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Administrative Detention of Food for Human or Animal Consumption Under the Public Health Security and Bioterrorism Preparedness and Response Act of 2002; Final Rule

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

21 CFR Parts 1, 10, and 16

[Docket No. 2002N–0275]

RIN 0910–AC38

Administrative Detention of Food for Human or Animal Consumption Under the Public Health Security and Bioterrorism Preparedness and Response Act of 2002

AGENCY: Food and Drug Administration, HHS.

ACTION: Final rule.

SUMMARY: The Food and Drug Administration (FDA) is issuing a final regulation that provides procedures for the detention of an article of food, if an officer or qualified employee of FDA has credible evidence or information indicating that such article presents a threat of serious adverse health consequences or death to humans or animals (''administrative detention''). The final rule implements the Public Health Security and Bioterrorism Preparedness and Response Act of 2002 (the Bioterrorism Act), which authorizes the use of administrative detention and requires regulations establishing procedures for instituting on an expedited basis certain enforcement actions against perishable food subject to a detention order.

DATES: This rule is effective July 6, 2004.

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SUPPLEMENTARY INFORMATION:

Table of Contents

I. Background and Legal Authority

On May 9, 2003 (68 FR 25242), FDA issued a proposed rule providing procedures for the detention of an article of food, if an officer or qualified employee of FDA has credible evidence or information indicating that such article presents a threat of serious adverse health consequences or death to humans or animals. The events of September 11, 2001, had highlighted the need to enhance the security of the United States' food supply. Congress responded by enacting the Bioterrorism Act (Public Law 107–188), which was signed into law on June 12, 2002. Section 303 of the Bioterrorism Act amends section 304 of the Federal Food, Drug, and Cosmetic Act (the FD&C Act) (21 U.S.C. 334) by adding paragraph (h) to provide that an officer or qualified employee of FDA may order the detention of any article of food that is found during an inspection, examination, or investigation under the act if the officer of 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. This provision also requires the Secretary of Health and Human Services (the Secretary) to provide by regulation procedures for instituting seizure or injunction actions against perishable food subject to a detention order on an expedited basis. Section 303 of the Bioterrorism Act also amends the FD&C Act by adding a new prohibited act as paragraph (bb) to section 301 of the FD&C Act (21 U.S.C. 331).

The major components of section 303 of the Bioterrorism Act are as follows:

- *Criteria used to trigger an administrative detention:* Amends section 304 of the FD&C Act to authorize an officer or qualified employee of FDA to order the detention of any article of food that is found during an inspection, examination, or investigation under the FD&C Act, if the officer or qualified employee has credible evidence or information indicating such article presents a threat of serious adverse health consequences or death to humans or animals.
- *Approval required:* The Secretary, or an official designated by the Secretary, must approve the detention order. An ''official designated by the Secretary'' means the District Director of the district where the detained article of food is located, or an FDA official senior to such director.
- *Period of detention:* The detention period will be for a reasonable period, not to exceed 20 calendar days, unless a greater period, not to exceed 30 calendar days, is necessary to enable the Secretary to institute a seizure or injunction action.
- *Required rulemaking:* The Secretary must, by regulation, provide for procedures for instituting certain enforcement actions on an expedited basis with respect to perishable food subject to a detention order.
- *Security of detained article of food:* The detention order may require that the detained article of food be labeled or marked as detained. The order must require the removal of the detained article of food to a secure facility, as appropriate.
- *Appeal procedure:* Any person who would be entitled to claim the detained article of food if such article were seized may appeal the detention order to the Secretary. Within 5 calendar days after

such appeal is filed, after providing opportunity for an informal hearing, the Secretary must confirm or terminate the detention order. The appeal process terminates if the Secretary institutes an action for seizure or injunction regarding the article of food involved. Confirmation of a detention order is considered a final agency action.

- *Prohibited act:* Amends section 301 of the FD&C Act making it a prohibited act to transfer a detained article of food in violation of a detention order, or to remove or alter any mark or label required by the detention order to identify the article of food as detained.
- Section 303 of the Bioterrorism Act also includes a provision authorizing temporary holds at ports of entry that will not be addressed in this final regulation. The temporary hold provision authorizes FDA to ask the Secretary of the Treasury to institute a temporary hold for up to 24 hours on an article of food offered for import at a U.S. port of entry if FDA has credible evidence or information indicating that an article of food presents a threat of serious adverse health consequences or death to humans or animals, and FDA is unable immediately to inspect, examine, or investigate such article. FDA has received comments on the temporary hold provision in the public docket (Docket No. 2002N–0275). FDA plans to consider these comments as we develop our approach on how best to implement this provision of the Bioterrorism Act.

Under the Homeland Security Act of 2002 (Public Law 107–296), the responsibilities and functions of the Secretary of the Treasury for all relevant Customs authorities have been transferred to the Secretary of Homeland Security, who has in turn delegated them to the Commissioner of the Bureau of Customs and Border Protection (CBP). Thus, wherever section 303 of the Bioterrorism Act refers to the Secretary of Treasury, we will refer to the Secretary of Homeland Security.

In addition to amending title 21 of the Code of Federal Regulations (21 CFR) by establishing a new subpart to part 1 (21 CFR part 1) consisting of subpart K entitled, ''Administrative Detention of Food for Human or Animal Consumption,'' this final rule also makes conforming amendments to part 16 (21 CFR part 16) entitled ''Regulatory Hearing Before the Food and Drug Administration'' and part 10 (21 CFR part 10) entitled ''Administrative Practices and Procedures.''

Although the statutory requirements in section 303 of the Bioterrorism Act are self-executing and are currently in effect, FDA is issuing this regulation to further refine aspects of the administrative detention requirements. Section 303 of the Bioterrorism Act requires FDA only to issue regulations establishing procedures for instituting on an expedited basis certain enforcement actions against perishable food subject to a detention order; however, FDA also is describing in this regulation the procedures for how we will detain both perishable and nonperishable articles of food and the process for appealing a detention order. FDA established requirements for the process for appealing a detention order in this final rule to ensure that we meet section 303's timing requirements and to define certain terms used in the Bioterrorism Act (*e.g.*, perishable food).

This final rule is not related to, and does not implement, section 801(a) of the FD&C Act (21 U.S.C. 381), even though it uses the term ''detention.'' This final rule implements section 303 of the Bioterrorism Act, which amends the seizure provision at section 304 of the FD&C Act by adding paragraph (h) to that section. This amendment grants FDA the authority to detain (*i.e.*, prevent the further movement of) any article of food that is found during an inspection, examination, or investigation if FDA has credible evidence or information indicating that such article presents a threat of serious adverse health consequences or death to humans or animals.

Some of the comments that we received continue to reflect some confusion of our authority to detain food administratively under section 304(h) of the FD&C Act (as added by the Bioterrorism Act) with our authority to refuse admission of imported food under section 801(a) of that act, despite our explanation of this issue in the proposed rule. (See 68 FR 25242.) The following discussion provides additional explanation of FDA's authority under each of these provisions so as to make clear that our authority to detain food administratively under section 304(h) of the FD&C Act is separate and distinct from our authority to refuse admission of imported food under section 801(a) of the FD&C Act.

Section 801 of the FD&C Act sets out standards and procedures for FDA review of imports under its jurisdiction. Generally, when an FDA-regulated product is imported, customs brokers submit entry information to CBP on behalf of the importers of record. CBP then provides entry information to FDA to enable admissibility decisions to be made. If FDA determines that refusal under section 801(a) FD&C Act appears appropriate, FDA, as set out in its regulations, gives written notice to the owner or consignee. (See § 1.90(a).) In guidance dating back many years, FDA refers to this written notice as the notice of detention and hearing.

FDA's evaluation of imported foods under section 801(a) of the FD&C Act largely focuses on whether the article of food appears to have been safely produced, packed, and held; contains no contaminants or illegal additives or residues; and is properly labeled. Section 801(a) of the FD&C Act provides that an article of food is subject to refusal of admission if it ''appears, from physical examination or otherwise'': (1) To have been manufactured, processed, or packed under insanitary conditions; (2) to be forbidden or restricted in sale in the country in which it was produced or from which it was exported; or (3) to be adulterated or misbranded. The food adulteration and misbranding provisions (sections 402 and 403 of the FD&C Act (21 U.S.C. 342 and 21 U.S.C. 343)) set out most of the FD&C Act's requirements for foods.

In section 304(h) of the FD&C Act, Congress gave FDA the authority to detain food administratively where we have credible evidence or information that the article of food presents a threat of serious adverse health consequences or death to humans or animals so that we can bring such food under FDA control. Historically, FDA has had the authority to seize misbranded or adulterated food in domestic commerce; however, adulterated food could enter commerce and put consumers at risk during the time that it takes to file a seizure action. In some instances, FDA has been able to partner with State authorities to have such food embargoed by the State where the food is located so that it is under their control while the seizure action is being prepared and filed, until the court issues the warrant, and until the U.S. marshal can seize the food. However, this process is not always possible.

We do not, at this time, foresee frequently using administrative detention under section 304(h) of the FD&C Act to control the movement of imported food subject to section 801 of the FD&C Act. When FDA determines it is appropriate to bring imported food under FDA control using the authority under section 304(h) of the FD&C Act, the standard for administrative detention will be the same as it is for other products, *i.e.*, we must have credible evidence or information that the article of food presents a threat of serious adverse health consequences or death to humans or animals.

This final rule implements the administrative detention requirements in section 303 of the Bioterrorism Act.

This final rule, published today, as well as the interim final rules that FDA and CBP published on October 10, 2003, to implement section 307, prior notice of imported food shipments (68 FR 58974), and section 305, registration of food facilities (68 FR 58893), of the Bioterrorism Act, along with the final rule implementing section 306 of the Bioterrorism Act (maintenance and inspection of records for food), which will be published in the **Federal Register** in the near future, will help FDA act quickly when responding to a threatened or actual bioterrorist attack on the U.S. food supply or to other food-related emergencies. Administrative detention will provide FDA with an added measure to help ensure the safety of the nation's food supply. In establishing and implementing this final rule, FDA believes it has complied fully with the United States' international trade obligations, including the applicable World Trade Organization (WTO) agreements and the North American Free Trade Agreement (NAFTA).

In addition to section 303 of the Bioterrorism Act, which amends the FD&C Act as described previously in this document, FDA is relying on section 701(a) of the FD&C Act (21 U.S.C. 371(a)) in issuing this final rule. Section 701(a) authorizes the agency to issue regulations for the efficient enforcement of the FD&C Act.

II. Highlights of the Final Rule

The key features of this final rule are as follows:

- An officer or qualified employee of FDA may order the detention of food for up to 30 calendar days if FDA has credible evidence or information that the food presents a threat of serious adverse health consequences or death to humans or animals.
- FDA's District Director in the district in which the article of food is located, or an FDA official senior to such director, must approve a detention order.
- FDA may require that the detained article of food be labeled or marked as detained with official FDA tags or labels. FDA's tag or label will include, among other information, a statement that the article of food must not be consumed, moved, altered, or tampered with in any manner for the period shown, without the written permission of an authorized FDA representative.
- A violation of a detention order or the removal or alteration of the tag or label is a prohibited act.
- FDA will state in the detention order the location and any applicable conditions under which the food is to be held.
- If FDA determines that removal to a secure facility is appropriate, the article of food must be removed to a secure facility. An article of food moved to a secure facility remains under detention before, during, and after such movement.
- FDA may approve a request for modification of a detention order to permit movement of a detained article of food for purposes of destruction, movement to a secure facility, preservation of the detained article of food, or any other purpose that FDA believes is appropriate. In any of these circumstances, an article of food may be transferred but remains under detention before, during, and after the transfer.
- Any transfer of a detained article of food in violation of a detention order is a prohibited act.
- Any person who would be entitled to be a claimant for the article of food, if seized, may appeal a detention order and, as part of that appeals process, may request an informal hearing. If a hearing is granted, an FDA Regional Food and Drug Director (RFDD) or another official senior to an FDA District Director will serve as the presiding officer of the hearing.
- This rule includes appeal and hearing timeframes for both perishable and nonperishable detained articles of food.
- *Perishable food:*
- An appeal must be filed within 2 calendar days of receipt of the detention order.
- If a hearing is requested in the appeal and FDA grants the request, the hearing will be held within 2 calendar days after the date the appeal is filed.
- FDA's decision on appeal will be issued 5 calendar days after the appeal is filed.
- *Nonperishable food:*
- A notice of intent to file an appeal and to request a hearing must be filed within 4 calendar days of receipt of the detention order.
- An appeal must be filed within 10 calendar days of receipt of the detention order.
- If a hearing is requested in the notice of intent and the appeal and FDA grants the request, the hearing will be held within 2 calendar days after the appeal is filed.
- FDA's decision on appeal will be issued 5 calendar days after the appeal is filed.
- The expedited procedures for initiating certain enforcement actions with respect to perishable foods require FDA to submit a seizure recommendation to the Department of Justice (DOJ) within 4 calendar days after the detention order is issued, unless extenuating circumstances exist.
- Confirmation of a detention order by FDA's presiding officer is considered final agency action.

In response to comments that were received, FDA has made two changes to the proposed rule. First, the required information in the detention order did not include the name of the authorized FDA representative who approved the detention order. This is required information in this final rule (§ 1.393(b)(14)). Second, the proposed rule stated that, if a hearing is requested in the appeal, and FDA grants the request, the hearing will be held within 2 calendar days after the date the appeal has been filed for perishable food, and within 3 calendar days after the date the appeal has been filed for nonperishable food (§ 1.402(d)). This section III.I.2 of this final rule is revised to state that the hearing will be held within 2 calendar days after the date the appeal is filed for both perishable and nonperishable foods. In addition, FDA has also made clarifying revisions to the procedures that apply to an informal hearing on an administrative detention. Revised §§ 1.403(h) and 1.405(a) provide that the presiding officer must issue a written report of the hearing, including a proposed decision with a statement of reasons. The hearing participant may review this report and suggest changes within 4 hours of the issuance of the report. The presiding officer will then issue the final agency decision. In addition, FDA has added § 1.403(i) and (k) to clarify the components of the administrative record and the record of the administrative proceeding. We have also included clarifying comments in the preamble to this final rule.

We have made two other changes to the proposed rule in order to avoid confusion with CBP terminology and requirements. First, the proposed rule used the term ''limited conditional release'' to refer to the process whereby FDA grants a request to modify a detention order to permit movement of a detained article of food. The term ''limited conditional release'' has a different meaning as used by CBP. In order to avoid confusion, we have therefore changed applicable sections of the codified in this final rule to eliminate the use of this term, and instead use the term ''request for modification of a detention order.''

Second, § 1.381(a) in the proposed rule prohibited delivery of a detained article of food ''to another entity under the execution of a bond.'' This section could have been misinterpreted to prohibit delivery of an article to a

storage facility just because it is under a customs bond (as opposed to a penal bond), thereby potentially slowing the flow of trade. In the final rule, § 1.381(a) has been revised to make clear that the existence of an appropriate customs bond required by Customs law and regulation does not prohibit movement of a detained article at FDA's direction.

As noted in the proposed rule, FDA intends to define ''serious adverse health consequences'' in a separate rulemaking.

III. Comments on the Final Regulation

FDA received approximately 100 submissions in response to the proposed rule, and each of them raised one or more comments. To make it easier to identify comments and FDA's responses to the comments, the word ''Comment'' will appear in parentheses before the description of the comment, and the word ''Response'' will appear in parentheses before FDA's response. FDA also has numbered the sets of comments to make it easier to identify a particular issue. The number assigned to each set of comments is purely for organizational purposes and does not signify the comment's value or importance or the order in which it was submitted to FDA's docket.

A. General Comments

(Comment 1) Many comments state that administrative detention should be limited to use only when there is intentional adulteration (bioterrorism) against the food supply. One comment indicates that administrative detentions should be imposed only when there are no other means to prevent the product from moving in commerce, *e.g.*, when a responsible company will not recall or hold the product. Some comments argue specifically that we should continue to request Class I recalls in situations involving unintentional adulteration. One comment argues that we should not use administrative detention to deal with imported food containing undeclared allergens.

(Response) The Bioterrorism Act gives FDA the authority and flexibility to detain administratively articles of food for which FDA has credible evidence or information indicating that such article presents a threat of serious adverse health consequences or death to humans or animals. The Bioterrorism Act does not limit FDA's administrative detention authority to only those situations involving intentional adulteration. Unintentional adulteration can pose the same threats of serious adverse health consequences or death. Therefore, the agency has not changed the final rule as requested by comment 1 in section III A. of this document.

In response to the comment that FDA should only employ an administrative detention when voluntary cooperation is not available, FDA believes that a detention may not be necessary if a firm takes prompt and complete voluntary action, *e.g.*, in a Class I recall situation. However, FDA may nonetheless choose to detain administratively an article of food that has been recalled. Circumstances under which FDA may choose to do so include, but are not limited to, when there is concern that the food may reenter commerce. Thus, FDA will not limit its authority to detain an article of food that presents a threat of serious adverse health consequences or death to humans or animals.

(Comment 2) FDA sought comments on whether its conclusion that it has authority to detain food in intrastate commerce administratively is correct, and if so, whether the agency should use that authority. A few comments agree with FDA's conclusion that it has authority to impose an administrative detention on articles of food that are only in intrastate commerce. One comment is concerned about the broader jurisdictional implications of FDA not meeting the interstate commerce criterion. Another comment argues that FDA's conclusion that it has authority to detain food administratively that does not enter interstate commerce is inconsistent with limitations imposed by the commerce clause of the U.S. Constitution. In response to FDA's assertion that Congress, in the Bioterrorism Act, gave the agency authority to detain food administratively in intrastate commerce, this comment states that the commerce clause generally restricts Congress' power to regulate purely intrastate commerce, and that Congress cannot delegate power to FDA that it does not possess. The comment argues that FDA should have assumed that Congress did not intend to violate the Constitution, and that FDA should amend the administrative detention provisions accordingly.

Another comment argues that the agency's use of administrative detention authority on articles of food that are engaged only in intrastate commerce challenges long established federal and state jurisdictional boundaries. This comment further states that, under these new regulations, FDA is moving into areas delegated to state control under the enabling statute and the 10th Amendment to the U.S. Constitution, and that by proposing this regulatory scheme, the agency can avoid and circumvent the very safeguards established to provide against rampant unauthorized expansion of federal authority.

(Response) In the preamble to the proposed rule, FDA tentatively concluded that all food would be subject to administrative detention under section 303 of the Bioterrorism Act if the agency has credible evidence or information that the food presents a threat of serious adverse health consequences or death to humans or animals, whether or not the food enters interstate commerce. FDA is mindful that our interpretation of the Bioterrorism Act should not cast doubt on the constitutionality of the statute. (See *Solid Waste Agency of Northern Cook County* v. *U.S.,* 531 U.S. 159 (2001).) The agency has considered the relevant provisions of the Bioterrorism Act, the comments submitted on this issue, FDA's responsibilities in implementing the Bioterrorism Act, and the law interpreting the commerce clause of the Constitution (Art. I, section 8). Based on these considerations, FDA does not change its conclusion that it has the authority to detain food administratively that does not enter interstate commerce.

Section 304(h) of the FD&C Act, as added by section 303 of the Bioterrorism Act, provides that:

> 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 credible evidence or information indicating that such article presents a threat of serious adverse health consequences or death to humans or animals.

This language does not include a limitation similar to that in section 304(g) of the FD&C Act providing for administrative detentions of devices during inspections conducted under section 704 of that act (21 U.S.C. 374), a provision that has an interstate commerce component. In addition, the prohibited act related to administrative detention of food, section 301(bb) of the FD&C Act, unlike some other prohibited acts in section 301, does not include an interstate commerce component. Accordingly, FDA concludes that the Bioterrorism Act does not limit administrative detention only to those foods that enter interstate commerce.

Congress's constitutional power to legislate under the commerce clause is very broad. However, such power is not without limits, see, *e.g, United States* v. *Lopez,* 514 U.S. 549, 567 (1995); *U.S.* v.

Morrison, 529 U.S. 598, 618 (2000), and these limits have been construed in light of relevant and enduring precedents. In particular, in *Lopez, supra,* the Supreme Court acknowledged the continuing vitality of *Wickard* v. *Filburn,* 317 U.S. 111 (1942), noting that, ''although Filburn's own contribution to the demand for wheat may have been trivial by itself, that was not 'enough to remove him from the scope of federal regulation where, as here, his contribution, taken together with that of many others similarly situated, is far from trivial.' '' 514 U.S. at 556. This principle applies to the administrative detention provision of the Bioterrorism Act. Administrative detention prevents the movement of food where there is credible evidence or information that the food presents a threat of serious adverse health consequences or death. Even if that food is so-called ''intrastate'' food, the collective impact of that food on interstate commerce is such that FDA believes Congress acted within its power under the commerce clause when it enacted legislation subjecting that food to administrative detention.

FDA's conclusion is also consistent with section 709 of the FD&C Act, which states that, in any action to enforce the FD&C Act's requirements respecting foods, drugs, devices, and cosmetics, any necessary connection with interstate commerce is presumed. Likewise, this outcome is consistent with Congress' goal in enacting the Bioterrorism Act because the potential harm from bioterrorist attacks or other food emergencies can be great, whether or not the food moves from one state to another. The usefulness of the administrative detention authority also can be significant in food emergencies where interstate shipment has not occurred. As a practical matter, FDA believes that this decision should have little if any impact on whether a given food is subject to administrative detention because virtually all food manufactured, processed, packed, transported, distributed, received, held, or imported, moves, or is considered to move, in interstate commerce. Accordingly, FDA is retaining its conclusion that it has the authority to detain any food administratively when the agency has credible evidence or information that the food presents a threat of serious adverse health consequences or death to humans or animals, regardless of whether that food enters interstate commerce.

(Comment 3) A few comments state that FDA should make clear that the detention of cargo always should be managed so as to minimize delay or interference with the orderly movement of an oceangoing vessel or other conveyance. They note that this clarification will be consistent with the intent of the Bioterrorism Act and FDA's relationship with CBP. These comments state that the Bioterrorism Act grants FDA limited detention authority, which should not be interpreted as expanding the agency's authority to inspect and detain imported food on a vessel at a port of entry when this authority belongs, in the first instance, to CBP. These comments note FDA's acknowledgment in our proposal that it intends, primarily, to continue to regulate imported food in conjunction with CBP and under section 801(a) of the FD&C Act. They also note that the provision in section 303(c) of the Bioterrorism Act, which allows an officer of qualified employee of FDA to ''* * * request the Secretary of Treasury to hold the food at the port of entry for a reasonable period of time, not to exceed 24 hours, for the purpose of enabling the Secretary to inspect, examine, or investigate the article as appropriate'' further confirms that the authority to detain cargo on board a vessel remains primarily with the CBP service and not FDA.

(Response) As stated in the background section I. of this rule, because of the authorities available to FDA and CBP to control the movement of imported food under section 801(a) of the FD&C Act and various provisions of title 19 of the U.S. Code, FDA does not foresee frequently using administrative detention under section 303 of the Bioterrorism Act to control the movement of imported food subject to those authorities. However, it is within FDA's authority to detain food under section 303 of the Bioterrorism Act that has been offered for import into the United States upon credible evidence or information that the article of food presents a threat of serious adverse health consequences or death to humans or animals. Consequently, FDA may detain imported food cargo on a conveyance under section 303 of the Bioterrorism Act. If FDA detains imported articles of food on a conveyance, we will consult with CBP to minimize the disruption of the conveyance movement in trade.

(Comment 4) One comment indicates that most tank truckloads of food are sealed at all openings and that these seals will be broken by FDA inspectors who investigate a suspected problem load. They state that, in the bulk food trucking industry, ''a broken seal equals a rejected load.'' The comment requests that FDA develop a process whereby an FDA representative who breaks a seal to gain access to a load that is found not to present a problem would then reseal the load with an FDA seal and so indicate it on an official FDA document. While not required to, a receiver may be more inclined to accept the load.

(Response) FDA agrees in part with this comment, but is not sure what is meant by an official document upon resealing. Under current practice, which will be continued after the effective date of this rule, whenever FDA reseals a conveyance (*e.g.*, a truckload of goods) after an FDA investigator has broken the seal to examine the goods, the FDA investigator reseals the conveyance with an official FDA metal seal. An FDA document does not accompany the metal seal because the FDA seal is the official indication that FDA has opened and resealed the conveyance. Our internal practice is to record the number of the seal in the investigator's official notes.

(Comment 5) A couple of comments suggest that FDA should avoid implementing a ''one size fits all'' rule for transportation providers to accommodate the operational differences within the transportation industry. These comments suggest that, instead, FDA should examine the operational capabilities and realities of the differing transport modes to formulate mode-specific rules, as is currently being done by CBP for the Trade Act of 2002 (Trade Act). These comments further suggest that the agency work closely with CBP to ensure that any rules for importation and exportation of food do not conflict with CBP requirements. The comments suggest that FDA work with CBP to take advantage of the cross-border supply chain security program already in place, to avoid burdensome duplication of effort.

(Response) FDA does not agree that it is necessary to adopt different administrative detention requirements for different modes of transport. The Trade Act deals with advance notice of items arriving in the United States, not with detention of potentially unsafe food to ensure it does not move into distribution pending the filing of a court action. Congress specifically directed CBP to consider different advance notice timeframes for items arriving on different modes of transport (*e.g.*, truck, air, vessel, rail). This Congressional directive did not extend to actions taken by FDA to implement section 303 of the Bioterrorism Act. In the implementation of section 303, different transport modes are irrelevant because food subject to administrative detention will either be detained in place or detained by offloading it from the transport mode

and transferring it to another facility. This is true regardless of whether the mode of transport is truck, air, vessel, or rail. FDA will continue to work with CBP to coordinate actions at the border.

(Comment 6) One comment states that bulk transportation of food products in tank trailers and dry bulk trailers is significantly different from packaged or prepared food transportation. This comment urges FDA to recognize these differences either in the language of the regulation, or by a separate section strictly dealing with bulk transportation.

(Response) Section 1.393(b)(8) states that FDA must include in the detention order any applicable conditions of transportation of the detained article of food. FDA will take into consideration the mode of transportation being used for the detained product, and the form in which the article of food is being transported, *e.g.*, packaged or dry bulk, when setting forth these conditions.

(Comment 7) With respect to detained shipments of imported food, one comment believes that FDA should work with CBP to immediately control these foods, and to program CBP's Automatic Commercial System (ACS) and Automated Broker Interface (ABI) to not issue a CBP release for any such shipment.

(Response) When imported food at the border is found to warrant administrative detention under section 304(h) of the FD&C Act, FDA will continue to work with CBP as the agency currently does with respect to section 801(a) of the FD&C Act. FDA will issue a detention order under §§ 1.392 and 1.393, which will specify the terms of the detention. Under § 1.393(b)(9), the order will include a statement that ''the article of food is not to be consumed, moved, altered, or tampered with in any manner during the detention period, unless the detention order is first modified under § 1.381.'' Accordingly, FDA does not believe it is necessary to communicate detentions through ACS or ABI.

(Comment 8) One comment is concerned about where imported food will be detained. The comment describes FDA's current procedures of only detaining imported food at the port where the consumption entry is filed with CBP, which may not be the port of arrival. Currently, imported food is detained at the port where the consumption entry is filed after FDA receives the declaration and the Operational and Administrative System Import Support declaration is made. The comment wants this procedure to continue unchanged.

(Response) In this comment, the person is describing FDA's current procedures for refusing admission under section 801(a) of the FD&C Act. In the event that imported food is detained administratively under section 303 of the Bioterrorism Act, the product would be detained as soon as FDA had credible evidence or information that the food product posed a threat of serious adverse health consequences or death. This could presumably occur while the product was still at the port of entry where the goods arrived in the United States. Thus, it is conceivable that FDA could administratively detain a food product at the port of entry where arrival took place, the port of destination, or any location in between. This is consistent with the purpose of administrative detention, which is to hold in place, and protect against any movement that could lead to further distribution of, the food that poses the threat of serious adverse health consequences or death to humans or animals. Under § 1.393(b)(7), the detention order will specify the address and location where the article of food is to be detained and the appropriate storage conditions.

(Comment 9) One comment suggests that their written comments can at best only highlight some of the issues and implications raised by FDA's proposal. The comment further states that the best way to address these subjects is through a working group that brings together members of the trading community with officials from FDA and CBP. If a meeting is not possible, the comment requests to schedule a meeting at FDA's earliest convenience to further discuss the matter.

(Response) FDA conducted extensive outreach on the proposed administrative detention rule, including attending international and domestic meetings to ensure that affected parties were aware of the Bioterrorism Act administrative detention requirements and understood the proposed requirements so that they could provide meaningful comments. On May 7, 2003, FDA held a public meeting (via satellite downlink) to discuss both the administrative detention and recordkeeping proposed rules. (See 68 FR 16998, April 8, 2003 or *http://www.accessdata.fda.gov/scripts/oc/ohrms/advdisplay.cfm*.) The live broadcast was available to participants in North America, Central America, and South America, and the Caribbean. The meeting was later rebroadcast to Europe, Southern Africa, Asia, and the Pacific. FDA also has posted transcripts of the broadcast in English, French, and Spanish (the three official WTO languages) on the agency's Web site.

(Comment 10) One comment is concerned that pet products will be administratively detained due to unwarranted association with countries or geographic areas that may face animal health or food safety emergencies. Another comment questions whether FDA's administrative detention authority applies to transit shipments in the United States, *i.e.*, goods in transit through the United States that are not declared for U.S. consumption. Another comment asks what relationship or obligation has been established between the Bioterrorism Act and hazard analysis and critical control points (HACCP) and good manufacturing practices (GMPs).

(Response) FDA can detain an article of food administratively only if FDA has credible evidence or information indicating that such article presents a threat of serious adverse health consequences or death to humans or animals. That is the standard that must be met for administrative detention of all food, including pet food. FDA also has authority to detain administratively any food in the United States that meets the standard for administrative detention, including transit shipments of food. Finally, it is not clear what is meant by the terms ''relationship'' and ''obligation'' with respect to the Bioterrorism Act and HACCP and GMPs. FDA has authority to detain food administratively when that food meets the standard for administrative detention, regardless of how the food comes to meet that standard, *e.g.*, by failure to follow GMPs, as the result of an act of bioterrorism, etc. FDA's decision to employ administrative detention or other applicable authorities under the FD&C Act will be made on a case-by-case basis depending on the facts of each particular case.

(Comment 11) One comment asks if FDA is suggesting that carriers, warehouses and others in the supply chain process must adhere to specific security standards, and if so, suggests that such standards be clearly identified.

(Response) This final rule does not establish general requirements or guidance relating to specific security standards or practices for carriers, warehouses and others in the supply chain. However, FDA recently published several guidance documents concerning preventative food safety measures that individual firms may wish to consider as they develop their own security measures. FDA's guidance documents can be found on the agency's Web site. (See *http://www.cfsan.fda.gov/~dms/fsterr.html*.) If FDA does issue a detention order, the order would

contain the address and location where the article of food is to be detained, and the appropriate storage conditions.

(Comment 12) One comment indicates that if an officer detains a product in temporary hold for 24 hours, then the total time invested in the appeal and hearing process will exceed the timeframe for perishable foods. This comment asks FDA to specify 7 days for the detention process from the formal detention until the final resolution or termination based on the definition for perishable food, which is that the quality of the product is adversely affected after 7 days of storage. The comment states that a product that has been under a temporary hold and detained for 7 days will exceed the useful time of a perishable food.

Another comment states that FDA must take into account the 24-hour period of the temporary hold in the detention time of 30 days. Another comment states that they do not challenge the right of FDA to inspect food products at the border, but that, in their view, the 24 hour temporary hold is an unreasonable time to force a truck and driver to wait for FDA to conduct an inspection and issue a decision. This comment indicates that the proposed recordkeeping rule will require companies to turn over records to FDA within 4 hours during normal business hours, and 8 hours on evenings and weekends, and suggests that, if FDA is willing to impose such short timeframes on industry, then it should also be required to adhere to them in the conduct of its own operations.

Another comment suggests that the guidance on temporary holds should be made available as soon as possible because there is no explanation about why FDA must ask specifically the ''Secretary of Treasury'' to institute the temporary hold. This comment states that it is not clear if the alternative exists for the ''Secretary of Treasury'' to designate or to enable someone with proper skills to replace him when he is not available. A few comments state that the proposed provision for the temporary holding of imports for 24 hours is open to abuse. They indicate that not only is there no comparable provision for domestic products, but there is a real risk that the provision could amount to a ''holding bay'' for import inspections while FDA resources are used to deal with domestic alerts elsewhere.

(Response) As indicated in the background section I. of this rule, the temporary hold provisions authorized in section 303 of the Bioterrorism Act are outside the scope of this rulemaking. FDA plans to consider these comments as we develop our approach on how best to implement this provision of the Bioterrorism Act.

FDA notes, however, that the period of detention for administrative detention under section 303 of the Bioterrorism Act does not begin until the detention order is issued.

(Comment 13) Several comments ask that the implementation date of these regulations be pushed back because the new authorities are extensive and the timeframe for implementation is unusually quick for such a sweeping change. Furthermore, the comments state that the proposed timeframes are not sufficient for producers in exporting countries to adapt their products to the requirements of the Bioterrorism Act, and will result in unnecessary costs and delays.

(Response) Even if FDA delayed implementation of the regulations, the authority for administrative detention is self-executing and currently in effect. In addition, FDA believes that it is in the public's interest to implement these regulations as soon as possible to facilitate the resolution of administrative detentions.

(Comment 14) One comment indicates that the new regulations are burdensome and overlap with current requirements under parts 7, 110, 123, and 1240 (21 CFR parts 7, 110, 123, and 1240). This comment states that if these provisions were properly implemented, they would be more than adequate to address concerns FDA may have with rapid location of affected product and ingredient traceability that are the major concerns with this new provision. Another comment states that FDA's Investigations Operations Manual (IOM), subchapter 750, describes the procedure that FDA must follow currently for detention activities and that the new regulations do not appear substantially different. Another comment questions the need for this rulemaking because it appears that FDA considers the threshold for detention to be equivalent to the standard for initiating a Class I recall.

(Response) FDA disagrees with these comments. The regulations in parts 7, 110, 123, and 1240, and subchapter 750 of the IOM, do not address administrative detentions of food under section 303 of the Bioterrorism Act. Further, the regulations cited in the comment are not based on the substantive standard for administrative detention under section 303 of the Bioterrorism Act, which is that the detained article of food presents a threat of serious adverse health consequences or death to humans or animals.

(Comment 15) Numerous comments ask that FDA provide compensation for losses incurred as a result of a detention. Some comments refer to detentions where the product is eventually released, but is no longer marketable. Other comments want compensation for detentions in which damages are incurred as a result of any detention, *i.e.*, including detentions where the product is confirmed to present a threat of serious adverse health consequences or death to humans or animals. Another comment states that the regulation does not adequately address the legal and financial responsibility for the disposal of food as a result of the threat it presents. This comment suggests that an entity with a vested interest in the product, *e.g.*, the owner, would bear the responsibility, and that failure on the part of the food product owner to pay storage, handling and related costs should be considered a violation of the FD&C Act. One comment argues that, rather than adding to industry's burden for food security, we should provide government funding to help industry institute measures to improve food security.

(Response) Neither the FD&C Act nor the Bioterrorism Act provides for damages or other costs associated with administrative detention. In addition, the failure to pay storage, handling, and related costs is not a violation of the FD&C Act. With respect to the comment that FDA should provide government funding to help industry institute measures to improve food security, that issue is beyond the scope of this rulemaking and would require statutory authorization and appropriations.

(Comment 16) A few comments suggest that the rule should require that FDA determine the party actually responsible for the threat against the food and define their responsibility. One comment indicates that FDA must consider that the party responsible for the threat could be a third party, *i.e.*, a party not included in the importation or distribution of the product. Another comment asks who will be held responsible in the case where a product is packaged in bulk in one country and repackaged in another country for export to the United States. One comment asks how FDA will differentiate between an actual threat and a hoax and if it will matter. Another comment asks what penalty exists for the supplier of suspect shipments. Another comment requests that FDA provide the owner of the food with information about the threat even if the credible evidence is classified information.

(Response) The Bioterrorism Act allows FDA to detain articles of food for which the agency has credible evidence or information that the food presents a threat of serious adverse health consequences or death to humans or animals. It does not require FDA to determine who is responsible for the threat in order to detain the product. Whether the person responsible for that threat or the person responsible for supplying the suspect article of food may be held liable or subject to criminal prosecution under other statutory provisions is beyond the scope of this rulemaking.

The purpose of any FDA investigation is to determine and document facts concerning a particular issue so that the agency can make informed and sound decisions. FDA cannot rule out the possibility that a hoax could give rise to an administrative detention and, in evaluating the evidence or information to determine whether it is credible, FDA will be mindful of the fact that hoaxes do occur.

In response to the comment that FDA provide the owner of the food with information about the threat even if the credible evidence is classified information, we will provide a statement of the reasons for a detention in the detention order, but we will not divulge classified information to those without the proper security clearance.

(Comment 17) Many comments state that industry is motivated to cooperate with FDA to protect consumers and maintain national security interests in the event of a real threat. They indicate that it is imperative that FDA and industry work together as a team to quickly address such occurrences. These comments state that FDA must devise a clear communications strategy and that the agency should test such plans to make sure that they will work seamlessly.

(Response) These comments are outside the scope of this rulemaking. We agree that it is imperative that FDA and industry work together to protect the U.S. food supply. The agency recognizes the cooperation and effort that the industry has already shown in the area of food safety and security. One such example of industry and FDA partnering to protect the U.S. food supply was in the development of a Food Security Guidance that food producers can use if they choose to improve the protection of their products against tampering or terrorist actions. (See *http://www.cfsan.fda.gov/~dms/fsterr.html*.) FDA also agrees that it is imperative to have clear communication strategies in place and to test such plans to ensure that they will be effective in the event of a bioterrorism or other food-related emergency. We have been developing plans in this area and continue to examine other possible ways to better manage food emergencies and consult with industry on this.

(Comment 18) One comment states that development of reasonable preventative measures and appropriate responses, including rational governmental activities that are effective within every facet of the food system, are critical to protecting public safety. This comment asserts that, to be effective, these measures must be driven by the public and the food industry, not by regulation.

(Response) This comment is outside of the scope of this rulemaking. As stated in FDA's response to the previous comments, the agency recognizes the outside cooperation and effort that have already been shown in the area of food safety and security. However, FDA also believes that it is important for the agency to implement the statutory provisions on food safety and to fulfill its statutory mandates concerning food safety. FDA will provide ongoing opportunities for consumers, industry, state and local governments, and other constituents to keep informed of, and involved in, the agency's activities related to the development of preventative measures and responding to a threatened or actual bioterrorist attack on the U.S. food supply or to other food-related emergencies. Before issuing the proposed rules concerning sections 303, 305, 306, and 307 of the Bioterrorism Act, the agency provided an opportunity for constituents to identify concerns and suggest ways to address them. It is imperative that FDA and its constituents work together to protect the U.S. food supply.

(Comment 19) Some comments assert that the regulation is burdensome, costly, discriminatory, and will have a negative impact on foreign trade. One comment states that this negative impact will likely result in negative ramifications for U.S. food exports because the future may well find retaliatory trade restrictions placed upon U.S. exports as a direct result of the regulatory requirements generated from the Bioterrorism Act.

(Response) In drafting the final rule, FDA structured the rule to be consistent with the statutory mandates of the Bioterrorism Act. FDA carefully considered comments received regarding the burden imposed by this rule, including its impact on international trade.

(Comment 20) Several comments ask that FDA provide clear guidance and training to industry personnel at all levels and agency field personnel about the procedures for implementing the regulation. A few comments suggest that an easy to follow guide for the appeal process would be desirable. A few comments request that FDA establish consultation services at U.S. embassies staffed with speakers of various different foreign languages, such as Japanese and Spanish, and that the Bioterrorism Act and all documents associated with the detention be accompanied by official translations to facilitate comprehension and proper use. The comments suggest that we disseminate the translated material on our Web site and by other means.

(Response) FDA conducted extensive outreach on the proposed administrative detention rule, including attending international and domestic meetings, to ensure that affected parties were aware of the Bioterrorism Act administrative detention requirements.

FDA plans similar future outreach efforts. More specifics regarding our outreach activities will be included on FDA's Web site at *http://www.fda.gov.*

FDA also plans training for its field personnel on the administrative detention procedures.

FDA does not have the resources to establish consultation services at U.S. embassies staffed with speakers of foreign languages, or to provide official translations of all documents associated with a detention and the Bioterrorism Act.

(Comment 21) One comment asks whether the United States has developed biosecurity and sophisticated devices to test and control dangerous biological agents and toxins, including those that present a threat to plants or animals. This comment also asks if the United States has developed new methods to detect contaminated foods, to work with state food safety regulators, and to protect crops and livestock.

(Response) The issues described in these comments are outside the scope of this final rule. However, we are sensitive to these concerns and wish to assure the comments that the agency is doing a number of things to increase our ability to detect the presence of agents that may present a threat to foods for human and animal consumption. We do not believe it is appropriate to discuss these activities in this final rule; however, more information can be obtained on FDA's Web site. (See ''Hot Topics'' on the Web site at: *http://www.fda.gov*.)

(Comment 22) Two comments state that every effort should be made to ensure that information regarding the detention of a product is accurate and publicized only when necessary in an

effort to protect public health. The comments state that such publicity should be transmitted in a clear, unemotional, and factual manner without unduly or inaccurately raising public concern. The comments also indicate that the agency should be aware that if the public is told a product has been detained and it is later found to be nonviolative, the reputation of the company likely will be damaged due to the public perception that the product was somehow unsafe because it had been detained. The comment is concerned that information that a detained product has been released seldom reaches the public. One of these comments states that to minimize these losses, the detention order should become a part of the public record only if FDA determines that the product presents a threat of serious adverse health consequences or death to humans or animals.

(Response) FDA has no plans to routinely publicize the issuance of detention orders. However, in the event of a public health emergency, FDA may issue a Talk Paper or Press Release with information regarding a detained article of food that presents a threat of serious adverse health consequences or death to humans or animals. In such an emergency, FDA may also inform other departments, agencies or governments. In addition, administrative detentions can be precursors to enforcement action in Federal court, particularly seizures, which are public filings in the courts. Information regarding a detention could be included in the complaint for forfeiture. Information regarding administrative detentions also may be released under a Freedom of Information Act (FOIA) request after FDA has removed any information that is protected from disclosure to the public.

(Comment 23) Several comments request clarity concerning which rule will be applied to imports and under what circumstances. These comments indicate that FDA's regulatory framework for imports is more stringent than that applied to domestic products. One of these comments suggests that an administrative detention mechanism that allows FDA to take action against domestic foods that appear to be adulterated or misbranded is needed. Another of these comments indicates that historically, detention orders have not been delivered directly to the owners or importer of record in a timely fashion. This comment further indicates that, because detention orders have historically covered future shipments of the product and included nonrelated growers, FDA should consider removing the time limit to file appeals regarding detention orders.

Another comment argues that the proposed rule would give a competitive advantage to domestic food over imported food because domestic food would be subject only to administrative detention, while imported food would be subject to both administrative detention and ''normal'' import detention.

(Response) The issues concerning how FDA has implemented section 801 of the FD&C Act are outside the scope of this regulation. FDA reiterates that this final rule does not implement section 801 of the FD&C Act, despite its use of the term ''detention.'' This final rule implements section 303 of the Bioterrorism Act, which amends section 304 of the FD&C Act, by adding paragraph (h) to that section.

Section 304(h) of the FD&C Act applies the same standard to domestic and imported food. The criteria for administrative detention under section 304(h) of the FD&C Act are credible evidence or information that an article of food presents a threat of severe adverse health consequences or death to humans or animals. The procedures for administrative detention under section 304(h) of the FD&C Act are described in this rule and will be applied in the same way to both imported and domestic food that is detained administratively under section 304(h).

FDA disagrees that domestic food has a competitive advantage over imported food. FDA investigators and inspectors are authorized under the FD&C Act to inspect domestic food manufacturers, packers, and distributors to determine their compliance with the FD&C Act and its implementing regulations. As part of its vigorous domestic enforcement program, FDA inspects domestic food facilities and collects domestic food product samples for examination by FDA scientists or for label checks. When warranted, judicial enforcement actions are brought against violative articles of food and their manufacturers and distributors.

B. Comments on Foreign Trade Issues

(Comment 24) Some comments question the consistency of the regulation with U.S. obligations under the NAFTA and various WTO agreements.

(Response) FDA is aware of the international trade obligations of the United States and has considered these obligations throughout the rulemaking process for this regulation. FDA believes that these regulations are consistent with these international trade obligations. In addition, and as discussed elsewhere in this preamble, FDA does not foresee frequently using administrative detention under section 304(h) of the FD&C Act to control the movement of imported food subject to section 801 of the FD&C Act.

(Comment 25) Some comments assert that the regulation is burdensome, costly, discriminatory, and will have a negative impact on foreign trade.

(Response) In drafting the final rule, FDA structured the rule to be consistent with the statutory mandates of the Bioterrorism Act and, at the same time, to reduce the costs associated with compliance. FDA carefully considered comments received regarding the burden imposed by this rule, including its impact on international trade.

C. Comments on What Definitions Apply to This Subpart? (Proposed § 1.377)

1. Definition of ''The Act''

(Comment 26) FDA did not receive comments on the definition of ''the act.''

(Response) We did not change the definition in the final rule.

2. Definition of ''Authorized FDA Representative''

(Comment 27) Several comments state that based on the serious nature of administrative detentions, decisions to detain products administratively should be made by an official at the regional FDA director level or higher because of the cost implications and serious business impact such an action would cause. In addition, some comments state that approval at the FDA District Director level allows too much discretion, and that a higher level of approval is necessary to ensure some level of uniformity.

(Response) Permitting approval of an administrative detention at the FDA District Director level is consistent with section 303 of the Bioterrorism Act, which allows such approval at the FDA district level, or above. As required by § 1.391, all detention orders must be approved by an authorized FDA representative. FDA defines authorized FDA representative for the purpose of this final regulation as an FDA District Director in whose district the detained article of food is located or an FDA official senior to such director. For example, an RFDD is an FDA official senior to an FDA District Director.

(Comment 28) A couple of comments state that defining ''qualified employee'' at even the District Director level is problematic because of what the comments characterize as FDA's erroneous decisions in the past regarding ''tainted foods'' (*e.g.*, fish,

fruits, vegetables). They note that these industries have fallen victim to otherwise ''qualified'' federal and state employees who have wrongly accused many commodities of potential contamination.

(Response) Although a comment alleged that FDA has made wrong decisions in the past, they did not identify any particular wrong decision.

FDA is not limiting ''officer or qualified employee'' to the District Director level or higher. The officers or qualified employees of FDA who may order a detention include, but are not limited to, FDA field investigators; FDA employees who have security clearance to receive national security information; and health, food, or drug officers or employees of any State, Territory, or political subdivision thereof, duly commissioned by FDA as officers of the Department under section 702(a) of the FD&C Act (21 U.S.C. 372). Only an authorized FDA representative, however, can approve a detention order. FDA is defining an ''authorized FDA representative'' as an FDA District Director in whose district the detained article of food is located, or an FDA official senior to an FDA District Director. This language is drawn from section 303 of the Bioterrorism Act. Clearly, Congress envisioned that only FDA officials with a given level of seniority would have authority to approve a detention order.

(Comment 29) One comment questions how the owner/carrier will know that FDA's personnel are authorized to detain their product.

(Response) Section 1.391 states that an authorized FDA representative, *i.e.*, the FDA's District Director in whose district the article of food is involved is located or an FDA official senior to such director, must approve the detention order. If prior written approval is not feasible, prior oral approval must be obtained and confirmed in writing as soon as possible. Consequently, all FDA personnel issuing a detention must be authorized in advance to issue the detention order. Under § 1.393(b)(13), the detention order must indicate the manner in which approval of the detention order was obtained, *i.e.*, verbally or in writing.

We have revised the final rule to include § 1.393(b)(14), which requires that the name and title of the authorized FDA representative who approved the detention order be included in the detention order.

Section 1.392(a) of the final rule requires FDA to issue the detention order to the owner, operator, or agent in charge of the place where the article of food is located. If the owner of the article of food is different from the owner, operator, or agent in charge of the place where the article is detained, FDA must provide a copy of the detention order to the owner of the article of food if the owner's identity can be determined readily. Under § 1.392(b), if FDA issues a detention order for an article of food located in a vehicle or other carrier used to transport the detained article of food, we also must provide a copy of the detention order to the shipper of record and the owner and operator of the vehicle or other carrier, if their identities can be determined readily. Thus, the owner and carrier will know from the detention order how the approval was obtained and the name and title of the authorized FDA representative who approved the detention order.

(Comment 30) One comment notes that FDA must employ strict internal procedural requirements for FDA officers and employees and our agents that are involved in determination of potential adulteration or intentional contamination.

(Response) FDA officers, employees, and agents authorized to carry out an administrative detention will be fully trained.

3. Definition of ''Calendar Day''

(Comment 31) FDA did not receive comments on the definition of ''calendar day.''

(Response) We did not change the definition in the final rule.

4. Definition of ''Food''

(Comment 32) A few comments state that alcoholic beverages should not be covered under this provision because they are regulated by the Alcohol and Tobacco Tax and Trade Bureau (TTB), as well as by individual states. One of these comments suggests that FDA should revise the rule to specify that TTB officials are responsible for ordering any administrative detentions of alcoholic beverages. Another comment states that FDA should secure a legislative amendment to the Bioterrorism Act that exempts wines and spirits and other alcoholic beverages under the jurisdiction of TTB from its application, in the same way as meat, poultry, and egg products under the jurisdiction of the U.S. Department of Agriculture (USDA) are excluded from its scope. This comment indicates that the inconsistency does not appear to be founded on any objective criteria such as risk analysis.

(Response) This rule complies with section 315 of the Bioterrorism Act, ''Rule of Construction,'' which states that nothing in Title III of the Bioterrorism Act, or an amendment made by Title III, shall be construed to alter the jurisdiction between USDA and the U.S. Department of Health and Human Services (HHS) under applicable statutes and regulations. Accordingly, this final rule does not apply to food regulated exclusively by USDA under the Federal Meat Inspection Act (21 U.S.C. 601 *et seq.*), the Poultry Products Inspection Act (21 U.S.C. 451 *et seq.*), or the Egg Products Inspection Act (21 U.S.C. 1031 *et seq.*).

Unlike USDA, there are no provisions in section 303 of the Bioterrorism Act that specifically address the jurisdiction of TTB. Under existing law, TTB does not have exclusive jurisdiction over alcoholic beverages. TTB establishes tariffs and licensure requirements, and has primary jurisdiction over the labeling of alcoholic beverages. However, FDA exercises jurisdiction over alcoholic beverages as ''food'' for the purposes of the adulteration and other provisions of the FD&C Act.

FDA recognizes that working in conjunction with TTB and individual states is an important tool we have in the event of a threat to the nation's food supply. However, alcoholic beverages are covered under the administrative detention regulation because alcohol is food, as that term is defined in section 201(f) of the FD&C Act (21 U.S.C. 321(f)). As stated in the proposed rule, and discussed in detail in the following paragraphs, the term ''food'' as used in section 303 of the Bioterrorism Act has the meaning given in section 201(f) of the FD&C Act.

FDA reiterates that, under this final rule, any administrative detention ordered by an officer or qualified employee must be approved by an authorizing official.

Comments suggesting that FDA should request a legislative amendment to the Bioterrorism Act are outside the scope of this rulemaking.

(Comment 33) A few comments state that indirect food additives, such as color pigments for packaging, packaging polymers, and coatings should be exempt from coverage under section 303 of the Bioterrorism Act because, by definition as a food additive, the manufacturer must demonstrate under FDA's food additive regulations that they are safe and stable. One comment suggests that we exempt raw materials and formulated products that are used as components in the manufacture of food contact articles, such as conveyor belts, oven gaskets, coatings for film, paper, and metal substrates, adhesives, antifoam agents, antioxidants, polymeric resins, polymer emulsions, colorants for polymers, rubber articles,

release coatings, and the like. Another comment suggests that tableware, including ceramic and lead crystal, also should be exempt from coverage under this provision of the Bioterrorism Act because Congress did not intend such a broad scope. This comment states that contaminated food products present an immediate risk to public health, whereas adulterated food contact articles present a risk only once they have contact with food, and only if the poisonous or deleterious substance actually migrates into the food. The comment further states that the lack of immediacy means that there is a significant potential for intervening actions; for example, washing purchased tableware items before using them for the first time to reduce or eliminate any risks posed by a bioterrorist act aimed at food contact articles.

Two comments state the belief that live food animals, pet food, and animal feed, including fertilizers that end up in animal feed, should not be covered by this rule because Congress did not intend such a broad scope. Another comment states that any material that might end up in food, but that has nonfood uses, should be exempt from coverage under section 303 of the Bioterrorism Act unless the manufacturer knows the material will be consumed in the United States as food. One comment states that food that will be used in trade shows should be exempt from coverage under this provision because the trade shows have their own self-regulation and because FDA could visit the trade shows and easily inspect the products. Another comment states that technical samples of food, *e.g.* less than 100 grams (g) of a product, should be exempt from coverage under this rule.

(Response) FDA disagrees with these comments and is finalizing the definition of ''food'' as proposed. FDA is not excluding food contact materials, live animals, alcoholic beverages, or other articles of food from coverage under this regulation.

These comments raise the question of what Congress intended ''food'' to mean for purposes of administrative detention. In construing the administrative detention provision of the Bioterrorism Act, FDA is confronted with two questions. First, has Congress directly spoken to the precise question presented (''*Chevron* step one'') *Chevron, U.S.A., Inc.* v. *NRDC, Inc.,* 467 U.S. 837, 842 (1984). To find no ambiguity, Congress must have focused directly on the question presented and have articulated clearly its intention. *Young* v. *Community Nutrition Institute,* 476 U.S. 974, 980 (1986). If Congress has spoken directly and plainly, the agency must implement Congress's unambiguously expressed intent. *Chevron,* 467 U.S. at 842–843. If, however, the Bioterrorism Act is silent or ambiguous as to the meaning of ''food,'' FDA may define ''food'' in a reasonable fashion (''*Chevron* step two''). *Chevron,* 467 U.S. at 842–843; *FDA* v. *Brown & Williamson Tobacco Corp.,* 529 U.S. 120, 132 (2000).

The agency has determined that, in enacting section 303, Congress did not speak directly and precisely to the meaning of ''food.'' As noted, the FD&C Act has a definition of ''food'' in section 201(f) of the FD&C Act. It is a reasonable assumption that, when the term ''food'' is used in the FD&C Act, section 201(f) applies. However, although there may be ''a natural presumption that identical words used in different parts of the same act are intended to have the same meaning [citation omitted], * * * the presumption is not rigid. * * *'' *Atlantic Cleaners & Dyers, Inc.* v. *U.S.,* 286 U.S. 427, 433 (1932). *Accord: U.S.* v. *Cleveland Indians Baseball Co.,* 532 U.S. 200, 213 (2000). Thus, the same word may be given different meanings, even in the same statute, if different interpretations are what Congress intended. (*Atlantic Cleaners & Dryers, Inc., supra.*)

Even before the Bioterrorism Act amendments, the term ''food'' was not given an identical meaning throughout the FD&C Act. For example, in construing the parenthetical ''(other than food)'' in section 201(g)(1)(C) of the FD&C Act, the Seventh Circuit noted that Congress meant to exclude only ''articles used by people in the ordinary way that most people use food—primarily for taste, aroma, or nutritive value'' and not all substances defined as food by section 201(f) of the FD&C Act. *Nutrilab, Inc.* v. *Schweiker,* 713 F.2d 335, 338 (7th Cir. 1983). Similarly, section 409(h)(6) of the FD&C Act (21 U.S.C. 348(h)(6) defines a food contact substance as ''any substance intended for use as a component of materials used in manufacturing, packing, packaging, transporting, or holding food if such use is not intended to have any technical effect in such food (emphasis added).'' This definition makes sense only if ''food'' in that section is interpreted to exclude materials that contact food because components of food contact materials are plainly intended to have a technical effect in such materials.[1]

Thus, in this larger statutory context, FDA has evaluated section 303 of the Bioterrorism Act to determine whether the meaning of the word ''food'' is ambiguous. In conducting this *Chevron* step one analysis, all of the traditional tools of statutory interpretation are available to determine whether Congress's intent is ambiguous. *Pharmaceutical Research & Manufacturers of America* v. *Thompson,* 251 F. 3d 219, 224 (D.C. Cir. 2001). Beginning with the language of the statute, in section 303 of the Bioterrorism Act, ''food'' is used to describe which subset of FDA-regulated articles are subject to administrative detention: An officer or qualified employee of the Food and Drug Administration may order the detention, in accordance with this section, of any article of food that is found during an inspection, examination, or investigation under the Bioterrorism Act conducted by such officer or qualified employee, if the officer or qualified employee has credible evidence or information indicating that such article presents a threat of serious adverse health consequences or death to humans or animals (emphasis added).

The Bioterrorism Act is silent as to the meaning of ''food.'' Congress did not specify whether it intended the definition in section 201(f) of the FD&C Act to apply, one of the other possibilities noted previously, or another meaning. Where, as here, the statutory language on its face does not clearly establish Congressional intent, it is appropriate to consider not only the particular statutory language at issue, but also the language and design of the statute as a whole. *Martini* v. *Federal Nat'l Mortgage Association,* 178 F. 3d 1336, 1345 (D.C. Cir. 1999), citing *K Mart Corp.* v. *Cartier, Inc.,* 486 U.S. 281 (1988). Indeed, the analysis should not be confined to the specific provision in isolation, because the meaning or ambiguity of a term may be evident only when considered in a larger context. *FDA* v. *Brown & Williamson Tobacco Corp., supra* at 132 (2000).

FDA has considered other sections of the Bioterrorism Act and has concluded that the meaning of ''food'' in the Bioterrorism Act is ambiguous. FDA previously considered the meaning of

[1] FDA's long-standing interpretation of the act's definition of color additive, section 201(t) of the FD&C Act (21 U.S.C. 201(t)), is an additional example of where ''food'' is used more narrowly than as defined in section 201(f). A color additive is defined in section 201(t) of the FD&C Act as a substance that ''when applied to a food * * * is capable * * * of imparting color thereto * * *'' The agency's food additive regulations distinguish between color additives and ''colorants,'' the latter being used to impart color to a food-contact material. (21 CFR 178.3297(a), see also 21 CFR 70.3 (f).) Thus, ''food'' as it appears in the statutory definition of color additive, necessarily excludes food contact materials.

''food'' in section 305 of the Bioterrorism Act, governing registration of food facilities, and concluded that it is ambiguous (68 FR 58894). Section 305 of the Bioterrorism Act amends the FD&C Act by adding section 415 to that act. In section 415(a)(1) of the FD&C Act, the word ''food'' is modified by the phrase ''for consumption in the United States.'' It's not clear whether this modifying phrase limits the definition of ''food'' to food that is ingested—a narrower definition of ''food'' than that in section 201(f) of the FD&C Act. In addition, the definition of ''facility'' in section 415(b)(1) of the FD&C Act exempts ''farms; restaurants; other retail establishments.'' It's not clear whether the phrase ''other retail establishments'' includes retailers of food contact materials; the legislative history indicates that it does not, thereby giving rise to additional ambiguity about which definition of ''food'' applies to section 415 of the FD&C Act.

FDA also considered the meaning of ''food'' in section 307 of the Bioterrorism Act, governing prior notice of imported food shipments, and concluded that it is ambiguous (68 FR 58974). Section 307 of the Bioterrorism Act amends the FD&C Act by adding section 801(m) to that act. Section 801(m) of the FD&C Act refers to an ''article of food.'' However, the legislative history of section 307 of the Bioterrorism Act indicates that packaging materials are not subject to section 307, and can be read to imply that Congress was not relying on the definition of food in section 201(f) of the FD&C Act, thereby giving rise to ambiguity about which definition of ''food'' applies to section 307 of the Bioterrorism Act.

Finally, FDA considered the meaning of ''food'' in developing a final rule to implement section 306 of the Bioterrorism Act, governing maintenance and inspection of records for foods, which will be published in this issue of the **Federal Register** in the near future. ''. . . which will be published in the **Federal Register** in the near future. Section 306 of the Bioterrorism Act amends the FD&C Act by adding section 414 to that act. Section 414(a) of the FD&C Act, which covers inspection of records, refers to ''an article of food,'' and ''food.'' But section 414(b) of the FD&C Act, which covers establishment and maintenance of records, refers to ''food, including its packaging.'' Elsewhere in the record provisions, section 414 of the FD&C Act refers to ''food safety,'' ''a food to the extent it is within the exclusive jurisdiction of [USDA],'' and ''recipes for food.'' There is, thus, ambiguity about which definition of ''food'' applies to section 306 of the Bioterrorism Act.

The ambiguity surrounding Congress's use of ''food'' in sections 303, 305, 306, and 307 of the Bioterrorism Act, coupled with the lack of a definition of the term in that act, support a conclusion that the meaning of ''food'' in the Bioterrorism Act is ambiguous.

Having concluded that the meaning of ''food'' in the Bioterrorism Act and in section 303 of that act is ambiguous, FDA has considered how to define the term to achieve a ''permissible construction'' of the administrative detention provision. *Chevron, USA, Inc.* v. *NRDC, Inc., supra* at 843. In conducting this *Chevron* step two analysis, the agency has considered the same information evaluated at step one of the analysis. *Bell Atlantic Telephone Co.* v. *FCC,* 131 F. 3d 1044, 1049 (D.C. Cir. 1997); *Chevron U.S.A., Inc.* v. *FERC,* 193 F. Supp. 2d 54, 68 (D.D.C. 2002). FDA has determined that it is permissible, for purposes of the administrative detention provision, to use the definition of ''food'' in section 201(f) of the FD&C Act.[2]

Use of the definition of food in section 201(f) of the FD&C Act is consistent with the language of section 303 of the Bioterrorism Act. Section 303 of the Bioterrorism Act repeatedly uses the term ''food'' without adjectives. There is only one instance in which section 303 uses an adjective with the term ''food,'' and that is in section 304(h)(2) of the FD&C Act, which directs the Secretary to provide for procedures for instituting certain judicial enforcement actions on an expedited basis with respect to ''perishable foods.'' Use of the adjective ''perishable'' in this context does not limit the reach of section 303 of the Bioterrorism Act to a subset of ''food'' as defined in section 201(f) of the FD&C Act. Rather, the adjective ''perishable'' serves to distinguish perishable from nonperishable food for purposes of deciding what type of food is subject to the procedures mandated by section 304(h)(2) of the FD&C Act. Nonperishable food, though not necessarily subject to the procedures mandated by section 304(h)(2) of the FD&C Act, is nonetheless subject to administrative detention.

Use of the definition of ''food'' in section 201(f) of the FD&C Act is also consistent with the fact the judicial enforcement actions that may be instituted under administrative detention have been consistently interpreted to use that same definition. Section 304(a)(1) of the FD&C Act authorizes seizure of any ''article of food'' that is adulterated or misbranded under specified conditions. In applying section 304(a)(1) of the FD&C Act, FDA and the federal courts use the definition of ''food'' in section 201(f) of the FD&C Act. *See, e.g., Natick Paperboard Corp.* v. *Weinberger,* 525 F.2d 1103 (1st Cir. 1975); *U.S. v. An Article of Food*, 752 F.2d 11 (1st Cir. 1985). Section 302 of the FD&C Act authorizes injunction to restrain violation of certain provisions of section 301 of that act, which repeatedly uses the term ''food.'' In applying section 302 of the FD&C Act (21 U.S.C. 332), FDA and the federal courts use the definition of ''food'' in section 201(f) of the FD&C Act. *See, e.g., U.S.* v. *Blue Ribbon Smoked Fish, Inc.,* 179 F.Supp.2d 30 (E.D.N.Y. 2001).

FDA is therefore retaining its interpretation of ''food'' in section 303 of the Bioterrorism Act to mean ''food'' as defined in section 201(f) of the FD&C Act. Food subject to section 303 of the Bioterrorism Act thus includes, but is 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 (such as hogs and elk), bakery goods, snack foods, candy, and canned foods.[3]

The standard for administrative detention-credible evidence or information indicating that an article of food presents a threat of serious adverse health consequences or death to humans or animals is a high threshold. Where this threshold is met for any article of food, it is appropriate for FDA to use the full authority provided by the Bioterrorism Act and thereby protect public health to the fullest extent possible.

[2] Alternatively, it may be argued that the meaning of ''food'' in section 303 of the Bioterrorism Act is not ambiguous, and that the *Chevron* analysis stops at step one. Under either approach, the definition of ''food'' in section 201(f) of the FD&C Act applies to section 303 of the Bioterrorism Act.

[3] The agency notes that the scope of the definition of ''food'' in the regulations implementing section 303 of the Bioterrorism Act (administrative detention) is broader than the scope of the definition of ''food'' in the regulations implementing sections 305 (registration) and 307 (prior notice) (68 FR 58894, October 10, 2003, and 68 FR 58974, respectively).

5. Definition of ''Perishable Food''

(Comment 34) FDA sought comments and supporting data on how to best define ''perishable food'' for purposes of this rule. Several comments state that the definition for ''perishable food'' should be revised to mean foods with a shelf life of 90 days from the date of packaging, including products that are thermally processed or treated to extend the shelf life to 90 days from the date of packaging. Another comment states that FDA should use the definitions in the National Institute of Standards and Technology (NIST) handbook, which are: Perishable, 60-day shelf life from date of packaging; semiperishable, 60 days to 6 months shelf life from the date of packaging; and long shelf life, greater than 6 months shelf life from the date of packaging. Yet another comment suggests that we use the definition for perishable foods as it is described in the Perishable Commodities Act. One comment states that live animals should be considered perishable food items because they must be fed, watered, and possibly medicated to stay alive. That comment asks who will be responsible for feeding, watering, and medicating the animals if they are detained. A few comments state that the definitions should consider loss of marketability, and not just loss of physical and biological properties. These comments indicate that many products have optimum release dates, such as seasonal items (Valentine's candy), special release items (wines), and strict stock rotational items (snack foods, baked goods, and tortillas) that would quickly lose their marketability. Many comments suggest that the definition for ''perishable food'' should be revised to include foods that have 120 days of shelf life because products with older ''sell by'' dates lose their marketability. One comment asks whether products in bulk form that are intended for further processing and have a short shelf life are covered under the definition of ''perishable food.''

(Response) FDA disagrees with these comments and is finalizing the proposed definition for ''perishable food'' without any revisions. The context in which the term ''perishable food'' appears in section 303 of the Bioterrorism Act indicates that, at least with respect to administrative detention, Congress was concerned with articles of food that would spoil relatively quickly. It is unlikely that Congress would have mandated expedited procedures for instituting certain enforcement actions against foods that have a shelf life of up to 90 days, given that the statute only allows FDA to detain foods for a maximum of 30 days while it seeks to initiate certain judicial enforcement actions.

The definition of ''perishable food'' in this final rule has been modeled after the current Regulatory Procedures Manual (RPM) definition of ''perishable commodity.'' We decided to use the RPM definition of ''perishable commodity'' as the basis for the definition of ''perishable food'' because the RPM definition is commonly used and understood by both industry and FDA. Furthermore, we believe this definition is appropriate in light of the 5-calendar day (maximum) deadline for FDA to issue a decision on an appeal of a detention order. Under the deadline for appeals involving the detention of a perishable food, FDA would issue a decision on an appeal before the expiration of the 7-calendar day period. FDA believes that this timeframe offers the best protection to appellants and products. FDA notes that a claimant for any nonperishable detained product may file for an appeal within the first 2 calendar days after receipt of a detention order, similar to the procedures set forth in § 1.402(a)(1) for perishable foods.

FDA will determine the conditions for holding detained food, including live animals, on a case-by-case basis based upon the totality of information available to us about the article of food. If necessary, FDA may consult with the owner of the food, if readily known, about appropriate storage conditions. The business arrangements for storing detained food, including live animals, are a private matter between the recipient of the detention order and the facility where the food will be stored. The recipient of the detention order is responsible for making these arrangements.

6. Definition of ''We''

(Comment 35) FDA did not receive comments on the definition of ''we.''

(Response) We did not change the definition in the final rule.

7. Definition of ''Working Day''

(Comment 36) FDA did not receive comments on the definition of ''working day.''

(Response) We did not change the definition in the final rule.

8. Definition of ''You''

(Comment 37) FDA did not receive comments on the definition of ''you.''

(Response) We did not change the definition in the final rule.

D. Comments on What Criteria Does FDA Use To Order a Detention? (Proposed § 1.378)

(Comment 38) One comment agrees that FDA should not define the term ''credible evidence or information'' and should evaluate such decisions on a case-by-case basis, given that a bioterrorism event may arise in an unanticipated scenario. This comment agrees that FDA should not bind its discretion by identifying the types of evidence that it ultimately may need to rely upon to support a detention order.

The majority of comments request that FDA define by regulation or guidance clear evidentiary standards and procedures for the determination of ''credible evidence or information.'' These comments state that the term should be defined to ensure that the Bioterrorism Act is not interpreted more broadly than Congress intended and to ensure that affected persons have some protection against arbitrary or unsupported detentions. A few comments state that as long as the factors on which a detention decision is based are not known, there is no possibility to assess and evaluate the legitimacy of the decision. These comments request that FDA publish guidance on how the credible evidence or information standard will be documented (*e.g.*, name all sources of information that may be considered ''reliable,'' describe the requirements with respect to accuracy of the information, etc.). Another comment suggests that guidance should indicate the authorities that FDA might rely upon to determine whether information it receives is credible, such as health authorities (*i.e.*, Centers for Disease Control and Prevention), law enforcement authorities (*i.e.*, Federal Bureau of Investigation), or other appropriate authorities (*i.e.*, Department of Homeland Security). A few comments state that ''credible evidence/information'' should be similar to a ''probable cause'' standard and more than mere speculation or an anonymous telephone tip.

One comment states that, because administrative detention authority also is triggered in the context of FDA inspection and sampling authorities, the agency should ensure that the evidentiary standards and procedures adopted satisfy applicable Fourth Amendment and other constitutional requirements. In particular, the comment urges the agency to examine the ''credible evidence'' standard with reference to Fourth Amendment and related evidentiary standards developed in case law, and not to rely on a

superficial reading of the Bioterrorism Act or a plain language interpretation drawn from Webster's Dictionary. The comment states that the ''public health triggers'' defining FDA authority under the Bioterrorism Act are critically important jurisdictional provisions, which authorize extraordinary intrusions and control over private commercial property, including products subject to administrative detention.

(Response) FDA has considered these comments, and we have decided to maintain our decision not to define the term ''credible evidence or information.'' The decision to not define credible evidence or information reflects how the credible evidence or information standard has been applied in various other judicial and administrative contexts, and the need to maintain flexibility, given the range of circumstances in which articles of food might be detained under the administrative detention authority. The ''credible evidence or information'' standard requires fact-specific inquiries for which maximum interpretive discretion should be maintained. FDA intends to apply the credible evidence standard consistent with the terms of that standard and with applicable Fourth Amendment principles and case law.

(Comment 39) One comment states that administrative detention is triggered by two undefined criteria: The first is ''credible evidence or information,'' and the second is ''serious adverse health consequences or death to humans or animals.'' Many comments express concern that if these standards are not defined, detention decisions would be subjective, discriminatory and void of objective, scientific grounds. The comments argue that the question of the role of the application of the ''precautionary principle'' likewise arises.

(Response) The comment expressing concern about the application of the ''precautionary principle'' did not explain what they meant by their use of the term in the context of this rule. The standard for administrative detention as set out in the Bioterrorism Act is whether credible evidence or information exists indicating that an article of food presents a threat of serious adverse health consequences or death to humans or animals. This is the standard that we must apply. FDA intends to define ''serious adverse health consequences'' in a separate rulemaking. We will not define ''credible evidence or information'' for reasons set forth in our prior response to a similar comment.

(Comment 40) A few comments state that FDA should have clear evidence, such as laboratory analysis, to confirm the presence of an adulterant, and/or affidavits sworn under penalty of perjury. Several comments ask that FDA use internationally recognized methods for laboratory analyses, as well as internationally recognized standards such as Codex Alimentarius, an international food code, and provide countersamples to the owner of the article of food. One comment requests that FDA require that sampling and diagnostic testing (to confirm or deny suspicions of food tampering) be initiated within 24 hours of the date the detention order is issued.

(Response) FDA disagrees with these comments. Given the range of circumstances in which articles of food may be detained under the administrative detention authority, the agency needs to maintain flexibility to respond appropriately on a case-by-case basis. The ''credible evidence or information'' standard requires fact-specific inquiries for which maximum interpretive discretion should be maintained. FDA intends to apply the credible evidence standard consistent with the terms of that standard and with applicable constitutional principles and case law.

With respect to providing what some comments refer to as countersamples, section 702(b) of the FD&C Act describes FDA's responsibility to provide a part of an official sample of food to certain individuals, when a sample is collected for analysis under the FD&C Act. Section 702(b) of the FD&C Act requires the Secretary to, upon request, provide a part of such official sample for examination or analysis by any person named on the label of the article, or the owner thereof, or his attorney or agent; except that the Secretary is authorized, by regulations, to make such reasonable exceptions from, and impose such reasonable terms and conditions relating to, the operation of this section as he finds necessary for the proper administration of the provisions of this act. Exceptions from this section are set forth in 21 CFR 2.10.

(Comment 41) One comment suggests that credible evidence or information be directly related to a serious health consequence. Another comment is concerned whether the evidence for suspicion will be corroborated before an order for detention is made, or whether such an order would be made on a totally discretionary/subjective basis.

(Response) The Bioterrorism Act authorizes FDA to order an administrative detention only when an officer or qualified employee of FDA has credible evidence or information indicating that such article presents a threat of serious adverse health consequences or death to humans or animals. Consequently, serious adverse health consequences or death is an element of the standard FDA will apply in ordering that an article of food be detained. In evaluating whether credible evidence or information exists for purposes of administrative detention, FDA may 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.

(Comment 42) A few comments recommend issuing guidance with a list of criteria that define ''serious adverse health consequences'' because an illustrative list from FDA will ensure that excess (or unnecessary) detentions do not occur.

A few comments state that indications should be given to limit the scope of implementation of the law. These comments specifically request that interpretation of serious adverse health consequences should be based on the risk to a large part of the population, as opposed to merely a few individuals. These comments state that in situations where the risk associated with a food product only affects a very limited group of people, detention would not be the appropriate action to take. Furthermore, they state that the health consequences must be severe to the average person to justify a detention.

(Response) FDA agrees with the comments that the agency should define the term, ''serious adverse health consequences'' and intends to define the term in a separate rulemaking. The agency is developing a separate rule because the term is used in several provisions in Title III of the Bioterrorism Act, not just in section 303. FDA believes that defining ''serious adverse health consequences'' will promote uniformity and consistency across the agency in the understanding of this term and in the actions taken, as well as inform the public of what FDA considers a ''serious adverse health consequence.''

(Comment 43) One comment states that non-FDA employees from other agencies or states commissioned or deputized by FDA should not be considered officers or qualified employees of FDA for purposes of administrative detention.

(Response) Section 303 of the Bioterrorism Act provides that an officer or qualified employee of FDA may order a detention of a food found during an inspection, examination, or investigation under the FD&C Act. FDA

agrees that, under existing law, employees of other Federal agencies cannot be considered officers or qualified employees of FDA for purposes of ordering an administrative detention. The same cannot be said of State employees commissioned by FDA as officers of the Department. Section 702(a) of the FD&C Act authorizes the Secretary to conduct examinations and investigations for purposes of the FD&C Act, through officers and employees of the Department, or through health, food, or drug officers or employees of any State, Territory, or political subdivision thereof, duly commissioned as officers of the Department. Because they are ''officers'' of the Department, FDA believes that such State and local officers or employees have authority to order an administrative detention under section 303 of the Bioterrorism Act. FDA reiterates that under this final rule, any administrative detention ordered by an officer or qualified employee must be approved by an authorizing official.

(Comment 44) One comment states that ''qualified employee'' must be limited to those in FDA who, in their day-to-day job responsibilities, conduct food inspections, examinations and investigations.

(Response) Consistent with section 303 of the Bioterrorism Act, § 1.378 provides that an officer or qualified employee of FDA may order the detention of any article of food that is found during an inspection, examination, or investigation under the FD&C Act if the officer or qualified employee has credible evidence or information indicating that such article of food presents a threat of serious adverse health consequences or death to humans or animals. Consequently, any FDA employees, or State or local officers or employees commissioned by FDA as officers of the Department, may order a detention as part of their function of inspecting, examining or investigating an article of food. FDA does not believe the limitation proposed by the comment is necessary. Section 1.391 requires any detention to be approved by the FDA District Director in whose district the article of food is located or an FDA official senior to such director.

E. Comments on How Long May FDA Detain an Article of Food? (Proposed § 1.379)

(Comment 45) Many comments state that FDA should be required to limit the detention period to that period that is absolutely minimally necessary to undertake an investigation into the possible threat that underlies the detention order. These comments further state that the extension of time up to 30 calendar days must not be by a ''block'' of 10 calendar days, but rather a possible extension of up to 10 extra calendar days. One comment states that they agree that an article may be detained for an additional 10 calendar days; however, they want the reason for the extension to be limited to certain conditions, such as waiting for test results. This comment also states that the company should be immediately informed of any additional time requirement, the reason for the additional time, and the actual time period that will be required (up to 10 calendar days).

One comment proposes that the only reason a detention should be extended from 20 to 30 calendar days is to take legal action in a civil suit. A few comments state that the extension of the detention period should not be considered justified or ''necessary'' if the reason for the extension is because the testing of the affected product had not been conducted expeditiously, or that it could have been completed within the 20-calendar day period had it been accorded appropriate priority. One comment asks how FDA is going to notify the owner of the article of food if the detention period is extended beyond the initial 20 calendar days. Another comment states that there is no indication of the criteria used to determine the ''reasonableness'' of the detention period.

(Response) As FDA stated earlier, we intend to proceed as expeditiously as possible to resolve all issues involved with administrative detentions. However, FDA disagrees with the comments that want to preclude FDA from extending a detention in a ''block'' of 10 calendar days. It is not the best use of the agency's resources to grant extensions of the detention period in small increments, *e.g.* 1 day at a time. Moreover, the fact that a detention is extended for a ''block'' of 10 calendar days does not mean that an article will always be detained 10 additional calendar days; just as FDA may terminate a detention order on any day during the period initially specified in the detention order, FDA may terminate the detention on any one of the 10 calendar days covered by the extension. FDA has authority to extend a detention for 10 calendar days as necessary to enable the agency to institute a seizure or injunction action. Because the development of a seizure or injunction action is fact-specific, FDA will not always be able to specify, at the time of the extension, the precise steps that remain. Indeed, Congress made clear that a maximum detention period of 20 or 30 calendar days is reasonable when Congress included these detention timeframes in the Bioterrorism Act. Any extension of the length of a detention period to 30 calendar days requires the agency to prepare a new detention order and, if applicable, to place new tags or labels on the detained article of food to indicate the change in the detention dates.

In addition, FDA notes that under § 1.379(a), FDA can order detention of the article of food for 30 calendar days in the original detention order, if we know from the outset that 30 calendar days rather than 20 calendar days will be needed to institute a seizure or injunction against the detained article of food.

(Comment 46) Several comments suggest that the maximum length of time for a detention should be shortened, *e.g.*, to 15 calendar days, 10 calendar days, or 7 calendar days, and for perishable food, to 24 hours, because of the impact a detention can have on the normal flow of trade. A few comments suggest that fresh fruit should be kept in detention for only a few hours. A few other comments state that the maximum period of detention should be in accordance with the type of product to minimize costs for the exporters.

(Response) FDA disagrees with these comments because it is not appropriate to limit the authority and flexibility that Congress intended FDA to have under section 303 of the Bioterrorism Act, which authorizes FDA to detain an article of food that presents a threat of serious adverse health consequences or death to humans or animals for 20 calendar days, unless a greater period, not to exceed by 30 calendar days, is necessary to institute a seizure or injunction action. However, FDA intends to act as expeditiously as possible on all detentions. Detentions of perishable foods are subject to the shortened timeframes for filing an appeal and convening a hearing in § 1.402(a)(1) and (d), respectively, to process these detentions as quickly as possible. These shortened timeframes require both FDA and affected parties to move expeditiously.

(Comment 47) A few comments state that the availability of FDA resources and staff shortages should not be a justification for FDA's failure to act quickly on administrative detentions. Another comment states that any sampling and testing conducted with respect to a detention order should be given top priority at the appropriate FDA laboratory (or FDA contract laboratory) to expedite the process, such that the need for an additional 10

calendar days can be eliminated or shortened to less than 10 calendar days.

(Response) As we stated previously, FDA intends to proceed as expeditiously as possible to resolve all issues involved with administrative detentions. FDA agrees that any investigation and sampling of articles of food associated with an administrative detention should be given high priority.

1. Comments on Where and Under What Conditions Must the Detained Article of Food Be Held? (Proposed § 1.380)

FDA received many comments on this section III.E.1 of the rule. To clarify the resolution of the issues raised in the comments, we grouped the comments into topic areas that reflect the paragraphs in § 1.380.

As noted previously, the term ''limited conditional release,'' which was used in proposed rule, has been replaced by the term ''modification of a detention order'' in this final rule. Therefore, our responses to the comments that discuss a ''limited conditional release'' refer instead to a ''modification of a detention order.''

- Hold the detained article of food in the location and under the conditions specified by FDA in the detention order (proposed § 1.380(a)).

(Comment 48) One comment asks how FDA will determine the conditions under which detained food will be kept and how we will notify the owner. A few comments recommend that FDA should develop procedures for administrative detention of perishable foods that include a process for asking from the owners of such foods information as to the best storage methods to ensure the salvage of such foods. Another comment indicates that the rule should include a provision to allow, at the request of the owner, operator, or agent in charge, the freezing of detained ''fresh'' product that is (or will likely be) detained for 4 or more calendar days. One comment indicates that the Bioterrorism Act provides FDA with the authority to direct articles of food to be moved to a secure facility and, if necessary, to be moved from refrigerated storage to a freezer (§ 1.381), but that such an action is usually not neutral for the quality and integrity of the food, given that frozen food may then no longer be marketed as ''fresh'' food. The comments state that this action will change the intrinsic nature of the food.

(Response) FDA will determine the conditions for holding detained food on a case-by-case basis based on the totality of information available to us about the article of food. For example, if the food item is simply labeled ''Keep Refrigerated,'' with no additional information in the shipping documents, we are likely to specify that the food be stored under refrigerated conditions that comply with appropriate temperature recommendations (*e.g.*, recommended refrigeration temperatures for food in retail establishments listed in FDA's Model Food Code or common commercial practices). On the other hand, if the shipping documents specify that a specific refrigeration temperature must be maintained, we are likely to order that the food be stored at the temperature specified by the shipper. As stated in § 1.393(b)(7), the detention order will describe the appropriate storage conditions, *e.g.*, storage temperature. If necessary, FDA may consult with the owner of the food, if readily known, about appropriate storage conditions.

FDA advises that the removal of a detained article of ''fresh'' food from refrigerated storage to a freezer is an appropriate basis upon which the person who received the detention order, or that person's representative, may seek modification of the detention order of the detained food. However, FDA is unlikely to order a fresh food to be moved from refrigerated storage to a freezer, unless the owner, or that person's representative, advises us that such a move is appropriate. Section 1.381(c)(3) allows for a request to modify a detention order for this purpose, inasmuch as it provides that the request may be ''to maintain or preserve the integrity or quality of the article of food * * *''. Consequently, FDA does not believe a revision in the rule is needed.

(Comment 49) A few comments state that FDA should, upon request of the owner, provide the records of the storage conditions maintained during detention. Several comments state that if the storage conditions indicated in the detention order are not complied with during detention, causing loss of quality, there must be an opportunity to submit a claim to FDA for reimbursement. These comments suggest that FDA should include an appeal structure in the rules and create a fund for this purpose.

(Response) As we stated previously, the business arrangements for storing detained food are a private matter between the recipient of the detention order and the facility where the food will be stored. The recipient of the detention order is responsible for these arrangements, including matters concerning records to document that the specified storage conditions were maintained throughout the detention period. Neither the FD&C Act nor the Bioterrorism Act includes a provision for FDA compensating affected parties for any losses.

(Comment 50) Several comments address concerns about food being subject to administrative detention aboard a conveyance, *i.e.*, ships, trucks and railcars. These comments urge FDA to revise the regulation to require that when FDA issues an administrative detention order and the food is on a ship, truck, or railcar, FDA also must issue an order to the transporter to deliver the food to either the consignee or to a secure location, as determined by FDA officials. The comments further state that the order should specify that the person with the legal title to the food (*i.e.*, the shipper, the consignee, or a food broker), should bear the cost to store the detained food. Some comments state that the detention order should include provisions for the immediate removal to secure storage of a food that is detained administratively aboard a conveyance. One comment suggests that we define and make available for public comment the conditions that we believe would warrant transporting administratively detained food to secure storage facilities. Others state that the bases upon which a claimant may seek a limited conditional release should explicitly include the removal of a product from a conveyance to secure storage.

Another comment states that detaining food in place on a ship will affect the ship's schedule, causing deliveries of other cargoes to be delayed, which could cause plant shutdowns for lack of product. This comment also states that discharging a suspect cargo ashore into storage tanks would allow the cargo to be tested while under government supervision, which would provide the most cost effective solution while providing for security concerns.

(Response) FDA understands that detention of food aboard a conveyance may impact other activities of commerce that are dependent upon the ongoing operation of the conveyance. FDA will consult with CBP concerning the movement of food detained administratively aboard a conveyance to limit the impact on the flow of trade. However, we disagree with the suggestion that we should revise the regulation to obligate FDA to issue an order to the transporter to deliver the food to a specified destination at the expense of the person with the legal title to the food. We believe that the determination of whether we should order the food to 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 administrative detention. Based on our historical use of administrative detention with medical devices, we believe that we would detain food on a conveyance only under rare circumstances. It is more likely that we will allow the detained food to be removed from the conveyance to a storage facility.

FDA also disagrees with the suggestion that we specify in the detention order that a third party (*e.g.*, the shipper, consignee, or food broker) bear the cost of the transport of the food to secure storage. The business arrangements for storing detained food are a private matter between the recipient of the detention order and the facility where the food will be stored. The recipient of the detention order is responsible for making these arrangements.

With regard to the transporter's concerns that the detention of food aboard a conveyance has the potential to impact other activities of commerce that are dependent upon the ongoing operation of the ship, truck, or railcar, FDA advises that a transporter may seek modification of a detention order in order to remove a detained food from a conveyance to a storage facility. In § 1.381(c)(4), allows the transporter to request modification of a detention order for this purpose, inasmuch as it provides that the request may be ''for any other purpose that the authorized FDA representative believes is appropriate * * *.'' Accordingly, FDA does not believe a revision to § 1.381(c)(4) is warranted. However, FDA also advises that, although the regulations allow a transporter to request modification of a detention order to move the food from a conveyance to a storage facility, we will evaluate any such request on a case-by-case basis, considering all of the factors relevant to the specific case, such as whether the storage facility identified in the request can provide the necessary level of security for the food.

(Comment 51) One comment states that the proposed rule does not adequately address the case in which pet food products are detained administratively with shipments that may contain suspect food. The comment further states that the resulting delay could result in great loss to firms who plan to exhibit the detained products at a trade show.

(Response) If articles of detained food are part of a shipment containing food that is not subject to the detention order, the articles of food that are not subject to the detention order and can be readily segregated, can be so segregated and moved.

(Comment 52) One comment states that the detention process itself could increase the risk of intentional contamination of food because food, which normally moves quickly from farm to table, would be more vulnerable to attack when held for periods of time in storage or on a truck. The comment expresses concern about attacks on food under detention occurring in unguarded storerooms and garage sheds. Several comments ask that the detention be done where the merchandise is dispositioned to avoid the increase of the storage costs and the risk of robbery or damage of the merchandise. Another comment asks whether an article of food that is subject to a detention order must always be moved to a secure location.

(Response) The purpose of administrative detention is to help ensure that food for which the agency has credible evidence or information that the food presents a threat of serious adverse health consequences or death to humans or animals does not move in commerce, and to help ensure that such food is not distributed before the agency can initiate judicial enforcement actions against the food as appropriate. If FDA is concerned that a detained food is vulnerable to attack while under storage, we would order the storage to take place in an appropriately secured facility.

Section 1.380(b) states that if FDA determines that removal to a secure facility is appropriate, the article of food must be removed to a secure facility. FDA will consider, on a case-by-case basis, whether the article of food must be moved to a secure facility based on the situation and whether a given facility can provide the appropriate level of security.

(Comment 53) One comment addresses the potential impact of administrative detention on farmers. The comment states that, for many farmers, and all dairy farms, limited on-farm storage of perishable products will lead to a complete loss of value if products are stopped from shipment to markets or for further processing. The comment urges FDA to be careful when prohibiting shipment of food products from farms due to the unrecoverable costs of unmarketable product to the affected farm or farms. The comment further states that, for certain products, a critical market opportunity and the reputation of that farm as a reliable supplier could be lost for many years by a disruption in their ability to market their products.

(Response) FDA notes that the standard to detain any article of food is very high—credible evidence or information that the food presents a threat of serious adverse health consequences or death to humans or animals. If FDA orders a food to be detained administratively on a farm, and storage at the farm is limited, the farmer may, under § 1.381(d), request modification of the detention order to move the food to an offsite facility. In evaluating the request, we will consider, on a case-by-case basis, whether the facility identified in the request can provide an appropriate level of security.

In addition, we reiterate that we intend to proceed as expeditiously as possible to resolve all issues associated with particular administrative detentions.

- Removal to a secure facility, if FDA determines that such movement is appropriate (proposed § 1.380(b)).

(Comment 54) One comment states that it would be beneficial for FDA to identify any specific security requirements for storing detained product. This comment also states that nothing in the proposed regulation should be interpreted as elevating a warehouse's duty of care beyond that identified in the Uniform Commercial Code (UCC), as to do so will jeopardize the warehouse's insurance coverage.

(Response) Under the final rule, the detention order will identify specific storage security requirements for the detained food at issue. Issues regarding a warehouse's duty of care are beyond the scope of this rulemaking.

(Comment 55) One comment states that, if FDA orders the movement of a detained article of imported food to a secure location before a consumption entry is filed at the port of entry, the shipment would have to be moved in-bond, creating additional work and expense to the carrier and consumer. This comment suggests that FDA should publish, for public comment, the conditions that would warrant detained food articles to be transported before finalizing this rule. The comment states that it is critical that affected persons understand what the conditions are to ensure compliance with such conditions.

(Response) There are many situations that may arise that would warrant the movement of detained food to secure locations. At the present time, it is extremely difficult for FDA to anticipate and describe all scenarios and all conditions that would warrant detained food to be transported to a secure facility. When it is necessary for such transportation to occur, FDA will specify the appropriate conditions on a case-by-case basis in the detention order.

(Comment 56) One comment believes that FDA stated that detained articles of food should be moved by bonded carriers to make sure that the merchandise will be delivered to the facility that will be selected by FDA after the merchandise is released by CBP. In this situation, the comment asks that FDA put a high security seal (provided by the U.S. broker ahead of time) on the trailer and release the food to the U.S. broker or the trucking company facility. The comment states that this would be less expensive to the importers due to the fact that bonded carriers are expensive; demurrage charges are based on how many days it will take an FDA inspector to release or refuse the merchandise. Affected parties also will incur additional costs from the company that will be receiving the trailers, swamper and forklift services.

(Response) We do not define the security requirements for carriers or storage facilities in this rule. Instead, we will determine the relevant level of security of the facility on a case-by-case basis.

In some cases, we might require higher security, such as that associated with secure government storage facilities. In other cases, we might require lower security.

We note that we do not define the term ''secure facility'' either in this final rule or the final rule on prior notice. As we stated in the proposed rule on administrative detention, we will determine the relevant level of security for storage facilities on a case-by-case basis. Although we do not define the term ''secure facility,'' we note that the range of facilities available for storage of food that is detained administratively is broader than the range of facilities available for storage of food offered for import that is refused admission for a prior notice violation. This is because food offered for import that is refused admission for a prior notice violation is ''general order merchandise'' under title 19 of the United States Code. (See § 1.283(a)(2).) That merchandise must be stored in a bonded warehouse authorized to accept general order merchandise if one is available and capable of such storage. By comparison, food that is detained administratively has not been deemed to be subject to title 19 of the United States Code's limitations on general order merchandise. Accordingly, if the food product is imported and still subject to CBP control, FDA and CBP may determine that a facility other than a general order warehouse constitutes a ''secure facility'' for purposes of administrative detention.

(Comment 57) One comment states that detained articles of food should only be ordered moved to a secure facility in exceptional circumstances.

(Response) FDA will not know in advance all of the circumstances that may warrant removal to a secure facility. Each administrative detention action will be assessed based on the facts of the particular situation, including whether the storage facility can provide the necessary level of security for the food.

(Comment 58) Several comments raise issues concerning the costs for secure and nonsecure storage of detained food. One comment asks how recipients of the detention order would be informed about the costs charged by secure facilities for holding food. Other comments ask FDA whether there would be a standard fee for the storage costs, and whether FDA would ensure that the responsible party is able to afford the storage costs.

(Response) If removal to a secure facility is appropriate, FDA will state a specific location for storage of the food in the detention order, as provided in § 1.380(a), or in response to a request for modification of the detention order under § 1.381(c). The recipient of the detention order may contact the storage facility to determine the costs for storing the detained product. It is also possible that FDA could order a detained article of food to be stored in government storage, which may be less expensive.

(Comment 59) A few comments address the importance of adequate facilities being available for holding detained food. One comment states that FDA must guarantee that there will be enough facilities to ''ensure the conservation of the merchandise that is detained.''

(Response) Inasmuch as FDA will not operate the facilities that will be used to store detained foods, we are unable to guarantee that any particular facility will be available for use in storing detained foods at any particular time. However, we note that detained food will not necessarily be required to be removed to a secure facility. If detained food is required to be removed to such a facility, then, as we stated in the proposed rule, secure facilities are readily available throughout the United States.

(Comment 60) One comment states that it is necessary to know who is in charge of transporting food that is under administrative detention and where FDA has ordered such transportation.

(Response) FDA will decide on a case-by-case basis who will be responsible for transporting detained food. In some cases it may be necessary for us to designate a third party to transport the food, for example, if we believe that control of the food could be lost if the recipient of the detention order transported it. In cases where we believe that this risk is not present, we may direct the recipient of the detention order to transport the food.

- If FDA directs you to move the detained article of food to a secure facility, you must receive a modification of the detention order before you move the detained article of food. (proposed § 1.380)(c))

See comments under § 1.381, ''May a Detained Article of Food be Delivered to Another Entity or Transferred to Another Location?''

- You must ensure that any required tags or labels accompany the detained article during and after movement. (proposed § 1.380)(d))

See comments under § 1.382, ''What Labeling or Marking Requirements Apply to a Detained Article of Food?''

- The movement of an article of food in violation of a detention order is a prohibited act under section 301 of the FD&C Act. (proposed § 1.380(e))

(Comment 61) FDA did not receive comments on this issue.

(Response) We did not make any changes to this section.

2. Comments on May a Detained Article of Food be Delivered to Another Entity or Transferred to Another Location? (Proposed § 1.381)

(Comment 62) A few comments state that FDA should be required to allow detained food to be delivered to the importer, owner or consignee, subject to conditional recall, except where FDA believes there is an immediate threat of harm. One of these comments states that FDA could retain a bond to allow detained articles to be released for delivery to the importer, owner, or consignee until the detention has been terminated.

(Response) FDA disagrees with these comments because we do not have the authority to allow the delivery of foods that have been detained administratively to the owner's or importer's premises under bond. Section 303 of the Bioterrorism Act specifically states that this section may not be construed as authorizing the delivery of an article of food that is subject to a detention order under the execution of a bond while the article of food is subject to a detention order, and section 801(b) of the FD&C Act does not authorize the delivery of the article under the execution of a bond while the article is subject to the order.

(Comment 63) A couple of comments ask if FDA will ensure fast procedures

with respect to requests for the authorized movement of the detained article of food.

(Response) FDA intends to proceed as expeditiously as possible to resolve all issues involved with particular administrative detentions.

(Comment 64) One comment asks if the period of detention is suspended for the amount of time that it takes to complete the request and move the article of food under a limited conditional release.

(Response) The length of time to process a request for modification of a detention order and to move an article of food does not affect or extend the period of detention stated in the detention order (a maximum of 20 or 30 calendar days, as appropriate).

(Comment 65) One comment states that, if the distributor does not have direct control of the mode of transport, FDA's limited conditional release should stipulate that the mode of transport must not introduce any condition or substance that would adulterate or otherwise deleteriously impact the quality of the detained food.

(Response) As stated previously, FDA will decide on a case-by-case basis who will be responsible for transporting food that is detained administratively. In some cases it may be necessary for us to designate a third party to transport the food, if we believed that control of the food could be lost if the recipient of the detention order transported it. In cases where we believed that this risk is not present, we may direct the recipient of the detention order to transport the food. FDA does not believe that it is necessary to state in its approval of a request for modification of a detention order that the mode of transportation must not introduce an adulterant or otherwise deleteriously impact the quality of the detained food. However, if the food does become further adulterated during transport, possible ultimate release of the food could be affected.

(Comment 66) One comment indicates that FDA's current practice is to place routine imports of certain items on the ''Refused Entry/Administrative Detention'' status as part of the standard protocol for items such as raisins and avocado paste. The comment states that such a product is then held for additional testing in the United States before release when the product is shown to present no threat to U.S. health. The comment encourages FDA to exhibit discretion and allow for limited conditional release of such items and allow the product to be held in a facility capable of maintaining and preserving the integrity and quality of the article of food because they are low risk.

(Response) FDA believes that this comment is confusing FDA's refusal authority under section 801(a) of the FD&C Act and our ''administrative detention'' authority under section 303 of the Bioterrorism Act. Any current import alerts, such as those for raisins and avocado paste, are unaffected by this final rule.

3. Comments on What Labeling or Marking Requirements Apply to a Detained Article of Food? (Proposed § 1.382)

(Comment 67) One comment recommends that, in addition to the information on the FDA tags or labels described in § 1.382(d) of this rule, they should also include the expiration date of the detention order and the name of the authorized FDA representative who approved the detention order. This comment also states that if the detention period is extended for any additional time up to the 10-calendar day limit, the detention order and the affixed tags or labels should be amended accordingly.

(Response) FDA disagrees with the comment to revise § 1.382(d) to add the expiration date of the detention order and the name of the authorized FDA representative who approved the detention order to FDA's tags or labels. The name of the person who issued the detention order is required to be on the tag or label. In addition, FDA is revising the final rule to include § 1.393(b)(14), which requires that the detention order include the name and title of the authorized FDA representative who approved the detention order.

The period of detention is required on the tag or label; thus, the expiration date of the detention can be determined from this information. FDA agrees that, in the event that a detention is extended from 20 to 30 calendar days, another detention order must be issued and new tags affixed to the articles.

(Comment 68) A few comments state that applying a label or mark to the detained product should be avoided at all cost because, if the product is detained erroneously, the label or mark may make the food unmarketable. A few other comments ask whether FDA will remove the labels or marks upon termination of a detention order. One comment strongly recommends that detained articles be marked only on the packing cases, because any visible detention mark would make the food unmarketable.

(Response) As FDA stated in the proposed rule, any label or mark of detention will be attached as appropriate given the circumstances. In some instances, the mark or label may be attached to the food container, while in other instances, the mark may be fastened to a packing container. Where the agency cannot mark or label a container or packing container, a mark or label may be attached to accompanying documents. FDA may use other means of marking or labeling as appropriate or necessary. Once the detention order is terminated, FDA will remove, or authorize the removal of, the required labels or tags, as described in § 1.384. Accordingly, we would not expect the labeling and marking provision to impair the marketability of an article of food for which the detention order is terminated.

F. Comments on What Expedited Procedures Apply When FDA Initiates a Seizure Action Against a Detained Perishable Food? (Proposed § 1.383)

(Comment 69) FDA requested comments on this or other procedures that would address concerns about expedited enforcement actions with respect to perishable food. One comment states that the provision for expedited procedures to initiate a seizure action against a detained perishable food is unfair because the claimant would be robbed of any right to appeal a detention order in certain circumstances. The comment states that if the detention order is issued on a Wednesday, the claimant would be required to file its appeal by Friday. However, according to this comment, the FDA also is obligated to ''file'' its seizure action with the DOJ on that same day (Friday) because the actual 4th calendar day after detention is Sunday, when the Court is not in session. The comment argues that the claimant would not have a chance to appeal since the right to appeal is terminated when a seizure action is initiated.

(Response) FDA disagrees with this comment. The Bioterrorism Act requires FDA to provide by regulation, expedited procedures for instituting certain judicial enforcement actions involving perishable foods that are detained under section 303 of the Bioterrorism Act. The purpose of this statutory requirement is to ensure that FDA decides on an expedited basis whether to pursue Federal court seizure of detained perishable food, and that the owners of such perishable food have timely information about how the government plans to proceed with respect to their detained food.

The final rule is consistent with the Bioterrorism Act's directive. The comment appears to misunderstand the mechanics of the regulation's procedures. FDA's process of sending a

seizure recommendation to DOJ is not contemporaneous with the filing of that action in federal court. FDA anticipates that, if we send a seizure recommendation in these circumstances, the seizure will be filed, the court will issue a warrant, and the U.S. Marshal will seize the food, soon after the recommendation is sent to the DOJ. FDA lacks authority to mandate the timing of these actions. As a result, the filing and execution of the seizure may not occur on the same calendar day that the recommendation is sent to DOJ.

Moreover, the Bioterrorism Act provides that an appeal of an administrative detention is terminated once an enforcement action involving the detained food is instituted in Federal court, that is, when the court has issued a warrant, and the U.S. Marshal has seized the food. The regulation is consistent with this statutory provision. Until the seizure action is filed in Federal court, the appeal process will continue. Owners of detained food can increase their chances of having their views heard in the administrative forum of the appeal process by submitting an appeal immediately after the food is detained. Once a seizure action has been filed in Federal court, and the food has been seized, however, any challenge to the administrative detention would be moot, as the food would be under seizure under Federal district court rules. The owner of the food, or another party with sufficient interest in the food, can then contest the seizure action in Federal court. There, it can challenge the government's position that the food is adulterated or misbranded and is subject to seizure, condemnation, and forfeiture under section 304(a) of the FD&C Act. A claimant in a seizure action has the same opportunity to be heard in Federal court as the government. Although the forum may change from an administrative hearing before an FDA presiding officer to a judicial proceeding before a Federal court judge, the claimant nonetheless has the right to challenge FDA's determination that the food should be removed from commerce.

G. Comments on When Does a Detention Order Terminate? (Proposed § 1.384)

(Comment 70) One comment asks how a detention order can expire if confirmation of a detention order is considered final agency action.

(Response) Confirmation of a detention order by the presiding officer at a hearing on an appeal of a detention order is considered final agency action for purposes of the judicial review provisions of the Administrative Procedure Act (5 U.S.C. 702). Even if the order is confirmed, it expires on the 21st calendar day (or 31st calendar day if the detention has been extended) following the issuance of the detention order.

(Comment 71) One comment suggests that FDA amend § 1.379(c) to state that, in accordance with § 1.384, information regarding the termination of a detention shall be provided to the company in writing within calendar day of the decision by FDA that the order shall be terminated.

(Response) FDA expects that we would normally be able to issue the detention termination notice to the person who received the detention order (*e.g.*, the owner, operator or agent in charge of the place where the food is located and the owner of the food, if known) within 1 calendar day of the decision to terminate a detention, unless extenuating circumstances exist. However, we are not revising the rule to incorporate such a deadline because in some instances it may not be possible to inform the company in writing within 1 calendar day due to unforeseen circumstances beyond the agency's control.

H. Comments on How Does FDA Order a Detention?

1. Comments on Who Approves a Detention Order? (Proposed § 1.391)

(Comment 72) One comment recommends the establishment of a national detention approval board to ensure a uniform application of the regulation and to avoid costly errors and delays. A few comments state that the detention order must be approved at the Regional Food and Drug Director level or higher because the judgment of credible threats is case-by-case and the District Director level provides too much discretion.

(Response) FDA disagrees with these comments. Congress included language in the Bioterrorism Act that specifies who is authorized to approve a detention order, *i.e.*, the Secretary or an official designated by the Secretary (who may not be so designated unless the official is the director of the district in which the article involved is located, or is an official senior to such director). FDA believes that the Bioterrorism Act does not contemplate any sort of a national detention approval board. To the contrary, the statute makes clear that Congress expected that FDA District Directors, or officers senior to such directors, could and would exercise this authority.

(Comment 73) One comment states that the approval of a detention order should always be written to avoid misunderstandings.

(Response) Written approval of a detention order is required under § 1.391. This § 1.391 states that prior written approval must be obtained, or if prior written approval is not feasible, prior oral approval must be obtained and confirmed in writing as soon as possible. Thus, written approval always will be obtained.

2. Who Receives a Copy of the Detention Order? (Proposed § 1.392)

(Comment 74) Many comments state that it is imperative that FDA provide a copy of the detention order to the owner of the article of food that has been detained to ensure that such owner has all of the necessary information to address any potential corrective action or to determine if an appeal should be filed. These comments suggest that the recordkeeping and facility registration provisions of the Bioterrorism Act should permit identification of the owner of the food.

(Response) As provided in § 1.392, FDA will provide the detention order to the owner or agent in charge of the place where the detained article of food is located and the owner of the food, if the owner's identity can be determined readily. Examples of steps FDA will take to determine the identity of the owner of a detained article of food include examining any readily available bills of lading or invoices for the article of food and asking the owner, operator, or agent in charge of the place where the detained article of food is located for any information he or she may have regarding the identity of the owner of the article of food.

As the comment suggests, section 305 of the Bioterrorism Act requires facilities that manufacture, process, pack, or hold food for human or animal consumption in the United States to register with FDA by December 12, 2003 (68 FR 58893); however, this registration information does not always identify the owner of a particular article of food. The registration documents contain information such as the name of the facility that manufactured/processed the food (which may or may not be the current owner of the food), the type of establishment and what product(s) the facility manufactures/processes. Therefore, the fact that FDA has a registration from a manufacturer, processor, packer, or holder of an article of food does not necessarily facilitate contacting the owner of an article of food that has been detained. Nor is information identifying the owner of the food necessarily readily available from the records that are required to be

maintained under section 306 of the Bioterrorism Act.

(Comment 75) One comment asks whether the agent in charge of the place where the article of food is located is the same U.S. agent who is responsible for registration and prior notice under the Bioterrorism Act.

(Response) Use of the term ''agent in charge'' in this final rule simply means the person who is in charge of the place where an article of food is located at the time of a detention. The registration interim final rule (68 FR 58893), issued under section 305 of the Bioterrorism Act, requires that all foreign facilities required to register have a U.S. agent. The U.S. agent must be a person residing or maintaining a place of business in the United States, whom the owner, operator, or agent in charge of a foreign facility designates as its U.S. agent for purposes of registration. Thus, depending on where and when an article of food is detained, the U.S. agent may or may not be the same person as the agent in charge of the place where an article of food is located at the time of a detention. The prior notice interim final rule (68 FR 58974) does not require a U.S. agent.

(Comment 76) Several comments state that the exporting country of an article of food that has been detained must receive information concerning the detention so that it may take appropriate action. These comments suggest that FDA should contact the embassy of the country or the competent authority of the country. A few comments state that various parties should be informed of the administrative detention of imported articles of food (*e.g.*, the exporter, agent or importer, and the customhouse broker). A few other comments state that FDA should be able to notify the recipients of products subject to the detention order at multiple locations by accessing records maintained under the recordkeeping section of the Bioterrorism Act.

(Response) FDA disagrees with these comments in part. FDA will issue the detention order to the owner or agent in charge of the facility where the food is located and, as stated previously, the owner of the food, if their identity is readily available. However, FDA does not currently plan to routinely publicize the issuance of detention orders. The parties who receive the detention order may choose to inform any additional interested parties regarding the detention. In the event of a public health emergency, FDA may issue a Talk Paper or Press Release with information regarding an article of food that presents a threat of serious adverse health consequences or death to humans or animals. In such an emergency, FDA also may inform other departments, agencies or governments to ensure public health protection, as deemed appropriate based on the circumstances of each case.

Although it may be possible to identify other interested parties by accessing records maintained under the recordkeeping provisions, we do not believe that it is appropriate for FDA to be obligated to notify all of the various parties requested by the comments. Interested parties may request information regarding administrative detentions under an FOIA request. Such information may be released after FDA has removed any information that is protected from disclosure to the public.

(Comment 77) One comment suggests that FDA should publish information concerning administrative detentions in the Import Refusal Report. A few other comments state that information concerning administrative detentions should be considered confidential and only disclosed to the owner of the products and the exporting country when there is a proven threat of serious adverse health consequences or death to humans or animals. These comments suggest that such disclosure should be through a rapid alert system. Some comments suggest that we devise and test a method of communicating essential information to key industry officials in the United States in the event of a food security event.

(Response) As we stated previously, FDA will issue the detention order to the owner, operator, or agent in charge of the facility where the detained article of food is located, and as stated previously, the owner of the food if its identity is readily available. At this time, we have no plans to routinely publicize the issuance of detention orders, *e.g.*, in Import Refusal Reports or the European Union's Rapid Alert System. This is consistent with the practice FDA uses for medical device detentions, which are not routinely publicized in the manner suggested by these comments.

However, FDA agrees that there may be information related to administrative detention of food that is confidential or classified. A number of statutes, regulations, and policies address protection of these kinds of information from unauthorized disclosure.

We believe the request for FDA to devise and test a method of communicating essential information to key industry officials in the United States in the event of a food security event is intended to include activities beyond administrative detention. Consequently, this discussion is outside the scope of this rulemaking.

(Comment 78) One comment states that procedural safeguards should be put in place to protect both manufacturers and their customers during what is essentially a seizure-type action. This comment recommends that FDA revise the regulation to ensure that, similar to FDA's seizure authority under the FD&C Act and relevant court rules, notice of detention be accompanied by personal service upon the responsible party at individual locations.

(Response) FDA believes that the regulation in its present form adequately protects the interests of potential claimants. We note that administrative detention is not the equivalent of a seizure action, but is instead an administrative action that may precede a seizure action in Federal Court. If we were to institute a seizure after an administrative detention, the government would provide notice of that action in accordance with the Federal Rules of Civil Procedure and applicable local rules, which vary as to their requirements for personal service.

3. Comments on What Information Must FDA Include in the Detention Order? (Proposed § 1.393)

(Comment 79) A couple of comments state that the detention order should include a copy of the written approval granted by the authorized FDA representative. These comments state that the approval should include the information upon which the administrative detention was based, what actions will be taken with the product, and the expected time period for which the product will be held. A few other comments state that the detention order should include information such as grower codes, lot codes and other identifiers. A few comments believe it would be valuable for the appeal procedures and applicable deadlines to be explained in the detention order. One comment suggests that the detention order should include provisions regarding the appropriate storage and transportation conditions, such as refrigerated foods kept under 40 degrees Fahrenheit (F) and frozen foods kept under −4 degree F to meet the regulatory requirements and common industry practices and satisfy their customer expectations.

(Response) FDA agrees in part with these comments. Section 1.393(b)(6) requires that the detention order include a brief, general statement of the reason for the detention. Section 1.393(b)(4) requires that the detention order include the period of the detention. Section 1.393(b)(3) requires that the detention

order include information about the identification of the detained article of food. Identifying codes, such as lot numbers, may be included in the description of the detained article of food provided on the detention order. However, most food products are not required to bear a manufacturer's code; thus, this information may not be available. FDA notes that section 303 of the Bioterrorism Act provides that FDA may detain food for up to 30 calendar days to enable FDA to institute a seizure or an injunction action. Section 1.393(b)(10) requires that the detention order include the text of section 304(h) of the FD&C Act (section 303 of the Bioterrorism Act), as well as §§ 1.401 and 1.402, which describe the administrative detention authority, who may submit an appeal, and the requirements for submitting an appeal, respectively.

Section 1.393(b)(7) requires that the detention order include a description of the appropriate storage conditions, and § 1.393(b)(8) requires a description of any applicable conditions of transportation. As we stated earlier, FDA will determine the conditions under which detained food must be held on a case-by-case basis, based upon the totality of information available to us about the article of food. The record evidencing written approval and the detention order would be released to a requester under an FOIA request after FDA removes any information that is protected from disclosure to the public.

(Comment 80) Another comment states that the detention order should include the type of analysis, procedures for analysis, and the criteria used to determine if the product is adulterated. This comment further states that it is not clear who will do the sampling, who will pay for this process, and whether there will be a guarantee that the food has not been contaminated.

(Response) FDA disagrees with this comment because the nature of bioterrorist attacks or other food emergencies makes it difficult to predict whether sampling and analysis will be necessary, or the types of analyses that will be needed. If an analysis is done, FDA may disclose the type of analysis or the analytical procedure during an informal hearing. FDA routinely uses approved and validated methods. For information related to FDA's laboratory, laboratory procedures, new techniques and useful analytical findings in support of FDA regulatory activities. (See *http://www.fda.gov/ora/science_ref/default.htm*.) In most situations, FDA will do the sampling and offer to pay for the sample. FDA will do the sample analyses. However, the agency cannot guarantee that a particular article of food has not been contaminated, even if there are negative analytical findings of samples of the article. Given the nature of bioterrorist acts, the varied possible scenarios for contamination of food, and the various possible contaminants that may be used, we do not believe that it is possible for anyone to absolutely guarantee that a particular article of food has not been contaminated.

I. Comments on What Is the Appeal Process for a Detention Order?

1. Comments on Who is Entitled To Appeal? (Proposed § 1.401)

(Comment 81) One comment asks whether someone who does not have a proprietary interest in the detained object, but has a commercial interest (*e.g.*, the importer, U.S. agent (as defined in the registration interim final rule), or shipper), can appeal a detention order. Another comment asks whether someone designated by the owner, such as a lawyer or food technologist, can appeal a detention order. One comment indicates that the rule should state whether the person who appeals the detention has to have certain characteristics and reside in the United States.

(Response) We do not know what is meant by ''certain characteristics,'' but a person entitled to appeal a detention order need not be a resident of the United States. With respect to whether a proprietary interest is required, section 304(h)(4) of the FD&C Act states in part that ''any person who would be entitled to be a claimant for such article if the article were seized under section (a) may appeal the order.'' Thus, if a person were entitled to be a claimant in a seizure action, that person would also be entitled to be a claimant in an appeal from a detention order. To be a claimant in a seizure action, a person must have an interest in the seized goods sufficient to confer standing under both Article III of the U.S. Constitution, and Supplemental Rule C(6) of the ''Federal Rules of Civil Procedure'' (available at *http://www.uscourts.gov/rules*). The local rules of the Federal Court district in which a seizure or administrative detention occurs set forth the procedures by which a party establishes entitlement to be a claimant. A person who asserts an interest in, or right against, property that is the subject of an action must file a verified statement identifying the interest or right. The meaning of ''verified statement'' under Supplemental Rule C(6) is governed by the local Federal District Court rules in which the detention takes place, and usually means that the statement must be accompanied by an oath or affirmation attesting to the statement's veracity. A determination of whether a party has a sufficient interest in the food is made on a case-by-case basis. As such, it is outside the scope of this rulemaking.

2. Comments on What Are the Requirements for Submitting an Appeal? (Proposed § 1.402)

(Comment 82) FDA sought comments on whether there are other ways we should be counting days for filing appeals, while adhering to the statutory deadline of 5 days for FDA to issue a decision on appeal (for both perishable and nonperishable food). One comment states that for appeals, and any other sections of the regulations that incorporate specific timeframes, the timeframes should be ruled by ''international timetables.''

(Response) FDA's understanding is that the comment is asking FDA to take international time zones into consideration when counting calendar days to meet the various timeframe deadlines described in this final rule. FDA disagrees with this comment. It is not feasible for FDA to make exceptions on how we count calendar days based on the time zone where the owner of the goods is located. The total elapsed time from the time the detention order is issued throughout the detention process will be the same regardless of the time zone in which the detention order was issued. Under the final rule, the ''start'' and ''end'' times of a detention order, and all deadlines within that period, will be measured by the time zone in which the detention order was issued.

(Comment 83) One comment says that FDA stated that the request for appeal by the industry could be verbal, and FDA will respond by mail or letter, but it is not clear how quickly FDA is going to answer the request. Another comment asks whether the 5 days from the date of appeal that FDA has to issue a decision on an appeal are natural or working days.

(Response) FDA believes that this comment misunderstood the requirements in § 1.402(a). Section 1.402(a) of this rule requires all appeals to be submitted in writing. The written appeal can be delivered to the FDA District Director in person, by mail, e-mail, or fax. As stated previously, the Bioterrorism Act requires FDA to issue a decision on an appeal within 5 calendar days after the date of appeal. Therefore, FDA will issue a decision within the 5-calendar day statutory deadline. However, as FDA states earlier in this rule, FDA is committed to acting

as expeditiously as possible when we detain an article of food, especially in the case of an article of perishable food. Section 1.405 requires FDA to issue a decision on appeal within 5 calendar days from the date of appeal. Section 1.377 of the rule defines ''calendar day'' to mean every day shown on the calendar, which includes holidays and weekends.

(Comment 84) One comment states that Congress's directive that FDA issue procedures to expedite detention of perishable food appears at section 304(h)(2) of the FD&C Act as added by section 303(a) of the Bioterrorism Act, which is a provision relating to the ''period of detention.'' The comment asserts that FDA's proposal to implement this directive, however, relates only to appeals of detention orders, a subject addressed at section 304(h)(4) of the FD&C Act. In the comment's opinion, Congress's decision to place its mandate for the expediting of administrative detention procedures for perishable foods in the section entitled ''period of detention,'' rather than in the section entitled ''appeal of detention order,'' indicates its intent that FDA take direct action to accelerate the pace with which erroneously detained perishable food may be released, not merely the pace at which an informal hearing may be convened. The comment states that Congress required issuance of the expedited procedures to safeguard a claimant's rights with respect to perishable food, and FDA's proposal to restrict the rights of prospective claimants to appeal detention of such food is inconsistent with that objective. Another comment is concerned that the appeals procedure may cause undue delay in the detention process.

(Response) FDA disagrees with these comments. Section 303(a)(2) of the Bioterrorism Act requires the Secretary to provide procedures for instituting certain judicial enforcement actions under the FD&C Act on an expedited basis with respect to perishable foods. FDA provides for expedited procedures for initiating seizure actions in § 1.383 by requiring FDA to submit a seizure recommendation for a detained perishable food to DOJ within 4 calendar days after FDA issues the detention order, unless extenuating circumstances exist. Although a claimant may opt not to appeal the detention order, FDA is required to offer the opportunity to appeal under section 304(h)(4) of the FD&C Act.

The appeal and hearing procedures assist the process of appealing a detention order. Section 304(h)(4) of the FD&C Act requires FDA to confirm or terminate any detention order within 5 calendar days after an appeal is filed. However, if a claimant files an appeal sooner rather than later in the time period for filing appeals, a decision to terminate a detention order could occur before the 5-calendar day statutory deadline is reached.

(Comment 85) One comment suggests that FDA should provide for an ''automatic appeal'' on the second day after an administrative detention order is issued, with a decision on the appeal to be made within 24 hours of the hearing. Another comment requests that the appeal process for chilled, live shellfish that have a commercial shelf life of 48 hours following harvest, be measured in hours, with all attempts to release suitable consignments within 24 hours.

(Response) FDA disagrees with these comments and maintains the same timeframe for perishable food as we proposed. A more rapid procedure is not practicable. Furthermore, even a more rapid procedure would result in reductions in the shelf life of highly perishable food products, such as fresh seafood, possibly requiring such products to be reconditioned and sold as something other than ''fresh seafood.'' We do plan to work with claimants to preserve the article of food when possible; a request for modification of a detention order, for instance, may be used to move a detained article of food from refrigerated storage to a freezer. As we stated earlier, we are committed to acting as expeditiously as possible when we detain an article of food.

(Comment 86) A few comments ask that FDA treat all foods in the same manner as perishable foods for appeal purposes. Another comment indicates that a ''reasonable period'' of 20 calendar days, which could be extended to 30 calendar days, means in practical terms that all perishable foods/drinks, including those ''commercially'' perishable, are no longer suitable for sale. The comment states that this means that, if a ''fast-track'' appeal for perishable food does not allow a quicker release of detained food when it is found to be safe, the value of such an appeal is questionable.

(Response) FDA disagrees with these comments and is maintaining the same timeframes for appeal as we proposed. The Bioterrorism Act allows FDA to institute a detention for a reasonable period, not to exceed 20 calendar days, unless a greater period, not to exceed 30 calendar days, is necessary to enable the Secretary to institute a seizure or injunction action. As stated earlier, the Bioterrorism Act also requires FDA to provide an opportunity to file an appeal of the detention order and to confirm or terminate the detention order within 5 calendar days after an appeal is filed. If a claimant files for an appeal sooner rather than later in the time period for filing appeals, a decision to terminate a detention could occur before the 5-day statutory deadline for rendering a decision on appeal. The Bioterrorism Act also requires FDA to confirm or terminate a detention order within 5 calendar days after an appeal is filed, whether the food is a perishable commodity or not. Thus, the claimant of a nonperishable food, including one that is seasonal in nature could file an appeal within the first 2 calendar days after receipt of the detention order rather than later in the 10 calendar days allowed under the procedures for a nonperishable food, and obtain a decision as soon as than would occur under the ''fast-track'' appeal process for perishables.

(Comment 87) One comment states that FDA should establish that, in cases where the detention order is given to someone who is not authorized to appeal it, the time table for submitting the appeal should not begin until a person who has the right to appeal has been notified.

(Response) FDA disagrees with this comment. As described in § 1.392(a) of the final rule, FDA will provide a copy of the detention order to the owner or agent in charge of the place where the detained articles of food are located. Under § 1.392(a) of this rule, FDA also will provide a copy of the detention order to the owner of the food if their identities can be readily determined. Under § 1.392(b) of this rule, if FDA issues a detention order for an article of food located in a vehicle or other carrier used to transport the detained article of food, FDA also will provide a copy of the detention order to the shipper of record and the owner and operator of the vehicle or other carrier, if their identities can be determined readily. Examples of steps FDA will take to determine the identity of the owner of a detained article of food include examining any readily available bills of lading or invoices for the article of food and asking the owner, operator, or agent in charge of the place where the detained article of food is located for any information he or she may have regarding the identity of the owner of the article of food. There may be times when FDA cannot determine who would be entitled to be a claimant of the article. The purpose of administrative detention is to hold in place, and protect against any movement that could lead to further distribution of, the

food that poses the threat of serious adverse health consequences or death to humans or animals. Consequently, the action is against the articles, not the owner of the articles. We believe that it is likely that any responsible firm who has had product detained on their premises will notify the rightful owner. In addition, it is an owner's responsibility to know the whereabouts of its food product, and to be familiar with the chain of custody related to that food.

3. Comments on What Requirements Apply to an Informal Hearing? (Proposed § 1.403)

(Comment 88) Several comments argue that FDA should not have discretion to deny a request for an informal hearing; the comments argue that our interpretation is inconsistent with the Bioterrorism Act's plain meaning and legislative history, and violates due process under the Fifth Amendment. A few comments indicate that FDA must determine and specify the criteria used to concede or deny a hearing.

(Response) FDA disagrees with these comments because the Bioterrorism Act requires only that FDA ''provid[e] opportunity for an informal hearing''; the statutory language does not require FDA to conduct an informal hearing for every claimant who appeals a detention order. Our interpretation of this section of the Bioterrorism Act is consistent with our long-standing interpretation of similar statutory language in section 304(g) of the FD&C Act (21 U.S.C. 334(g)), which governs medical device detentions. FDA has authority to deny a hearing when the appeal raises no genuine and substantial issue of fact. (See *Weinberger* v. *Hynson, Westcott & Dunning,* 412 U.S. 609, 620–621 (1973).)

The final rule also is consistent with our regulation at § 16.26(a), which states that we do not have to grant all requests for hearings:

> A request for a hearing may be denied, in whole or in part, if the Commissioner or the FDA official to whom the authority to make the final decision on the matter has been delegated under part 5 determines that no genuine and substantial issue of fact has been raised by the material submitted. If the Commissioner or his or her delegate determines that a hearing is not justified, written notice of the determination will be given to the parties explaining the reason for denial.

(Comment 89) FDA sought comments on the timeframes for holding the informal hearing. One comment states that the hearing should be held within 2 calendar days from appeal. Another comment asks that FDA shorten the period for holding a hearing in appeals for perishable food to 3 calendar days. One other comment states that, because the timing of the hearing has no direct impact on the rendering of the agency's confirmation or termination of the detention order, FDA's proposal would have no inherent effect on expediting the release of erroneously detained perishable food. Another comment believes that the FDA has wisely decided upon an expedited hearing process for perishable foods that are detained administratively, but states that the proposed process is not fast enough. The comment notes that, as stated in the proposed regulation, an appeal and request for a hearing must be filed within 2 calendar days of receipt of a detention order. If FDA grants the request, the hearing will be within 2 calendar days after the date the appeal is filed. FDA's decision on the appeal must be issued within 5 calendar days of the date of the appeal filing. The comment states that this proposed procedure will still take up to 7 calendar days, and for highly perishable fresh seafood products, this would leave only 2 to 3 calendar days of acceptable shelf life remaining. Practically, these remaining days would be used in distribution so that a shipment of perishable food (*e.g.,* fresh seafood), in most cases, would be a total loss. One comment asks that FDA extend the time limit so that exporting countries will have enough time to prepare documents. Another comment states that, because the presiding officer may be an RFDD from another region or another official senior to the district director, the transit time from one region to the other must be factored into the established hearing deadlines.

(Response) FDA acknowledges that the timeframes for holding a hearing are relatively short. Because the Bioterrorism Act requires FDA to issue a decision on an appeal within 5 days after the appeal is filed, FDA had to establish quick timeframes for holding the hearing to ensure that we adhere to the statutory requirement. Short timeframes also should help to minimize the impact on an article of food that is detained, but is subsequently released from detention. FDA did not receive any comments that suggested alternate procedures that would both allow for a hearing and for compliance with the statutory requirement for the agency to issue a decision on an appeal within 5 days after the appeal is filed. Therefore, FDA is maintaining the timeframes we proposed.

If FDA grants a hearing, the timeframes will adhere to § 1.402(d) of the rule, which requires FDA to hold a hearing for food that has been detained within 2 calendar days after the date the appeal is filed. A claimant can control the time by which the hearing has to take place and the time by which FDA has to issue a decision if the claimant appeals the detention order sooner rather than later, *i.e.*, this final rule specifies the maximum timeframes claimants have to file an appeal. Claimants certainly can file earlier.

4. Comments on Who Serves as the Presiding Officer at an Informal Hearing? (Proposed § 1.404)

(Comment 90) Many comments recommend that the individual presiding over an appeal hearing must be senior to the individual who approved the detention order. Another comment suggests that the informal hearing on an appeal of a detention order also should allow third-party participants or attendees, not just participation by an FDA Regional Food and Drug Director or another FDA official senior to an FDA District Director.

(Response) FDA disagrees with the comment that the individual presiding over an appeal hearing must be senior to the individual who approved the detention order. FDA's regulation on presiding officers, § 16.42, ensures that the officer presiding over an appeal hearing is free from bias or prejudice.

Under §§ 16.42(c)(2) and 1.404, an FDA Regional Food and Drug Director, or another FDA official senior to an FDA District Director, may preside over an appeal hearing as long as that person has not participated in the investigation or action that is the subject of the hearing, or is subordinate to a person, other than the Commissioner of Food and Drugs (the Commissioner), who has participated in such investigation or action.

With respect to the suggestion that the hearing should allow participation or attendance by third parties, § 16.60 states that ''a regulatory hearing is public, except when the Commissioner determines that all or part of a hearing should be closed to prevent a clearly unwarranted invasion of personal privacy; to prevent the disclosure of a trade secret or confidential commercial or financial information * * *.'' FDA also notes that, if the hearing involves the discussion of classified information, we only would allow participation by parties, both within and outside FDA, by persons with the appropriate security clearance.

5. Comments on When Does FDA Have To Issue a Decision on an Appeal? (Proposed § 1.405)

(Comment 91) Several comments recommend that FDA's decision on appeal should be sooner than within 5 calendar days after the appeal is filed, *e.g.*, within 2 calendar days or 3 calendar days after the appeal is filed. Many comments recommend that FDA's decision on appeal should be made within 2 calendar days after the hearing for detained perishable and nonperishable foods. Another comment asks whether FDA can realistically accommodate administrative detention appeals in a timely manner. These comments state that, when identifying the detention and appellate timeframes, the agency must consider the logistical requirements (placing shipping orders, transportation and other distribution requirements) in evaluating the potential shelf life and value of the food product.

(Response) Under section 303 of the Bioterrorism Act, FDA must confirm or terminate a detention order within 5 calendar days after an appeal is filed. Because each detention and appeal will be assessed based on the facts of the particular situation, FDA can not know in advance what work will have to be accomplished or what information will have to be considered to make our decision to confirm or terminate a detention order following an appeal. Therefore, it is not appropriate to limit the authority and flexibility that Congress provided in the Bioterrorism Act by reducing the number of calendar days the agency has to confirm or terminate a detention order following an appeal. FDA notes that these are maximum timeframes for rendering a decision. As stated previously, FDA intends to act as expeditiously as possible. Thus, FDA may render decisions on appeal sooner than 5 calendar days if we are able to do so.

(Comment 92) One comment acknowledges that confirmation of a detention order by the presiding officer is to be considered a final agency action for purposes of the Administrative Procedure Act (5 U.S.C. 702) and asks if it is possible to further appeal a decision on the detention.

(Response) After the presiding officer confirms the detention order, no provisions for further review or appeal within the agency or HHS apply. A claimant's further recourse would be to initiate proceedings in Federal court.

In the proposed rule, § 1.402(d), which governs the requirements for submitting an appeal, referenced the definition of an informal hearing in section 201(x) of the FD&C Act. Section 201(x)(5) of the FD&C Act requires the presiding officer to prepare a written report of the hearing, and states that the participants in the hearing shall be given the opportunity to review and correct or supplement the presiding officer's report. FDA is revising §§ 1.403 and 1.405 to provide this opportunity for the hearing participant to review and request changes to the conclusions of the presiding officer, as reflected in his or her proposed decision. FDA is revising § 1.403(h) to clarify that § 16.60(e) and (f) does not apply to an informal hearing on an administrative detention. Revised §§ 1.403(h) and 1.405(a) provide that the presiding officer must issue a written report of the hearing, including a proposed decision with a statement of reasons. This section also provides for a 4-hour opportunity during which the hearing participant may review and comment on the written report. Under § 1.403(h), the presiding officer will then issue the final agency decision.

FDA is also revising § 1.403, which governs the requirements that apply to an informal hearing, by adding new paragraph (j) to make clear that § 16.119 does not apply to an informal hearing on an administrative detention. Section 16.119 states that, after any final administrative action that is the subject of a hearing under part 16, any party may petition the Commissioner for reconsideration or a stay of the decision or action.

FDA is revising § 1.403 to clarify that § 16.80(a)(4) does not apply to an informal hearing on administrative detention. Revised § 1.403(i) states that the presiding officer's report of the hearing and any comments on the report by the hearing participant under § 1.403(h) are part of the administrative record.

FDA is also revising § 1.403 to clarify that § 16.95(b) does not apply to an informal hearing on an administrative detention. New § 1.403(k) states that the administrative record of an informal hearing on an administrative detention as specified in §§ 16.80(a)(1), (a)(2), (a)(3), (a)(5), and 1.403(i) constitutes the exclusive record for the presiding officer's final decision on an administrative detention. In addition, § 1.403(k) states that, for purposes of judicial review under § 10.45, the record of the administrative proceeding consists of the record of the hearing and the presiding officer's final decision.

(Comment 93) One comment argued that the proposed expedited procedures for perishable foods do not accomplish what Congress intended in the Bioterrorism Act, *i.e.*, implementing regulations mandated by the Bioterrorism Act are supposed to achieve accelerated termination of detention orders and release of the detained perishable food when the agency finds there to be a lack of credible evidence or information that the detained article presents a threat of serious adverse consequences or death to humans or animals. The comment further explains that our proposed procedure would do nothing to expedite release of such food. The comment further states that, in some cases, the proposed procedure would allow FDA 3 calendar days after an informal hearing to render its decision with respect to perishable food, but only 2 calendar days with respect to nonperishable food (the example in the comment uses an appeal date of 2 calendar days after receipt of the detention order for both a perishable and nonperishable food).

(Response) FDA disagrees with this comment because it appears to confuse the expedited procedures mandated by the Bioterrorism Act for initiating certain enforcement actions against detained perishable food with the process for appealing a detention order. The Bioterrorism Act requires the Secretary to provide procedures for instituting certain judicial enforcement actions under the FD&C Act on an expedited basis with respect to perishable foods. Section 1.383 provides for expedited procedures for initiating seizure actions by requiring FDA to submit a seizure recommendation against a detained perishable food to DOJ within 4 calendar days after the detention order is issued, unless extenuating circumstances exist.

The appeal and hearing procedures assist the process of appealing a detention order. The Bioterrorism Act requires FDA to confirm or terminate any detention order within 5 days after an appeal is filed. However, if a claimant files for an appeal sooner rather than later in the time period for filing appeals, a decision on a detention order could occur before we are statutorily required to render that decision.

FDA notes that the comment is correct in that there is one situation where FDA would have more time to consider whether to confirm or terminate a detention order for perishable food than for nonperishable food and that would be if the appeals for both a perishable food and a nonperishable food were filed on the same calendar day and the hearings were held on the second and third calendar days following the appeals, respectively. The only way to eliminate this situation while still allowing FDA up to 5 calendar days to

render a decision on appeal is to revise the timeframe within which FDA would hold a hearing, if granted, to 2 calendar days after the date the appeal is filed for both perishable and nonperishable food. FDA is, therefore, revising § 1.402(d)(1) and (d)(2) to state that if a hearing is granted, it will be held within 2 calendar days after the date the appeal is filed for both perishable and nonperishable food. As we stated previously, FDA intends to proceed as expeditiously as possible to resolve all issues involved with administrative detentions.

6. Comments on How Will FDA Handle Classified Information in an Informal Hearing? (Proposed § 1.406)

(Comment 94) Many comments are concerned that this provision may lead to withholding information that a company would find necessary to prepare its defense against a detention order, including sampling and testing of the product to determine whether the article of food presents a threat of serious adverse health consequences or death to humans or animals. These comments also are concerned that this provision would restrict a company's ability to appeal or prepare for a hearing on the detention order. The comments ask that FDA provide, whenever possible, the specific reason why the agency believes the article of food presents a threat of serious adverse health consequences or death to humans or animals, *i.e.*, the product may be contaminated with agent X.

(Response) FDA is finalizing this provision as proposed. Under existing law, there is no accommodation or exception for disclosing classified information to individuals without the proper security clearance. However, we will provide as much information as we can without compromising the classified nature of the information. FDA notes that private companies can choose to obtain private facility security clearances through the Defense Industrial Security Clearance Office (DISCO) within the Defense Security Service (DSS), which is an agency within the Department of Defense.

FDA indicated in the proposed rule that the agency may develop general regulations for handling classified information on an agency-wide basis. After further review, however, we have decided that such regulations are unnecessary. The handling of classified information is a standardized process across the Federal Government and is governed by Executive Order 12958. Executive Order 12958 was last amended in March of 2003 (68 FR 15313, March 28, 2003).

IV. Conforming Amendment to Part 10

We are amending § 10.45(d) because under the administrative detention procedures, it is the final decision of the presiding officer, and not the Commissioner, that constitutes final agency action.

V. Conforming Amendment to Part 16

We are amending § 16.1(b)(1) to include section 304(h) of the FD&C Act relating to the administrative detention of food for human or animal consumption to the list of statutory provisions under which regulatory hearings are available.

VI. Analysis of Economic Impacts

A. Final Regulatory Impact Analysis

We have examined the economic implications of this final rule as required by Executive Order 12866. Executive Order 12866 directs us to assess all costs and benefits of available regulatory alternatives and, when regulation is necessary, to select regulatory approaches that maximize net benefits (including potential economic, environmental, public health and safety, and other advantages; distributive impacts; and equity). Executive Order 12866 classifies a regulatory action as a significant regulatory action if it meets any one of a number of specified conditions, including: Having an annual effect on the economy of $100 million or more, adversely affecting a sector of the economy in a material way, adversely affecting competition, or adversely affecting jobs. Executive Order 12866 also classifies a regulatory action as significant if it raises novel legal or policy issues. We have determined that this final rule is a significant regulatory action as defined by Executive Order 12866.

Costs and Benefits of Administrative Detention Final Rules: Summary

Administrative detention of food is a new enforcement tool, and we are not able to directly estimate how often it will be used. For an indirect estimate, we assumed that events that trigger certain existing enforcement actions represent a pool of events some of which might in the future trigger administrative detention. To estimate the size of this pool, we used the sum (for fiscal year 2002) of Class 1 recalls (184), instances in which we moved directly to seizure (16), and 10 percent of the instances referred to State authorities (23, or 0.01×230 actions referred to States). This sum—223 actions—represents the upper bound number of times we anticipate using administrative detention. The lower bound is zero; we may not use administrative detention at all.

The benefits of administrative detention will be the value of the illnesses or death prevented because the agency administratively detained food suspected of being adulterated. These benefits will be generated if the following two conditions hold: (1) The food is in fact adulterated, and (2) administrative detention prevents more illnesses or deaths than would have been prevented had we relied on our existing enforcement tools. The more often these conditions hold, and the larger the amount of adulterated food administratively detained, the larger will be the benefits of this final rule. There may also be benefits in terms of deterrence, to the extent that administrative detention increases the likelihood that adulterated products will not be shipped in the future.

One of the main costs of administrative detention, the loss of product value over the detention period, is associated with the administrative detention of food that is not in fact adulterated.

We do not know what fraction of detained products will prove to not be adulterated. For an upper bound we used the fraction of imported foods that we detain and then release: 48 percent. This percentage is an overestimate as applied to administrative detention, because less evidence is needed to detain an import under our current program than will be required to detain a food administratively. The lower bound percentage is zero, because we might never detain a food administratively that is not adulterated.

We estimate the range of costs for this final rule using a range of 0 to 223 administrative detentions and a range of 0 to 48 percent of those detentions involving products that turn out not to be adulterated. The total costs of this final rule will be the sum of the following components:

- Additional transportation to secure storage facility,
- Additional storage,
- Delay of conveyances that contain detained products,
- Loss of product value for foods with limited shelf lives,
- Marking or labeling of detained products, and
- Costs of appeals of administrative detentions.

The following summary table 1 shows the estimated range of costs:

SUMMARY TABLE 1.—ANNUAL COSTS FOR ADMINISTRATIVE FINAL RULE

Types of cost	Costs (in millions)
Transportation	$0 to $4
Delay of Conveyances	$0 to $4
Storage	$0 to $2
Loss of Product Value	$0 to $22
Marking or Labeling	$0 to $2
Appeals	$0 to $16
Total	$0 to $50

Regulatory Options

We considered the following regulatory options in the analysis of the proposed rule: (1) Take the proposed action (establish a regulatory framework for detaining food administratively, with expedited procedures for instituting certain enforcement actions involving perishable food); (2) take the proposed action but change the definition of perishable food, the maximum timeframe for administrative detention of perishable food, or both; (3) take the proposed action but define the level of security we require for transportation and storage; (4) issue regulations only to establish expedited procedures for instituting certain enforcement actions involving perishable food (*i.e.*, limit the action to the regulations required by section 303 of the Bioterrorism Act). We received comments pertaining to the first two options. We also received some comments on the maximum timeframe for administrative detention of nonperishable food. We have included these under Option Two and have renamed that option as follows: Take the proposed action but change the definition of perishable food, the maximum timeframe for administrative detention, or both. In addition, we received comments suggesting that we revise the proposed rule in various ways that we did not address in any of the other regulatory options. We will discuss the economic implications of these comments under a new regulatory Option Five: Take the proposed action but revise the proposed action in some other way. In many cases, a comment discussed a cost and suggested a way to minimize that cost. In those cases, we discuss the portion of the comment that dealt with the cost of the proposed rule under Option One (take the proposed action), and we discuss the portion of the comment that suggested revising the rule under one of the other options.

1. Option One: Take the Proposed Action (Establish a Regulatory Framework for Detaining Food Administratively, With Expedited Procedures for Instituting Certain Enforcement Actions Involving Perishable Food)

General

(Comment 95) One comment argues that our analysis of the proposed rule did not meet guidelines established by the Office of Management and Budget (OMB) for the five elements of a regulatory impact analysis. According to this comment, we did not adequately consider the need for, and consequences of, the rule on society in general; we did not show that the potential benefit of the rule outweighs the costs; we did not select our regulatory objectives with the goal of maximizing net benefits for society; we did not select the regulatory alternative having the lowest net cost for society; and we did not consider the affected food industries, potential future regulatory actions, and the weak state of the national economy.

(Response) We disagree that we did not meet the guidelines established by OMB for a regulatory impact analysis. We were unable to estimate annual benefits because this rule addresses low probability but potentially high risk events. These events do not occur regularly, and we have insufficient information to predict their occurrence. Our inability to estimate annual benefits meant that we were also unable to evaluate regulatory options that generated tradeoffs between costs and benefits to the extent that we would normally do so. However, the guidelines for regulatory impact analyses acknowledge that we will not always have sufficient information to quantify all relevant effects.

Benefits

(Comment 96) One comment suggests that the proposed rule would not generate any benefits because we can already request Class I recalls in situations in which we could use administrative detention. Another comment argues that the proposed rule would do little to improve food safety.

(Response) We discussed the benefits of the proposed rule given our enforcement alternatives prior to enactment of the Bioterrorism Act, including Class I recalls, in the analysis of the proposed rule. These comments did not provide information that would allow us to revise that discussion.

(Comment 97) One comment argues that we failed to consider the potential benefits of the proposed rule that go beyond avoiding adverse health consequences. This comment notes that an intentional food contamination event could have significant national and international implications because it could lead authorities to impose restrictions on the distribution and sale of similar products or lead some consumers to avoid buying the product. As an example of the latter effect, this comment notes that the discovery of a single cow in Alberta, Canada that tested positive for bovine spongiform encephalopathy (BSE) caused significant changes in cattle prices and retail sales of beef products.

(Response) Preventing adverse health consequences from adulterated food may reduce disruptions in consumer demand for that type of food. The effect of changes in consumer demand is primarily distributional because such changes harm some industries and help others. Of course, these distributional effects may be significant for the firms involved. In addition, these effects could generate net social costs by causing temporary unemployment, the loss of value of specialized inputs, and the loss of inventory, that are not balanced by increases in employment and the value of specialized inputs, and the use of otherwise unusable inventory, in competing industries that benefit from the shift in demand. Preventing adverse health consequences from food may also reduce the probability that authorities would place restrictions on the distribution and sale of food. The effect on industry of these restrictions would be similar to the effect of a shift in consumer demand, but these restrictions might also generate social costs in the form of lost consumer utility and enforcement costs because they would not necessarily reflect underlying changes in consumer demand. We recognize that preventing such effects would be a benefit of this rule. However, we have insufficient information to quantify these effects.

Costs

In the analysis of the proposed rule, we requested comments on a number of issues. These issues included the type of transportation, the cost of any specialized transportation, the amount of food that we might detain in an average administrative detention, the size of an average truckload of food that we might detain, the distances that we might need to transport food, storage and handling rates, labeling and marking costs, and the impact of the specific requirements of the proposed appeals procedures. We did not receive comments on any of these issues except for the appeals procedures. However, we received comments on a number of

other issues relating to the costs of this rule.

(Comment 98) One comment argues that the administrative burden generated by the proposed rule would dilute effective food safety measures by industry and divert our resources away from more effective food safety measures. This comment suggests that the net effect of the proposed rule would be to reduce food safety rather than increase it. Another comment argues that the proposed rule might increase food safety risks because it would slow the movement of food through the distribution system, thereby creating additional opportunities for adulteration. The comment envisioned numerous unguarded storerooms or garage sheds containing detained food, which the comment suggests would significantly increase the statistical probability that that food would be attacked.

(Response) This rule will not generate any administrative burden for a particular firm unless that firm were actually involved in an administrative detention. In the analysis of the proposed rule, we estimated 0 to 223 administrative detentions per year, and we estimated the universe of potentially affected firms to be 1.6 to 1.8 million firms. Therefore, the expected annual administrative burden for all potentially affected firms would be quite small and would not significantly displace food safety expenditures by industry. Similarly, this rule will only generate enforcement costs in those cases in which we choose to use it, and we would only use it if it were the most effective enforcement alternative available in a particular situation. Therefore, we disagree that this rule will generate a significant reallocation of our enforcement resources away from more effective food safety measures. This rule would slow distribution times for any food that we detain administratively and subsequently release. However, we can require firms to move food to secure storage or take other actions to ensure that food that we detain administratively is secure. Therefore, food that we detain administratively would not make an easy target for intentional adulteration during the detention period.

(Comment 99) Some comments note that the proposed rule could affect a wide variety of firms. These comments discuss live food animals; restaurants; color pigments used in indirect food contact applications; outer food packaging; raw materials and formulated products that are used as components in the manufacture of food-contact articles, such as conveyor belts, oven gaskets, coatings for film, paper, and metal substrates, adhesives, antifoam agents, antioxidants, polymeric resins, polymer emulsions, colorants for polymers, rubber articles, release coatings, and the like; ceramic and lead crystal tableware; and animal feed and pet food.

(Response) We discussed the wide variety of firms that might be affected in the analysis of the proposed rule. However, we based the cost estimate on conventional fresh or processed food for human consumption. The cost of an administrative detention for each of the product categories and types of firms mentioned by these comments would vary along a number of dimensions, including the production and distribution system, the typical mode of transport, the typical lot or shipment size, handling and storage costs, and rate of product value loss, if any. The comments did not provide estimates of how the costs for these firms would differ from the costs we estimated for the analysis of the proposed rule, and it would be costly and time consuming for us to analyze the costs for every type of firm and product that this rule might affect. In addition, as we discuss later in this analysis, if it were technically difficult or impossible to adulterate these types of food, then we would rarely or never receive information that would require us to detain it administratively. Based on these considerations, we have not revised the analysis to include a discussion of each of these types of products and firms.

(Comment 100) Some comments were concerned that any labeling or marking that we put on food that we detain administratively would remain on the food if we later determined that the food was not adulterated and terminated the detention order. One comment argues that we should place any marking or labeling on packing cases and not on the product itself. The comment notes that consumers would be skeptical of purchasing a product that we had marked in conjunction with an administrative detention.

(Response) Labeling or marking would not lead to a loss of product value because, if we terminated an administrative detention order, we would remove any labeling or marking, or authorize someone else to remove it.

(Comment 101) One comment suggests that we add the expiration date of administrative detention orders to the information that we put on the tags or labels that we affix to food that we detain administratively. The comment also suggests that we amend the tags or labels if we later amend the expiration date.

(Response) We would indicate the initial 20- or 30-calendar day expiration date of an administrative detention order on any tags or labels that we affix to food that we detain administratively. If the initial period for the detention were 20 calendar days and we extended the period an additional 10 calendar days, then we would amend the tags or labels to reflect the new expiration date of the detention period. We did not include the cost of amending tags or labels in the analysis of the proposed rule. We assume that the cost of amending a tag or label is the same as the cost of affixing the tag or label. We do not know how frequently we may need to use the additional 10 calendar days of detention, so we also assume that we may need to amend every tag or label. Under these assumptions and using the same procedures that we used to estimate these costs in the analysis of the proposed rule, we estimate this cost to be $0 to $2 million per year, rather than $0 to $1 million per year that we reported in the analysis of the proposed rule.

(Comment 102) One comment argues that we might detain entire containers or truckloads, but subsequently determine that only one or a very few cases of food are actually adulterated. This comment suggests that we might release a majority of the food that we detain administratively. Another comment suggests that we might intentionally detain more food than we believed was actually adulterated. For example, we might believe that a particular lot was adulterated, but we might detain the container that holds that lot along with other lots. One comment notes that a single shipping container might hold many small shipments of different products of different origins. The comment suggested we might detain the entire container in such a situation.

(Response) In the analysis of the proposed rule, we estimated that we might release 0 to 48 percent of the food that we detain administratively. Although this is not consistent with the comment's suggestion that we might release a majority of the food that we detain administratively, it is consistent with the notion that we might release a considerable portion of it. As we discussed in the analysis of the proposed rule, we based the upper end estimate of 48 percent on the number of import detentions that we subsequently released during the first three quarters of 2002. As we discussed in that analysis, it is highly unlikely that we would release a higher proportion of the food that we detain administratively than the proportion of food that we

place on import detention and subsequently release because the legal standard for administrative detention is higher than the legal standard for import detention. The comment did not provide sufficient information for us to change this assessment. If we determine that a container of food products contains both food that meets the criteria for administrative detention and food or other items that do not meet the criteria, the food or other items that can be readily segregated and not detained can be segregated and moved.

(Comment 103) Some comments argue that some food that has a shelf life of more than 7 days might suffer a significant loss of value if we detained it administratively under the conditions applying to nonperishable foods. One comment argues that this is true of snacks and snack ingredients. Another comment discusses pasteurized chilled juices and juice beverages that are transported and stored under refrigeration. This comment argues that most consumer outlets (retail and institutional) would not accept this type of food unless it had a remaining shelf life greater than it would have if we detained it administratively for 20 calendar days prior to delivery. This comment argues that the rate at which this food would lose value during an administrative detention is greater than the 1 to 3 percent per day that we assumed in the analysis of the proposed rule.

Some comments note that bakery products such as tortillas or snack cakes, might have a shelf life of 10 to 35 days, but retailers and distributors are more likely to reject delivery of these products, if the expiration date is less distant than other comparable products that are available at the time of purchase because consumers prefer products with more distant expiration dates. According to these comments, even a relatively brief administrative detention could render such products unmarketable. These comments also note that potato chips and cookies might have a shelf life of 60 to 120 days, but would be subject to a loss of value by the same mechanism. Some comments made a similar point about ''nouveau'' wines, which firms release for consumption on a specific date. These comments argue that this product would lose a significant amount of its value if it were not available for sale at the optimum date. These comments also note that the annual sales of this product typically take place within a brief period of 2 to 3 weeks.

One comment notes that farms often have limited on-farm storage and inflexible deadlines for delivering products to markets or for further processing. The comment notes that the loss of value of food that we detain administratively on farms could be very rapid. One comment discusses ''fresh products'' that have a shelf life of more than 7 days. This comment argues that one would not be able to market these products if we detained them for 7 days because they would not have enough shelf life left.

(Response) In the analysis of the proposed rule, we assumed that all administrative detentions could last up to 30 calendar days. We also assumed that food with a shelf life of 8 to 30 days would lose 3 percent of its starting value per day, which would essentially reduce the value of that product to zero by day 30. We have revised the daily rate of value loss to the more precise 3.3 percent. It is possible that food with a shelf life of more than 30 days might also lose its entire market value during a 30-calendar day detention period. However, in many cases, one could presumably sell such food at a discount to reflect the shortened shelf life or the suboptimal selling time. To reflect the possibility that this food might lose all of its value during a 30-calendar day detention, we have revised the rate of product loss for all shelf life categories that we used in the analysis of the proposed rule to 3.3 percent per day. Under this assumption and using the same procedures that we used to estimate these costs in the analysis of the proposed rule, we estimate this cost to be $0 to $22 million per year, rather than $0 to $15 million per year that we reported in the analysis of the proposed rule.

(Comment 104) One comment notes that our proposed definition of perishable food refers to the shelf life of the food from the time it was produced rather than from the time we detain it administratively.

(Response) One implication of this comment is that food with a shelf life of more than 30 days might become unmarketable during the detention period if we detained it when it had only part of its shelf life remaining. We discussed this phenomenon in the context of a previous comment. However, another implication of this comment is that we may have overestimated the loss of value for food that we detain near the end of its normal shelf life. Under the linear method that we used to estimate loss of product value over time in the analysis of the proposed rule, such food would already have lost a considerable portion of its starting value for reasons unrelated to the detention. However, we do not need to revise our analysis to account for this effect because our estimated range of the potential annual loss of product value goes to $0 at the low end.

(Comment 105) One comment discusses the shelf life of air freighted fish and fish products. This comment notes that chilled finfish has a normal commercial shelf life of about 7 days from the time of capture. They argue that attempting to extend the shelf life of this fish by freezing it would destroy its commercial value. Some comments note that chilled, live shellfish and crustaceans have a commercial shelf life of about 48 hours from the time they are packed for export. This comment notes that one may extend the shelf life for some species by introducing them back into temperature controlled, oxygenated, salt water. However, these comments doubted that we intended to operate appropriate tanking facilities at airports to handle detained live seafood in this way. Consequently, these comments argue that the current timeframes for administrative detention would almost certainly eliminate the value of these products if we detained and subsequently released them. These comments argue that any detention period longer than 24 hours would result in a loss of the value of the product.

Another comment argues that a detention period of 7 calendar days was excessive in the case of fresh salmon because the quality of fresh salmon would begin to deteriorate within 4 days. One comment notes that, for perishable foods, the maximum time between receipt of the detention order and an appeal is 2 calendar days, and that we have 5 calendar days from receipt of the appeal to confirm or set aside the detention order. This comment argues that these time periods are impracticable and would lead to the loss of the product. Some comments note that the appeals process may take up to 7 calendar days, assuming owners request an appeal within 2 calendar days of receipt of the administrative detention notice and we would reach a decision on the appeal 5 calendar days after the date of the filing of the appeal. This comment suggests that this would leave only 2 or 3 days of acceptable shelf life for highly perishable fresh seafood products, which would be insufficient time to distribute it to retail outlets. Thus, this comment suggests that the proposed procedure would lead to a total loss of value for this type of product.

(Response) These comments are consistent with the analysis of the proposed rule, in which we estimated that perishable food might lose up to all of its value during the detention period.

We discuss suggestions to revise the rule under Options Two and Five.

(Comment 106) One comment argues that we might direct someone to move food that we detain administratively from refrigerated storage to a freezer. The comment notes that this might reduce the value of the food because the owner could no longer sell it as ''fresh.''

(Response) We would not direct someone to move food from refrigerated storage to a freezer. If we detained the food in place, then the food would remain under existing storage conditions unless the owner requested us to change those conditions. Similarly, if we directed a firm to transport food to a secure storage facility, then we would allow that firm to maintain existing storage conditions during transport and storage, unless the owner requested otherwise.

(Comment 107) Some comments were concerned about the economic consequences of detaining large oceangoing vessels. They noted that detaining such vessels administratively for up to 30 calendar days would generate large costs. One comment notes that detaining such vessels might cause the deliveries of other cargoes to be delayed, which could cause some manufacturing plants to shut down because they lacked necessary inputs. Some comments thought we might detain or reroute trucks and their drivers for up to 30 calendar days. One of these comments notes that we did not account for the costs associated with the idling of trucks and their drivers during administrative detentions. One comment discusses trucks that transport bulk food, including liquid commodities such as vegetable oil. This comment notes that if we detained such a vehicle, then the trailer would be unusable for the period of the detention.

(Response) In situations involving conveyances, a request can be made for modification of a detention order to offload the cargo to a secure storage facility. However, in some cases, it may not be feasible to offload the cargo. In that case, the conveyance itself might be delayed. The comment did not provide information on the costs of delaying a ship. However, a recent newspaper story suggested that delaying one ship for 1 day may cost as much as $80,000 (Ref. 1). This implies that detaining one ship for 30 calendar days could cost up to $2.4 million. It is possible, but unlikely, that a single administrative detention could involve more than one ship. We might also detain other types of conveyances.

The comment that discussed the costs of delaying tanker trailers did not provide information on those costs. However, one firm that posted a cost proposal on the Internet listed a standard rate as of July 1, 2002, of $250 per day for a semitrailer with code tanker and $200 per day for a semitrailer with liquid transporter (Ref. 2). These rates probably overstate the cost of the loss of a tanker trailer because in some cases in which we detain food on a tanker trailer, the semitrailer itself could probably be used with another tanker trailer. However, this might not always be possible. This implies that the loss of the use of one tanker trailer could cost up to $8,000 over a 30-calendar day detention period. In addition, in some cases, the drivers of tanker trailers may be idled during the detention period. The average wage of a truck driver in July 2002 was $14.40 per hour (Ref. 3). If we assume 100 percent overhead, then idling a truck driver for 30 calendar days would cost an additional $7,000. Therefore, the total potential cost of detaining one tanker truck and driver for 30 calendar days could be up to $15,000. A single administrative detention might involve more than one tanker trailer or other types of equipment. In the analysis of the proposed rule, we assumed that any given detention could involve up to 67 truckloads of food. Detaining 67 tanker trailers for up to 30 calendar days could generate estimated costs of up to $1 million.

We do not have information on the cost of delaying other types of conveyances such as trains, airplanes, or other types of trucks. However, those costs are probably similar to the cost of delaying ships and tanker trucks. Delaying conveyances could also generate costs by disrupting the delivery or production schedules of other firms. We do not have information on these costs. We could attempt to construct a model to estimate these costs. However, that would be costly and time consuming and would reflect a great deal of variability in the potential costs. Therefore, we determined that it would probably not be worthwhile to construct such a model for this rule. Although the costs of detaining conveyances are potentially quite high, the probability that we would need to detain conveyances is quite low. None of the 223 enforcement actions that we discussed in the analysis of the proposed rule in the context of estimating the maximum number of times we might use administrative detention per year involved a situation in which we would have detained conveyances. In addition, none of the 24 seizure actions that we took in fiscal year 2002 or in fiscal year 2003 involved a situation in which we would have detained conveyances. Therefore, our best estimate of the number of times per year that we might need to detain conveyances is zero.

Detaining food located on conveyances may also generate other costs that we did not discuss in the analysis of the proposed rule. In those cases in which we required a firm to transport the detained food to a secure storage facility, we would generate costs associated with the loss of the use of the conveyance and the idling of the crew or drivers during the offloading process and the costs for other firms generated by that delay. If we assume that offloading takes 0 to 6 hours, then the cost of delaying a ship would be $0 to $20,000 based on a cost of up to $80,000 for delaying a ship 24 hours. We do not have information on the costs for other firms generated by the delay of a ship, and the estimated cost of $80,000 per day might already reflect those costs. Again, it is unlikely that we would delay more than one ship as part of a single administrative detention.

The estimated cost of delaying a fleet of tanker trucks by 0 to 6 hours would be $0 to $8,000 based on the cost information we provided earlier. We assume that the cost of delaying other types of conveyances, such as trains, airplanes, and other types of trucks, would be less than the cost of delaying a ship, despite the higher probability that we might delay more than one of these other types of conveyances. We do not know how many of the 223 enforcement actions on which we based our estimate of the maximum number of administrative detentions in the proposed rule involved food located on conveyances. Therefore, we assume that between 0 and 223 of the estimated administrative detentions that we might take per year could involve food located on conveyances. In that case, the estimated cost from delaying conveyances would be $0 to $4 million per year.

(Comment 108) One comment notes that most tanker trucks containing food are sealed at all openings and that we would need to break those seals to investigate such food. The comment notes that receivers would not accept loads with broken seals. The comment suggests that some receivers might not accept such a load even if we resealed the load using an FDA seal.

(Response) If we were to break the seal on a truck or other conveyance and subsequently release all or some of the cargo on that conveyance, then we would reseal the conveyance with an FDA seal. Therefore, transporters would not need to deliver loads with broken

seals. In the analysis of the proposed rule, we did not account for the possibility that a receiver might not accept a load even if we resealed it with an FDA seal. The comment did not provide information on the prevalence of this practice. However, we would expect market forces to minimize this effect because investigating and resealing a load should have little effect on the underlying value of that load. Therefore, we have not revised the analysis to account for this possibility.

(Comment 109) One comment notes that firms challenge our food seizure actions 65 percent of the time and suggests that firms would probably challenge administrative detentions at least as often, and perhaps more often, because of the ambiguity of the legal criteria involved.

(Response) In the analysis of the proposed rule, we assumed that 65 percent of administrative detentions would result in appeal hearings based on the rate at which firms have contested recent seizure actions. It is possible that firms might be more likely to request appeal hearings for administrative detentions than they are to contest seizure actions. However, we have no information establishing this would be the case. In the proposed rule, we noted that the credible evidence or information standard has been applied in various other judicial and administrative contexts. In addition, we are currently developing a separate rulemaking that defines ''serious adverse health consequences,'' as this term is used in several provisions in Title III, Subtitle A, of the Bioterrorism Act, not just in its section 303. Therefore, the ambiguity surrounding the criteria for administrative detention may be less than suggested by this comment.

In addition, we would only grant a request for a hearing after an appeal is filed, if the information a firm submitted raised a genuine and substantial issue of fact. In contrast, we have no comparable pre-screening process to determine whether firms can contest seizure actions. This suggests that the rate at which firms contest seizure actions may be greater than the rate at which we would hold appeal hearings for administrative detentions. We have no way of knowing whether the rate for contesting seizure actions will be greater than the rate at which we would hold appeal hearings for administrative detentions. Therefore, we have assumed for purposes of this analysis that we will grant all requests for appeal hearings. Based on these considerations, we have not revised our assumption concerning the estimated number of appeal hearings.

(Comment 110) One comment notes that it appeared as though we attempted to expedite the appeals process for perishable food by conducting appeal hearings within 2 calendar days from when a firm filed a request for such a hearing rather than within 3 calendar days, as for nonperishable food. This comment notes that this provision would not necessarily reduce the timeframes for perishable food, because the date on which we hold an appeal hearing does not necessarily dictate when we will reach a decision on that appeal. Some comments note that we said that we would make a decision on an appeal involving nonperishable goods within 2 calendar days of the hearing, but that we committed to no comparable deadline for perishable food.

One comment notes that the expedited hearing process for perishable food is not fast enough to prevent the effective total loss of market value of fresh produce, fluid milk, and live fish and seafood. They note that a claimant must file an appeal within 2 calendar days of receiving the detention order. Then, if we grant a hearing, we would hold the hearing within 2 calendar days of when the appeal was filed. We would then reach a decision based on the hearing within 5 calendar days. This comment notes that this process implies a total time for the appeal hearing process for perishable food of 4 to 10 calendar days after a firm receives the administrative detention order.

(Response) The timeframe under which we must reach a decision on an appeal hearing is 5 calendar days after the appeal is filed for both perishable and nonperishable food. In the analysis of the proposed rule, we estimated that perishable food might lose up to all of its value during the detention period even under the expedited appeal hearing process.

(Comment 111) One comment argues that the ambiguity surrounding the legal criteria for using administrative detentions would encourage some firms to attempt to use administrative detention to discredit competitors.

(Response) If this effect were to occur, then it would decrease the net benefits of this rule by generating administrative detentions that have costs but no corresponding benefits. This effect would probably be minimal because of the legal and financial consequences of supplying us with false information to discredit competitors.

(Comments 112) Some comments argue that firms would not be able to provide counterevidence during an appeal because we would not provide them with complete information on the reasons we detained a food administratively. These comments argue that this would make the appeal process ineffective, which could lead to administrative detentions that appear arbitrary.

(Response) As we explain earlier, if we detain an article of food based on classified information, we will provide as much information as we can without divulging classified information to those without the proper security clearance. Finally, we disagree that the appeals process would necessarily be rendered ineffective because of our inability to share classified information with those that do not have the proper security clearance. Based on these considerations, we have not revised the rule.

Distributional Issues

(Comment 113) One comment thinks that we were unclear about who would pay for the storage of food that is detained administratively. The comment wonders how we intend to ensure that the owner or carrier would be able to afford the storage costs, if they were responsible for those costs. Another comment asks who would be responsible for feeding, watering, and providing adequate housing and medical care to live animals that we detain. One comment asks who would be responsible for the costs associated with administrative detention in the case of a food that was produced in one country and then repackaged in another country before being imported into the United States.

(Response) The party or parties responsible for paying the storage costs of food that we detain administratively is a matter between the private parties involved with the food. FDA is not liable for those costs. An owner, operator, or agent in charge of the place where the food is located can always request modification of a detention order to destroy the food if they do not want to store it. This does not change the analysis of the proposed rule because firms would not choose to destroy food unless the cost of doing so were less than the combined cost of storing the food and any loss of product value during the storage period. We set the low end of our range of potential costs to zero to account for the fact that we might not detain any food during a given year. Therefore, the estimated range includes the costs that would arise if some owners found it less costly to destroy food than to pay for storage.

(Comment 114) One comment argues that the proposed rule would give a

competitive advantage to domestic food over imported food because we only subject domestic food to administrative detention, but we subject imported food to both administrative detention and normal import detention. One comment notes that in the analysis of the proposed rule, we based the upper end of the estimated range of the potential number of administrative detentions per year that involve food that we later determine is not adulterated on the number of import detentions that we released per year. The comment notes that we stated that we expected that this rate would probably be less than the rate at which we release import detentions, because the criteria for administrative detention are more restrictive than the criteria for normal import detentions. The comment argues that this showed that we treated imported food unfairly relative to domestic food.

(Response) This rule covers both domestic and imported food, and we will apply it in the same way to both types of food.

(Comment 115) One comment notes that the costs associated with administrative detentions would impose a substantial hardship on farmers because they have little or no ability to pass on any costs. The comment also notes that administrative detentions could create marketing disruptions that could cause a farm to lose its reputation as a reliable supplier for many years. One comment argues that a motor carrier and driver would bear some of the costs of administrative detention because the motor carrier would lose the use of the equipment during the period of the detention, and the driver might be detained or rerouted, thereby losing compensation for miles driven.

(Response) This rule may adversely affect some farmers and motor carriers. We have insufficient information to quantify the expected or average effect on these specific types of firms, nor did comments submit such information.

(Comment 116) Some comments suggest that if we told the public that we detained a particular product, then we would damage the reputation of the company that manufactured the product, even if we subsequently found that the product was not adulterated and reported that information to the public.

(Response) We do not currently plan to routinely inform the public of administrative detentions, although we might if there were public health reasons for doing so. Therefore, it is possible that we might inform the public of an administrative detention that we later terminated based on a successful appeal or that we later determined involved food that did not pose a threat of serious adverse health consequences or death to humans or animals. In that case, our announcement of the administrative detention could generate changes in consumer perceptions that might adversely affect some firms. We classify this type of impact as a distributive issue rather than a social cost, per se, because reductions in the demand for a given product will be offset by increases in the demand for other products, so that the net impact to society is uncertain. We have insufficient information to quantify this effect, nor did comments provide this information.

TABLE 2.—ANNUAL COSTS FOR OPTION ONE: FINAL RULE

Types of cost	Costs (in millions)
Transportation	$0 to $4
Delay of Conveyances	$0 to $4
Storage	$0 to $2
Loss of Product Value	$0 to $22
Marking or Labeling	$0 to $2
Appeals	$0 to $16
Total	$0 to $50

2. Option Two: Take the Proposed Action but Change the Definition of Perishable Food, the Maximum Timeframe for Administrative Detention, or Both

(Comment 117) A number of comments address the option of changing the definition of perishable food or the maximum timeframe for administrative detentions. Many of these comments suggest changes that would reduce costs but might also reduce benefits. However, these comments did not provide sufficient information to allow us to quantify the changes in costs or benefits. Therefore, we are unable to revise our estimates of the costs and benefits of this option.

Some comments recommend that we define perishable food as food with a shelf life of 90 days or less. Other comments recommend that we define perishable food as food with a shelf life of 120 days or less. One comment suggests that we define perishable foods according to the definition in the Perishable Commodities Act, which includes fresh fruits and vegetables of every kind and character where the original character has not been changed. One comment suggests that we base our definition of a perishable food on the definition of perishable food in the NIST Handbook 130 Regulations for Uniform Open Dating. The comment also suggests that we adopt the definition of semiperishable foods from that regulation and that we treat semiperishable food the same as perishable food. The comment notes that the relevant definition of perishable food is any food having a significant risk of spoilage, loss of value, or loss of palatability within 60 days of the date of packaging, and the definition of semiperishable food is any food having a significant risk for spoilage, loss of value, or loss of palatability after a minimum of 60 days and a maximum of 6 months after the date of packaging.

One comment suggests that we revise the rule to define perishable food as ''food that may have been heat-treated or otherwise preserved so as to prevent the quality of the food from being adversely affected for a period of 90 days or less under normal shipping and storage conditions.'' This comment notes that this definition would include raw agricultural commodities, refrigerated pasteurized products (milk and milk products, juice and juice concentrates), and packaged produce, all of which have a short shelf life and need to move expeditiously through marketing channels to the consumer. However, the comment notes that, even under this revised definition, detaining perishable food which has less than 14 days of shelf life remaining would essentially prevent the product from reaching the market, even with an expedited appeal process and a decision in favor of the owner of the food. One comment argues that we should not consider the issue of whether a food had been subjected to heat treatment or thermal processing to be relevant to the definition of perishable food. Some comments argue that we should take into account not only physical or biological properties, but also how a product is marketed. Some comments argue that we should treat all food as perishable food for purposes of an appeal.

(Response) Changing the definition of perishable food as suggested by these comments would allow more products to qualify for the expedited procedures for appeals and for initiating certain judicial enforcement actions that we established for perishable food. The expedited procedures for initiating certain judicial enforcement actions may reduce the overall duration of an administrative detention in some cases. However, we have insufficient information to determine the impact of these procedures on the duration of administrative detentions. If these procedures reduced the duration of detentions, then it would also reduce storage and loss of product value in cases in which detentions involved food

that we later determined does not present a threat of serious adverse health consequences or death to humans or animals. However, it might also increase our enforcement costs or reduce benefits. It would increase our enforcement costs if we could compensate for the shortened timeframe by assigning additional personnel to the enforcement action. It would decrease benefits in those cases in which we could not fully compensate for the shortened timeframe by assigning additional personnel. Treating more or all food as perishable for appeal purposes would reduce the maximum timeframe in which firms must file appeals for that food from 10 calendar days to 2 calendar days after receipt of the detention order. The reduced timeframe would probably reduce the number of appeals, because any firm that could file an appeal within 2 calendar days is not precluded from doing so with a maximum specified timeframe for filing an appeal of 10 calendar days. Some firms, however, that would be able to file an appeal within 10 calendar days might have difficulty doing so with a maximum specified timeframe for filing an appeal of 2 calendar days. Reducing appeals would decrease our enforcement costs for administering hearings. However, it might also reduce benefits because appeals may allow us to terminate detention orders that we would not have terminated in the absence of appeals. Terminating detention orders would eliminate the storage and loss of product value for detained articles of food. However, reducing the timeframe in which we hold appeal hearings would also increase our enforcement costs and possibly reduce benefits. Again, it would increase our enforcement costs if we could compensate for the shortened timeframe by assigning additional personnel to the appeal hearing. It would decrease benefits in those cases in which we could compensate fully for the shortened timeframe by assigning additional personnel.

(Comment 118) A number of comments raised various issues relating to the timeframes involved in administrative detentions. Some comments argue that we should provide information on the criteria that we intend to use to determine the ''reasonable period'' of time that we detain food administratively because of the impact of that decision on the costs of administrative detention. One comment questions whether this reasonable period of time would depend on the availability of FDA resources. Another comment argues that we should give top priority to any sampling and testing associated with administrative detentions to ensure that we minimize the amount of time that we require. One comment suggests that we initiate any sampling and diagnostic testing within 24 hours of issuing an administrative detention order.

(Response) Defining the criteria that we would use to establish the reasonable amount of time that we would detain food administratively would increase the cost for us to develop this rule because we would need to evaluate every consideration that might affect that time. Also, if we wrote these criteria into the rule, and we failed to anticipate all considerations that might affect this timeframe, then we might need to release food that we detained administratively before we determined that such food should be released. The benefit of defining these criteria is that it would allow the public to provide input on the factors that we believe lead to these time requirements.

(Comment 119) Some comments suggest that we reduce the maximum time of administrative detentions from 30 to 15 days. One comment suggests a maximum of 10 days. One comment suggests a maximum of 7 days. One comment argues that we should revise the rule to limit the period of detention for perishable commodities, including fresh cut salads, fresh fruits, and vegetables to 7 days. One comment suggests that we revise the rule to limit the administrative detention period to 7 days for foods with a shelf life of between 8 and 30 days. Some comments suggest that we develop a system to determine within 24 hours if detention continues to be necessary for perishable food such as fruit, vegetables, and fresh fishery products. These comments suggest that we should only detain fresh noncitrus fruit a few hours, and that we should not detain peppers and citrus fruits for more than 24 hours.

(Response) Reducing the maximum time that we could detain food administratively would reduce storage costs and the loss of value of any food that we later determine is not adulterated. However, this change would also reduce benefits by increasing the risk that an administrative detention order would terminate before we were able to fully assess the health risks associated with the detained food.

(Comment 120) One comment argues that we should inform the owner within 1 calendar day if we terminate an administrative detention order. The comment argues that this would minimize the possible loss of market value by allowing the owner to distribute the food as soon as possible.

(Response) We would only directly inform the owner of the termination of a detention order if we had been able to readily identify the owner and had sent the owner a copy of the detention order. In such a case, we would normally be able to inform the owner of the termination of the detention order within 1 calendar day of when we terminated the detention order. In some other cases, owners could make arrangements with the owner, operator or agent in charge of the place where the food is located to notify them if we notified the owner, operator or agent in charge of the place where the food is located that we terminated a detention order. The timeframe in that case would also be 1 calendar day because we expect that we would normally be able to inform the owner, operator or agent in charge of the place where the food is located within 1 calendar day. Allocating additional employees to this task could generate opportunity costs by reducing the employees that we can assign to other tasks having public health consequences. We have insufficient information to quantify these opportunity costs. The benefit of committing to informing the owner within 1 calendar day, if we inform the owner, would be up to a 1-calendar day reduction in storage costs and loss of product value.

(Comment 121) Some comments state that we set a deadline for making decisions on appeals involving nonperishable food, but we did not set a comparable deadline for appeals involving perishable food. These comments suggest that we revise the rule to specify that the same deadline that applies to nonperishable foods also applies to perishable foods. One comment suggests that we reach decisions on appeals involving perishable foods within four days of the date of the appeal. One comment suggests that we commit to reaching decisions on appeals involving perishable food within 24 hours of the appeal hearing. One comment suggests that we set up an expedited appeal procedure for perishable food.

(Response) Our deadline for making decisions on appeals is the same for both perishable and nonperishable food, *i.e.*, no more than 5 calendar days after an appeal is filed. Reducing the timeframe in which we must render a decision on appeals involving perishable food from 5 to 4 calendar days or to 1 calendar day would either increase our enforcement costs or decrease benefits as per the mechanism we described earlier. It would increase

our enforcement costs if we could compensate for the shortened timeframe by assigning additional personnel to the appeal. In other cases, reducing the time we have to reach decisions might decrease benefits by increasing the risk that we would inappropriately terminate detention orders. However, reducing the time we have to reach decisions on appeals involving perishable foods would also reduce storage costs and loss of product value in those cases in which we terminated those detentions because of those appeals.

(Comment 122) One comment suggests that we extend the timeframe for appealing detentions beyond the proposed 4 calendar days for nonperishable foods and 2 calendar days for perishable food. The comment argues that, in the case of imports, the parties in the exporting countries would not have sufficient time to prepare the necessary documents under the proposed deadlines.

(Response) Although firms must indicate their intention to appeal administrative detentions of nonperishable food within 4 calendar days of when we deliver the detention notice to the owner, operator, or agent in charge of the place where the food is located, they have 10 calendar days to prepare and file their appeals. Therefore, in the case of nonperishable food, both the proposed rule and this final rule are consistent with the comment. Extending the timeframe for appealing nonperishable food would increase our enforcement costs because we would need to keep employees assigned to those cases throughout the potential appeal period to prepare for a possible appeal. It would also increase the number of appeals, which would increase our enforcement costs for reviewing those appeals and administering any appeal hearings that we might grant. However, increasing the number of appeals might also increase benefits by allowing us to terminate some detentions that we might not have otherwise terminated or that we might have terminated after a longer detention period.

We were unable to determine that any of the suggested revisions would generate higher net benefits than the actions that we discussed in the analysis of the proposed rule, which were to broaden the definition of perishable food to include any food with a shelf life of 30 days or less and reduce the maximum timeframe for detaining a perishable food administratively to 14 calendar days. However, we have updated the cost estimates for that action to reflect the revisions we previously discussed under Option One.

TABLE 3.—ANNUAL COSTS FOR OPTION TWO: ALTERNATIVE DEFINITION AND MAXIMUM DETENTION PERIOD FOR PERISHABLE FOOD

Types of cost	Costs (in millions)
Transportation	$0 to $4
Delay of Conveyances	$0 to $4
Storage	$0 to $1
Loss of Product Value	$0 to $15
Marking or Labeling	$0 to $2
Appeals	$0 to $16
Total	$0 to $42

3. Option Three: Take the Proposed Action, but Define the Level of Security We Require for Transportation and Storage

We did not receive any comments on this option. However, we have updated the cost estimates for that action to reflect the revisions we previously discussed under Option One.

TABLE 4.—ANNUAL COSTS FOR OPTION THREE: NO TRANSPORTATION AND ONE ADDITIONAL GUARD

Types of cost	Costs (in millions)
One Additional Guard	$0 to $11
Delay of Conveyances	$0 to $4
Storage	$0 to $2
Loss of Product Value	$0 to $22
Marking or Labeling	$0 to $2
Appeals	$0 to $16
Total	$0 to $56

4. Option Four: Issue Regulations Only to Establish Expedited Procedures for Instituting Certain Enforcement Actions Involving Perishable Food (*i.e.* Limit the Action to the Regulations Required by Section 303 of the Bioterrorism Act)

We did not receive any comments on this option.

5. Option Five: Take the Proposed Action But Revise the Proposed Action in Some Other Way

(Comment 123) In the analysis of the proposed rule, we requested comments on other regulatory options that we should consider. A number of comments suggested revisions that did not correspond to any of the other regulatory options. Many of these suggestions involved revisions that would reduce costs but might also reduce benefits. Other suggestions involved revisions that would reduce some costs, such as costs faced by industry, but would increase other costs, such as our enforcement costs.

(Response) The comments did not provide sufficient information to allow us to quantify the changes in costs or benefits. Therefore, we have insufficient information to determine that any of the recommended changes would increase the net benefits of this rule. Nevertheless, we list the more significant suggested revisions in the following paragraphs and indicate the tradeoffs that would be involved in those revisions.

a. *General.* (Comment 124) One comment argues that rather than adding to industry's burden for food security, we should provide government funding to help industry institute measures to improve food security.

(Response) This comment raises an issue that is beyond the scope of this rulemaking. In the discussion of Option One, we argued that the expected annual burden for all potentially affected firms would be quite small and would not significantly displace food safety expenditures by industry. Declining to issue this rule would generate minimal cost savings because the authority to detain food is self-implementing and is in effect now. This regulation specifies procedures and defines terms to ensure we meet the statutory timeframes for detaining food, and rendering a decision on appeal.

(Comment 125) Some comments suggested that we provide foreign language translations of the Bioterrorism Act and any explanatory information that we prepare on this regulation. The comments suggest that we disseminate the translated material on our Web site and by other means. Some comments request that we establish foreign language consultation services at U.S. embassies.

(Response) As stated earlier in this rule, we have posted on FDA's Web site transcripts of the May 7, 2003, public meeting that we held to discuss both the administrative detention and recordkeeping proposed rules. We also posted transcripts of the broadcast in English, French, and Spanish, which are the three official WTO languages. We plan to make similar outreach efforts directed to both domestic and international stakeholders after publication of this final rule. Providing other translations and foreign language consultants would increase our enforcement costs, but reduce the costs of foreign firms that wished to appeal administrative detentions. Reducing the cost of appeals for firms would probably increase the number of appeals. As we discussed earlier, increasing the number of appeals would increase our

enforcement costs but would also allow us to terminate administrative detentions that we would otherwise not have terminated or terminated after a longer detention period. Terminating administrative detentions would reduce storage costs and loss of product value.

b. *Coverage.* (Comment 126) One comment suggests that we exempt regulated indirect food contact color pigments that firms may use in the manufacture of food packaging. This comment argues that exempting these products would have a minimal effect on benefits. According to this comment, our regulations require that indirect food contact color pigments be proven safe and incapable of migrating into food in more than *de minimis* quantities. This comment also argues that color pigments must be almost completely insoluble in the medium in which they are used, particularly for food packaging, which means that the amount of contaminant that would be necessary to pose a threat to food by migration from polymers and coatings would almost certainly compromise the basic stable coloration function of the pigment. This comment also states that if someone did manage to adulterate these products, then it would probably affect the chemistry of these substances in such a way that the pigment would no longer function correctly in the packaging, polymer or coating systems. The comment also notes that they know of no biological contaminants that could occur in food that could survive in the harsh environment of bulk commercial color pigments or the severe environment that occurs in the manufacturing of plastics, inks and coatings. Finally, the comment notes that they know of no cases of foodborne illness that have been attributed to contaminants that migrated from a color pigment used in food packaging.

Some comments suggest that we exempt outer food packaging. These comments argue that the risk to humans and animals from the adulteration of outer food packaging is relatively small compared to the risk from the adulteration of food contact packaging.

One comment suggests that we exempt raw materials and formulated products that are used as components in the manufacture of food-contact articles, such as conveyor belts, oven gaskets, coatings for film, paper, and metal substrates, adhesives, antifoam agents, antioxidants, polymeric resins, polymer emulsions, colorants for polymers, rubber articles, release coatings, and the like.

One comment suggests that we exempt ceramic and lead crystal tableware. This comment argues that such products would be unlikely to feature in terrorist incidents and that deploying our resources to deal with these products would reduce our ability to deal with other products.

One comment suggests that we exempt animal feed and pet food and limit the scope of the proposed regulations to food that is intended for direct human consumption without further processing.

One comment suggests that we exempt food in purely intrastate commerce.

(Response) The scope of the detention authority extends to those articles that meet the definition of food in section 201(f) of the FD&C Act. Exempting the products in this comment that meet this definition would have little effect on estimated costs because, if it were technically difficult or impossible to adulterate these types of food, then we would rarely or never receive information that would require us to detain it administratively. There are no costs associated with this rule for products that do not appear to present a threat of serious adverse health consequences to humans or animals. However, exempting these products could significantly reduce benefits because we would be unable to use administrative detention in the unlikely case that someone did manage to adulterate these products in a way that generated a risk of serious adverse health consequences. This type of event, although rare, could generate significant health costs. Therefore, the net effect of this revision would be to reduce the net benefits of this rule.

(Comment 127) Some comments suggest that we limit our use of administrative detention to situations involving real or suspected intentional acts of terrorism. Some comments argue specifically that we should continue to request Class I recalls in situations involving unintentional adulteration. One comment argues that we should not use administrative detention to deal with imported food containing undeclared allergens.

(Response) Limiting the use of administrative detention to situations involving real or suspected terrorism would significantly reduce both the potential costs and benefits of this rule. Only one of the 223 enforcement actions upon which we based our estimate in the proposed rule of the potential maximum number of times we might use administrative detention in 1 year may have involved intentional contamination, and it is possible that none of them did. We did not estimate the number of outbreaks per year that this rule might prevent due to our ability to remove food that presents a threat of serious adverse health consequences or death to humans or animals from commerce by placing it under administrative detention while we pursue a seizure action. However, the number of intentional outbreaks would be much smaller than the number of intentional outbreaks plus the number of unintentional outbreaks because most outbreaks have been unintentional.

(Comment 128) Some comments suggest that we cooperate with TTB of the U.S. Department of the Treasury when detaining alcoholic beverages administratively because the TTB is normally responsible for regulating these products and has expertise on that sector of the economy. The comment suggests that we revise the rule to specify that TTB officials are responsible for ordering any administrative detentions of alcoholic beverages.

(Response) As stated previously, FDA recognizes that working in conjunction with TTB is an important tool we have in the event of a threat to the nation's food supply. However, TTB does not have exclusive jurisdiction over alcoholic beverages. FDA exercises jurisdiction over alcoholic beverages as ''food'' for the purposes of the adulteration provisions and other provisions of the FD&C Act. FDA has concluded that alcoholic beverages are covered under the administrative detention regulation because alcohol is food, as that term is defined in section 201(f) of the FD&C Act. The term ''food'' as used in section 303 of the Bioterrorism Act has the meaning given in section 201(f) of the FD&C Act.

c. *Definition of criteria.* (Comment 129) Some comments state that we should define ''credible evidence or information'' and ''threat of serious adverse health consequences or death to humans or animals.'' These comments argue that these steps would be necessary to protect against arbitrary or unsupported detentions that might function as trade barriers. Some comments suggest we use internationally valid standards, such as Codex standards, when defining these terms. One comment suggests that we provide additional guidance on ''credible evidence or information'' by naming all the sources of information that we consider reliable and describing requirements with respect to accuracy of the information. One comment suggests that we adopt a more precise definition of the criteria involved because it would minimize the cost of wrongly ordered detentions. One comment argues that we should not define the criteria for

administrative detention, but should instead decide whether a particular case meets the definition on a case-by-case basis, as we proposed. This comment argues that we should not limit our discretion to use administrative detention by identifying the types of evidence that we would need to support a detention order because terrorist events might arise under conditions that we could not anticipate.

One comment offers suggestions about how to define ''threat of serious adverse health consequences or death to humans or animals.'' Some comments suggest that we define ''credible evidence'' to require evidence, such as laboratory analyses, to confirm the presence of an adulterant or affidavits sworn to under penalty of perjury. One comment argues that we should define ''serious adverse health consequences or death to humans or animals'' so that it necessarily involves risks for a large part of the population and also for the average consumer, not just a sensitive subpopulation.

(Response) We are developing a separate rule in which we will define the phrase, ''serious adverse health consequences or death to humans or animals.'' This phrase is also used in other provisions in Title III, Subtitle A, of the Bioterrorism Act, not just in its section 303. Therefore, it would not be efficient to define this phrase in this rule.

More precisely defining ''credible evidence or information'' would increase the cost for us to develop this rule because we would need to consider and evaluate a number of possible scenarios in order to define that term. In addition, if we wrote a definition of this term into this rule, then we might need to revise the rule as we encountered new situations. Also, if we wrote a definition into the rule, and we failed to anticipate all relevant situations, then we might be unable to use administrative detentions in some situations in which there might be benefits from doing so. The benefit of more precisely defining this term is that it would reduce the possibility that some people might perceive administrative detentions as arbitrary. In the discussion of Option One, we pointed out that the credible evidence or information standard has been applied in various other judicial and administrative contexts.

d. *Administrative detention orders and the dissemination of other information relating to administrative detentions.* (Comment 130) A number of comments addressed the issue of who would receive copies of administrative detention orders. One comment notes that § 1.392 of the proposed rule provides that we would provide a copy of the detention order to the owner, operator or agent in charge of the place where the food is located, and that we would provide a copy to the owners of the food if we could readily determine their identity. The comment notes that because we are requiring operators to register with us, we should be able to readily identify the sending company, the buying company and all intermediaries of the food detained. The comment argues that at least one of these parties would typically be the owner and suggested that we inform all of them of detention orders. The comment suggests that this would be the only way to give the owner a realistic chance to file an appeal.

One comment notes that the owner of the place or the vehicle where we detain food administratively might not have a vested interest in the detained product. This comment suggests that we also notify the importer or the owner of the food. One comment suggests that if we detain an exporter's product, then we should notify that exporter. One comment suggests that we notify the importer and exporter of record and the Customhouse broker. One comment requests that we notify the agent or importer. One comment requests that we notify people of administrative detentions by both a formal written communication and a telephone call.

(Response) We will issue an administrative detention order to the owner, operator, or agent in charge of the place where the food is located. We will also provide a copy of the detention order to the owner of the food, if the owner of the food is different from the owner, operator, or agent in charge of the place where the food is located, and if we can readily determine the owner's identity. Finally, we will provide a copy of the detention order to the shipper of record and to the owner and operator of the vehicle or other carrier, if the food is located on a common carrier, and if we can readily determine the identities of the owners and operators. We intend personally to deliver the detention order to the owner, operator, or agent in charge of the place where the food is located because it permits our investigator to observe the article of food and therefore better describe it in the detention order. We will notify other parties using whatever method of communication is quickest, given the information that we can readily determine about how we can contact them. The registrations that we will be requiring in another rulemaking will not provide us with a list of parties that would probably include the owners of food that we detain administratively. Committing to notifying additional parties beyond those specified in the proposed rule, notifying owners even when we cannot readily determine their identities, or notifying owners by telephone and written communications even when we cannot readily determine their phone numbers or addresses, would increase our enforcement costs.

The benefit of such a revision is that it would increase the probability that we would notify a party that has an incentive to appeal an administrative detention in time for them to meet our deadlines for filing an appeal. This would increase the number of appeals. As we previously discussed, this may generate social benefits because appeals may allow us to terminate some detentions. Terminating detentions would limit the storage and loss of product value associated with those detentions.

(Comment 131) One comment suggests that we revise the rule to require that we accompany a notice of detention by personal service upon the responsible party at individual locations.

(Response) We will notify in person the owner, operator, or agent in charge of the place where the food is. If more than one location is involved, then we would notify in person the owner, operator, or agent in charge of each location. Committing to notifying other parties in person would substantially increase our enforcements costs and might decrease benefits because notifying other parties in person might not be the quickest way of notifying them. The comment did not provide a mechanism by which notifying other parties in person would generate benefits. Therefore, this change would probably not increase the net benefits of this rule.

(Comment 132) A number of comments ask questions about who would receive information on administrative detentions other than copies of detention orders. Some comments suggest that we provide essential information, such as the cause of administrative detentions, to key industry officials in the event of a food security event. One comment suggests that we provide information on administrative detentions to the government of the home country of the owner, operator, or agent in charge of the place where the food is located. Some comments suggest that we inform foreign governments if we detain products from their countries so they can take measures to recall or otherwise deal with the products. One comment suggests that we provide information on

administrative detentions to foreign governments only if the product from that country constituted a serious threat. Some countries suggest methods by which we could provide information. One comment suggests that we notify foreign governments using a rapid alert system, if a product from that country constituted a serious threat. Some comments suggest that we devise and test a method of communicating essential information to key industry officials in the United States in the event of a food security event.

(Response) We will directly notify foreign governments and industry officials of administrative detentions on a case-by-case basis when we think there would be benefits to doing so. Committing to notifying these parties of every administrative detention would increase our enforcement costs. However, it might also generate benefits because we might otherwise fail to notify these parties of administrative detention in some situations in which such notification would generate benefits. The probability that we would fail to notify these parties in situations in which such notification would generate benefits is probably small.

(Comment 133) Some comments raise the issue of the information that we would provide to owners or others, either as part of the administrative detention order or otherwise. Some comments request information that would help them identify the detained food. Some comments suggest that we provide owners with grower codes so that they or others could trace the secondary supplier. One comment suggests that we provide a description of the food, the quantity, and the lot or code numbers or other identifiers.

(Response) We will provide information relevant to identifying food that we detain administratively in the detention order. This information will typically include a description of the food, the quantity of food, and any identifying codes, such as grower codes and lot numbers, that we can readily determine. Committing to always providing particular codes would increase our enforcement costs. In some cases, such as a detention involving a number of pallets containing products from multiple lots, it might be difficult for us to identify all of the relevant lot codes. Committing to always providing particular identifying codes would generate benefits because it would help owners, and possibly other parties such as foreign governments, to take steps to investigate the potential problem and possibly reduce the risk of additional serious adverse health consequences. In addition, some parties may find particular identifying codes useful during the appeal process.

(Comment 134) One comment suggests that we provide foreign governments with the produce name and lot number, the producer, and the exporter of the detained food.

(Response) In those cases in which we directly inform foreign governments of administrative detentions, we would provide them with a copy of the detention order and any other information we deem appropriate, which may include the name of the product, the lot number, the producer, and the exporter. Committing to always providing foreign governments with this information would increase our enforcement costs and possibly increase other food safety risks. The benefit of committing to always providing this information is that foreign governments might be able to take more effective steps to address potential food safety risks than they would otherwise. We have insufficient information to quantify the net impact of this revision.

(Comment 135) Other comments discuss the information that we would provide as the bases for administrative detentions. One comment suggests that we include in the detention order the information upon which we based an administrative detention. Some comments suggest that we provide owners with complete information on the reasons for detentions so that owners can provide counterevidence during an appeal. One comment suggests that we should at least include a description of the ''credible evidence or information'' that resulted in the detention order, because without such information, the owner of the detained article would be denied information critical to its own investigation, which would hamper or deny its ability to make a meaningful appeal. The comment notes that we could provide information on why we believe the article of food subject to the order ''presents a threat of serious adverse health consequences or death to humans or animals'' even if the ''credible evidence'' that we used is classified information. One comment suggests that we provide foreign governments with the reasons for administrative detentions.

(Response) We will provide a statement of the reasons for a detention in the detention order, but we will not divulge classified information to those without the proper security clearance. Similarly, in those cases in which we directly notify foreign governments or other parties of administrative detentions, we will provide a statement of the reasons for those detentions as is consistent with national security considerations and applicable disclosure laws. Providing classified information to those without the proper security clearance could generate costs by increasing the risk of future food safety incidents. It would also be illegal.

(Comment 136) One comment suggests that we include in the detention order a description of the actions we intend to take with the product and the amount of time we intend to hold the product.

(Response) Detention orders will be dated and will include the period of detention. Therefore, anyone can determine the expiration date of that detention order. We could attempt to predict at the time we issued detention orders whether we might terminate those detention orders or move to seizure actions before the expiration date, or whether we might need to extend the detentions for an additional 10 calendar days. We could then revise detention orders as our assessment changed over time. However, that would substantially increase our enforcement costs. The benefit of this action is that the recipient of the detention order might be in a better position to plan any appeals or subsequent disposition of the food.

(Comment 137) One comment suggests that we provide information on the analyses and methods that we use to analyze food that we detain administratively.

(Response) As we discussed earlier in this preamble, information on the analyses and methods that we use to analyze food is available on FDA's Web site at *http://www.fda.gov.*

(Comment 138) Some comments suggest that we provide the owner a sample of the detained food to allow them to conduct their own tests.

(Response) With respect to providing counter-samples, section 702(b) of the FD&C Act describes FDA's responsibility to provide a part of an official sample of food to certain individuals, when a sample is collected for analysis under the FD&C Act. Section 702(b) of the FD&C Act requires the Secretary to, upon request, provide a part of such official sample for examination or analysis by any person named on the label of the article, or the owner thereof, or his attorney or agent; except that the Secretary is authorized, by regulations, to make such reasonable exceptions from, and impose such reasonable terms and conditions relating to, the operation of this section as he finds necessary for the proper administration of the provisions of the FD&C Act. Therefore, when our own collection of a sample requires us to

provide a part of that sample to the owners, we will do so. However, when we are not required to provide a part of that sample to the owners, we will not do so. If we do not take a sample, then we will also not provide owners with a sample. Always providing owners with a sample when we collect a sample would increase our enforcement costs but might reduce costs in some situations by allowing us to terminate some detention orders. Providing owners with samples in situations in which we do not take samples for our own purposes would increase our enforcement costs and would have a minimal impact on other costs. In particular, if we did not rely on testing to establish our case for an administrative detention, then providing owners with samples would probably likely have little impact on the appeal.

(Comment 139) One comment suggests that we allow owners of detained food to have access to the written approval granted by the authorized FDA representative to ensure that the owners have all of the necessary information to address any potential concerns.

(Response) The owner of detained food can obtain a copy of the written approval granted by the authorized FDA representative under FOIA, after we have removed any information that is protected from disclosure to the public. However, owners might not be able to get such a copy quickly enough to use during their appeal. Providing owners of food that we detain administratively faster access to written approvals granted by authorized FDA representatives would increase our enforcement costs and would probably generate no or minimal benefits. Allowing owners access to written approvals would allow them to confirm that administrative detention orders were properly approved. However, owners do not need access to those documents to raise this issue in an appeal. Therefore, making this change would probably not increase net benefits.

(Comment 140) Some comments were concerned about the information that we would provide to the public concerning administrative detentions. Some comments suggest that we should only make information on administrative detentions public if it were necessary to protect public health. These comments suggest that we ensure that any information that we release to the public on administrative detentions is accurate and that we transmit such information in a clear, unemotional, and factual manner without unduly or inaccurately raising public concern.

(Response) We do not currently plan to publicize administrative detentions unless it is necessary to protect the public health. However, members of the public can request information on administrative detentions under the Freedom of Information Act. If we found it necessary to inform the public for public health reasons, then we would ensure that the information that we provided to the public is accurate and that we transmitted it in an appropriate manner that would not unduly or inaccurately raise public concern.

(Comment 141) One comment suggests that we revise the rule to require that Regional FDA Directors or more senior level officials approve administrative detentions because of the serious cost implications involved.

(Response) This revision would increase our enforcement costs by reducing the number of eligible authorizing officials and by increasing the payroll and opportunity costs associated with approving detentions. The potential benefit would be a reduction in the number of administrative detentions that we later terminate because of a successful appeal or because we later determined that they involved food that did not pose a serious adverse health consequences or death to humans or animals threat. We have no information establishing that this benefit would occur.

(Comment 142) One comment notes that we proposed that government employees commissioned or deputized by FDA may order a detention. This comment argues that we should revise the rule to allow only FDA employees to order and administer detentions because that would aid in the credibility of the process.

(Response) Revising the rule to allow only FDA employees to order and administer administrative detentions would increase our enforcement costs. If this revision aided the credibility of the process, then it might reduce the possibility of legal complaints and might also reduce the number of unjustified appeals, both of which would decrease costs. However, the comment did not provide information establishing that this effect would occur.

e. *Compensation.* (Comment 143) Many comments argue that we should compensate firms for costs associated with administrative detentions that we later terminate because of a successful appeal or because we later determined that it involved food that did not pose a threat of serious adverse health consequences or death to humans or animals. One comment suggested that we should at least compensate firms for some percentage of the costs, because it would provide us with an incentive to avoid excessive use of administrative detentions. One comment suggests that we compensate farmers for the costs of administrative detentions.

(Response) Neither the FD&C Act nor the Bioterrorism Act provide FDA with authority to compensate firms for costs associated with administrative detention. Even if FDA had such authority, if we compensated firms for costs associated with administrative detentions, then we would shift the burden of those costs from the affected firms to taxpayers in general. This is primarily a distributional issue that goes beyond the scope of this analysis.

f. *Labeling and marking.* (Comment 144) One comment suggests that we add the name of the authorized FDA representative to the information that we put on the tags or labels that we affix to food that is detained administratively.

(Response) Including the name of the authorized FDA representative on the tags or labels that we affix to detained food would increase our enforcement costs slightly, but would not affect other costs or benefits. We will provide information on how to appeal or obtain more information on administrative detentions in the detention order. It is possible that someone might have access to the tag or label but not the detention order, so there could be some benefit to adding a contact name to the tag or label. However, this situation is probably unlikely. Most people who may be interested in appealing an administrative detention will probably be able to obtain a copy of the detention order. Therefore, this change would probably not increase net benefits.

g. *Transportation.* (Comment 145) One comment suggests that we define and make available for public comment the conditions that we believe would warrant transporting food that is detained administratively to secure storage facilities.

(Response) Defining the conditions that would warrant transporting food to secure storage facilities would increase the cost for us to develop this rule because we would need to consider and evaluate every scenario that might require transportation. In addition, if we wrote these conditions into the rule, then we might need to revise the rule as we gain experience with administrative detentions. Also, if we wrote these conditions into the rule, and we failed to anticipate all situations in which transportation was appropriate, then we might need to resort to relatively inefficient and expensive alternatives.

The benefit of defining the conditions warranting transporting food to secure storage facilities is that it would prevent inconsistent decisions about transporting food to secure storage and would allow the public to provide input on when transportation would be most worthwhile.

(Comment 146) One comment requests that we change the rule to include some provisions regarding appropriate transportation conditions, such as keeping refrigerated foods under 40 degrees F and frozen foods under −4 degrees F. One comment notes that we did not define the mode of transport in the case of limited conditional release and argues that we should require that the mode of transport not introduce any condition or substance that would adulterate or otherwise deleteriously impact the quality of the detained food.

(Response) We will normally maintain existing storage conditions during transportation to secure storage facilities. If the owner wishes, he or she can request that we maintain different storage conditions or request modification of a detention order. In the case of a request to modify the detention order, the party requesting modification of the detention order would determine the conditions during transportation.

(Comment 147) One comment requests that we revise the rule to require that the owner, purchaser, importer, or consignee, pay the transportation costs of food that is detained administratively. This comment notes that this would be consistent with the rule on prior notice (part 1, subpart I). The comment argues that a trucking company should not have to pay transportation costs because they have no control over the quality or safety of what a shipper loads into the trailer.

(Response) Resolving the issue of who should pay for transportation is a distributional issue that is beyond the scope of this analysis.

h. *Storage facilities.* (Comment 148) Some comments state that we should guarantee that we will have enough secure storage facilities with appropriate storage conditions for products that we detain administratively.

(Response) Guaranteeing that we have appropriate secure storage facilities for all food that we might detain administratively could generate significant costs because of the uncertainty over the number and location of detentions and whether there is a need to transport detained food to secure storage. It would generate minimal benefits because, in many cases, it may be cheaper and more or equally effective to secure detained food in place. Therefore, this change would probably increase the net costs of this rule.

(Comment 149) One comment notes that our decision to move food to secure storage, and our selection of appropriate storage facilities, could have a significant impact on the storage costs that the owners of detained food would face. The comment suggests that we ensure that such storage facilities impose the minimum cost necessary to achieve the objectives of the detention, with respect to both security and food storage conditions such as refrigeration.

(Response) Ensuring that storage facilities impose the minimum cost necessary to achieve the objectives of administrative detentions would increase our enforcement costs by requiring us to spend time shopping for storage facilities. This would also increase the time we need to implement administrative detentions, which might reduce benefits. The benefit of ensuring that we use the lowest cost storage facility is that it would give us an incentive to reduce storage costs to the lowest level possible. This benefit would probably be small. When we use commercial storage facilities, the price difference between the facility that we choose and the lowest cost appropriate storage facility would probably be relatively modest due to price competition in the commercial storage market. The same considerations apply to any conveyances that we use to move food that we detain administratively to secure storage facilities.

(Comment 150) One comment suggests that we require the person holding legal title to the food to bear the cost of storing food that is detained administratively. This person might be a shipper, the consignee, or a food broker. One comment requests that we revise the rule to require that the owner, purchaser, importer, or consignee pay any storage costs. This comment notes that this would be consistent with the rule on prior notice (part 1, subpart I). The comment argues that a trucking company should not pay storage costs because they have no control over the quality or safety of the food a shipper loads into the trailer.

(Response) The issue of who should pay for storing food that is detained administratively is a distributional issue that is beyond the scope of this analysis.

(Comment 151) One comment suggests that we provide records of storage conditions during detention to owners of detained food, upon request.

(Response) Providing records of storage conditions to owners upon request would increase our enforcement costs slightly. This revision would probably have a minimal impact on benefits or distributional effects because we will allow owners to verify storage conditions, except where security concerns prevent it.

(Comment 152) Some comments argue that owners should be able to inform us about the optimal storage conditions for food that we detain administratively and that they should be able to submit a claim against us if we do not follow their recommendations. One comment requests that we revise the rule to include some provisions regarding appropriate storage, such as keeping refrigerated foods under 40 degrees F and frozen foods under −4 degrees F. One comment requests that we commit to holding refrigerated and frozen food at the same refrigerated and frozen temperatures and conditions that are found in U.S. commercial cold storage facilities. This comment also suggests that we allow owners, operators, or agents to request that we freeze detained fresh products that are or are likely to be, detained for 4 or more days. One comment recommends that we develop procedures regarding administrative detention for perishable foods, including a specific process that would ensure the preservation of such foods until we resolve the administrative detention.

(Response) We will normally maintain existing storage conditions during administrative detentions. If the owner wishes, he or she can request that we hold the food under different conditions or request modification of the detention order. We would accede to one or the other of these requests except where security concerns prevent it. We know of no process that would ensure the preservation of perishable foods during the detention period.

i. *Off loading from conveyance/partial loads.* (Comment 153) One comment suggests that we reduce the potential economic effects of detaining large oceangoing vessels by taking one of the following actions: (1) Not detaining products on vessels at ports without first allowing the product to be offloaded to secure storage; (2) specifically providing for the removal of products from vessels to secure storage in the detention order; or (3) specifying that moving detained product from the vessel qualifies as a basis for a conditional release, thus permitting the movement of detained product to secure storage. One comment notes that ships carrying bulk vegetable oils hold the oil in individual parcel tanks. This comment notes that a ship might transport many parcel tanks of various types of vegetable oil to many buyers in different locations. The comment notes

that a single ship could carry more than 50 separate parcel tanks. This comment argues that if we receive intelligence on the potential contamination of a particular parcel tank, then we should remove that parcel tank to secure shore storage and allow the ship to proceed with deliveries of the remaining parcel tanks. One comment argues that removal of a product from a conveyance to secure storage should be one of the bases on which a claimant may seek a limited conditional release. Another comment suggests that we revise the rule to indicate that, if we detain food on a truck, then we will issue an order to the trucking company to deliver the food to either the consignee or to a secure location.

(Response) Owners and operators of conveyances may request modification of a detention order to move food from a conveyance to other storage. We generally would accede to such requests unless they generated health risks or raised security concerns. If we determine that only a portion of a cargo of food products meets the criteria for administrative detention, the food or other items that can be readily segregated and not detained can be segregated and moved. In the analysis of the proposed rule, we noted that our experience with other enforcements actions is that we would not cause significant delays in the delivery of food that is packed with food that we detain administratively. These comments did not provide information that would require us to revise that assessment.

(Comment 154) One comment requests that we develop a process by which we would reseal a tank truck load that we determined did not present a problem with an FDA seal and indicate the resealing on an official FDA document. The comment notes that receivers might still reject the load, but that they would be less likely to reject it under these conditions.

(Response) We will reseal a tank truck load that did not present a problem with an FDA seal, but we will not provide an official FDA document to that effect. Providing an official FDA document would increase our enforcement costs slightly. It is possible that such a document might reduce costs by encouraging receivers to accept resealed loads. However, in the discussion of this issue under Option One, we concluded that market forces would probably minimize unnecessary rejections of resealed loads. The comment did not provide information that would allow us to quantify this practice or to estimate the effect of an official FDA document on reducing it.

j. *Timeframes.* (Comment 155) One comment argues that if we needed to use any of the additional 10 calendar days beyond the initial 20-calendar day period, then we should inform the owner of the food of this additional time requirement, the reasons we need the additional time, and the actual time period that we will require, up to the maximum of 10 calendar days.

(Response) The initial detention order will include an expiration date based on the initial 20-calendar day period. In addition, FDA notes that under § 1.379(a), FDA can order detention of the article of food for 30 calendar days in the original detention order, if we know from the outset that 30 rather than 20 calendar days will be needed to institute a seizure or injunction against the detained article of food.

If we needed to use the additional 10 calendar days, then we would issue a new detention order with a new period of detention based on that time period. Basing the period of detention of the new detention order on our estimate of the portion of the maximum period of 10 calendar days that we think we might require would increase our enforcement costs because it would require us to develop a model to estimate the time required, and we might need to prepare additional detention orders if we underestimated the time that we needed. The benefit of this change is that it would allow owners to make plans based on our current assessment of the time that we require. This benefit would probably be minimal because we will inform owners as quickly as possible if we terminate a detention order before the detention period has expired. Providing owners with the reasons we need additional time would also increase our enforcement costs. The benefit of providing this information to owners is unclear. Any benefit would probably be minimal because we intend to proceed as quickly as possible with activities pertaining to food that we detain administratively. Therefore, these changes would probably not increase net benefits.

k. *Appeal hearings.* (Comment 156) One comment suggests that we start the timeframe for appeal when we notify someone who is authorized to file an appeal. One comment requests that we revise the rule to give the shipper the right to appeal. One comment wonders whether everyone with a commercial interest in the food, such as an importer, could file an appeal. One comment suggests that we revise the rule to allow the owner to designate someone else to appeal a detention order, such as a lawyer or a food engineer, in case the owner felt that he or she did not have the proper skills to do so.

(Response) 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 an administrative detention. The local rules of the Federal court district in which a seizure or administrative detention occurs set forth the procedures by which a party establishes entitlement to be a claimant, or files a statement of interest under the revised Supplemental Rule C(6) of the ''Federal Rules of Civil Procedure,'' and a determination of whether a party has a sufficient interest in the goods is made on a case-by-case basis.

As required in § 1.392, we will provide a copy of the detention order to the owner, operator or agent in charge of the place where the food is located and to the owner of the food, if the owner's identity can be determined readily. Examples of steps FDA will take to determine the identity of the owner of a detained article of food include examining any readily available bills of lading or invoices for the article of food and asking the owner, operator, or agent in charge of the place where the detained article of food is located for any information he or she may have regarding the identity of the owner of the article of food. Though FDA will make reasonable efforts to identify the owner of the food and to notify that person of the administrative detention while there is still time to file an appeal, it may not always be possible for us to identify the owner of the food.

Other parties with a commercial interest in the food, including importers and shippers, would generally be able to file an appeal. Owners or other parties who wished to appeal an administrative detention may choose to have other parties, such as lawyers and food engineers, represent them for purposes of the appeal, once the appeal is filed in the owner's name.

Changing the rule to ensure that at least one party that is able to file an appeal has time to file an appeal after they learn of the detention, or that everyone with a financial interest in the food has time to appeal a detention, or that owners or other parties who wished to appeal a detention have an opportunity to arrange for other parties to represent them, would increase our enforcement costs. It would also probably increase the number of appeals, which would further increase our enforcement costs but also increase benefits by the mechanism we described earlier. These changes might also address some distributional concerns.

The revised §§ 1.403(h) and 1.405(a) require the presiding officer to issue a report, including a proposed decision confirming or revoking the detention order, by noon on the fifth calendar day, while giving the participant 4 hours to submit changes and corrections before a final decision is issued. These changes will increase the probability that we will correctly terminate a detention order when the food does not present a risk, but will also increase our enforcement costs by some amount.

(Comment 157) Some comments argue that we should guarantee the right to a hearing. One comment suggests that we establish a national detention approval board to ensure uniform application of the regulation. The comment argues that establishing such a board would allow us to avoid costly errors and delays.

(Response) As we indicated earlier, we would only grant a request for a hearing after an appeal is filed, if a firm submitted material that raised a genuine and substantial issue of fact. Guaranteeing the right to an appeal hearing would increase our enforcement costs. It might also increase benefits, because in some cases, our initial assessment of whether a firm submitted material that raised a genuine and substantial issue of fact might be incorrect. In that case, we might fail to terminate a detention that we would otherwise have terminated. This effect would probably be minimal because, as stated earlier, we will probably grant a hearing in most cases in which a hearing is requested.

Establishing a national detention approval board would increase our enforcement costs. It might reduce the costs of this rule by allowing us to avoid costly errors and delays. However, the comment did not provide evidence that this effect would occur.

(Comment 158) Some comments request that we provide additional guidance on how to file an appeal, addressing such issues as whether we require all appeals to include certain basic information. One comment suggests that we run workshops for local trainers and prepare slide and video presentations, online training manuals, and explanatory leaflets on how to appeal administrative detentions. One comment suggests that we describe appeal procedures and deadlines in the detention order. The comment suggests that we include the following information in the detention order: The claimant has a right to appeal the order; the appeal must be submitted in writing to the appropriate (and identified) FDA District Director, the number of days the claimant has to file the appeal and request a hearing, and the date by which such an appeal and request must be made.

(Response) We will provide information on how to appeal administrative detentions in the detention orders. As stated previously, we also plan extensive outreach materials, including explanatory materials, such as slide presentations, a satellite downlink meeting, and fact sheets, to explain the requirements of the final rule, similar to what we did for the proposed rule. Providing other information and guidance would increase our enforcement costs. It would probably have a minimal impact on other costs and distributional effects because anyone wishing to file an appeal could learn what to do from these materials.

(Comment 159) Some comments suggest that we revise the rule to require that the official presiding at an informal hearing be senior to the official who approved the detention order. They argue that presiding officials may be less likely to terminate detention orders if FDA employees senior to those presiding officials authorized those orders.

(Response) Revising the rule as this comment suggests might increase the likelihood that we would terminate some administrative detention orders during the appeal process for the reasons this comment suggests. However, we have insufficient information to establish that this effect would take place. This revision would increase our enforcement costs by reducing the pool of employees that would be eligible to either authorize administrative detentions or to preside at appeals hearings.

(Comment 160) One comment suggests that appeals hearings should include participation or attendance by third parties.

(Response) Including a third party in appeals hearings would increase the costs associated with those hearings. The comment did not explain the mechanism by which the presence of a third party would reduce costs or increase benefits. We note, however, that hearings generally are open to anyone who wishes to attend as a nonparticipant, unless classified or confidential information (*e.g.*, information exempt from disclosure under applicable laws) is being discussed.

1. *Summary.* Table 5 of this document summarizes the range of costs and benefits for the five options that we have considered. We have indicated that we cannot determine the effects of many of the suggested revisions that we discussed under Option Five. However, we have insufficient information to establish that any of those revisions would increase net benefits.

TABLE 5.—SUMMARY OF ANNUAL COSTS AND BENEFITS

Option	Costs (in millions)	Benefits
One—Transportation and Perishable Foods as Proposed	$0 to $50	>$0.
Two—Perishable Foods Alternatives	$0 to $42	>$0, But < Option One.
Three—No Transportation, But One Additional Guard	$0 to $56	>$0.
Four—Limited to the Bioterrorism Act	>$0 to >$50	>$0, But ≤ Option One.
Five—Revise in Other Ways	N/A	N/A.

B. Final Regulatory Flexibility Analysis

We have examined the economic implications of this final rule as required by the Regulatory Flexibility Act (5 U.S.C. 601–612). If a rule has a significant economic impact on a substantial number of small entities, the Regulatory Flexibility Act requires us to analyze regulatory options that would lessen the economic effect of the rule on small entities. We find that this final rule would not have a significant economic impact on a substantial number of small entities.

(Comment 161) In the analysis of the proposed rule, we requested comments on the impact of the proposed rule on small entities. The only comment we received on this issue noted that most firms making indirect food contact color pigments that firms may use in the manufacture of food packaging are small businesses.

(Response) This comment is consistent with the analysis in the proposed rule. Therefore, we have not

revised the analysis that we presented in the proposed rule.

C. Unfunded Mandates

Title II of the Unfunded Mandates Reform Act of 1995 (Pub. L. 104–4) requires cost-benefit and other analyses before any rulemaking if the rule would include a ''* * * Federal mandate that may result in the expenditure by State, local, and tribal governments, in the aggregate, or by the private sector, of $100,000,000 or more (adjusted annually for inflation) in any 1 year.'' The current inflation-adjusted statutory threshold is $112.3 million per year. We have estimated that the total cost of the proposed rule would be no more than $50 million per year. Therefore, we have determined that this final rule does not constitute a significant rule under the Unfunded Mandates Reform Act.

D. Small Business Regulatory Enforcement Fairness Act (SBREFA) Major Rule

SBREFA (Pub. L. 104–121) defines a major rule for the purpose of congressional review as having caused, or being likely to cause, one or more of the following: An annual effect on the economy of $100 million; a major increase in costs or prices; significant adverse effects on competition, employment, productivity, or innovation; or significant adverse effects on the ability of U.S.-based enterprises to compete with foreign-based enterprises in domestic or export markets. In accordance with SBREFA, OMB has determined that this final rule is not a major rule for the purpose of congressional review.

VII. Paperwork Reduction Act of 1995

This final rule contains information collection provisions that are subject to review by OMB under the Paperwork Reduction Act of 1995 (44 U.S.C. 3501–3520).

We conclude that these information collection provisions are exempt from OMB review under 44 U.S.C. 18(c)(1)(B)(ii) and 5 CFR 1320.4(a)(2) as collections of information obtained during the conduct of a civil action to which the United States or any official or agency thereof is a party, or during the conduct of an administrative action, investigation, or audit involving an agency against specific individuals or entities. The regulations in 5 CFR 1320(c) provide that the exception in 5 CFR 1320.4(a)(2) applies during the entire course of the investigation, audit or action, but only after a case file or equivalent is opened with respect to a particular party. Such a case file would be opened as part of the decision to detain an article of food.

VIII. Analysis of Environmental Impact

The agency has carefully considered the potential environmental effects of this action. FDA has concluded under 21 CFR 25.30(h) that this action is of a type that does not individually or cumulatively have a significant effect on the human environment. Therefore, neither an environmental assessment nor an environmental impact statement is required.

IX. Federalism

FDA has analyzed this final rule in accordance with the principles set forth in Executive Order 13132. FDA has determined that the final rule does not contain policies that have substantial direct effects on the States, on the relationship between the National Government and the States, or on the distribution of power and responsibilities among the various levels of government. Accordingly, the agency concludes that the final rule does not contain policies that have federalism implications as defined in the Executive Order and, consequently, a federalism summary impact statement has not been prepared.

X. References

The following references have been placed on display in the Division of Dockets Management (HFA–305), Food and Drug Administration, 5630 Fishers Lane, rm. 1061, Rockville, MD 20852 and may be seen by interested persons between 9 a.m. and 4 p.m., Monday through Friday. FDA has verified the Web site addresses, but FDA is not responsible for any subsequent changes to the Web sites after this document publishes in the **Federal Register**.

1. Holcomb, Harry, Area officials have adapted a tracking system to watch over U.S. ships in an age of terrorism, accessed on the Internet at *http://www.philly.com/mld/inquirer/5369951.htm,* accessed on September 16, 2003.

2. AAA Environmental Industry, Inc., Cost Proposal, Schedule of Standard Rates Effective July 1, 2002, available on the Internet at *http://vendornet.state.wi.us/vendornet/wais/bulldocs/1431_4.doc,* accessed on September 16, 2003.

3. National Compensation Survey: Occupational Wages in the United States, July 2002. U.S. Department of Labor, Bureau of Labor Statistics, June 2003. Available on the Internet at *http://stats.bls.gov/ncs/ocs/sp/ncbl0539.pdf,* accessed on September 16, 2003.

List of Subjects

21 CFR Part 1

Cosmetics, Drugs, Exports, Food labeling, Imports, Labeling, Reporting and recordkeeping requirements.

21 CFR Part 10

Administrative practice and procedure, News media.

21 CFR Part 16

Administrative practice and procedure.

■ Therefore, under the Federal Food, Drug, and Cosmetic Act and under authority delegated to the Commissioner of Food and Drugs, 21 CFR parts 1, 10, and 16 are amended as follows:

PART 1—GENERAL ENFORCEMENT REGULATIONS

■ 1. The authority citation for 21 CFR part 1 continues to read as follows:

Authority: 15 U.S.C. 1453, 1454, 1455; 19 U.S.C. 1490, 1491; 21 U.S.C. 321, 331, 332, 333, 334, 335a, 343, 350c, 350d, 352, 355, 360b, 362, 371, 374, 381, 382, 393; 42 U.S.C. 216, 241, 243, 262, 264.

■ 2. Subpart K is added to part 1 to read as follows:

Subpart K—Administrative Detention of Food for Human or Animal Consumption

General Provisions

Sec.

How Does FDA Order a Detention?

What is the Appeal Process for a Detention Order?

Subpart K—Administrative Detention of Food for Human or Animal Consumption

General Provisions

§ 1.377 What definitions apply to this subpart?

The definitions of terms that appear in section 201 of the act (21 U.S.C. 321) apply when the terms are used in this subpart. In addition, for the purposes of this subpart:

Act means the Federal Food, Drug, and Cosmetic Act.

Authorized FDA representative means an FDA District Director in whose district the article of food involved is located or an FDA official senior to such director.

Calendar day means every day shown on the calendar.

Food has the meaning given in section 201(f) of the act (21 U.S.C. 321(f)). 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.

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.

We means the U.S. Food and Drug Administration (FDA).

Working day means any day from Monday through Friday, excluding Federal holidays.

You means any person who received the detention order or that person's representative.

§ 1.378 What criteria does FDA use to order a detention?

An officer or qualified employee of FDA may 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.

§ 1.379 How long may FDA detain an article of food?

(a) FDA may detain an article of food for a reasonable period that may not exceed 20 calendar days after the detention order is issued. However, an article may be detained for 10 additional calendar days if a greater period of time is required to institute a seizure or injunction action. The authorized FDA representative may approve the additional 10-calendar day detention period at the time the detention order is issued, or at any time within the 20-calendar day period by amending the detention order.

(b) The entire detention period may not exceed 30 calendar days.

(c) An authorized FDA representative may, in accordance with § 1.384, terminate a detention order before the expiration of the detention period.

§ 1.380 Where and under what conditions must the detained article of food be held?

(a) You must hold the detained article of food in the location and under the conditions specified by FDA in the detention order.

(b) If FDA determines that removal to a secure facility is appropriate, the article of food must be removed to a secure facility. A detained article of food remains under detention before, during, and after movement to a secure facility. FDA will also state in the detention order any conditions of transportation applicable to the detained article.

(c) If FDA directs you to move the detained article of food to a secure facility, you must receive a modification of the detention order under § 1.381(c) before you move the detained article of food to a secure facility.

(d) You must ensure that any required tags or labels under § 1.382 accompany the detained article during and after movement. The tags or labels must remain with the article of food until FDA terminates the detention order or the detention period expires, whichever occurs first, unless otherwise permitted by the authorized FDA representative.

(e) The movement of an article of food in violation of a detention order issued under § 1.393 is a prohibited act under section 301 of the act (21 U.S.C. 331).

§ 1.381 May a detained article of food be delivered to another entity or transferred to another location?

(a) An article of food subject to a detention order under this subpart may not be delivered under the execution of a bond. Notwithstanding section 801(b) of the act (21 U.S.C. 381(b)), while any article of food is subject to a detention order under section 304(h) of the act (21 U.S.C. 334(h)), it may not be delivered to any of its importers, owners, or consignees. This section does not preclude movement at FDA's direction of imported food to a secure facility under an appropriate Customs' bond when that bond is required by Customs' law and regulation.

(b) Except as provided in paragraph (c) of this section, no person may transfer a detained article of food within or from the place where it has been ordered detained, or from the place to which it was removed, until an authorized FDA representative releases the article of food under § 1.384 or the detention period expires under § 1.379, whichever occurs first.

(c) The authorized FDA representative may approve, in writing, a request to modify a detention order to permit movement of a detained article of food for any of the following purposes:

(1) To destroy the article of food,

(2) To move the detained article of food to a secure facility under the terms of a detention order,

(3) To maintain or preserve the integrity or quality of the article of food, or

(4) For any other purpose that the authorized FDA representative believes is appropriate in the case.

(d) You must submit your request for modification of the detention order in writing to the authorized FDA representative who approved the detention order. You must state in your request the reasons for movement; the exact address of and location in the new facility (or the new location within the same facility) where the detained article of food will be transferred; an explanation of how the new address and location will be secure, if FDA has directed that the article be detained in a secure facility; and how the article will be held under any applicable conditions described in the detention order. If you are requesting modification of a detention order for the purpose of destroying the detained article of food, you also must submit a verified statement identifying the ownership or proprietary interest you have in the detained article of food, in accordance with Supplemental Rule C to the ''Federal Rules of Civil Procedure.''

(e) If FDA approves a request for modification of a detention order, the article may be transferred but remains under detention before, during, and after the transfer. FDA will state any conditions of transportation applicable to the detained article. You may not transfer a detained article of food without FDA supervision unless FDA has declined in writing to supervise the transfer. If FDA has declined in writing to supervise the transfer of a detained article, you must immediately notify in writing the authorized FDA representative who approved the modification of the detention order that the article of food has reached its new location, and the specific location of the detained article within the new location. Such written notification may be in the form of a fax, e-mail, or other form as agreed to by the authorized FDA representative.

(f) You must ensure that any required tags or labels under § 1.382 accompany the detained article during and after movement. The tags or labels must remain with the article of food until FDA terminates the detention order or the detention period expires, whichever occurs first, unless otherwise permitted by the authorized FDA representative who approves the modification of a detention order under this section.

(g) The transfer of an article of food in violation of a detention order issued under § 1.393 is a prohibited act under section 301 of the act.

§ 1.382 What labeling or marking requirements apply to a detained article of food?

The officer or qualified employee of FDA issuing a detention order under § 1.393 may label or mark the detained article of food with official FDA tags or labels that include the following information:

(a) A statement that the article of food is detained by FDA in accordance with section 304(h) of the act;

(b) A statement that the article of food must not be consumed, moved, altered, or tampered with in any manner for the period shown, without the written permission of an authorized FDA representative;

(c) A statement that the violation of a detention order or the removal or alteration of the tag or label is a prohibited act, punishable by fine or imprisonment or both; and

(d) The detention order number, the date and hour of the detention order, the detention period, and the name of the officer or qualified employee of FDA who issued the detention order.

§ 1.383 What expedited procedures apply when FDA initiates a seizure action against a detained perishable food?

If FDA initiates a seizure action under section 304(a) of the act against a perishable food subject to a detention order under this subpart, FDA will send the seizure recommendation to the Department of Justice (DOJ) within 4 calendar days after the detention order is issued, unless extenuating circumstances exist. If the fourth calendar day is not a working day, FDA will advise the DOJ of its plans to recommend a seizure action on the last working day before the fourth calendar day and send the recommendation as soon as practicable on the first working day that follows. For purposes of this section, an extenuating circumstance includes, but is not limited to, instances when the results of confirmatory testing or other evidentiary development requires more than 4 calendar days to complete.

§ 1.384 When does a detention order terminate?

If FDA terminates a detention order or the detention period expires, an authorized FDA representative will issue a detention termination notice releasing the article of food to any person who received the detention order or that person's representative and will remove, or authorize in writing the removal of, the required labels or tags. If FDA fails to issue a detention termination notice and the detention period expires, the detention is deemed to be terminated.

How Does FDA Order a Detention?

§ 1.391 Who approves a detention order?

An authorized FDA representative, *i.e.*, the FDA District Director in whose district the article of food involved is located or an FDA official senior to such director, must approve a detention order. If prior written approval is not feasible, prior oral approval must be obtained and confirmed in writing as soon as possible.

§ 1.392 Who receives a copy of the detention order?

(a) FDA must issue the detention order to the owner, operator, or agent in charge of the place where the article of food is located. If the owner of the article of food is different from the owner, operator, or agent in charge of the place where the article is detained, FDA must provide a copy of the detention order to the owner of the article of food if the owner's identity can be determined readily.

(b) If FDA issues a detention order for an article of food located in a vehicle or other carrier used to transport the detained article of food, FDA also must provide a copy of the detention order to the shipper of record and the owner and operator of the vehicle or other carrier, if their identities can be determined readily.

§ 1.393 What information must FDA include in the detention order?

(a) FDA must issue the detention order in writing, in the form of a detention notice, signed and dated by the officer or qualified employee of FDA who has credible evidence or information indicating that such article of food presents a threat of serious adverse health consequences or death to humans or animals.

(b) The detention order must include the following information:

(1) The detention order number;

(2) The date and hour of the detention order;

(3) Identification of the detained article of food;

(4) The period of the detention;

(5) A statement that the article of food identified in the order is detained for the period shown;

(6) A brief, general statement of the reasons for the detention;

(7) The address and location where the article of food is to be detained and the appropriate storage conditions;

(8) Any applicable conditions of transportation of the detained article of food;

(9) A statement that the article of food is not to be consumed, moved, altered, or tampered with in any manner during the detention period, unless the detention order is first modified under § 1.381(c);

(10) The text of section 304(h) of the act and §§ 1.401 and 1.402;

(11) A statement that any informal hearing on an appeal of a detention order must be conducted as a regulatory hearing under part 16 of this chapter, with certain exceptions described in § 1.403;

(12) The mailing address, telephone number, e-mail address, and fax number of the FDA district office and the name of the FDA District Director in whose district the detained article of food is located;

(13) A statement indicating the manner in which approval of the detention order was obtained, *i.e.*, verbally or in writing; and

(14) The name and the title of the authorized FDA representative who approved the detention order.

What Is the Appeal Process for a Detention Order?

§ 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 act, may appeal a detention order as specified in § 1.402. Procedures for establishing entitlement to be a claimant for purposes of section 304(a) of the act are governed by Supplemental Rule C to the ''Federal Rules of Civil Procedure.''

§ 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 § 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 § 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 act or an injunction under section 302 of the act (21 U.S.C. 276) 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.

§ 1.403 What requirements apply to an informal hearing?

If FDA grants a request for an informal hearing on an appeal of a detention order, FDA must conduct the hearing in accordance with part 16 of this chapter, except that:

(a) The detention order under § 1.393, rather than the notice under § 16.22(a) of this chapter, provides notice of opportunity for a hearing under this section and is part of the administrative record of the regulatory hearing under § 16.80(a) of this chapter;

(b) A request for a hearing under this section must be addressed to the FDA District Director in whose district the article of food involved is located;

(c) The provision in § 16.22(b) of this chapter, providing that a person not be given less than 3 working days after receipt of notice to request a hearing, does not apply to a hearing under this subpart;

(d) The provision in § 16.24(e) of this chapter, stating that a hearing may not be required to be held at a time less than 2 working days after receipt of the request for a hearing, does not apply to a hearing under this subpart;

(e) Section 1.406, rather than § 16.24(f) of this chapter, describes the statement that will be provided to an appellant where a detention order is based on classified information;

(f) Section 1.404, rather than § 16.42(a) of this chapter, describes the FDA employees, *e.g.*, Regional Food and Drug Directors or other officials senior to a District Director, who preside at hearings under this subpart;

(g) The presiding officer may require that a hearing conducted under this section be completed within 1 calendar day, as appropriate;

(h) Section 16.60(e) and (f) of this chapter does not apply to a hearing under this subpart. The presiding officer must prepare a written report of the hearing. All written material presented at the hearing will be attached to the report. The presiding officer must include as part of the report of the hearing a finding on the credibility of witnesses (other than expert witnesses) whenever credibility is a material issue, and must include a proposed decision, with a statement of reasons. The hearing participant may review and comment on the presiding officer's report within 4 hours of issuance of the report. The presiding officer will then issue the final agency decision.

(i) Section 16.80(a)(4) of this chapter does not apply to a regulatory hearing under this subpart. The presiding officer's report of the hearing and any comments on the report by the hearing participant under § 1.403(h) are part of the administrative record.

(j) No party shall have the right, under § 16.119 of this chapter to petition the Commissioner of Food and Drugs for reconsideration or a stay of the presiding officer's final agency decision.

(k) If FDA grants a request for an informal hearing on an appeal of a detention order, the hearing must be conducted as a regulatory hearing pursuant to regulation in accordance with part 16 of this chapter, except that § 16.95(b) does not apply to a hearing under this subpart. With respect to a regulatory hearing under this subpart, the administrative record of the hearing specified in §§ 16.80(a)(1), (a)(2), (a)(3), and (a)(5), and 1.403(i) constitutes the exclusive record for the presiding officer's final decision on an administrative detention. For purposes of judicial review under § 10.45 of this chapter, the record of the administrative proceeding consists of the record of the hearing and the presiding officer's final decision.

§ 1.404 Who serves as the presiding officer for an appeal, and for an informal hearing?

The presiding officer for an appeal, and for an informal hearing, must be an FDA Regional Food and Drug Director or another FDA official senior to an FDA District Director.

§ 1.405 When does FDA have to issue a decision on an appeal?

(a) The presiding officer must issue a written report that includes a proposed decision confirming or revoking the detention by noon on the fifth calendar day after the appeal is filed; after your 4 hour opportunity for submitting comments under § 1.403(h), the presiding officer must issue a final decision within the 5-calendar day period after the appeal is filed. If FDA either fails to provide you with an opportunity to request an informal hearing, or fails to confirm or terminate the detention order within the 5-calendar day period, the detention order is deemed terminated.

(b) If you appeal the detention order, but do not request an informal hearing, the presiding officer must issue a decision on the appeal confirming or revoking the detention within 5 calendar days after the date the appeal is filed. If the presiding officer fails to confirm or terminate the detention order during such 5-calendar day period, the detention order is deemed terminated.

(c) If you appeal the detention order and request an informal hearing and your hearing request is denied, the presiding officer must issue a decision

on the appeal confirming or revoking the detention within 5 calendar days after the date the appeal is filed. If the presiding officer fails to confirm or terminate the detention order during such 5-calendar day period, the detention order is deemed terminated.

(d) If the presiding officer confirms a detention order, the article of food continues to be detained until we terminate the detention under § 1.384 or the detention period expires under § 1.379, whichever occurs first.

(e) If the presiding officer terminates a detention order, or the detention period expires, FDA must terminate the detention order as specified under § 1.384.

(f) Confirmation of a detention order by the presiding officer is considered a final agency action for purposes of 5 U.S.C. 702.

§ 1.406 How will FDA handle classified information in an informal hearing?

Where the credible evidence or information supporting the detention order is classified under the applicable Executive order as requiring protection from unauthorized disclosure in the interest of national security (''classified information''), FDA will not provide you with this information. The presiding officer will give you notice of the general nature of the information and an opportunity to offer opposing evidence or information, if he or she may do so consistently with safeguarding the information and its source. If classified information was used to support the detention, then any confirmation of such detention will state whether it is based in whole or in part on that classified information.

PART 10—ADMINISTRATIVE PRACTICES AND PROCEDURES

■ 3. The authority citation for 21 CFR part 10 continues to read as follows:

Authority: 5 U.S.C. 551–558, 701–706; 15 U.S.C. 1451–1461; 21 U.S.C. 141–149, 321–397, 467f, 679, 821, 1034; 28 U.S.C. 2112; 42 U.S.C. 201, 262, 263b, 264.

■ 4. Section 10.45 is amended by revising paragraph (d) introductory text to read as follows:

§ 10.45 Court review of final administrative action; exhaustion of administrative remedies.

* * * * *

(d) Unless otherwise provided, the Commissioner's final decision constitutes final agency action (reviewable in the courts under 5 U.S.C. 701 *et seq.* and, where appropriate, 28 U.S.C. 2201) on a petition submitted under § 10.25(a), on a petition for reconsideration submitted under § 10.33, on a petition for stay of action submitted under § 10.35, on an advisory opinion issued under § 10.85, on a matter involving administrative action which is the subject of an opportunity for a hearing under § 16.1(b) of this chapter, or on the issuance of a final regulation published in accordance with § 10.40, except that the agency's response to a petition filed under section 505(j)(2)(C) of the act (21 U.S.C. 355(j)(2)(C)) and § 314.93 of this chapter will not constitute final agency action until any petition for reconsideration submitted by the petitioner is acted on by the Commissioner.

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PART 16—REGULATORY HEARING BEFORE THE FOOD AND DRUG ADMINISTRATION

■ 5. The authority citation for 21 CFR part 16 continues to read as follows:

Authority: 15 U.S.C. 1451–1461; 21 U.S.C. 141–149, 321–394, 467f, 679, 821, 1034; 28 U.S.C. 2112; 42 U.S.C. 201–262, 263b, 364.

■ 6. Section 16.1 is amended in paragraph (b)(1) by adding an entry in alphanumerical order as follows:

§ 16.1 Scope.

* * * * *

(b) * * *

(1) * * *

Section 304(h) of the act relating to the administrative detention of food for human or animal consumption (see part 1, subpart k of this chapter).

* * * * *

Dated: May 13, 2004.

Lester M. Crawford,

Acting Commissioner of Food and Drugs.

Dated: May 25, 2004.

Tommy G. Thompson,

Secretary of Health and Human Services.

[FR Doc. 04–12366 Filed 5–27–04; 10:57 am]

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