm's operations and behavior, for example complete change of ownership and procedures, out-of-business, etc.

## MODEL WARNING LETTER - SECURED STORAGE

### **Failure to hold – first occurrence:**

On \_\_\_\_\_, we attempted to examine a shipment of \_\_\_\_\_ in accordance with our Notice of FDA Action dated \_\_\_\_\_. The shipment was offered for import (imported) into the United States by your firm on \_\_\_\_\_ under entry number \_\_\_\_\_. We found the shipment unavailable. This is a violation of 21 CFR Section 1.90 which requires the importer to hold an imported article and not distribute it pending receipt of the results of examination of the sample. Failure to promptly correct this situation and prevent future premature distribution of imported product may result in requiring that future shipments be held in secured storage. Secured storage will be under the supervision and direction of U.S. Customs, such as in a bonded warehouse. You will be responsible for all costs incurred in secured storage.

In addition, we are requesting U.S. Customs Service to order redelivery of the shipment.

Within 15 working days of receipt of this letter, notify this office in writing of the specific steps you have taken to correct this violative situation, including an explanation of each step being taken to prevent recurrence.

### **Failure to hold – second occurrence:**

On \_\_\_\_\_, we attempted to examine a shipment of \_\_\_\_\_ in accordance with our Notice of FDA Action dated \_\_\_\_\_. The shipment was offered for import (imported) into the United States by your firm on \_\_\_\_\_ under entry number \_\_\_\_\_. We found the shipment unavailable. This is a violation of 21 USC 381(a) and 21 CFR Section 1.90 that requires the importer to hold an imported article and not distribute it pending receipt of the results of examination of the sample. This is the second time you have failed to hold a shipment for FDA examination. The previous shipment was entered under entry number \_\_\_\_\_. As a result, we have recommended that the U.S. Customs Service require that future shipments of food by your firm be held in secured storage. If required secured storage will be under the supervision and direction of U.S. Customs, such as in a bonded warehouse. You will be responsible for all costs incurred at secured storage.

In addition, we are requesting U. S. Customs Service to order redelivery of the shipment.

Within 15 working days of receipt of this letter, notify this office in writing of the specific steps you have taken to correct this violative situation, including an explanation of each step being taken to prevent recurrence.

**Distribution prior to release:**

On \_\_\_\_\_, we sampled/detained/refused a shipment of \_\_\_\_\_ (see Notice of FDA Action dated \_\_\_\_\_ enclosed). The shipment was offered for import (imported) into the United States by your firm on \_\_\_\_\_ under entry number \_\_\_\_\_. We found the shipment has been distributed into U.S. commerce without a proper FDA release. This is a violation of 21 USC 381(a) and 21 CFR Section 1.90 that requires the importer to hold an imported article and not distribute it pending receipt of the results of examination of the sample.

Failure to promptly correct this situation and prevent future premature distribution of imported product may result in requiring that future shipments be held in secured storage. Secured storage will be under the supervision and direction of U.S. Customs, such as in a bonded warehouse. You will be responsible for all costs incurred at secured storage.

In addition, we are requesting U.S. Customs Service to order redelivery of the shipment.

Within 15 working days of receipt of this letter, notify this office in writing of the specific steps you have taken to correct this violative situation, including an explanation of each step being taken to prevent recurrence.

**Distribution prior to release – second occurrence:**

On \_\_\_\_\_, we sampled/detained/refused a shipment of \_\_\_\_\_ see Notice of FDA Action dated \_\_\_\_\_ enclosed). The shipment was offered for import (imported) into the United States by your firm on \_\_\_\_\_ under entry number \_\_\_\_\_. We found the shipment has been distributed into U.S. commerce without a proper FDA release. This is a violation of 21 USC 381(a) and 21 CFR Section 1.90 that requires the importer to hold an entry intact pending receipt of the results of examination of the sample. This is the second time you have distributed a shipment without a proper FDA release. The previous shipment was entered under entry number \_\_\_\_\_.

As a result, we have recommended that the U.S. Customs Service require that future shipments of food by your firm be held in secured storage. Secured storage will be under the supervision and direction of U.S. Customs, such as a bonded warehouse. You will be responsible for all costs incurred at secured storage.

In addition, we are requesting U. S. Customs Service to order redelivery of the shipment.

Within 15 working days of receipt of this letter, notify this office in writing of the specific steps you have taken to correct this violative situation, including an explanation of each step being taken to prevent recurrence.

**Substitution or misrepresentation of material fact:**

On \_\_\_\_\_, we attempted to examine a shipment of \_\_\_\_\_ in accordance with our Notice of FDA Action dated \_\_\_\_\_. The shipment was offered for import (imported) into the United States by your firm on \_\_\_\_\_ under entry number \_\_\_\_\_. Our examination of the shipment revealed the actual product to be \_\_\_\_\_.

As a result, we have recommended that the U.S. Customs Service require that future shipments of food by your firm be held in secured storage. Secured storage will be under the supervision and direction of U.S. Customs, such as in a bonded warehouse. You will be responsible for all costs incurred at secured storage.

In addition, we are requesting U.S. Customs Service to order redelivery of the shipment.

Within 15 working days of receipt of this letter, notify this office in writing of the specific steps you have taken to correct this violative situation, including an explanation of each step being taken to prevent recurrence.

FIELD RECOMMENDATION FOR SECURED STORAGE

DATE:

TO: Division of Import Operations and Policy (HFC-170)

FROM: \_\_\_\_\_ District (HFR- ) Name/Title:  
Contact: Phone/FAX:

Importer Identification:

Name:

Address:

MID:

Entry Number:

FEI:

Invoice Number:

IRS/SSN:

Other business names:

Other addresses:

Other IRS/SSN/FEI:

Warning Letter issued:

Date:

Response to Warning Letter: Y/N

Date:

Reason for Recommendation:

Failure to Hold:

Date of First Occurrence:

Failure to Redeliver:

Date of First Occurrence:

Substitution:

Prior to Entry Decision:

After Refusal:

Misleading Information Material to FDA entry decision:

Investigation conducted:

Results of investigation:

\*\*\*\*\*

Concur:

Additional Information Needed:

W/L:

IRS/SSN:

Entry #:

Other:

Do Not Concur:

Reason:

Name:

(HFC-170) Phone:

Date:

\*\*\*\*\*

CC: Warning Letter, Importer's response to W/L, Memorandum of Investigation, Entry, Invoice, Other

HEADQUARTERS RECOMMENDATION FOR SECURED STORAGE

TO: <<Director, Office of Trade Compliance>>  
U.S. Customs Service

FROM: Director, Division of Import Operations and Policy (HFC-170)  
U.S. Food and Drug Administration

Based on the attached documentation, we recommend that the following firm(s) be required to hold all future shipments of imported foods under secured storage conditions, under the control and/or supervision of U.S. Customs Service pending FDA action. We recommend that these procedures be required for a period of 12 months, effective upon your concurrence. Shipments held under secured storage should remain under secured storage until written release by FDA, supervised exportation or destruction, or upon written approval by FDA for testing, reconditioning or relabeling.

Importer name:  
Address:  
IRS/SSN:

FDA District Contact:

Name:  
Address:  
Phone: Fax: Email:

Name/Title: Date:  
Phone/FAX: Email:  
\*\*\*\*\*

TO: Director, Division of Import Operations and Policy (HFC-170), FDA  
FROM: Director, Office of Trade Compliance, Customs

Concur:  
Date Secured Storage Begins:  
Date Secured Storage Ends:

Do Not Concur:  
Reason:

U.S. Customs District Contact:

Name:  
Address:  
Phone: FAX: Email:

Name/Title: Date:  
Phone/FAX: Email:

FIELD RECOMMENDATION FOR EXTENSION OF SECURED STORAGE

DATE:

TO: Division of Import Operations and Policy (HFC-170)

FROM: \_\_\_\_\_ District (HFR- ) Name/Title:  
Contact: Phone/fax:

Importer Identification:

Name:

Address:

MID:

Entry Number:

FEI:

Invoice Number:

IRS/SSN:

Other business names:

Other addresses:

Other IRS/SSN/FEI:

Dates of Secured Storage:

Reason for Recommendation:

\*\*\*\*\*

TO: (HFR- )

DATE:

Concur:

Do Not Concur:

Reason:

Name/Title:

Phone/FAX

HEADQUARTERS REQUEST FOR EXTENSION OF SECURED STORAGE

TO: <<Director, Office of Trade Compliance>> Date:  
U.S. Customs Service

FROM: Director, Division of Import Operations and Policy (HFC-170)  
U.S. Food and Drug Administration

For the following reason, we recommend that the requirement that the following firm hold imported shipments of food under secured storage be extended for an additional 12 months, effective upon your concurrence. Future shipments should remain under secured storage until written release by FDA, supervised exportation or destruction, or upon written approval by FDA for testing, reconditioning or relabeling.

Importer Identification:

Name:

Address:

MID:

Entry Number:

FEI:

Invoice Number:

IRS/SSN:

Other business names:

Other addresses:

Other IRS/SSN/FEI:

Dates of Secured Storage:

Reason for Recommendation:

Name/Title:

Phone/FAX:

-----  
TO: FDA, Director  
Division of Import Operations and Policy

DATE:-----

U.S. Customs concurs with your recommendation and has instituted procedures to assure that the above firm(s) will be directed to deliver future entries of food to secured storage.

Effective Date:

Date of Removal:

U.S. Customs contact:

Phone/FAX:

## MODEL SECURED STORAGE NOTIFICATION LETTER

On \_\_\_\_\_ FDA's \_\_\_\_\_ District Office issued the attached letter to your firm. Based upon your (lack of/inadequate) response we have requested U.S. Customs to direct your future entries of food products to a secure storage facility. This requirement will commence on xx/xx/xxxx and continue through xx/xx/xxxx. (NOTE: this period may be extended if additional acts of substitution or misdeclaration occur.)

You may wish to have your customs broker or freight forwarder contact their local U.S. Customs office to identify adequate secure storage facilities prior to the arrival of future shipments. You may contact (US Customs name/#/fax) if you have further questions on secure storage procedures.

If you have further questions regarding the events leading up this requirement, you may contact (DIOP name/#/fax).