**Authority:** 49 U.S.C. 106(g); 40103, 40113, 40120; E.O. 10854, 24 FR 9565, 3 CFR, 1959–1963 Comp., p. 389.

**§ 71.1 [Amended]**

■ 2. The incorporation by reference in 14 CFR 71.1 of Federal Aviation Administration Order 7400.9W, Airspace Designations and Reporting Points, dated August 8, 2012, effective September 15, 2012, is amended as follows:

*Paragraph 5000 Class D Airspace*

* * * * *

**ASO TN D Tri-Cities, TN [Amended]**

Tri-Cities Regional Airport, TN/VA
(Lat. 36°28′31″ N., long. 82°24′27″ W.)
Edwards Heliport, TN
(Lat. 36°25′57″ N., long. 82°17′37″ W.)

That airspace extending upward from the surface to and including 4,000 feet MSL within a 6.8-mile radius of Tri-Cities Regional Airport, excluding the 2.5-mile radius of Edwards Heliport. This Class D airspace area is effective during the specific days and times established in advance by a Notice to Airmen. The effective days and times will thereafter be continuously published in the Airport/Facility Directory.

*Paragraph 6002 Class E Airspace Designated as Surface Areas*

* * * * *

**ASO TN E2 Tri-Cities, TN [Amended]**

Tri-Cities Regional Airport, TN/VA
(Lat. 36°28′31″ N., long. 82°24′27″ W.)

That airspace extending upward from the surface within a 6.8-mile radius of Tri-Cities Regional Airport. This Class E airspace area is effective during the specific days and times established in advance by a Notice to Airmen. The effective days and times will thereafter be continuously published in the Airport/Facility Directory.

*Paragraph 6004 Class E Airspace Designated as an Extension to a Class D Surface Area.*

* * * * *

**ASO TN E4 Tri-City, TN [Removed]**

*Paragraph 6005 Class E Airspace Areas Extending Upward from 700 feet or More Above the Surface of the Earth.*

* * * * *

**ASO TN E5 Tri-Cities, TN [Amended]**

Tri-Cities Regional Airport, TN/VA
(Lat. 36°28′31″ N., long. 82°24′27″ W.)

That airspace extending upward from 700 feet above the surface within a 9.3-mile radius of Tri-Cities Regional Airport and within 4-miles west and 8-miles east of the 223° bearing from the airport extending from the 9.3-mile radius to 23 miles southwest of the airport, and within 2-miles either side of the 43° bearing from the airport extending from the 9.3-mile radius to 14.5 miles northeast of the airport.

* * * * *

**ASO TN E5 Rogersville, TN [New]**

Hawkins County Airport, TN
(Lat. 36°27′27″ N., long. 82°53′06″ W.)

That airspace extending upward from 700 feet above the surface within a 7-mile radius of Hawkins County Airport, and within 7 miles each side of Runway 07/25 centerline, extending from the 7-mile radius to 12 miles east of Hawkins County Airport.

* * * * *

**ASO VA E5 Abingdon, VA [New]**

Virginia Highlands Airport, VA
(Lat. 36°41′14″ N., long. 82°02′00″ W.)

That airspace extending upward from 700 feet above the surface within a 17-mile radius of Virginia Highlands Airport.

Issued in College Park, Georgia, on January 23, 2013.

**Barry A. Knight,**

*Manager, Operations Support Group, Eastern Service Center, Air Traffic Organization.*

[FR Doc. 2013–02324 Filed 2–4–13; 8:45 am]

**BILLING CODE 4910–13–P**

## DEPARTMENT OF HEALTH AND HUMAN SERVICES

### Food and Drug Administration

### 21 CFR Part 1

**RIN 0910–AG67**

**[Docket No. FDA–2011–N–0197]**

## Criteria Used To Order Administrative Detention of Food for Human or Animal Consumption

**AGENCY:** Food and Drug Administration, HHS.

**ACTION:** Final rule.

**SUMMARY:** The Food and Drug Administration (FDA) is issuing a final regulation that adopts, without change, the interim final rule (IFR) entitled ''Criteria Used to Order Administrative Detention of Food for Human or Animal Consumption'' that published in the Federal Register on May 5, 2011, (the 2011 IFR). This final rule affirms the IFR's change to the criteria for ordering administrative detention of human or animal food as required by the FDA Food Safety Modernization Act (FSMA). Under the new criteria, FDA can order an administrative detention if there is reason to believe that an article of food is adulterated or misbranded. This final rule does not make any changes to the regulatory requirements established by the IFR. The final regulation also responds to comments submitted in response to the request for comments in the IFR.

**DATES:** This final rule is effective February 5, 2013.

**FOR FURTHER INFORMATION CONTACT:** William A. Correll, Jr., Office of Compliance, Center for Food Safety and Applied Nutrition, Food and Drug Administration, 5100 Paint Branch Pkwy., College Park, MD 20740, 301–436–1611.

**SUPPLEMENTARY INFORMATION:**

### I. Background

Each year about 48 million people (1 in 6 Americans) get sick, 128,000 are hospitalized, and 3,000 die from food borne diseases, according to 2011 data from the Centers for Disease Control and Prevention (*http://www.cdc.gov/foodborneburden/2011-foodborne-estimates.html*). This is a significant public health burden that is largely preventable.

FSMA (Pub. L. 111–353), signed into law by President Obama on January 4, 2011, enables FDA to better protect public health by helping to ensure the safety and security of the food supply. It enables FDA to focus more on preventing food safety problems rather than relying primarily on reacting to problems after they occur. The law also provides FDA with new enforcement authorities to help it achieve higher rates of compliance with prevention- and risk-based food safety standards and to better respond to and contain problems when they do occur. The law also gives FDA important new tools to better ensure the safety of imported foods and directs FDA to build an integrated national food safety system in partnership with State and local authorities.

Section 207 of FSMA amends the criteria for ordering administrative detention of human or animal food in section 304(h)(1)(A) of the Federal Food, Drug, and Cosmetic Act (FD&C Act) (21 U.S.C. 334(h)(1)(A)). Under the new criteria established by FSMA, FDA can order an administrative detention if there is reason to believe that an article of food is adulterated or misbranded. Section 207 of FSMA also requires that the Secretary of Health and Human Services issue an IFR implementing this statutory change no later than 120 days following the date of enactment of FSMA and further specified that the amendment made by section 207 take effect 180 days after the date of FSMA's January 4, 2011, enactment, which was July 3, 2011. On May 5, 2011, FDA issued an IFR (76 FR 25538) that implemented section 207 of FSMA and contained a request for comments. The IFR became effective on July 3, 2011. This final rule adopts, without making any changes, the regulatory requirements established in the IFR.

To the extent that 5 U.S.C. 553 applies to this action, the Agency's implementation of this action with immediate effective date comes within the good cause exception in 5 U.S.C. 553(d)(3) (21 CFR 10.40(c)(4)(ii)). As this final rule imposes no new regulatory requirements, a delayed effective date is unnecessary.

**II. Comments on the Interim Final Rule**

FDA received 12 responsive comments to the IFR. However, after considering these comments, the Agency is not making any changes to the regulatory language included in the IFR. Relevant portions of the responsive comments are summarized and responded to in this document. The Agency did not consider nonresponsive comments in developing this final rule. To make it easier to identify comments and FDA's responses, the word ''Comment,'' in parenthesis, appears before the comment's description, and the word ''Response,'' in parenthesis, appears before FDA's response. Each comment is numbered to help distinguish between different comments. The number assigned to each comment is purely for organizational purposes and does not signify the comment's value or importance.

(Comment 1) Several comments expressed support for the IFR, the food safety principles embodied in the new criteria for administrative detention, and FDA's use of this tool.

(Response) FDA appreciates the sentiments expressed in these comments and intends to use this administrative tool in appropriate situations to temporarily hold food that the Agency has reason to believe is adulterated or misbranded. Administrative detention provides the Agency with a tool that can be used to prevent such articles of food from reaching the marketplace.

(Comment 2) FDA received a number of comments requesting that the Agency clarify the meaning of the new criteria for ordering administrative detention in section 304(h)(1)(A) of the FD&C Act (21 U.S.C. 334(h)(1)(A)), and in particular the phrase ''reason to believe that an article of human or animal food is adulterated or misbranded. ''

(Response) As stated in the IFR (76 FR 25538 at 25539), decisions regarding whether FDA has ''reason to believe'' that food is adulterated or misbranded will be made on a case-by-case basis because such decisions are fact specific. The Agency will consider the individual facts in each particular situation to inform its reason to believe that an article of food is adulterated or misbranded. Because such decisions are fact specific, FDA has not, therefore, amended the regulation to provide additional explanation of the criteria for ordering administrative detention.

(Comment 3) Several comments stated that FDA should implement the new administrative detention criteria in a consistent, judicious way. Other comments stated that the Agency should restrict the use of administrative detention to food that significantly adversely affects human or animal health and that FDA would consider classifying as a Class 1 recall.[1]

(Response) FDA intends to use administrative detention in a manner that is consistent with and furthers the prevention-based goals of FSMA and the Agency's public health mission. The Agency also is aware that the new criteria provide FDA with more flexibility in its use of administrative detention and intends to use this tool as appropriate. The Agency will also continue to use its advisory action tools, such as Warning Letters and untitled letters, to achieve voluntary compliance and voluntary corrective action to address adulteration or misbranding violations, as appropriate.

(Comment 4) Several comments requested that the Agency amend the regulations to restrict the authority to authorize administrative detention to the FDA Commissioner or to the Directors of the Center for Food Safety and Applied Nutrition (CFSAN) or the Center for Veterinary Medicine (CVM). These comments stated that such a restriction was necessary to ensure that the new criteria for ordering administrative detention are applied consistently.

(Response) FDA agrees that the new criteria for ordering administrative detention should be applied carefully and consistently when there is a reason to believe that an article of food is adulterated or misbranded. The Agency does not agree that the only way that goal can be achieved is by limiting the authority to order administrative detention to three Agency officials. FDA has a number of internal mechanisms to ensure that FDA will use administrative detention in a consistent manner across the District Offices. It is, therefore, unnecessary to change the IFR to adopt the restriction suggested by the comments.

(Comment 5) Several comments emphasized the importance of transparency regarding administrative detention, including the need to simplify and streamline the process for appealing administrative detention orders, communicate information about the detention process to importers and exporters, and the suggestion that there be a contact person to provide such information.

(Response) FDA agrees that it is important to be transparent regarding the administrative detention process and thus, the procedures for administrative detention, including the process for appealing and requesting an informal hearing on the matter, are clearly set forth in FDA's regulations in Title 21, Code of Federal Regulations (CFR) part 1, subpart K and part 16. At this time, it is not necessary to make any changes to these procedures. The District Director of the involved FDA District Office serves as the contact for any administrative detention matter in that District Office. Additionally, FDA often makes information about actions taken under this authority publicly available through mechanisms such as press statements on enforcement actions.

(Comment 6) Some comments noted that there could be confusion between the term administrative detention as used under section 304 of the FD&C Act and the term detention as used during the importation process, where a product is often referred to as detained when it appears the product may be subject to refusal of admission and the owner or consignee has been given an opportunity to present testimony regarding admissibility under 21 CFR 1.94.

(Response) Given the procedural and substantive differences between administrative detention and detention that occurs during import admissibility review, confusion between the two is unlikely. Moreover, when the Agency gives written notice in either circumstance, it will make clear which type of detention is involved. For instance, FDA uses ''Form FDA 2289 Detention Order'' for administrative detentions, including administrative detentions brought under section 304(h) of the FD&C Act. On this form FDA will clearly identify under which authority the administrative detention is ordered.

(Comment 7) Two comments asked if FDA would issue a notice of termination of administrative detention on the same day as the decision is made.

(Response) FDA intends to issue a notice of termination of administrative detention on the same day as the decision is made, whenever practicable. The Agency understands the importance of providing notice of a termination decision so that the article of food can reenter the stream of commerce in a timely manner. If FDA fails to issue a detention termination notice and the

[1] See 21 CFR 7.3(m)(1) for definition of a Class I recall.

detention period expires (a maximum of 30 days from the date the detention was ordered), the detention is deemed to be terminated (21 CFR 1.384).

(Comment 8) One comment asked the Agency to clarify which party will be responsible for the costs associated with an administrative detention (e.g., storage or moving costs) or with the disposal of the detained products (e.g., reconditioning, re-export, or destruction).

(Response) As stated in its response to a comment to the 2004 administrative detention final rule (69 FR 31660 at 31690, June 4, 2004), the responsibility for paying the storage costs of administratively detained food is a matter to be resolved between the private parties involved. FDA is not liable for these costs. An owner, operator, or agent in charge of the place where the food is located can request modification of a detention order under 21 CFR 1.381 to allow the food to be moved or destroyed if they do not want to store it.

## III. Executive Order 12866 and Executive Order 13563: Cost Benefit Analysis

FDA has examined the impacts of this final rule under Executive Order 12866, Executive Order 13563, the Regulatory Flexibility Act (5 U.S.C. 601–612), and the Unfunded Mandates Reform Act of 1995 (Pub. L. 104–4). Executive Orders 12866 and 13563 direct Agencies 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 13563 emphasizes the importance of quantifying both costs and benefits, of reducing costs, of harmonizing rules, and of promoting flexibility. The Office of Management and Budget (OMB) has determined that this is a significant regulatory action as defined by the Executive Orders.

The Regulatory Flexibility Act requires Agencies to determine whether a final rule will have a significant impact on small entities when an Agency issues a final rule ''after being required * * * to publish a general notice of proposed rulemaking.'' Although we are not required to perform a regulatory flexibility analysis because we were not required to publish a proposed rule prior to this final rule, we have nonetheless conducted a regulatory flexibility analysis for this final rule. Because the additional costs per entity of this rule are negligible if any, the Agency also concludes that this final rule will not have a significant economic impact on a substantial number of small entities.

Section 202(a) of the Unfunded Mandates Reform Act of 1995 requires that Agencies prepare a written statement, which includes an assessment of anticipated costs and benefits, before proposing ''any rule that includes any 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 one year.'' The current threshold after adjustment for inflation is $139 million, using the most current (2011) Implicit Price Deflator for the Gross Domestic Product. FDA does not expect this final rule to result in any 1-year expenditure that would meet or exceed this amount.

In 2003 FDA issued a proposed rule on administrative detention (2003 proposed rule) (68 FR 25242 at 25250, May 9, 2003), in which the Agency analyzed the economic impact of the proposed procedures for administrative detention of food for human or animal consumption which were established to implement changes to the FD&C Act made by section 303 of the Public Health Security and Bioterrorism Preparedness and Response Act of 2002 (Pub. L. 107–188). When FDA issued the administrative detention final rule in 2004 (2004 final rule) (69 FR 31660 at 31685), the Agency revised the economic analysis set forth in the 2003 proposed rule. The analysis in the 2004 final rule explained that any costs and/or benefits of the rule can be generated only in those circumstances in which FDA would choose to order administrative detention instead of using other enforcement tools available to the Agency, such as requesting voluntary recall, instituting a seizure action, or referring the matter to State authorities. In this analysis, FDA noted that because administrative detention was a new enforcement tool, the Agency was not able to directly estimate how often it would be used. FDA indirectly estimated the number of potential events that would trigger an administrative detention as a subset of other existing enforcement actions at the time. The analysis assumed that FDA would likely choose administrative detention only if it were the most effective enforcement tool available in a particular situation.

In 2011, FDA issued the IFR amending the criteria for ordering administrative detention. This final rule adopts, without making any changes, the regulatory requirements established in the IFR. The economic impact analysis of the IFR (76 FR 25538 at 25539) explained and further revised the analysis set forth in the 2004 final rule by addressing the economic impact of the new criteria in section 304(h)(1)(A) of the FD&C Act.

FDA did not receive any comments that would warrant further revising the economic analysis of the IFR. Thus, this economic analysis confirms the economic impact analysis of the IFR. For a full explanation of the economic impact analysis of this final rule, interested persons are directed to the text of the economic impact analyses in the IFR (76 FR 25538 at 25539) and the 2004 final rule (69 FR 31660 at 31685).

## IV. Small Entity Analysis (or Final Regulatory Flexibility Analysis)

A regulatory flexibility analysis is required only when an Agency must publish a notice of proposed rulemaking (5 U.S.C. 603 and 604). Section 207 of FSMA directed us to issue an IFR implementing that statutory provision, and FDA published the IFR and this final rule without a notice of proposed rulemaking. Although FDA was not required to publish a notice of proposed rulemaking and, therefore, no regulatory flexibility analysis is required, FDA has nonetheless conducted such an analysis and examined the economic implications of this final rule on small entities. Although this final rule is a significant regulatory action as defined by Executive Order 12866, FDA also concludes that this final rule will not have a significant impact on a substantial number of small businesses.

## V. Paperwork Reduction Act of 1995

FDA concludes that the requirements of this final rule are not subject to review by OMB because they do not constitute a ''collection of information'' under the Paperwork Reduction Act of 1995 (44 U.S.C. 3501–3220).

## VI. 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.

## VII. Federalism

FDA has analyzed this final rule in accordance with the principles set forth in Executive Order 13132. FDA has determined that the 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 has concluded that the rule does not contain policies that have federalism implications as defined in the Executive order and, consequently, a federalism summary impact statement is not required.

**List of Subjects in 21 CFR Part 1**

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

## PART 1—GENERAL ENFORCEMENT REGULATIONS

■ Accordingly, the interim rule amending 21 CFR part 1 which was published at 76 FR 25538 on May 5, 2011, is adopted as a final rule without change.

Dated: January 31, 2013.

**Leslie Kux,**

*Assistant Commissioner for Policy.*

[FR Doc. 2013–02497 Filed 2–4–13; 8:45 am]

**BILLING CODE 4160–01–P**

## DEPARTMENT OF THE TREASURY

### Internal Revenue Service

### 26 CFR Part 1

**[TD 9612]**

**RIN 1545–BA53**

## Noncompensatory Partnership Options

**AGENCY:** Internal Revenue Service (IRS), Department of the Treasury.

**ACTION:** Final regulations.

**SUMMARY:** This document contains final regulations relating to the tax treatment of noncompensatory options and convertible instruments issued by a partnership. The final regulations generally provide that the exercise of a noncompensatory option does not cause the recognition of immediate income or loss by either the issuing partnership or the option holder. The final regulations also modify the regulations under section 704(b) regarding the maintenance of the partners' capital accounts and the determination of the partners' distributive shares of partnership items. The final regulations also contain a characterization rule providing that the holder of a noncompensatory option is treated as a partner under certain circumstances. The final regulations will affect partnerships that issue noncompensatory options, the partners of such partnerships, and the holders of such options.

**DATES:** *Effective Date:* These regulations are effective on February 5, 2013.

*Applicability Date:* These regulations apply to noncompensatory options (as defined in § 1.721–2(f)) that are issued on or after February 5, 2013.

**FOR FURTHER INFORMATION CONTACT:** Benjamin Weaver at (202) 622–3050 (not a toll-free number).

**SUPPLEMENTARY INFORMATION:**

### Background

This document contains amendments to 26 CFR part 1 under sections 171, 704, 721, 761, 1272, 1273, and 1275 of the Internal Revenue Code (Code). On January 22, 2003, proposed regulations (REG–103580–02) relating to the tax treatment of noncompensatory options and convertible instruments issued by a partnership were published in the **Federal Register** (68 FR 2930). On March 28, 2003, corrections to the proposed regulations were published in the **Federal Register** (68 FR 15118). Because no requests to speak were submitted by April 29, 2003, the public hearing scheduled for Tuesday, May 20, 2003, was cancelled (see 68 FR 24903). The Treasury Department and the IRS received a number of comments in response to the proposed regulations. After consideration of the comments, the proposed regulations are adopted as revised by this Treasury decision. The final regulations apply to certain call options, warrants, convertible debt, and convertible equity that are not issued in connection with the performance of services (noncompensatory options). All comments are available at *www.regulations.gov* or upon request.

### Summary of Comments and Explanation of Provisions

The final regulations describe certain of the income tax consequences of issuing, transferring, and exercising noncompensatory partnership options. The final regulations apply only if the call option, warrant, or conversion right grants the holder the right to acquire an interest in the issuer (or cash measured by the value of the interest). The final regulations generally provide that the exercise of a noncompensatory option does not cause recognition of gain or loss to either the issuing partnership or the option holder. In addition, the final regulations modify the regulations under section 704(b) regarding the maintenance of the partners' capital accounts and the determination of the partners' distributive shares of partnership items. Finally, the final regulations contain a characterization rule providing that the holder of a call option, warrant, convertible debt, or convertible equity issued by a partnership (or an eligible entity, as defined in § 301.7701–3(a), that would become a partnership if the option holder were treated as a partner) is treated as a partner under certain circumstances.

A number of comments were received regarding the proposed regulations. The comments included requests for clarification and recommendations relating to (1) the issuance and exercise of noncompensatory options; (2) accounting for noncompensatory options; (3) the characterization rule; (4) the convertible bond provision; and (5) the application of the original issue discount provisions. Significant comments are further discussed in this preamble.

*1. Issuance, Exercise, Lapse, Repurchase, and Other Terminations of a Noncompensatory Option*

Like the proposed regulations, the final regulations under section 721 define a noncompensatory option as an option issued by a partnership, other than an option issued in connection with the performance of services. For this purpose, an option is defined as a call option or warrant to acquire an interest in the issuing partnership, the conversion feature of convertible debt, or the conversion feature of convertible equity.

A. Application of Section 721 on Issuance of a Noncompensatory Option

The proposed regulations provide that section 721 does not apply to a transfer of property to a partnership in exchange for a noncompensatory option. Several commenters observed that the proposed regulations do not exclude options issued in satisfaction of interest or similar items, such as unpaid rent or royalties. Accordingly, the final regulations provide that section 721 does not apply to the transfer of property to a partnership in exchange for a noncompensatory option, or to the satisfaction of a partnership obligation with a noncompensatory option. The final regulations contain an example illustrating that a transfer of appreciated or depreciated property to a partnership in exchange for a noncompensatory option generally will result in the recognition of gain or loss by the option recipient. Under open transaction principles applicable to noncompensatory options, the partnership will not recognize income for receipt of the property while the