

Revisions made in Response to Comments  
or Suggestions from OMB/OIRA, or Any Other  
Agency or Governmental Component to Which  
OMB/OIRA Sent the Document for Review

Revisions made in Response to Comments  
or Suggestions from DHHS, including FDA,  
In Consultation with OMB/OIRA, while the  
Document was Under Review at OMB/OIRA

April 25, 2003  
and  
April 29, 2003

**REVISIONS**

APR 29 2003

NOT REFLECTED IN APPENDUM

GREEN P. 27 P. 19 (ms) P. 85

Addendum to Administrative Detention Responses to OMB Questions

**REVI**

- Changes made to the text and tables to explain calculations (underlined text indicates new text):

(A)

55  
Page 83, next to the last sentence before Table 2, the following insertion is made:

In Table 2, we estimate the range of additional trips to secure facilities to be 0 to 1587. The number is based on 0 to 16 seizures (in row 1), a maximum of 67 truckloads per seizure, and a maximum of 48% additional trips for those products cleared to enter commerce. We calculate the maximum number of trips as:  $(16 \times 67) + (0.48 \times 16 \times 67) = 1587$ .

OK

percent

bb

OK

bb

OK

(B)

56  
Page 85, Table 2. The heading of column 2 now reads:

Number of Actions (see Table 1)

bb

(C)

57  
Page 87. The last sentence of the ~~last~~ <sup>first</sup> paragraph should now read:

These rates imply storage costs of \$0 to \$600 per day per administrative detention, and handling rates of \$0 to \$20,000 per administrative detention, based on a shipment size of 0 to 1 million pounds (67 truckloads per shipment x 15,000 pounds per truckload).

\*\*Please note that the change from \$21,000 to \$20,000 above is due to a previous, inadvertent error.

(D)

63  
Page 97. Last sentence of first paragraph should now read:

Based on the rates of value loss given earlier, the average loss of value per administrative detention action per day would be \$0 to \$102,000 (14 percent loss per day x \$730,000) per day for perishable food, and \$0 to \$22,000 (3 percent loss per day x \$730,000) per day for non-perishable food.

\*\*Please note that we deleted "per day" above, not because it is incorrect, but redundant.

OK

word bb

(E)

63  
Page 98. Insert following sentence immediately before Table 4:

We estimate the maximum loss of value as the maximum number of actions in which the product is not violative, multiplied by the maximum loss per action: \$730,000, the average total value of a shipment.

OK

✓

(F)

64  
Page 100. The last paragraph on this page, 2<sup>nd</sup> sentence, should now read:

In that analysis, we assumed that an average shipment of imported food would contain about 300 cartons of containers, and that a worker could attach 100 labels per hour.

now bb

(G)

64  
Page 101. Approximately 7 lines down, the text should now read:

We earlier assumed that the average amount of food in a line is 15,000 pounds, so we estimate that a shipment contains 0.02 cartons per pound (300 cartons per shipment/15,000 pounds per shipment). Therefore, an administrative detention action involving between 0 and 1 million pounds would require 0 to 200 hours of labor time

g  
y  
bb  
JK  
(0.02 cartons per pound x 1 million pounds / 100 labels per hour), and 0 to 20,000 labels (100 labels per hour x 200 hours). The cost of the labor time necessary to attach the labels to the cartons would be \$0 to \$3,500 (\$17.64 per hour x 200 hours), and the cost of the labels would be \$0 to \$900 (\$0.045 per label x 20,000 labels).

\*\*Please note that the change from \$0.025 to \$0.045 above is due to a previous, inadvertent error.

- Additional corrections due to previous, inadvertent errors

(H)

58  
Pages ~~89-90~~. Table 3. The 4<sup>th</sup> column of the table should be changed to \$0 to \$600. The 5<sup>th</sup> column should be changed to \$0 to \$20,000.

(I)

64 in the 2d parag.  
Page 101. The 1st full sentence. Change "300 labels at \$0.025 per label" to "300 labels at \$0.045 per label."

JK  
JK

DEPARTMENT OF HEALTH AND HUMAN SERVICES

FOOD AND DRUG ADMINISTRATION

21 CFR PART 1

[DOCKET NO. 02N-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: Notice of proposed rulemaking.

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SUMMARY: The Food and Drug Administration (FDA) is proposing a 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 proposed regulation implements section 303 of the Public Health Security and Bioterrorism Preparedness Act of 2002 ("the Bioterrorism Act"), which authorizes the use of administrative detentions and requires regulations establishing procedures for instituting on an expedited basis certain enforcement actions against perishable

employee may order a detention.

3. How long may FDA detain an article of food? (Proposed § 1.379)

Proposed § 1.379 sets forth the period of administrative detention, (i.e., the length of time an article of food may be detained), consistent with the requirements of section 303 of the Bioterrorism Act. The period of administrative detention must be a reasonable period that may not exceed 20 calendar days after the detention order is issued, unless it is determined that a greater period is required either to seize the article of food or to institute injunction proceedings. [REDACTED]

[REDACTED]

[REDACTED]

10 /

[REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]

[REDACTED] The authorized FDA representative, defined in proposed § 1.377, may approve the additional ten days of detention at the time the detention order is issued, or at any

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these figures by multiplying the number of truckloads that ~~may~~we  
estimated would be involved in an administrative detention (0 to  
67) by the number of times we might ~~replace~~use administrative  
detention ~~for~~in place of Class I recall requests, ~~or~~ cases of  
moving directly to seizure, or referring a matter to state  
authorities. ~~We calculated the number of round trips by~~  
~~multiplying the number of one way trips times the estimated~~  
~~percentage of cases in which we might release a detention order~~  
~~and allow food back into commerce.~~The number of one way trips  
includes return trips, which we calculated by multiplying the  
number of trips to secure storage facilities by the estimated  
percentage of cases in which we might terminate a detention order  
and allow food back into commerce (0% to 48%). [REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]

[REDACTED] Again, estimated costs are higher for  
administrative actions that replace cases of moving directly to  
seizure actions or referring matters ~~problems~~ to states than for  
administrative actions that replace Class I recalls because we  
are using the costs of those other actions as the baseline, and

| <u>Table 2 -<br/>Annual<br/>Transportation<br/>Costs</u>   |  |   |                                      |  |
|--|--|---|--------------------------------------|--|
| <u>Action</u>  | <u>Number<br/>of<br/>Actions</u><br>██████<br>██████████ | <u>Additional<br/>One Way<br/>Trips per<br/>Year, in<br/>Truckloads</u> | <u>Cost per<br/>One Way<br/>Trip</u> | <u>Total<br/>Transportation<br/>Cost (in<br/>millions)</u> |
| <u>Admini-<br/>strative<br/>Detention<br/>that<br/>Replaces<br/>Case of<br/>Moving<br/>Directly<br/>to<br/>Seizure</u> | <u>0 to 16</u>   | <u>0 to 1,587</u>   | ██████<br>██████                     | <u>\$0 M to \$2 M</u>                                      |
| <u>Admini-<br/>strative<br/>Detention<br/>that<br/>Replaces<br/>Class I<br/>Recall</u>                                 | <u>0 to 184</u>  | <u>0</u>  | ██████<br>██████                     | <u>\$0</u>   |
| <u>Admini-<br/>strative</u>  | <u>0 to 23</u>   | <u>0 to<br/>2,323</u>   | ██████<br>██████                     | <u>\$0 to \$2 M</u>  |

require higher security, such as that associated with secure government storage facilities, for example, Customs Examination Stations. In other cases, we might require lower security, such as that associated with a firm's own warehouses. We understand from a discussion with a representative of the International Association of Refrigerated Warehouses that the cost difference between bonded and non-bonded public warehouses is probably quite small. (Ref. 2) Therefore, we use the same storage costs for both bonded and non-bonded warehouses.

Storage costs vary with the type of food being stored. However, we were unable to find data on average storage rates for different types of food under different conditions. (Ref. 2) One cold storage facility gave us food storage rates that varied from \$0.0002 to \$0.0006 per pound per month for a range of food types. (Ref. 3) Rates for food that does not need to be refrigerated might be lower than the lower bound of the rates for cold storage. However, we do not have information on these rates, and we assume that these rates will fall in the same range. The same source listed handling rates per shipment of \$0.01 to \$0.02 per pound. We request comments on these rates. These rates imply storage costs of \$0 to \$600 per day per administrative detention, and handling rates of \$0 to [REDACTED] per administrative detention [REDACTED]

[REDACTED]

[REDACTED]

We estimate overall storage costs based on the handling fee per pound, the storage costs per pound per day, the amount of food we might administratively detain, and the change in the maximum number of days that we might require firms to store the food. We assume that there would be no increase in storage costs if we substituted an administrative detention action for a Class I recall, because firms probably already store food as part of such a recall. There is no storage associated with taking no preliminary enforcement action prior to a seizure action or a referral of a ~~problem-matter~~ to a state authority. Therefore, any storage associated with an administrative detention would be an additional cost in comparison to moving directly to seizure or referring a ~~problem-matter~~ to a state authority.

Administrative detention involves a maximum storage time of up to 30 days. The actual amount of time that firms would store detained food depends on whether and when they appeal the administrative detention order. Firms would appeal if they expected the costs of doing so would be less than the costs of storing the food until we completed our investigation, or until the detention period expired. We have insufficient information to estimate the percentage of administrative detentions that

|   |          |         | <u>ship-</u><br><u>Ment)</u> |                      |                |
|---|----------|---------|------------------------------|----------------------|----------------|
| <p>No preliminary action (move directly to seizure) <u>Administrative Detention</u> that <u>Replaces Case of Moving Directly to Seizure</u></p> | 0 to 16  | 0 to 30 | \$0 to \$ [REDACTED]         | \$0 to \$ [REDACTED] | \$0 M to \$1 M |
| <p><u>Class I recalls Administrative Detention</u> that <u>Replaces Class I Recall</u></p>  | 0 to 184 | 0       | \$0 to \$ [REDACTED]         | \$0 to \$ [REDACTED] | \$0 M          |
| <p><u>Administrative Detention</u> that</p>   | 0 to 23  | 0 to 30 | \$0 to [REDACTED]            | \$0 to [REDACTED]    | \$0 to \$1 M   |

the total value to the value of an average line for those types of food, we extrapolated data on the number of lines in the OASIS system for the three quarters of FY 2002 for human and animal food to estimate a total of approximately four million lines for human and animal food by the end of fiscal year 2002. This implies an average value per line of about \$11,000. We did not have information on the value of other types of imported food, such as dietary supplements or live animals. Therefore, we assumed that the average value per line for all types of food is approximately \$11,000. If an average line is 15,000 pounds, then this corresponds to a value per pound of \$0.73. Therefore, the value of 0 to 1 million pounds would be \$0 to \$730,000. Based on the rates of value loss given earlier, the average loss of value per administrative detention action [REDACTED] would be \$0 to \$102,000 [REDACTED] for perishable food, and \$0 to [REDACTED] [REDACTED] per day for non-perishable food.

We have set the maximum time frame for all administratively detained food, including perishable food, at 30 days. Therefore, we calculated the loss of value for all food based on 0 to 30 days of additional storage. As we discussed earlier in the preamble, we intend in the case of perishable food to send a seizure recommendation to the Department of Justice within four

calendar days after we issue an administrative detention order, unless extenuating circumstances exist. However, we do not know how often extenuating circumstances will exist, or how much time will elapse between our recommendation and the subsequent seizure.

We do not estimate any change in the loss of value if we substitute an administrative detention action for a Class I recall request, because we previously assumed that substituting an administrative detention action for a Class I recall would not change the amount of time a firm would store the food in question. Therefore, any loss of value resulting from taking action against food that was actually not violative would be the same under either type of action. In contrast, there is no storage associated with moving directly to a seizure action or referring a ~~problem-matter~~ to state authorities. Therefore, any loss of value from storage associated with an administrative detention action would be an additional cost in those that cases.

We provide estimates of the value loss for food in Table 54.

[REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]

|  |  |  |  |
|--|--|--|--|
|  |  |  |  |
|--|--|--|--|

Costs of Marking or Labeling

We might label or mark food that we have administratively detained. If we were to label or mark food that we have administratively detained, we could do so in several ways, including, but not limited to, affixing a tag having a self-locking pin that would be inserted in an appropriate seam, border, flap, or other area of the container or product; taping or tying a tag firmly onto the container or item; or affixing the tag to the accompanying documents, or to the carrier. However, if we subsequently cancelled the administrative detention order, then either we, or the firm, would need to remove the label or mark. Class I recalls do not involve marking or labeling.

Moving directly to a seizure action or referring a ~~problem-matter~~ to state authorities also does not involve marking or labeling prior to the seizure action.

In an analysis of another proposed rule that we published in 2001, we discussed the costs of marking cartons of imported food with printed labels that we could affix with label guns. (Ref. 8) In that analysis, we assumed that an average shipment of imported food would contain about 300 cartons or containers [REDACTED]

[REDACTED]. We estimated that the cost of the labor time necessary to attach the labels would be \$53 (three hours at \$17.64 per hour), and that the cost of labels would be \$13 (300 labels at [REDACTED] per label). A shipment of imported food can involve any number of lines of imported food. Therefore, we assume that one line could contain between 1 and 300 cartons. We earlier assumed that the average amount of food in a line is 15,000 pounds [REDACTED]

[REDACTED]. Therefore, an administrative detention action involving between 0 and 1 million pounds would require 0 to 200 hours of labor time [REDACTED], and 0 to 20,000 labels [REDACTED]. The cost of the labor time necessary to attach the labels [REDACTED] would be \$0 to \$3,500 [REDACTED], and the cost of the labels would be \$0 to \$900 [REDACTED].

We assume that the costs associated with the type of labeling we would require for administrative detention would be similar to the costs associated with the type of labeling we discussed in the 2001 analysis. We also assume it would take the same amount of labor time to remove the labels, if we canceled the administrative detention order, as it would take us to affix

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– 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 appeal, and FDA grants the request, the hearing will be held within 3 calendar days after the appeal is filed.

– FDA's decision on appeal will be issued 5 days after the appeal is filed.

• The proposed expedited procedures for certain enforcement actions with respect to perishable foods require FDA to send a seizure recommendation to the Department of Justice within 4 calendar days after the detention order is issued, unless extenuating circumstances exist.

• Confirmation of a detention order by the FDA presiding officer is considered final agency action.

### *B. General Provisions*

#### 1. What Definitions Apply to This Subpart? (Proposed § 1.377)

Proposed § 1.377 describes the definitions that apply to this subpart and states that the definition of terms that appear in section 201 of the act (21 U.S.C. 321) apply to such terms when used in this subpart.

Proposed § 1.377 also defines specific terms used in the proposal.

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

• *Authorized FDA representative* means the FDA District Director in whose district the article of food involved is located or an FDA official senior to such director. FDA's Office of Regulatory Affairs (ORA) is responsible for FDA's field operations and compliance related functions. The ORA field organization is divided into regional offices, which are headed by RFDDs. The regions are

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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-day (maximum) deadline for FDA to issue a decision on an appeal of a detention. Under the proposed deadlines for appeals involving the detention of a perishable food, FDA would issue a decision on an appeal prior to the expiration of the 7-day period. We believe the timeframes proposed here offer the best protection to appellants and products.

We invite comments and supporting data on how to best define “perishable food” for the purposes of this proposed rule.

- We means the U.S. Food and Drug Administration.
- *Working day* means any day from Monday through Friday, excluding federal holidays.
- *You* means any person who receives the detention order or that person’s representative.

*italics*

## 2. What Criteria Does FDA Use to Order a Detention? (Proposed § 1.378)

Proposed § 1.378 states the criteria FDA would use to order a detention. These criteria are taken directly from section 303 of the Bioterrorism Act. FDA may order a detention of an article of food that is found during an inspection, examination, or investigation under the act if an officer or qualified employee of 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.

The Bioterrorism Act articulates a standard of “credible evidence or information” for determinations of whether the evidence or information

requirements of section 303 of the Bioterrorism Act. The period of administrative detention must be a reasonable period that may not exceed 20 calendar days after the detention order is issued, unless it is determined that a greater period is required either to seize the article of food or to institute injunction proceedings. *The Bioterrorism Act provides that FDA may insert here* When a greater period of time is necessary, the *detain food for up to 10 additional calendar days if necessary to enable FDA* Bioterrorism Act provides that an article of food may be detained for up to *to institute a seizure or an injunction.* *Proposed § 1.379 incorporates this* 10 additional calendar days. The authorized FDA representative, defined in *authority. An example of when FDA envisions using this authority is* proposed § 1.377, may approve the additional 10 days of detention at the time *when the results of confirmatory testing or other evidentiary development* the detention order is issued, or at any time within the initial 20-calendar-day period, by amending the detention order. *is not complete.*

Proposed § 1.379 states that the entire detention period may not exceed 30 calendar days in total. This proposed section also allows the authorized FDA representative, in accordance with proposed § 1.384, to approve the termination of a detention order before the expiration of the detention period. FDA intends to proceed as expeditiously as possible to resolve all issues involved with particular administrative detentions.

#### 4. Where and Under What Conditions Must the Detained Article of Food be Held? (Proposed § 1.380)

Proposed § 1.380(a) requires you to hold the detained article of food in the location and under the conditions specified by FDA in the detention order. Use of appropriate storage conditions, such as temperature, humidity, and other conditions may be necessary to protect the safety and wholesomeness of the detained article of food. This proposed requirement is consistent with the legislative history of the Bioterrorism Act (see H. Conf. Rept. No. 107-481, at 131 (2002)).

are comparable to the social costs associated with administrative detention actions for purposes of determining baseline costs. If we did not treat these costs as social costs, then substituting administrative detention for class I recalls would generate additional social costs related to transporting food.

Moving directly to a seizure action or referring a matter to State authorities does not involve any transportation costs prior to the seizure action or referral. Therefore, all transportation costs associated with an administrative detention are relevant in the case of an administrative detention that replaces a case of moving directly to a seizure action or a referral to State authorities. Any transportation costs associated with the actual seizure or State action would not be relevant in this context, because administrative detentions may be followed by seizure actions or State actions, so any transportation associated with the seizure action or State action would take place irrespective of whether it was preceded by an administrative detention or not.

We present transportation costs in table 2 of this document. We calculated these figures by multiplying the number of truckloads that we estimated would be involved in an administrative detention (0 to 67) by the number of times we might use administrative detention in place of class I recall requests, cases of moving directly to seizure, or referring a matter to State authorities. The number of one way trips includes return trips, which we calculated by multiplying the number of trips to secure storage facilities by the estimated percentage of cases in which we might terminate a detention order and allow food back into commerce (0 to 48 percent). <sup>Insert A</sup> Again, estimated costs are higher for administrative actions that replace cases of moving directly to seizure actions or referring matters to States than for administrative actions that replace class I recalls because we are using the costs of those other actions

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as the baseline, and class I recalls already involve transportation, while cases

of moving directly to seizure actions or referring matters to States do not.

TABLE 2.—ANNUAL TRANSPORTATION COSTS

| Action  | Number of Actions<br>(see Table 1) | Additional One Way Trips per Year, in Truckloads | Cost per one Way Trip  | Total Transportation Cost (in millions) |
|---|------------------------------------|--|--|---|
| Administrative Detention that Replaces Case of Moving Directly to Seizure | 0 to 16                            | 0 to 1,587                                       | <sup>100</sup><br><del>\$1,700</del> to <sup>1,000</sup><br><del>\$2,000</del> | \$0 to \$2                              |
| Administrative Detention that Replaces Class I Recall                     | 0 to 184                           | 0  | <sup>100</sup><br><del>\$1,700</del> to <sup>1,000</sup><br><del>\$2,000</del> | \$0                                     |
| Administrative Detention that Replaces Referral to States                 | 0 to 23                            | 0 to 2,323                                       | <sup>100</sup><br><del>\$1,700</del> to <sup>1,000</sup><br><del>\$2,000</del> | \$0 to \$2                              |
| Total   |                                    |  |  | \$0 to \$4                              |

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### Storage

The cost of storing food in secure storage facilities depends on the following factors: (1) Level of security of the facility; (2) type of food; (3) length of time the food is stored; (4) amount of food; and (5) miscellaneous factors, such as geographic location of facility, whether the customer is a regular or repeat customer, volume discounts, etc.

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We do not define the security requirements for storage facilities in this rule. Instead, we will determine the relevant level of security on a case-by-case basis. We tentatively assume that the normal or average level of security that we would require is the level associated with bonded or third party public warehouses. Using these warehouses should provide some additional security because the owner of the food relinquishes custody of the food to the warehouse. In some cases, we might require higher security, such as that associated with secure government storage facilities, for example, Customs Examination Stations. In other cases, we might require lower security, such as that associated with a firm's own warehouses. We understand from a discussion with a representative of the International Association of Refrigerated Warehouses that the cost difference between bonded and

nonbonded public warehouses is probably quite small (Ref. 2). Therefore, we use the same storage costs for both bonded and nonbonded warehouses.

Storage costs vary with the type of food being stored. However, we were unable to find data on average storage rates for different types of food under different conditions (Ref. 2). One cold storage facility gave us food storage rates that varied from \$0.0002 to \$0.0006 per pound per month for a range of food types (Ref. 3). Rates for food that does not need to be refrigerated might be lower than the lower bound of the rates for cold storage. However, we do not have information on these rates, and we assume that these rates will fall in the same range. The same source listed handling rates per shipment of \$0.01 to \$0.02 per pound. We request comments on these rates. These rates imply storage costs of \$0 to \$600 per day per administrative detention, and handling rates of \$0 to \$20,000 per administrative detention. *These rates imply storage costs of \$0 to \$600 per day per administrative detention, and handling rates of \$0 to \$20,000 per administrative detention. <sup>based on a shipment size of 0 to 1 million pounds (67 truckloads per shipment x 15,000 pounds per-truckload)</sup>*

We estimate overall storage costs based on the handling fee per pound, the storage costs per pound per day, the amount of food we might administratively detain, and the change in the maximum number of days that we might require firms to store the food. We assume that there would be no increase in storage costs if we substituted an administrative detention action for a class I recall, because firms probably already store food as part of such a recall. There is no storage associated with taking no preliminary enforcement action prior to a seizure action or a referral of a matter to a State authority. Therefore, any storage associated with an administrative detention would be an additional cost in comparison to moving directly to seizure or referring a matter to a State authority.

Administrative detention involves a maximum storage time of up to 30 days. The actual amount of time that firms would store detained food depends

on whether and when they appeal the administrative detention order. Firms would appeal if they expected the costs of doing so would be less than the costs of storing the food until we completed our investigation, or until the detention period expired. We have insufficient information to estimate the percentage of administrative detentions that firms would appeal. Therefore, we use a maximum of 30 days additional storage time for all administrative detentions. We do not know how long firms store food that they voluntarily recall before reconditioning or destroying the food. We tentatively assume that the storage time associated with class I recalls would be similar to the storage time associated with administrative detention.

We provide estimates of annual storage costs, rounded to the nearest million dollars, in table 3.

TABLE 3.—ANNUAL STORAGE COSTS

| Action  | Number of Actions | Change in Days Storage per Action | Cost per Day (based on average shipment) | Handling Cost per Action | Change in Total Storage Cost (in millions) |
|---|-------------------|-----------------------------------|--|--------------------------|--|
| Administrative Detention that Replaces Case of Moving Directly to Seizure | 0 to 16           | 0 to 30                           | \$0 to \$500                             | \$0 to \$21,000          | \$0 to \$1                                 |
| Administrative Detention that Replaces Class I Recall                     | 0 to 184          | 0                                 | \$0 to \$500                             | \$0 to \$21,000          | \$0  |
| Administrative Detention that Replaces Referral to State                  | 0 to 23           | 0 to 30                           | \$0 to \$500                             | \$0 to \$21,000          | \$0 to 1                                   |
| Total   |                   |                                   |  |                          | \$0 to \$2                                 |

*Loss of product value over detention period, if we later find the product is not violative*

Food may lose some or all of its value during an administrative detention because the food may deteriorate, and because firms would have less time to sell food that has a finite shelf life. Reducing the time available to sell food reduces the value of that food because consumers only desire a given quantity of a particular food in a particular time period. In order to sell additional units of that food during that time period, retailers would need to lower the price

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63 (14 percent loss per day X \$730,000) per day

administrative detention action per day would be \$0 to \$102,000 for perishable food, and \$0 to \$10,000 per day for nonperishable food.

22 (3 percent loss per day x \$730,000)

We have set the maximum timeframe for all administratively detained food, including perishable food, at 30 days. Therefore, we calculated the loss of value for all food based on 0 to 30 days of additional storage. As we discussed earlier in the preamble, we intend in the case of perishable food to send a seizure recommendation to the DOJ within 4 calendar days after we issue an administrative detention order, unless extenuating circumstances exist. However, we do not know how often extenuating circumstances will exist, or how much time will elapse between our recommendation and the subsequent seizure.

We do not estimate any change in the loss of value if we substitute an administrative detention action for a class I recall request, because we previously assumed that substituting an administrative detention action for a class I recall would not change the amount of time a firm would store the food in question. Therefore, any loss of value resulting from taking action against food that was actually not violative would be the same under either type of action. In contrast, there is no storage associated with moving directly to a seizure action or referring a matter to State authorities. Therefore, any loss of value from storage associated with an administrative detention action would be an additional cost in those cases.

We provide estimates of the value loss for food in table 4 of this document.

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TABLE 4.—ANNUAL LOSS OF VALUE

| Action  | Number of Actions in which Product Not Violative | Change in Days Storage per Action | Change in Total Loss of Value (in millions) |
|---|--|-----------------------------------|---|
| Administrative Detention that Replaces Case of Moving Directly to Seizure | 0 to 8   | 0 to 30                           | \$0 to \$6                                  |
| Administrative Detention that Replaces Class I Recall                     | 0 to 88  | 0                                 | \$0   |
| Administrative Detention that Replaces Referral to State                  | 0 to 23  | 0 to 30                           | \$0 to 9                                    |
| Total   |  |                                   | \$0 to \$15                                 |

We estimate the maximum loss of value as the maximum number of actions in which the product is not violative, multiplied by the maximum loss per action: \$730,000, the average total value of a shipment

### Costs of marking or labeling

We might label or mark food that we have administratively detained. If we were to label or mark food that we have administratively detained, we could do so in several ways, including, but not limited to, affixing a tag having a self-locking pin that would be inserted in an appropriate seam, border, flap, or other area of the container or product; taping or tying a tag firmly onto the container or item; or affixing the tag to the accompanying documents, or to the carrier. However, if we subsequently cancelled the administrative detention order, then either we, or the firm, would need to remove the label or mark. Class I recalls do not involve marking or labeling. Moving directly to a seizure action or referring a matter to State authorities also does not involve marking or labeling prior to the seizure action.

In an analysis of another proposed rule that we published in 2001, we discussed the costs of marking cartons of imported food with printed labels that we could affix with label guns (Ref. 8). In that analysis, we assumed that an average shipment of imported food would contain about 300 cartons of <sup>f</sup> and that a worker could attach 100 labels per hour <sup>h</sup> containers. We estimated that the cost of the labor time necessary to attach the labels would be \$53 (three hours at \$17.64 per hour), and that the cost of labels would be \$13 (300 labels at \$0.045 per label). A shipment of imported food can involve any number of lines of imported food. Therefore, we assume <sup>(I)</sup> that one line could contain between 1 and 300 cartons. We earlier assumed <sup>(G)</sup> that the average amount of food in a line is 15,000 pounds. <sup>so we estimate that a shipment contains 0.02 cartons per pound (300 cartons per shipment / 15,000 pounds)</sup> Therefore, an administrative detention action involving between 0 and 1 million pounds <sup>(0.02 cartons per pound x 1 million pounds / 100 labels per hour)</sup> would require 0 to 200 hours of labor time, and 0 to 20,000 labels. <sup>(100 labels per hour x 200 hours)</sup> The cost of the labor time necessary to attach the labels would be \$0 to \$3,500, and <sup>(0.045 per label x 20,000 labels)</sup> the cost of the labels would be \$0 to \$900.

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4. Section 16.1 is amended in paragraph (b) (1) by adding a new statutory provision in numerical order to read 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).

\* \* \* \* \*

~~§~~

(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 16—REGULATORY HEARING BEFORE THE FOOD AND DRUG ADMINISTRATION**

3. 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.

**§ 16.1** ~~[Amended]~~ <sup>Scope</sup> 

*Smart* 

4. Section 16.1 ~~Scope~~ is amended in paragraph (b)(1) by numerically adding a new statutory provision <sup>in numerical order to read as follows:</sup> (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). <sup>→</sup>

|     |   |   |   |   |
|-----|---|---|---|---|
| *   | * | * | * | * |
| (b) | * | * | * |   |
| (1) | * | * | * |   |

\* \* \* \* \*

Dated: \_\_\_\_\_

[FR Doc. 03-????? Filed ??-??-03; 8:45 am]

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