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Inspections, Compliance, Enforcement, and Criminal Investigations

SUBCHAPTER 2.7 - DETENTION ACTIVITIES

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2.7 - DETENTION ACTIVITIES

2.7.1 - OVERVIEW AND AUTHORITY

The objective of any detention is to protect the consumer by preventing movement in interstate commerce or by removing from interstate commerce a food or device that may be adulterated or misbranded. The specific statutory authorities, as well as specific set of guidelines that would apply to either foods or medica

devices are outlined in this section of the [IOM](#)¹. The detaining of foods or medical devices will depend on the product/s involved; the situation and evidence observed/collected; and which statutory authority is being invoked to accomplish the detention.

2.7.1.1 - Overview

Detention differs from controlling the distribution of violative products in interstate commerce by civil judicial actions such as seizures or injunctions accomplished under a court order (See [IOM 2.2.6](#)² and [2.2.8](#)³).

Foods or medical devices in "domestic import" as well as "import status" could be detained as described in this subchapter provided they meet the criteria listed below. Normally, however, detention of foods and medical devices in import status are covered separately in [IOM Chapter 6 - Imports](#)⁴.

2.7.1.1.1 - ACCOMPLISHING A DETENTION

Accomplishing a Detention can take one or more paths depending on the product/s involved and the actual statutes invoked, which are covered under the "Authorities" section of this subchapter. Some of the statute under which detentions can be accomplished are under [section 304](#)⁵ (Seizure) of the Federal Food Drug and Cosmetic Act (FD&C), including 304(g) and 304(h), which cover Medical Devices and Foods, both human and animal. Other statutes which cover detention are those involving products under dual jurisdiction of the US Food and Drug Administration (FDA) and the US Department of Agriculture (USDA), specifically meat, poultry, and egg products.

2.7.1.1.2 - DETENTION OF MEDICAL DEVICES

Detention of medical devices believed to be adulterated or misbranded can only be accomplished under one statutory path: [FD&C 304](#)⁶(g) - covered under the regulations set forth in [21 CFR 800.55](#)⁷.

2.7.1.1.3 - DETENTION OF FOODS

Detention of foods (human or animal) can be accomplished under one of two statutory paths:

1. [FD&C 304](#)⁸(h) - added to the FD&C Act as part of the Public Health Security and Bioterrorism Preparedness and Response Act of 2002 ("Bioterrorism Act") and covers any article of food that presents a threat of serious adverse health consequences or death to humans or animals. Although section 304(h) was added to the FD&C Act by the "Bioterrorism Act", an act or threat of terrorism is not required to use the authority. Credible evidence or information indicating that the article presents a threat of serious health consequences or death is the primary evidentiary requirement for this authority. In addition, although the section 304(h) authority applies to food in import status, FDA does not expect to use this authority to control such food. Generally, FDA will use the authority of [section 801](#)⁹(a) to detain articles of food in import status. See [21 CFR Part 1, subpart K](#)¹⁰ and FD&C Act section 304(h).
2. Detention of dual jurisdiction meat, poultry, or egg products: Such products that meet the jurisdictional requirements of section 304 of the FD&C may be adulterated or misbranded, and are covered under either sections 402 and 409(b) of the [Federal Meat Inspection Act](#)¹¹ (FMIA, 21 U.S.C. 601 et seq.), sections 19 and 24(b) of the [Poultry Products Inspection Act](#)¹² (PPIA, 21 U.S.C. 451 et seq.), or sections 19 and 23(d) of the [Egg Products Inspection Act](#)¹³ (EPIA, 21 U.S.C. 1031 et seq).

Detention authority under the FMIA, PPIA, and EPIA does NOT extend to meat, poultry, and egg products when those products are inside a USDA-inspected facility.

2.7.1.1.4 - DETENTION PROCEDURAL STEPS

The procedural steps to be followed in both executing and terminating a detention differ slightly depending on which statutory path is deemed most appropriate and chosen, and agency clearances that are required may differ depending on the type of detention. You should consult your supervisor before detaining dual jurisdiction FDA/USDA products under [FD&C section 304](#)¹⁴ and associated FDA/USDA statutes. You must have the approval of your District Director before detaining any devices under section 304(g). You must have the approval of your District Director or an official senior to such director prior to detaining foods under the authority of FD&C section 304(h).

2.7.1.2 - Authorities

The various Acts described in this subsection provide certain detention powers for FDA. Pertinent sections o

the FMIA, PPIA, EPIA, and FD&C Act, and its Regulations pertaining to detention of devices and food, are printed on the reverse of page 1 of the FDA 2289, Detention Notice ([IOM Exhibit 2-2](#)¹⁵).

2.7.1.2.1 - FOOD DRUG AND COSMETIC ACT

[Section 304\(g\) of the FD&C Act](#)¹⁶ provides FDA with authority to detain a device believed to be adulterated or misbranded. You should become familiar with this section and the regulations implementing it. See [21 CFR 800.55](#)¹⁷. At the present time, these regulations apply only to devices intended for human use. See FD&C Act section 304(g) [21 U.S.C. 334 (g)].

Section 304(h) of the FD&C Act provides FDA with the authority to order the detention of any article of food that is found during an inspection, examination, or investigation under the Act, if the officer or qualified employee has credible evidence or information indicating that the article of food presents a threat of serious adverse health consequences or death to humans or animals. See [21 CFR Part 1, subpart K](#)¹⁸.

2.7.1.2.2 - FEDERAL MEAT INSPECTION ACT

[Federal Meat Inspection Act](#)¹⁹ (FMIA) - Sections 402 and 409(b) provide the FDA with the authority to detain meat products subject to the FMIA, found outside an USDA inspected plant, if the FDA has reason to believe the products are adulterated or misbranded under the FD&C Act. The detention may not exceed twenty (20) days and the items detained shall not be moved by any person from the place of detention until released by the FDA representative.

2.7.1.2.3 - POULTRY PRODUCTS INSPECTION ACT

[Poultry Products Inspection Act](#)²⁰ (PPIA) - Sections 19 and 24(b) provide the FDA with the authority to detain poultry products subject to the PPIA found outside an USDA inspected plant, if the FDA has reason to believe the products are adulterated or misbranded under the FD&C Act. Detention may not exceed twenty (20) days and the items detained shall not be moved from the place of detention until released by the FDA representative.

2.7.1.2.4 - EGG PRODUCTS INSPECTION ACT

[Egg Products Inspection Act](#)²¹ (EPIA) - Sections 19 and 23(d) provide the FDA with the authority to detain egg products subject to the EPIA, found outside an USDA inspected plant, if the FDA has reason to believe the products are in violation of the EPIA Act. Detention may not exceed twenty (20) days and the items detained shall not be moved from the place of detention until released by the FDA representative.

2.7.1.3 - Definitions

2.7.1.3.1 - DEVICE

[Section 201\(h\) of the FD&C Act](#)²² [21 U.S.C. 321 (h)] defines a device as follows: "The term "device" *** means an instrument, apparatus, implement, machine, contrivance, implant, in-vitro reagent, or other similar or related article, including any component, part, or accessory, which is:

- 1. Recognized in the official National Formulary, or the United States Pharmacopoeia, or any supplement to them,
- 2. Intended for use in the diagnosis of disease or other conditions, or in the cure, mitigation, treatment, or prevention of disease, in man or other animals, or
- 3. Intended to affect the structure or any function of the body of man or other animals, and which does not achieve its primary intended purposes through chemical action within or on the body of man or other animals and which is not dependent upon being metabolized for the achievement of any primary intended purposes."

2.7.1.3.2 - FOOD

For the purpose of detention of food under section 304(h) of the FD&C Act, see section [201\(f\) of the FD&C Act](#)²³, which defines food as follows: "(1) articles used for food or drink for man or other animals, (2) chewing gum, and (3) articles used for components of any such article."

Examples of food include, but are not limited to, fruits, vegetables, fish, dairy products, eggs, raw agricultural commodities for use as food or components of food, animal feed, including pet food, food and feed ingredients and additives, including substances that migrate into food from food packaging and other articles that contact food, dietary supplements and dietary ingredients, infant formula, beverages, including

alcoholic beverages and bottled water, live food animals, bakery goods, snack foods, candy, and canned foods.

2.7.1.3.3 - PERISHABLE FOOD

For the purpose of detention of food under [section 304\(h\) of the FD&C Act](#)²⁴, the term "perishable food" means food that is not heat-treated; not frozen; and not otherwise preserved in a manner so as to prevent the quality of the food from being adversely affected if held longer than 7 calendar days under normal shipping and storage conditions. See [21 CFR 1.377](#)²⁵.

2.7.1.3.4 - MEAT PRODUCTS AND POULTRY PRODUCTS (DUAL JURISDICTION)

For FDA purposes, meat products and poultry products are defined as the carcasses of cattle, sheep, swine, goats, horses, mules, other equines, or domesticated birds, parts of such carcasses, and products made wholly or in part from such carcasses, except products exempted by U.S.D.A. because they contain a relatively small amount of meat or poultry products (e.g.; meat flavored sauces, pork and beans, etc.). Examine labels for USDA Shield or coding information to help determine if it is a USDA product.

2.7.1.3.5 - EGG AND EGG PRODUCTS (DUAL JURISDICTION)

The term "egg" means the shell egg of the domesticated chicken, turkey, duck, goose, or guinea.

The term "egg product" means any dried, frozen, or liquid eggs, with or without added ingredients, excepting products which contain eggs only in relatively small proportion or historically have not been, in the judgment of the Secretary, considered by consumers as products of the egg food industry, and which may be exempted by the Secretary under such conditions as he may prescribe to assure the egg ingredient are not adulterated and such products are not represented as egg products. This would be done on a case by case basis by USDA.

2.7.2 - INSPECTIONAL PROCEDURE

Direct attention to meat, poultry, or egg products only when found during your regular operations; when so instructed in a Compliance Program Guidance Manual; following up on complaints; or, on other assignment: as directed by your supervisor.

Detention of food under [section 304\(h\) of the FD&C Act](#) should be considered only when there is credible evidence or information indicating that the article of food presents a threat of serious adverse health consequences or death to humans or animals, and only when approved by the District Director or an FDA official senior to such Director.

In evaluating whether credible evidence or information exists for purposes of detention of food, consider a number of factors, including, but not limited to, the reliability and reasonableness of the evidence or information and the totality of the facts and circumstances.

2.7.2.1 - Criteria for Detention

[The criteria listed are for your guidance in judging whether or not the product or products should be detained. Detention may be made when all of the requirements listed for the particular detention authority are met.](#)

2.7.2.1.1 - DEVICES

For detention of devices under [section 304\(g\) of the FD&C Act](#), the requirements are:

1. You have reason to believe the device is adulterated or misbranded.
2. There is no reasonable assurance the device will not be used, moved, altered, or tampered with in any manner before the FDA can take appropriate legal action.
3. The device is intended for human use.

2.7.2.1.2 - FOOD

For detention of food under [section 304\(h\) of the FD&C Act](#)²⁶, the requirements are:

1. The article meets the definition of food in [section 201\(f\) of the FD&C Act](#)²⁷.
2. You have credible evidence or information that the article of food presents a threat of serious adverse health consequences or death to humans or animals.
3. A "serious adverse health consequences" determination should be made by CFSAN or CVM, as

appropriate.

4. The article of food is not a meat, poultry, or egg product inside a USDA-inspected facility. If the article of food is a meat, poultry, or egg product outside a USDA-inspected facility, consult with your supervisor.

2.7.2.1.3 - MEAT AND POULTRY PRODUCTS

For detention of products subject to the [Federal Meat Inspection Act](#)²⁸ or the [Poultry Products Inspection Act](#)²⁹ the requirements are:

1. The article meets the jurisdictional requirements of [section 304 of the FD&C Act](#)³⁰ and is in commercial channels.
2. The article is located in an establishment which does not have USDA meat or poultry inspection service.
3. The article is intended for human food channels or could be readily diverted into such channels.
4. The article appears to be adulterated or misbranded under the FD&C Act.

NOTE: For any contemplated detentions based on adulteration under [section 402\(b\) of the FD&C Act](#)³¹ [21 U.S.C. 342 (b)], check with your supervisor. These detentions should be cleared with the Center for Food Safety and Applied Nutrition.

2.7.2.1.4 - EGG AND EGG PRODUCTS

For detention of products subject to the [Egg Products Inspection Act](#)³² the requirements are:

1. The article, whether or not in interstate commerce, is located in an establishment which does not have USDA Egg Products Inspection Service.
2. The article is intended for human food channels or could be readily diverted into such channels.
3. There is reason to believe the article is in violation of the Egg Products Inspection Act.

2.7.2.2 - Detention Procedure

After assuring yourself the criteria for detention are met, immediately advise your supervisor of the situation. The information you furnish should consist of that requested in blocks numbered 2, 4, 5, 7, 8, 10, 11, 13, 15, 19, 20, 21, 22, 24 and 26 on the Detention Notice, FDA 2289. See [IOM 2.7.2.3](#)³³.

For detention of medical devices under section 304(g) and articles of food under section 304(h) of the FD&C Act, the District Director in whose District the device or article of food involved is located, or for foods, an FDA official senior to such director, must approve the detention order in writing. If prior written approval is not feasible, prior oral approval must be obtained and confirmed in writing as soon as possible.

2.7.2.2.1 - CONSIDERATIONS

If the article of food to be detained is in-transit aboard a conveyance, e.g., railcar, truck, or ship, be aware that that detention of food aboard a conveyance may impact other activities of commerce that are dependent upon the ongoing operation of the conveyance.

It is possible that we will allow the detained food to be removed from the conveyance to a storage facility. However, consult with your supervisor on this matter because the determination of whether the food can be moved from the conveyance to another location should be made based on considerations about the nature of the contaminant, security, preservation of the food, and accessibility to the food during the period of detention.

For all detentions, follow the guidance in IOM section 4.3.4 to determine when FDA may examine a package that is in the possession, control or custody of a common carrier. Guidance on resealing a conveyance is also found in [IOM section 4.3.4.3](#)³⁴.

If your supervisor instructs you to detain the article, proceed as in [IOM 2.7.2.3](#)³⁵, and [2.7.2.4](#)³⁶.

2.7.2.2.2 - EXECUTING THE DETENTION

When you have been authorized to place a detention proceed as follows:

1. Indicate conditions that are to be maintained while the article of food is detained in the "Remarks" section of the detention notice (block #26). If applicable, also indicate that the movement of the food to another facility during detention has been authorized in writing by an authorized FDA

representative, pursuant to [21 CFR 1.380](#)³⁷ and [1.381](#)³⁸.

- a. For detention of food under section 304(h), determine the storage conditions required, e.g., refrigeration, and whether movement to another facility is necessary to either provide the storage conditions required or for security purposes. Consult your supervisor for guidance. Indicate conditions that are to be maintained while the article of food is detained in the "Remarks" section of the detention notice (block #26). If applicable, also indicate that the movement of the food to another facility during detention has been authorized in writing by an authorized FDA representative, pursuant to [21 CFR 1.380](#)³⁹ and [1.381](#)⁴⁰.
 - b. Maintain surveillance on the detained in-transit products and after products are placed in storage if possible.
 - c. Arrange for the custodian to place the product in proper storage if the custodian will agree.
 - d. If neither (b) nor (c) is possible, place product under detention and remove it to a proper storage facility. Notify the custodian of the place of storage (use block 16 on the FDA-2289) and advise your supervisor of the necessity for including this information in the letter to the owner.
 - e. After a device is detained, it may not be moved unless specific procedures are followed. Consult your supervisor for guidance.
2. Personally inform the immediate custodian, at the highest management level, that the article is under FDA detention, and if a device, that the record keeping requirements of [21 CFR 800.55\(k\)](#)⁴¹ are in force. If an article of food is under detention, inform the custodian that the detained article of food may not be transferred within or from the place where it has been ordered detained, or from the place to which it was removed unless a request to modify the detention order has been authorized in writing by FDA.
 3. Prepare the "Notice of Detention, FDA-2289", as instructed in [IOM 2.7.2.3.1](#)⁴², and issue page 1, the original, to the custodian named. If the product is a device, or an article of food detained under section 304(h) of the FD&C Act, point out the appeal rights of the owner, which are listed on the back of Page 1 of the FDA-2289.
 4. Affix a sufficient number of "Detention Tag, FDA-2290" to the article in a manner to assure visibility. If necessary, a label other than the Detention Tag may be used to identify an article of food that has been detained, provided the label includes all the information listed on the current FDA-2290.

2.7.2.3 - Detention Notice FDA 2289

The Detention Notice, FDA 2289, is a pre-numbered five-part snap-out form, constructed and arranged to serve as a Notice of Detention and as a report of the action.

2.7.2.3.1 - PREPARATION OF DETENTION NOTICE

Print or type the information in the appropriate blocks. The first page blocks which must be filled in per statute [21 CFR 1.382](#)⁴³ are those numbered 1, 3, 6, 9, 10, 11, 12, 15, 16, 17, and 18. Indicate the name and title of the person who approved the detention order and the manner in which the approval was obtained in blocks #17 and 18. For devices mark #24 and #26 N/A. For meat, poultry or egg products not being detained under the authority of [section 304\(h\) of the FD&C Act](#)⁴⁴, mark #17 and 18 N/A. Block 2 should also be completed. Once page 1 is completed, signed, and issued to the custodian, it becomes an official document and the detention period begins.

You should immediately complete the additional pages of the Notice of Detention (2 through 5) and submit them to your supervisor, for processing the action. Blocks to be filled in on these pages are items 13, 14 and 19 through 28. These blocks should be completed as appropriate (e.g. if samples were collected) or according to the product being detained (e.g. device or food) if the pertinent information can be readily determined. See [IOM Exhibit 2-2](#)⁴⁵.

2.7.2.3.2 - PREPARATION OF PAGE 1 (FDA 2289)

Preparation of Page 1:

1. For detention of articles of food, the District Director's email address and fax number must also be included in this block. For detentions under the FMIA, PPIA, and EPIA, this information should also be included.
2. NAME OF CUSTODIAN - Obtain the name of the highest-ranking official of the firm at the place of detention. Page 1 of the FDA 2289 is to be issued to the person named in this block.

3. DETENTION NOTICE NUMBER - This is normally pre-stamped on each form. In the event that an electronic version of the form is utilized in the field, the detention number from a pre-printed detention form must be entered and the original pre-printed form bearing that number destroyed. Any correspondence or subsequent actions should reference this number.
4. TITLE OF CUSTODIAN - Insert proper official title such as president, warehouse manager, etc. Do not use courtesy titles.
5. TELEPHONE NO. - Insert the office telephone number, including area cod.
6. DATE AND HOUR DETAINED - Insert actual date and time you hand the original to the custodian. The period of detention begins when you issue the original to that person.
7. FIRM NAME - Enter the legal name of the custodial firm.
8. ADDRESS - Use complete street name, city, state and Zip Code of custodial firm.
9. MAXIMUM DETENTION _____ DAYS - Enter "20" for detention of meat, poultry or egg products. Enter either "20" or "30", as instructed by your supervisor, for detention of devices, or detention of articles of food under [section 304\(h\) of the FD&C Act](#)⁴⁶.
10. NAME OF DETAINED ARTICLE - Use the actual name of the actual product e.g., "Beef Pot Pies with mushrooms", not just "Pies"; "Dr. Z's Tongue Depressors", not just "device".
11. SIZE OF DETAINED LOT - Indicate number of cases or other type container or article and subordinate containers, e.g., 2000 cases/24/#2 cans, 250 half sides pork carcasses, 500/fore quarters veal, 95 crates/50 lbs. whole fryers, 25/30 lb. cans frozen eggs, etc.
12. DETAINED ARTICLE LABELED - Quote enough labeling so the article can be positively identified. Include product numbers, lot numbers, serial numbers, control codes, grade marks, etc.
13. APPROXIMATE VALUE OF LOT - This is the wholesale or invoice value of the merchandise. Estimate if there is no documentary reference you can quote.
14. SAMPLE NUMBER(S) - List numbers of any samples taken in connection with the detention.
15. REASON FOR DETENTION - Give a brief, general statement of the reasons for detention, i.e., describe the apparent violation and briefly list evidence available to substantiate it. In the case of detention of food under [section 304\(h\) of the FD&C Act](#)⁴⁷, include information about the "serious adverse health consequence" determination. Keep in mind that any classified information supporting the detention of food must be protected from unauthorized disclosure in the interest of national security. Consult with your supervisor for the requirement to protect classified information according to Executive Order 12866. If the product is a device, always state not only the section of the FD&C Act the device is believed to violate, but the particulars of the violation as well. Discuss the reasons for detention with your supervisor when you obtain the permission to detain a device. See page 3 of [IOM Exhibit 2-2](#)⁴⁸.
16. DETAINED ARTICLE STORED AT - In most instances this will be the same as the custodial firm indicated in blocks 7 and 8. However, if the product has been moved to another location, enter the name and address of the firm and location where it finally comes to rest and will stay until the detention is terminated. Once the product is detained, it is unlawful to move it without direct authority from FDA, except that devices may be moved and processed under [21 CFR 800.55](#)⁴⁹(h)(2) pursuant to [section 304\(g\)\(2\)\(B\) of the FD&C Act](#)⁵⁰ [21 U.S.C. 334 (g)(2)(B)]. Articles of food detained under section 304(h) of the FD&C Act may only be moved if FDA approves a request to modify a detention order under [21 CFR 1.381](#)⁵¹(c).
17. Name and title of person who approved the detention order. For detentions other than detention of food under section 304(h) of the FD&C Act, enter "N/A."
18. Indicate whether approval of the detention order was written or oral. If oral, you must obtain written confirmation of the approval as soon as possible. For detentions other than detention of food under [section 304\(h\) of the FD&C Act](#)⁵², enter "N/A."

NAME OF FDA EMPLOYEE - Print or type.

SIGNATURE - Sign the form.

TITLE - Enter your title.

2.7.2.3.3 - PREPARATION OF PAGE 2 THROUGH 5 (FDA-2289)

The blocks on pages 2 through 5 are identical and completion of these constitutes your report on the detention, unless directed otherwise by your supervisor.

19. In the case of detention of food under [section 304\(h\) of the FD&C Act](#)⁵³, if the owner of the article can be readily determined, you must issue a copy of the detention notice to the owner as well as the custodian listed in block #2.
20. NAME AND ADDRESS OF INITIAL SHIPPER OR SELLER - - Enter name and address of person or firm who first shipped or sold the product.
21. NAME AND ADDRESS OF SUBSEQUENT SHIPPERS OR SELLERS - If products have passed through more than one firm prior to coming to your attention, list these firms.
22. NAME OF CARRIERS - List carrier or carriers involved, starting with the one who first picked up the article.
23. DATE LOT SHIPPED - Use date on a shipping document, not the invoice date.
24. NAME AND ADDRESS OF PACKING PLANT - Enter firm name and address of the plant where products were actually packed, processed, manufactured or assembled. For devices or articles of food other than meat, poultry, and egg products, enter "N/A".
25. DATE LOT RECEIVED - Self-explanatory.
26. PACKING PLANT USDA NO. - All plants under U.S. Department of Agriculture inspections are numbered. This number is placed on products packed or processed in that particular plant. Enter the complete number. For devices and articles of food other than meat, poultry, and egg products, enter "N/A".
27. DESCRIPTION OF SAMPLE - Describe sample collected in connection with the detention operations. This will be the same as on the C/R.
28. REMARKS - Elaborate on items wherever necessary. List any recommendations you made to the custodian for special storage such as refrigerated, frozen, etc.

2.7.2.3.4 - DISTRIBUTION OF FDA-2289

Distribution of FDA-2289 - The five-part snap-out is distributed as follows:

1. Page 1, original - Give to custodian and, if applicable, give a copy of page 1 to the owner of the article
2. Page 2, 3, 4 - Turn in to your district immediately using the fastest means possible.
3. Page 5 - Retain in your possession.

2.7.2.4 - Detention Tag FDA 2290

This tag is a warning and identification device intended to be affixed to the detained products.

2.7.2.4.1 - PREPARATION

As soon as you have issued the Detention Notice, fill out Detention Tags, FDA 2290, following the instructions below. See [IOM Exhibit 2-3](#)⁵⁴.

2.7.2.4.2 - FRONT OF TAG

Front of Tag.

"DETENTION DATE AND HOUR" - Copy the date and hour of detention from block #6 of the Detention Notice.

"DETENTION NOTICE NO. DN" - Copy the exact number from block #3 of the Detention Notice.

"MAXIMUM DETENTION _____ DAYS" - Copy the number of days from block #9 of the Detention Notice.

"NAME FDA EMPLOYEE WHO ISSUED DETENTION NOTICE" - Print or type.

"SIGNATURE" - Sign.

"TITLE" - Enter your title.

"NAME OF THE EMPLOYEE AFIXING TAG (if different from issuing employee)"

"SIGNATURE OF EMPLOYEE AFIXING TAG (if different from issuing employee)"

"TITLE OF EMPLOYEE AFIXING TAG (if different from issuing employee)"

2.7.2.4.3 - REVERSE OF TAG

Reverse of Tag.

"NAME OF DETAINED ARTICLE" - Enter the name exactly as in Block #10 of Detention Notice.

"DETAINED ARTICLE LABELED" - Copy enough from Block #12 of Detention Notice to identify the product.

"SIZE OF DETAINED LOT" - Copy from Block #11 of Detention Notice.

2.7.2.4.4 - USE OF TAG

Complete and affix tags so they are visible on several sides of the lot detained. Use sufficient tags to give adequate warning the lot is under U.S FDA Detention and must not be used, moved, or tampered with, in any manner.

Each tag has a self-locking pin, the point of which should be firmly inserted in an appropriate seam, border, flap, or other area of the container or product, and pulled sharply downward to engage the top curve of the pin. Do not just lay tags on the articles. Secure them to the containers or products. If locking pin cannot be used, tape or tie the tag firmly onto the container or item.

Advise the custodian that Detention Tags have been affixed, and of the reason for the detention. Also advise the custodian that the merchandise may not be moved without written permission of the Agency. In-process devices may be completed without permission. For devices, see [21 CFR 800.55](#)⁵⁵(h)(2) for instructions. For detention of foods, see [21 CFR 1.381](#)⁵⁶(c).

2.7.2.5 - Termination of Detention

When final action has been taken on the detention, you will be authorized to terminate the detention. This will occur when one of the following conditions has been met.

1. For articles of food under detention, the article of food has been destroyed under appropriate supervision.
2. For devices, or for meat, poultry, or egg products detained under authority of the [FMIA](#)⁵⁷, [PPIA](#)⁵⁸, or [EPIA](#)⁵⁹, the product has been brought into compliance, denatured or destroyed under appropriate supervision.
3. For meat, poultry, and egg products detained under authority of the FMIA, PPIA, or EPIA, the USDA, state, county, or local authorities have accepted jurisdiction and control of the article.
4. For meat, poultry, and egg products detained under authority of the FMIA, PPIA, or EPIA, it has been determined there is no significant violation of the FD&C Act, or of the EPIA, whichever is applicable, and the USDA has been notified that FDA intends to terminate the detention.
5. Twenty consecutive days have expired (or 20 or 30 days, for detention of foods and devices), counting from the day and hour of detention of the product.
6. Seizure or other legal action has been accomplished.
7. The district director or the Regional Food and Drug Director order the termination.

2.7.2.5.1 - REMOVAL OF DETENTION TAGS

As soon as you are authorized to terminate the detention, proceed to where the detained material is stored personally remove and completely destroy all detention tags. Do not merely throw them in the trash.

2.7.2.5.2 - ISSUANCE OF DETENTION TERMINATION NOTICE FDA 2291

Issuance of Detention Termination Notice FDA 2291 - As soon as you have removed all detention tags, tell the custodian the article is no longer under detention. Immediately prepare a Detention Termination Notice by filling out blocks 1 through 12, and the bottom of the form to include name, title, and signature. Give the original (page 1) to the custodian. This terminates the detention.

Complete the "Remarks" section to elaborate on pertinent information such as supervision, reconditioning, destruction accomplished, etc. The Detention Termination Notice, FDA 2291, together with Detention Notice, FDA 2289, will, unless instructed otherwise, constitute the complete report on the detention. See [IOM Exhibit 2-4](#)⁶⁰.

2.7.3 - SAMPLING

Official samples of articles involved in this type of operation are collected, prepared, and submitted in the same manner as any other regulatory samples. In the case of food detained under [Section 304\(h\) of the FD&C Act](#)⁶¹, consult with your supervisor to determine whether the suspected contaminant in articles of food that have been detained makes it necessary to follow sampling procedures that may be different from

those followed for routine regulatory samples.

2.7.4 - SUPERVISION OF RECONDITIONING, DENATURING, OR DESTRUCTION

Methods and procedures for reconditioning, denaturing, or destruction, will be proposed to the district by the owner of the devices or meat, poultry, or egg products. For food detained under [Section 304\(h\) of the FD&C Act](#)⁶², destruction will likely be the only option, and it can only be done after FDA approves in writing a request to modify the detention order. For all detentions, do not take any action on reconditioning, denaturing, or destruction unless you are authorized by your supervisor. The district officials will determine the adequacy of the proposed method. If satisfactory, you will be advised of the procedure and authorized to monitor the action.

When the operation is satisfactorily completed, and when authorized, terminate the detention as indicated in [IOM 2.7.2.5.2](#)⁶³.

The results of the reconditioning, denaturing, or destruction may be described in the "Remarks" section on the Detention Termination Notice, FDA 2291, if desired. See [IOM Exhibit 2-4](#)⁶⁴.

2.7.5 - REPORTING

Except in unusual situations, or unless instructed otherwise by your supervisor, the Detention Notice, FDA 2289, the Detention Notice Termination, FDA 2291, and the FACTS Collection Record are designed to provide all information required to report the action from detention to termination.

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