

distribute or market the article of food if the detention order is terminated.

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

Section 303 of the Bioterrorism Act directs the Secretary to issue procedures for instituting certain judicial enforcement actions on an expedited basis with respect to perishable food subject to a detention order. This provision directs FDA to issue procedures for instituting on an expedited basis seizure actions under section 304(a) of the act, or injunction actions under section 302 of the act (21 U.S.C. 332), or both. We have concluded that it is appropriate to focus on procedures to institute seizure actions on an expedited basis because a seizure is the most efficient judicial action for rapid control of a violative article of perishable food.

Proposed § 1.383 describes FDA's procedure for sending a seizure recommendation under section 304(a) of the act to the Department of Justice (DOJ) for a perishable food (defined in proposed § 1.377) subject to a detention order. We propose to send the seizure recommendation to 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 when the government is open for business, we will advise the DOJ of our 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 example, if a detention order is issued on a Wednesday, the fourth calendar day would be the following Sunday. Because Sunday is a non-working day, we would advise the DOJ of our plans to recommend a seizure action on Friday and would send the recommendation as soon as practicable on the following Monday.

For purposes of this proposed section, extenuating circumstances include, but are not limited to, instances when the results of confirmatory testing or other evidentiary development require more than 4 calendar days to complete.

Proposed § 1.383 is designed to accelerate the procedure for seizure recommendations and takes into account the 7-day timeframe in the proposed definition of "perishable food." As noted previously in section III.B.7 of this document, we have focused our implementation of this provision of section 303 of the Bioterrorism Act on seizure

recommendation procedures. Use of injunctive relief may be appropriate in some circumstances involving detained perishable foods. However, expedited procedures for instituting injunction actions would not accelerate the judicial control of a particular violative article of perishable food as much as expedited procedures for seizure actions.

We invite comment on this or other procedures that would address concerns about expedited enforcement actions with respect to perishable food.

8. When Does a Detention Order Terminate? (Proposed § 1.384)

Under proposed § 1.384, an authorized FDA representative will issue a detention termination notice releasing the detained article of food if FDA decides to terminate a detention order or the detention period expires. FDA will issue the detention termination notice to any person who received the detention order or that person's representative. FDA also will remove, or authorize the removal of, the required labels or tags attached under proposed § 1.382. If FDA fails to issue a detention termination notice and the detention period expires, the detention order is deemed to be terminated.

C. How Does FDA Order a Detention?

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

Proposed § 1.391 requires that an authorized FDA representative approve a detention order. As defined in proposed § 1.377, an "authorized FDA representative" is 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. This is consistent with the approval requirements found in section 303 of the Bioterrorism Act. We are proposing that if prior written approval of a detention order is not feasible, prior oral approval must be obtained and confirmed in writing as soon as possible. We believe allowing for oral approval of a detention followed by written confirmation allows for efficient implementation of the administrative detention provisions.

For example, the investigator may be at a manufacturing plant located a great distance away from the district office and may determine that a detention is warranted. Instead of losing valuable time driving back to the district office to get a written signature in cases where a fax machine is not close by, the investigator may telephone the authorized FDA representative to get an oral approval. The authorized FDA

representative would subsequently confirm the oral approval in writing by sending written confirmation to the investigator. In other circumstances where there is risk of the product moving to another location, we would want to detain the product immediately and an oral approval of the detention order may be prudent, followed by confirmation in writing. These examples illustrate some situations where oral approval may be necessary, but do not constitute an all inclusive list.

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

Proposed § 1.392(a) 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 location of the food, 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.

Proposed § 1.392(b) would subject common carriers of articles of food to these administrative detention provisions. 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 would be required to provide a copy of the detention order to the shipper of record and the owner and operator of the vehicle or other carrier, if FDA can determine their identities readily.

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

Proposed § 1.393(a) requires FDA to issue the detention order in writing, 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. The written detention order serves as notice of the detention and provides notice that the persons with ownership rights to the detained article of food have the right to request an informal hearing.

Proposed § 1.393(b) requires the detention order to 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;