

Dated: January 21, 2014.

**Kevin J. Wolf,**

*Assistant Secretary for Export Administration.*

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## DEPARTMENT OF HEALTH AND HUMAN SERVICES

### Food and Drug Administration

#### 21 CFR Parts 16 and 121

[Docket No. FDA-2013-N-1425]

#### Focused Mitigation Strategies To Protect Food Against Intentional Adulteration; Public Meetings on Proposed Rule

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

**ACTION:** Notification of public meetings.

**SUMMARY:** The Food and Drug Administration (FDA or we) is announcing two public meetings to discuss the proposed rule to require domestic and foreign food facilities that are required to register under the Federal Food, Drug, and Cosmetic Act (the FD&C Act) to address hazards that may be intentionally introduced by acts of terrorism. FDA proposed these requirements as part of our implementation of the FDA Food Safety Modernization Act (FSMA). The purpose of the public meetings is to inform the public of the provisions of the proposed rule and the rulemaking process (including how to submit comments, data, and other information to the rulemaking docket) as well as solicit oral stakeholder and public comments on the proposed rule and to respond to questions about the rule.

**DATES:** See section II, “How to Participate in the Public Meeting” in the **SUPPLEMENTARY INFORMATION** section for dates and times of the public meetings, closing dates for advance registration, and information on deadlines for submitting either electronic or written comments to FDA’s Division of Dockets Management.

**ADDRESSES:** See section II, “How to Participate in the Public Meeting” in the **SUPPLEMENTARY INFORMATION** section.

**FOR FURTHER INFORMATION CONTACT:** *For questions about registering for the meeting, to register by phone, or to submit a notice of participation by mail, FAX, or email, contact: Nick Cane, Nakamoto Group, Inc., 11820 Parklawn*

*Dr., Suite 240, Rockville, MD 20852, 240-357-1176, FAX: 301-468-6536, email: nick.cane@nakamotogroup.com. For general questions about the meeting; to request an opportunity to make an oral presentation at the public meeting; to submit the full text, comprehensive outline, or summary of an oral presentation; or for special accommodations due to a disability, contact: Juanita Yates, Center for Food Safety and Applied Nutrition (HFS-009), Food and Drug Administration, 5100 Paint Branch Pkwy., College Park, MD 20740, 240-402-1731, email: Juanita.yates@fda.hhs.gov.*

#### **SUPPLEMENTARY INFORMATION:**

##### **I. Background**

FSMA (Pub. L. 111-353) was signed into law by President Obama on January 4, 2011, to better protect public health by helping to ensure the safety and security of the food supply. FSMA amends the FD&C Act to establish the foundation of a modernized, prevention-based food safety system. Among other things, FSMA requires FDA to issue regulations requiring domestic and foreign food facilities that are required to register under the FD&C Act to address hazards that may be intentionally introduced by acts of terrorism. These food facilities would be required to identify and implement focused mitigation strategies to significantly minimize or prevent significant vulnerabilities identified at actionable process steps in a food operation. We expect the rulemaking would help to protect food from intentional adulteration caused by acts of terrorism.

FDA is announcing additional public meetings so that the food industry, consumers, foreign governments, and other stakeholders can better evaluate and comment on the proposals. These meetings, following the College Park, MD, public event on February 20, are the final two public meetings FDA plans to hold during the proposed rule comment period. All three public meetings are intended to facilitate and support the proposed rule’s evaluation and commenting process.

##### **II. How To Participate in the Public Meetings**

FDA is holding the public meetings on “Focused Mitigation Strategies to Protect Food Against Intentional Adulteration” to: (1) Inform the public about the rulemaking process, including how to submit comments, data, and other information to the rulemaking

docket; (2) respond to questions about the proposed rules; and (3) provide an opportunity for interested persons to make oral presentations. Due to limited space and time, FDA encourages all persons who wish to attend the meetings to register in advance. There is no fee to register for the public meetings, and registration will be on a first-come, first-served basis. Early registration is recommended because seating is limited. Onsite registration will be accepted, as space permits, after all preregistered attendees are seated.

Those requesting an opportunity to make an oral presentation during the time allotted for public comment at the meetings are asked to submit a request and to provide the specific topic or issue to be addressed. Due to the anticipated high level of interest in presenting public comment and limited time available, FDA is allocating 3 minutes to each speaker to make an oral presentation. Speakers will be limited to making oral remarks; there will not be an opportunity to display materials such as slide shows, videos, or other media during the meetings. If time permits, individuals or organizations that did not register in advance may be granted the opportunity to make an oral presentation. FDA would like to maximize the number of individuals who make a presentation at each meeting and will do our best to accommodate all persons who wish to make a presentation or express their opinions at a meeting.

FDA encourages persons and groups who have similar interests to consolidate their information for presentation by a single representative. After reviewing the presentation requests, FDA will notify each participant before the meeting of the approximate time their presentation is scheduled to begin, and remind them of the presentation format (i.e., 3-minute oral presentation without visual media).

While oral presentations from specific individuals and organizations will be necessarily limited due to time constraints during the public meetings, stakeholders may submit electronic or written comments discussing any issues of concern to the administrative record (the docket) for the rulemaking. All relevant data and documentation should be submitted with the comments to the relevant docket, i.e., Docket No. FDA-2013-N-1425.

Table 1 of this document provides information on participation in the public meetings:

TABLE 1—INFORMATION ON PARTICIPATION IN THE MEETINGS AND ON SUBMITTING COMMENTS TO THE RULEMAKING DOCKETS

	Date	Electronic address	Address	Other information
Chicago, IL, Public meeting.	February 27, 2014 .....	<a href="http://www.fda.gov/Food/GuidanceRegulation/FSMA/ucm247568.htm">http://www.fda.gov/Food/GuidanceRegulation/FSMA/ucm247568.htm</a> .	Hilton Chicago, 720 South Michigan Ave., Chicago, IL 60605.	Onsite registration from 8 a.m. to 8:30 a.m.
Chicago, IL, Advance registration.	Until February 18, 2014.	<a href="http://www.fda.gov/Food/GuidanceRegulation/FSMA/ucm247568.htm">http://www.fda.gov/Food/GuidanceRegulation/FSMA/ucm247568.htm</a> .	We encourage you to use electronic registration if possible. <sup>1</sup>	There is no registration fee for the public meetings. Early registration is recommended because seating is limited.
Chicago, IL, Request to make a Public Comment.	February 10, 2014 .....	<a href="http://www.fda.gov/Food/GuidanceRegulation/FSMA/ucm247568.htm">http://www.fda.gov/Food/GuidanceRegulation/FSMA/ucm247568.htm</a> . <sup>2</sup>	.....	Requests made on the day of the meeting to make an oral presentation will be granted as time permits. Information on requests to make an oral presentation may be posted without change to <a href="http://www.regulations.gov">http://www.regulations.gov</a> , including any personal information provided.
Chicago, IL, Request special accommodations due to a disability.	February 10, 2014 .....	Juanita Yates, email: <a href="mailto:Juanita.yates@fda.hhs.gov">Juanita.yates@fda.hhs.gov</a> .	See <b>FOR FURTHER INFORMATION CONTACT</b> .	
Chicago, IL, Closing date for electronic or written comments.	March 31, 2014 .....	Docket No. FDA–2013–N–1425.		
Anaheim, CA, Public meeting.	March 13, 2014 .....	<a href="http://www.fda.gov/Food/GuidanceRegulation/FSMA/ucm247568.htm">http://www.fda.gov/Food/GuidanceRegulation/FSMA/ucm247568.htm</a> .	Sheraton Park Hotel, 1855 South Harbor Blvd., Anaheim, CA 92802.	Onsite registration from 8 a.m. to 8:30 a.m.
Anaheim, CA, Advance registration.	Until March 4, 2014 ...	<a href="http://www.fda.gov/Food/GuidanceRegulation/FSMA/ucm247568.htm">http://www.fda.gov/Food/GuidanceRegulation/FSMA/ucm247568.htm</a> .	We encourage you to use electronic registration if possible. <sup>1</sup>	There is no registration fee for the public meetings. Early registration is recommended because seating is limited.
Anaheim, CA, Request to make a Public Comment.	February 18, 2014 .....	<a href="http://www.fda.gov/Food/GuidanceRegulation/FSMA/ucm247568.htm">http://www.fda.gov/Food/GuidanceRegulation/FSMA/ucm247568.htm</a> . <sup>2</sup>	.....	Requests made on the day of the meeting to make an oral presentation will be granted as time permits. Information on requests to make an oral presentation may be posted without change to <a href="http://www.regulations.gov">http://www.regulations.gov</a> , including any personal information provided.
Anaheim, CA, Request special accommodations due to a disability.	February 18, 2014 .....	Juanita Yates, email: <a href="mailto:Juanita.yates@fda.hhs.gov">Juanita.yates@fda.hhs.gov</a> .	See <b>FOR FURTHER INFORMATION CONTACT</b> .	
Anaheim, CA, Closing date for electronic or written comments.	March 31, 2014 .....	Docket No. FDA–2013–N–1425.		

<sup>1</sup> You may also register via email, mail, or FAX. Please include your name, title, firm name, address, and phone and FAX numbers in your registration information and send to: Nick Cane, Nakamoto Group, Inc., 11820 Parklawn Dr., Suite 240, Rockville, MD 20852, 240–357–1176, FAX: 301–468–6536, email: [nick.cane@nakamotogroup.com](mailto:nick.cane@nakamotogroup.com). Onsite registration will also be available.

<sup>2</sup> You may also request to make an oral presentation at the public meetings via email. Please include your name, title, firm name, address, and phone and FAX numbers as well as the full text, comprehensive outline, or summary of your oral presentation and send to: Juanita Yates, Center for Food Safety and Applied Nutrition, Food and Drug Administration, 5100 Paint Branch Pkwy., College Park, MD 20740, 240–402–1731, email: [Juanita.yates@fda.hhs.gov](mailto:Juanita.yates@fda.hhs.gov).

**III. Comments, Transcripts, and Recorded Video**

Information and data submitted voluntarily to FDA during the public meetings will become part of the administrative record for the rulemaking and will be accessible to the public at <http://www.regulations.gov>. The transcript of the proceedings from the public meetings will become part of the administrative record for the rulemaking. Please be advised that as

soon as a transcript is available, it will be accessible at <http://www.regulations.gov> and at FDA’s FSMA Web site at: <http://www.fda.gov/Food/GuidanceRegulation/FSMA/default.htm>. It may also be viewed at the Division of Dockets Management (HFA–305), Food and Drug Administration, 5630 Fishers Lane, Rm. 1061, Rockville, MD 20852. A transcript will also be available in either hardcopy or on CD–ROM, after submission of a Freedom of Information request. Written requests

are to be sent to the Division of Freedom of Information (ELEM–1029), 12420 Parklawn Dr., Element Bldg., Rockville, MD 20857. Additionally, FDA will be video recording and live Web casting both of the public meetings. Once the recorded video is available, it will be accessible at FDA’s FSMA Web site at <http://www.fda.gov/Food/GuidanceRegulation/FSMA/default.htm>.

Dated: January 28, 2014.

**Leslie Kux,**

*Assistant Commissioner for Policy.*

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## POSTAL REGULATORY COMMISSION

### 39 CFR Part 3010

[Docket No. RM2014-3; Order No. 1879]

#### Price Cap Rules for Market Dominant Price Adjustments

**AGENCY:** Postal Regulatory Commission.

**ACTION:** Proposed rulemaking.

**SUMMARY:** The Commission is proposing rules addressing the price cap for market dominant price adjustments as part of an ongoing review. This stage of the review concerns rate reductions, rate incentives, and de minimis rate increases. The Commission invites public comment on the proposals.

**DATES:** *Comments are due:* March 17, 2014. *Reply comments are due:* April 16, 2014.

**FOR FURTHER INFORMATION CONTACT:** Brian Corcoran, Acting General Counsel, 202-789-6820.

#### SUPPLEMENTARY INFORMATION:

##### Regulatory History

72 FR 5230, February 5, 2007  
 72 FR 29284, May 25, 2007  
 72 FR 33261, June 15, 2007  
 72 FR 63622, November 9, 2007  
 74 FR 49326, September 28, 2009  
 78 FR 22490, April 16, 2013  
 78 FR 52694, August 26, 2013  
 78 FR 67951, November 8, 2013

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#### I. Introduction

With this Notice of Proposed Rulemaking, the Commission is continuing a review of its rules in 39 CFR part 3010 and requesting comments and suggestions regarding the treatment of rate reductions, rate incentives, and de minimis rate increases under part 3010.

The purposes of this rulemaking are to clarify and standardize the Commission's previous treatment of rate reductions and rate incentives, to establish a type of de minimis rate adjustment that would allow the Postal Service to make extremely minor increases to rates without requiring the

Postal Service to calculate the annual limitation or generate unused rate adjustment authority, and to improve other aspects of the process of adjusting rates for market dominant products. The proposed rules are intended to provide more certainty for the Postal Service and the mailing community as they make decisions that rely upon the Postal Service's authority to adjust rates for market dominant products under 39 U.S.C. 3622(d) and part 3010.

#### II. Background

In Docket No. RM2013-2, the Commission began the process of reviewing its rules in 39 CFR part 3010, with the intent of clarifying and improving those rules.<sup>1</sup> The Commission adopted final rules in that docket that, among other minor changes, reorganized part 3010; added definitions; clarified the information required to be submitted with proposed workshare discounts; clarified that the rules require that a 12-month period be used to calculate the annual limitation when notices of rate adjustment are more than 12 months apart; clarified that the Postal Service may not rely on anticipated changes in mailer behavior to make adjustments to billing determinants; and revised the rule establishing the maximum size of unused rate adjustment authority for rate changes to align with statutory language.<sup>2</sup>

Order No. 1786 noted that the Commission's proposed treatment of promotional rates and incentive programs generated significant disagreement among commenters. *Id.* at 28. The Commission stated its intent to establish a separate docket for the consideration of this issue. *Id.* at 29, 33.

#### III. Proposed Rules

The proposed rules included in this Notice of Proposed Rulemaking contain: (1) A separate process for rate adjustments that consist solely of rate decreases, designated as a "Type 1-C rate adjustment"; (2) revisions to the rules for the treatment of rate incentives for rates of general applicability (Type 1-A and Type 1-B rate adjustments); (3) revisions to clarify the treatment of rate incentives that are not rates of general applicability; (4) revisions to clarify the treatment of deleted rate cells; and (5)

a separate process for de minimis rate increases.

##### A. Type 1-C Rate Adjustments

The Commission proposes allowing the Postal Service to request certain rate reductions without the calculation of the annual limitation and allowing the Postal Service to recoup associated unused rate adjustment authority by using it in future rate adjustments. These proposed rules apply to notices that only contain rate decreases. If the Postal Service proposes a rate increase in a notice of rate adjustment, the adjustment must still be filed as a Type 1-A or Type 1-B rate adjustment. Proposed §§ 3010.3(b)(2), 3010.6, 3010.20(e), 3010.23(b)(2), and 3010.27 are designed to facilitate mid-year rate reductions by allowing the Postal Service to recoup unused rate adjustment authority from those rate reductions.

Under the Commission's existing rules, even for a rate decrease, the Postal Service must file a Type 1-A rate adjustment to create unused rate authority.<sup>3</sup> In the past, when the Postal Service has filed rate reductions that are not part of an omnibus rate adjustment, the Postal Service has elected to not utilize the existing rules to generate unused rate adjustment authority.

However, recently, the Postal Service has sought to use rate reductions that are not part of an omnibus rate adjustment to generate unused rate adjustment authority. In its Full-Service Intelligent Mail Barcode Technology Credit Promotion (Technology Credit Promotion) request, the Postal Service proposed to create unused rate adjustment authority that it could use in its next omnibus notice of rate adjustment.<sup>4</sup> Specifically, the Postal Service proposed to use the unused rate adjustment authority generated as a result of the Technology Credit Promotion before it used any of the unused rate adjustment authority generated during the previous 5 years. Technology Credit Notice at 5. The Commission rejected this proposal, on the basis that it violated the first-in, first-out rule established under 39 U.S.C. 3622(d)(2)(C)(iii)(III). Order No. 1743 at 12. The proposed rules would

<sup>3</sup> For example, if the annual limitation was 2 percent, and the Postal Service requested a rate reduction that resulted in a 0.5 percent rate decrease, unused rate adjustment authority after that adjustment would equal 2.5 percent (2% - (-0.5%)).

<sup>4</sup> Docket No. R2013-6, United States Postal Service Notice of Market-Dominant Price Adjustment (Technology Credit Promotion), April 16, 2013 (Technology Credit Notice); Docket No. R2013-6, Order Approving Technology Credit Promotion, June 10, 2013 (Order No. 1743).

<sup>1</sup> Docket No. RM2013-2, Notice of Proposed Rulemaking Requesting Comments on Proposed Commission Rules for Determining and Applying the Maximum Amount of Rate Adjustments, March 22, 2013, at 1-2 (Order No. 1678).

<sup>2</sup> Docket No. RM2013-2, Order Adopting Final Rules for Determining and Applying the Maximum Amount of Rate Adjustments, July 23, 2013 (Order No. 1786).