

DEPARTMENT OF HEALTH AND HUMAN SERVICES FOOD AND DRUG ADMINISTRATION DETENTION ORDER		1a. DISTRICT ADDRESS		1c. NAME OF DISTRICT DIRECTOR	
				1d. EMAIL ADDRESS	
		1b. PHONE NUMBER		1e. FAX NUMBER	
2. NAME OF CUSTODIAN TO:			3. DETENTION ORDER NUMBER DO		
4. TITLE OF CUSTODIAN		5. TELEPHONE NUMBER		6. DATE AND HOUR DETAINED a.m. p.m.	
7. FIRM NAME					
8. ADDRESS (Street, City, State, ZIP Code)			9. MAXIMUM DETENTION _____ DAYS		
Pursuant to (Check applicable Section(s)) <input type="checkbox"/> Section 304(h) of the Federal Food, Drug and Cosmetic Act (FD&C Act), <input type="checkbox"/> Section 304(g) of the FD&C Act, <input type="checkbox"/> Sections 402 and 409b of the Federal Meat Inspection Act, <input type="checkbox"/> Sections 19 and 24(b) of the Federal Poultry Inspection Act, and/or <input type="checkbox"/> Sections 19 and 23(d) of the Federal Egg Products Inspection Act, the article(s) listed in blocks 10 - 12 below on this form must not be used, moved, altered or tampered with in any manner during the detention period without the written permission of an authorized representative of the Secretary of the U.S. Department of Health and Human Services, except that, pursuant to Section 304(g)(2)(B) of the FD&C Act, 1) a device may be moved and processed under 21 CFR 800.55(h)(2), and 2) a drug may be moved and processed under 21 CFR 1.980(h)(2). An article of food detained pursuant to Section 304(h) of the FD&C Act shall not be consumed, moved, altered or tampered with in any manner during the detention period, unless the detention order is first modified under 21 CFR 1.381(c).					
10. NAME OF DETAINED ARTICLE(S)			11. SIZE OF DETAINED LOT		
12. DETAINED ARTICLE(S) LABELED (Include Master Carton Label)					
15. REASON FOR DETENTION		16. DETAINED ARTICLE(S) STORED AT (Name, Address, ZIP Code)			
17. NAME AND TITLE OF PERSON WHO APPROVED THE DETENTION ORDER			18. APPROVAL OF DETENTION ORDER <input type="checkbox"/> Written <input type="checkbox"/> Verbal		
28. STORAGE OF DETAINED ARTICLES (Select appropriate - Per 21 CFR 1.303(b)(7), the detained articles must be stored by only these methods.) <input type="checkbox"/> N/A <input type="checkbox"/> Frozen <input type="checkbox"/> Other (For non-temperature related storage conditions; specify): _____ <input type="checkbox"/> Refrigerated at _____ °F <input type="checkbox"/> Ambient					
NAME OF FDA EMPLOYEE (Type or print)		TITLE (FDA Employee)		SIGNATURE (FDA Employee)	

See instructions following page 5 in this electronic form version.

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Pursuant to (Check applicable Section(s)) <input type="checkbox"/> Section 304(h) of the Federal Food, Drug and Cosmetic Act (FD&C Act), <input type="checkbox"/> Section 304(g) of the FD&C Act, <input type="checkbox"/> Sections 402 and 409b of the Federal Meat Inspection Act, <input type="checkbox"/> Sections 19 and 24(b) of the Federal Poultry Inspection Act, and/or <input type="checkbox"/> Sections 19 and 23(d) of the Federal Egg Products Inspection Act, the article(s) listed in blocks 10 - 12 below on this form must not be used, moved, altered or tampered with in any manner during the detention period without the written permission of an authorized representative of the Secretary of the U.S. Department of Health and Human Services, except that, pursuant to Section 304(g)(2)(B) of the FD&C Act, 1) a device may be moved and processed under 21 CFR 800.55(h)(2), and 2) a drug may be moved and processed under 21 CFR 1.960(h)(2). An article of food detained pursuant to Section 304(h) of the FD&C Act shall not be consumed, moved, altered or tampered with in any manner during the detention period, unless the detention order is first modified under 21 CFR 1.381(c).				
10. NAME OF DETAINED ARTICLE(S)			11. SIZE OF DETAINED LOT	
12. DETAINED ARTICLE(S) LABELED (Include Master Carton Label)			13. APPROXIMATE VALUE OF LOT	
			14. SAMPLE NUMBER	
15. REASON FOR DETENTION		16. DETAINED ARTICLE(S) STORED AT (Name, Address, ZIP Code)		
17. NAME AND TITLE OF PERSON WHO APPROVED THE DETENTION ORDER			18. APPROVAL OF DETENTION ORDER <input type="checkbox"/> Written <input type="checkbox"/> Verbal	
19. NAME AND ADDRESS OF ARTICLE(S) OWNER		20. NAME AND ADDRESS OF INITIAL SHIPPER OR SELLER		
21. NAME AND ADDRESS OF SUBSEQUENT SHIPPERS OR SELLERS (Continue in Remarks, if necessary)		22. NAME OF CARRIERS		
		23. DATE LOT SHIPPED		
24. NAME AND ADDRESS OF PACKING PLANT			25. DATE LOT RECEIVED	
			26. PACKING PLANT USDA NUMBER	
27. DESCRIPTION OF SAMPLE				
28. STORAGE OF DETAINED ARTICLES (Select appropriate - Per 21 CFR 1.303(b)(7), the detained articles must be stored by only these methods.) <input type="checkbox"/> N/A <input type="checkbox"/> Frozen <input type="checkbox"/> Other (For non-temperature related storage conditions; specify): _____ <input type="checkbox"/> Refrigerated at _____ ° F <input type="checkbox"/> Ambient				
NAME OF FDA EMPLOYEE (Type or print)		TITLE (FDA Employee)		SIGNATURE (FDA Employee)

Section 304(h) of the Food, Drug and Cosmetic Act is quoted below:

“(h) Administrative Detention of Foods.

(1) Detention Authority.

(A) In general. An officer or qualified employee of the Food and Drug Administration may order the detention, in accordance with this subsection, of any article of food that is found during an inspection, examination, or investigation under this Act conducted by such officer or qualified employee, if the officer or qualified employee has reason to believe that such article is adulterated or misbranded.

(B) Secretary's approval. An article of food may be ordered detained under subparagraph (A) only if the Secretary or an official designated by the secretary approves the order. An official may not be so designated unless the official is the director of the district under this Act in which the article involved is located, or is an official senior to such director.

(2) Period of detention. An article of food may be detained under paragraph (1) for a reasonable period, not to exceed 20 days, unless a greater period, not to exceed 30 days, is necessary, to enable the Secretary to institute an action under subsection (a) or section 302. The Secretary shall by regulation provide for procedures for instituting such action on an expedited basis with respect to perishable foods.

(3) Security of detained article. An order under paragraph (1) with respect to an article of food may require that such article be labeled or marked as detained, and shall require that the article be removed to a secure facility, as appropriate. An article subject to such an order shall not be transferred by any person from the place at which the article is ordered detained, or from the place to which the article is so removed, as the case may be, until released by the Secretary or until the expiration of the detention period applicable under such order, whichever occurs first. This subsection may not be construed as authorizing the delivery of the article pursuant to the execution of a bond while the article is subject to the order, and section 801(b) does not authorize the delivery of the article pursuant to the execution of a bond while the article is subject to the order.

(4) Appeal of detention order.

(A) In general. With respect to an article of food ordered detained under paragraph (1), any person who would be entitled to be a claimant for such article if the article were seized under subsection (a) may appeal the order to the Secretary. Within five days after such an appeal is filed, the Secretary, after providing opportunity for an informal hearing, shall confirm or terminate the order involved, and such confirmation by the Secretary shall be considered a final agency action for purposes of section 702 of title 5, United States Code. If during such five-day period the Secretary fails to provide such an opportunity, or to confirm or terminate such order, the order is deemed to be terminated.

(B) Effect of instituting court action. The process under subparagraph (A) for the appeal of an order under paragraph (1) terminates if the Secretary institutes an action under subsection (a) or section 302 regarding the article of food involved.”

Please see 21 CFR 1.402 (copied here) for the requirements for submitting an appeal for administrative detention of foods. If you decide to appeal the detention order, you may also request a hearing as part of the appeal by filing a timely notice of intent to request a hearing and then noting your request for a hearing as part of your appeal. Pursuant to 21 CFR 16.26, a request for a hearing may be denied, in whole or in part, if the Presiding Officer determines that no genuine and substantial issue of fact has been raised by the material submitted. A hearing will not be granted on issues of policy or law. If you request a hearing as part of your appeal, you should submit with your appeal and request for a hearing the materials, data, and information that you believe shows there is a genuine and substantial issue of fact regarding the propriety of the detention and any other information you would like the presiding officer to consider when deciding your appeal and request for a hearing. If your appeal is denied, written notice of a determination of summary judgment will be provided, explaining the reasons for denial. If you do not request a hearing as part of your appeal, you should submit with your

appeal all of the materials, data and information that you would like the Presiding Office to consider when deciding your appeal.

Section 1.401 and 1.402 of Title 21, Code of Federal Regulations, are quoted below as notice of opportunity for appeal and a regulatory hearing for administrative detention of foods:

***Section 1.401 Who is entitled to appeal?**

Any person who would be entitled to be a claimant for the article of food, if seized under section 304(a) of the FD&C Act, may appeal a detention order as specified in section 1.402. Procedures for establishing entitlement to be a claimant for purposes of section 304(a) of the FD&C Act are governed by Supplemental Rule C to the “Federal Rules of Civil Procedure.”

Sec. 1.402 What are the requirements for submitting an appeal?

“(a) If you want to appeal a detention order, you must submit your appeal in writing to the FDA District Director, in whose district the detained article of food is located, at the mailing address, e-mail address, or fax number identified in the detention order according to the following applicable timeframes:

(1) **Perishable food:** If the detained article is a perishable food, as defined in section 1.377, you must file an appeal within 2 calendar days of receipt of the detention order.

(2) **Nonperishable food:** If the detained article is not a perishable food, as defined in section 1.377, you must file a notice of an intent to request a hearing within 4 calendar days of receipt of the detention order. If the notice of intent is not filed within 4 calendar days, you will not be granted a hearing. If you have not filed a timely notice of intent to request a hearing, you may file an appeal without a hearing request. Whether or not it includes a request for hearing, your appeal must be filed within 10 calendar days of receipt of the detention order. (b) Your request for appeal must include a verified statement identifying your ownership or proprietary interest in the detained article of food, in accordance with Supplemental Rule C to the Federal Rules of Civil Procedure.

(c) The process for the appeal of a detention order under this section terminates if FDA institutes either a seizure action under section 304(a) of the FD&C Act or an injunction under section 302 of the FD&C Act (21 U.S.C. 275) regarding the article of food involved in the detention order.

(d) As part of the appeals process, you may request an informal hearing. Your request for a hearing must be in writing and must be included in your request for an appeal specified in paragraph (a) of this section. If you request an informal hearing, and FDA grants your request, the hearing will be held within 2 calendar days after the date the appeal is filed.”

Any informal hearing of a detention order for food must be conducted as a regulatory hearing under 21 CFR Part 16 as modified by section 1.403.

For more information, please see 21 CFR Part 1, subpart K and 21 CFR Part 16.

Section 304(g) of the Food, Drug and Cosmetic Act is quoted below:

(g)(1) If during an inspection conducted under section 704 of a facility or a vehicle, a device, drug, or tobacco product which the officer or employee making the inspection has reason to believe is adulterated or misbranded is found in such facility or vehicle, such officer or employee may order the device, drug, or tobacco product detained (in accordance with regulations prescribed by the Secretary) for a reasonable period which may not exceed twenty days unless the Secretary determines that a period of detention greater than twenty days is required to institute an action under subsection (a) or section 302, in which case he may authorize a detention period of not to exceed thirty days. Regulations of the Secretary prescribed under this paragraph shall require that before a device, drug, or tobacco product may be ordered detained under this paragraph the Secretary or an officer or employee designated by the Secretary approve such order. A detention order under this paragraph may require the labeling or marking of a device, drug, or tobacco product during the period of its

(Continued on the reverse of this page)

detention for the purpose of identifying the device, drug, or tobacco product as detained. Any person who would be entitled to claim a device, drug, or tobacco product if it were seized under subsection (a) may appeal to the Secretary a detention of such device, drug, or tobacco product under this paragraph. Within five days of the date an appeal of a detention is filed with the Secretary, the Secretary shall after affording opportunity for an informal hearing by order confirm the detention or revoke it.

"(2)(A) Except as authorized by subparagraph (B), a device, drug, or tobacco product subject to a detention order issued under paragraph

(1) shall not be moved by any person from the place at which it is ordered detained until -

"(I) released by the Secretary, or

"(II) the expiration of the detention period applicable to such order, whichever occurs first.

"(B) A device subject to a detention order under paragraph (1) may be moved -

(1) may be moved -

"(I) in accordance with regulations prescribed by the Secretary, and

"(II) if not in final form for shipment, at the discretion of the manufacturer of the device for the purpose of completing the work required to put it in such form."

Section 800.55(g)(1)-(2) of Title 21, Code of Federal Regulations, is quoted below as notice of opportunity for appeal and a regulatory hearing:

"(g) Appeal of a detention order.

(1) A person who would be entitled to claim the devices, if seized, may appeal a detention order. Any appeal shall be submitted in writing to FDA District Director in whose district the devices are located within 5 working days of receipt of a detention order. If the appeal includes a request for an informal hearing, as defined in Section 201(y) of the Act, the appellant shall request either that a hearing be held within 5 working days after the appeal is filed or that the hearing be held at a later date, which shall not be later than 20 calendar days after receipt of the detention order.

(2) The appellant of a detention order shall state the ownership or proprietary interest the appellant has in the detained devices. If the detained devices are located at a place other than an establishment owned or operated by the appellant, the appellant shall include documents showing that the appellant would have legitimate authority to claim the devices if seized."

Any informal hearing on an appeal of a detention order for devices shall be conducted as a regulatory hearing under 21 CFR Part 16, with certain exceptions Described in 21 CFR § 800.55(g)(3).

Sections 402 and 409(b) of the Federal Meat Inspection Act is quoted below:

"Sec. 402. Whenever any carcass, part of a carcass, meat or meat food product of cattle, sheep, swine, goats, horses, mules, or other equines or any product exempted from the definition of a meat food product, or any dead, dying, disabled, or diseased cattle, sheep, swine, goat, or equine is found by any authorized representative of the Secretary upon any premises where it is held for purposes of, or during or after distribution in, commerce or otherwise subject to Title I or II of this Act, and there is reason to believe that any such article is adulterated or misbranded and is capable of use as human food, or that it has not been inspected, in violation of the provisions of Title I of this Act or of any other Federal law or the laws of any State or Territory or the District of Columbia, or that such article or animal has been or is intended to be, distributed in violation of any such provisions, it may be detained by such representative for a period not to exceed twenty days, pending action under Section 403 of this Act or notification of any Federal, State, or other governmental authorities having jurisdiction over such article or animal, and shall not be moved by any person, firm, or corporation from the place at which it is located when so detained, until release by such representative. All official marks may be required by such representative to be removed from such article or animal before it is released unless it appears to the satisfaction of the Secretary that the article or animal is eligible to retain such marks. (21 U.S.C. 672.)

Sec. 409.

(b) The detainer authority conferred by Section 402 of this Act shall apply to any authorized representative of the Secretary of Health and Human Services for purposes of the enforcement of the Federal, Food, Drug, and Cosmetic Act with respect to any carcass, part thereof, meat, or meat food product of cattle, sheep, swine, goats, or equines that is outside any premises at which inspection is being maintained under this Act, and for such purposes the first reference to the Secretary in Section 402 shall be deemed to refer to the Secretary of Health and Human Services. (21 U.S.C. 679)"

Sections 19 and 24(b) of the Poultry Products Inspection Act is quoted below:

"Sec. 19. Whenever any poultry product, or any product exempted from the definition of a poultry product, or any dead, dying, disabled, or diseased poultry is found by an authorized representative of the Secretary upon any premises where it is held for purposes of, or during or after distribution in, commerce or otherwise subject to this Act, and there is reason to believe that any such article is adulterated or misbranded and is capable of use as human food, or that it has not been inspected, in violation of the provisions of this Act or of any other Federal law or the Laws of any State or Territory, or the District of Columbia, or that it has been or is intended to be, distributed in violation of any such provisions, it may be detained by such representative for a period not to exceed twenty days, pending action under Section 20 of this Act or notification of Any Federal, State, or other governmental authorities having jurisdiction over such article or poultry, and shall not be moved by any person, from the place at which it is located when so detained, until released by such representative. All official marks may be required by such representative to be removed from such article or poultry before it is released unless it appears to the satisfaction of the Secretary that the article or poultry is eligible to retain such marks."

Sec. 24.

"(b) The detainer authority conferred by Section 19 of this Act shall apply to any authorized representative of the Secretary of Health and Human Services for purposes of the enforcement of the Federal Food, Drug and Cosmetic Act with respect to any poultry carcass, or part or product thereof, that is outside any official establishment, and for such purposes for first reference to the Secretary in Section 19 shall be deemed to refer to the Secretary of Health and Human Services."

Sections 19 and 23(d) of the Egg Products Inspection Act is quoted below:

"Sec. 19. Whenever any eggs or egg products subject to the Act, are found by any authorized representative of the Secretary upon any premises and there is reason to believe that they are or have been processed, brought, sold, possessed, used, transported, or offered or received for sale or transportation in violation of this Act or that they are in any other way in violation of this Act, or whenever any restricted eggs capable of use as human food are found by such a representative in the possession of any person not authorized to acquire such eggs under the regulations of the Secretary, such articles may be detained by such representative for a reasonable period but not to exceed twenty days, pending action under Section 20 of this Act or notification of any Federal, State, or other governmental authorities having jurisdiction over such articles and shall not be moved by any person from the place at which they are located when so detained until released by such representative. All official marks may be required by such representative to be removed from such articles before they are released unless it appears to the satisfaction of the Secretary that the articles are eligible to retain such marks."

"Sec. 23(d). The detainer authority conferred on representatives of the Secretary of Agriculture by Section 19 of this Act shall apply to any authorized representative of the Secretary of Health and Human Services for the purposes of paragraph (d) of Section 5 of this Act, with respect to any eggs or egg products that are outside any plant processing egg products."

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Section 1.980(g)(1)-(2) of Title 21, Code of Federal Regulations, is quoted below as notice of opportunity for appeal and a regulatory hearing for administrative detention of drugs"

"(g) Appeal of a detention order. (1) A person who would be entitled to claim the drugs, if seized, may appeal a detention order. Any appeal must be submitted in writing to the FDA District Director in whose district the drugs are located within 5 working days of receipt of a detention order. If the appeal includes a request for an informal hearing, as defined in section 201(x) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 321(x)), the appellant must request either that a hearing be held within 5 working days after the appeal is filed or that the hearing be held at a later date, which must not be later than 20 calendar days after receipt of a detention order.

(2) The appellant of a detention order must state the ownership or proprietary interest the appellant has in the detained drugs. If the detained drugs are located at a place other than an establishment owned or operated by the appellant, the appellant must include documents showing that the appellant would have legitimate authority to claim the drugs if seized."

Any informal hearing on an appeal of a detention order for drugs shall be conducted as a regulatory hearing under 21 CFR Part 16, with certain exceptions described in 21 CFR § 1.980(g)(3)."