

10.115). The revised draft guidance, when finalized, will represent the current thinking of FDA on this topic. It does not establish any rights for any person and is not binding on FDA or the public. You can use an alternate approach if it satisfies the requirements of the applicable statutes and regulations.

On October 10, 2003, FDA issued an interim final rule (68 FR 58893) to implement amendments to the FD&C Act made by the Public Health Security and Bioterrorism Preparedness and Response Act of 2002 (Pub. L. 107-188). Section 415 of the FD&C Act (21 U.S.C. 350d) requires domestic and foreign facilities that manufacture, process, pack, or hold food for human or animal consumption in the United States to register with FDA by December 12, 2003. Section 102 of the FDA Food Safety Modernization Act (FSMA) (Pub. L. 111-353), enacted on January 4, 2011, amended section 415 of the FD&C Act to, among other things, require facilities engaged in manufacturing, processing, packing, or holding food for consumption in the United States to submit additional registration information to FDA. Section 102 of FSMA also directed FDA to amend the definition of “retail food establishment” in 21 CFR 1.227. On July 14, 2016, FDA issued a final rule (Registration Final Rule) to amend and update FDA’s registration regulation and implement the FSMA revisions (81 FR 45912; July 14, 2016).

This revised draft guidance was developed to answer frequently asked questions relating to the registration requirements of section 415 of the FD&C Act. The first edition of the guidance was issued as Level 2 guidance consistent with our good guidance practices regulation (21 CFR 10.115) and was made available on FDA’s Web site on December 4, 2003. The second, third, fourth, and fifth editions of the guidance were issued as Level 1 guidance documents under 21 CFR 10.115 and were made available on FDA’s Web site on January 12, 2004; February 17, 2004; August 6, 2004; and December 17, 2012, respectively. The sixth edition of the guidance was issued as Level 1 guidance and included one additional question and answer relating to a proposed amendment to the “farm” definition in 21 CFR 1.227 (see 79 FR 58523; September 29, 2014). Since publication of the sixth edition of the guidance, we have issued the Registration Final Rule. In addition, we have issued the Current Good Manufacturing Practice, Hazard Analysis, and Risk-Based Preventive Controls for Human Food final rule (80

FR 55908; September 17, 2015) that, among other things, revised the definition of “farm” in 21 CFR 1.227. We have also issued the Current Good Manufacturing Practice, Hazard Analysis, and Risk-Based Preventive Controls for Food for Animals final rule (80 FR 56169; September 17, 2015). We are issuing a seventh edition of the guidance to add information relating to the Registration Final Rule and the revised “farm” definition, as well as to address questions received from stakeholders since publication of the sixth edition.

This edition of the guidance also revises information in existing questions and answers, removes some questions and answers, and makes editorial changes (e.g., we reorganized existing questions and answers) to improve clarity. For the revised questions and answers, we are not adding a date indicating when the questions and answers were revised. As in the previous editions, the following indicators are used to help users identify revisions: (1) The guidance is identified as a revision of a previously issued document; (2) the revision date appears on the cover of the guidance; (3) the edition number of the guidance is included in its title; and (4) questions and answers that have been added since the sixth edition are identified as such in the body of the guidance.

On November 8, 2016, we announced the availability of a draft guidance entitled “Questions and Answers Regarding Food Facility Registration (Seventh Edition): Guidance for Industry.” The draft guidance contained 15 sections of a multi-section guidance intended to provide updated information relating to the food facility registration requirements of section 415 of the FD&C Act. We reserved two sections in the draft guidance and stated that we would issue a revised draft guidance at a later date that would include those reserved sections.

This revised draft guidance supersedes the food facility registration draft guidance that we issued in November 2016. In the revised draft guidance, we are including the 15 sections that were announced in the **Federal Register** on November 8, 2016, as well as including the two sections we reserved, “Who is Exempt from Registration?” and “Definitions,” from the draft guidance. The revised draft guidance also includes an additional question and answer related to mobile facilities in the section entitled “What Information is Required in the Registration?”

We are inviting comments on the revised draft guidance as a whole. As

FDA considers the development of the final guidance, we will review comments received on the revised draft guidance, as well as the comments received on the food facility registration draft guidance we announced on November 8, 2016.

II. Electronic Access

Persons with access to the Internet may obtain the draft guidance at either <http://www.fda.gov/Food/GuidanceRegulation/FoodFacilityRegistration/default.htm> or <http://www.regulations.gov>. Use the FDA Web site listed in the previous sentence to find the most current version of the guidance.

III. Paperwork Reduction Act of 1995

This draft guidance refers to previously approved collections of information found in FDA regulations. These collections of information are subject to review by the Office of Management and Budget (OMB) under the Paperwork Reduction Act of 1995 (44 U.S.C. 3501-3520). The collections of information in 21 CFR 1.230 through 1.235 and 21 CFR 1.245 have been approved under OMB control number 0910-0502.

Dated: December 21, 2016.

Leslie Kux,

Associate Commissioner for Policy.

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POSTAL REGULATORY COMMISSION

39 CFR Part 3004

[Docket No. RM2017-2; Order No. 3671]

Changes to Procedures for the Freedom of Information Act

AGENCY: Postal Regulatory Commission.

ACTION: Notice of proposed rulemaking.

SUMMARY: The Commission is initiating a proceeding to revise its rules governing requests for agency records made under the Freedom of Information Act (FOIA), in accordance with the FOIA Improvement Act of 2016, Public Law 114-185, 130 Stat. 538. This notice informs the public of the filing, invites public comment, and takes other administrative steps.

DATES: Comments are due on or before January 26, 2017.

ADDRESSES: Submit comments electronically via the Commission’s Filing Online system at <http://www.prc.gov>. Those who cannot submit comments electronically should contact the person identified in the **FOR FURTHER**

INFORMATION CONTACT section by telephone for advice on filing alternatives.

FOR FURTHER INFORMATION CONTACT: David A. Trissell, General Counsel, at 202-789-6820.

SUPPLEMENTARY INFORMATION:

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- III. Proposed Rules
- IV. Comments Requested
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I. Introduction

The Postal Regulatory Commission (the Commission) proposes to revise its rules governing requests for agency records made under the Freedom of Information Act (FOIA), 5 U.S.C. 552, in accordance with the FOIA Improvement Act of 2016 (the Act), Public Law 114-185, 130 Stat. 538. Pursuant to section 3(a) of the Act, the head of each agency “shall review the regulations of such agency and shall issue regulations on procedures for the disclosure of records under [FOIA]” to implement the Act within 180 days of its enactment date. The Commission hereby provides this notice, in conformance with the Act’s deadline, describing its proposed changes and eliciting public comment.

II. Background

The Act was signed into law on June 30, 2016, and mandates that federal agencies review and revise their regulations by December 27, 2016. Among other things, the Act expands the dispute resolution process available to requesters, limits the use of FOIA exemptions, and codifies the so-called “Rule of 3” for frequently requested records. In order to implement the Act, the Commission must modify its FOIA regulations, which are set out in 39 CFR part 3004. The proposed modifications are set forth below, along with a brief description of the included changes.

III. Proposed Rules

The rules requiring changes in this notice of proposed rulemaking, pursuant to the Act, are §§ 3004.2, 3004.9, 3004.11, 3004.13, 3004.43, and 3004.52.

Proposed § 3004.2 adds the duty to identify and post frequently requested records. Additionally, the modified rule limits the Commission’s use of FOIA exemptions. Under the revised section, the Commission will only withhold information if it “reasonably foresees” that disclosure will harm an interest protected by an exemption or disclosure is otherwise prohibited by law.

Proposed § 3004.9 describes how to file a FOIA request. This section is a summary of basic information, added for clarity purposes.

Proposed § 3004.11 applies a 25-year sunset provision to the deliberative process privilege, which exempts certain inter-agency and intra-agency memoranda and letters from FOIA. Under the new rule, the deliberative process privilege does not apply to records created 25 years or more before a records request.

Proposed § 3004.13 specifies that frequently requested records will be posted on the Commission’s Web site.

Proposed § 3004.43 states that the Commission will offer the services of its FOIA Public Liaison to assist the requester and to provide dispute resolution services if necessary.

Proposed § 3004.52 revises the Commission’s rules for collecting fees when the Commission cannot issue its response during the initial 20-day response period.

IV. Comments Requested

Interested persons are invited to provide written comments concerning the proposed rule. Comments are due no later than 30 days after the date of publication of this notice in the **Federal Register**. All comments and suggestions received will be available for review on the Commission’s Web site, <http://www.prc.gov>.

Pursuant to 39 U.S.C. 505, Laura Zuber is appointed to serve as an officer of the Commission (Public Representative) to represent the interests of the general public in the above-captioned docket.

V. Ordering Paragraphs

It is ordered:

1. Docket No. RM2017-2 is established for the purpose of amending the Commission’s rules governing the Freedom of Information Act.

2. Pursuant to 39 U.S.C. 505, Laura Zuber is appointed to serve as an officer of the Commission (Public Representative) to represent the interests of the general public in this proceeding.

3. Interested persons may submit initial comments no later than 30 days from the date of publication of this notice in the **Federal Register**.

4. The Secretary shall arrange for publication of this order in the **Federal Register**.

By the Commission.

Stacy L. Ruble,
Secretary.

List of Subjects in 39 CFR Part 3004

Administrative practice and procedure, Freedom of information, Reporting and recordkeeping requirements.

For the reasons stated in the preamble, the Commission proposes to amend chapter III of title 39 of the Code of Federal Regulations as follows:

PART 3004—PUBLIC RECORDS AND FREEDOM OF INFORMATION ACT

■ 1. The authority citation for part 3004 continues to read as follows:

Authority: 5 U.S.C. 552; 39 U.S.C. 503.

■ 2. Revise § 3004.2 to read as follows:

§ 3004.2 Presumption of openness.

(a) The Commission shall be proactive and timely in identifying and posting public records and other frequently requested records to its Web site.

(b) It is the stated policy of the Commission that FOIA requests shall be administered with a clear presumption of openness. The Commission will only withhold information only if it reasonably foresees that disclosure would harm an interest protected by a FOIA exemption, as enumerated in § 3004.11, or disclosure is otherwise prohibited by law.

■ 3. Add § 3004.9 to read as follows:

§ 3004.9 How to make a request.

(a) To request Commission records, please contact the Secretary of the Commission via letter, telephone, or use the online request form provided on the Commission’s Web site at <http://www.prc.gov/foia/>.

(b) Requests must describe the records sought in sufficient detail to enable the Commission to locate them with a reasonable amount of effort. To the extent possible, please provide any specific information that might assist the Commission in responding to the request.

(c) Requesters must provide contact information to assist the Commission in communicating with them and providing Commission records.

■ 4. Amend § 3004.11 by revising paragraph (f) to read as follows:

§ 3004.11 Use of exemptions.

* * * * *

(f) Inter-agency or intra-agency memoranda or letters that would not be available by law to a party other than an agency in litigation with the agency, provided that the deliberative process privilege shall not apply to records

created 25 years or more before the date on which the records were requested.

* * * * *

■ 5. Amend § 3004.13 by revising paragraph (a) to read as follows:

§ 3004.13 Notice and publication of public information.

(a) Decisions, advisory opinions, orders, public reports, and frequently requested agency records will be made available to the public by posting on the Commission's Web site at <http://www.prc.gov>.

* * * * *

■ 6. Amend § 3004.43 by revising paragraph (a) and adding paragraph (d)(4) to read as follows:

§ 3004.43 Response to requests.

(a) Within 20 days (excluding Saturdays, Sundays and legal holidays) after receipt of a request for a Commission record, the Secretary or Assistant Secretary will notify the requester of its determination to grant or deny the request and the right to seek assistance from the Commission's FOIA Public Liaison.

* * * * *

(d) * * *

(4) The right to seek dispute resolution services from the Commission's FOIA Public Liaison or the Office of Government Information Services.

* * * * *

■ 7. Revise § 3004.45 to read as follows:

§ 3004.45 Extension of response time limit.

(a) The Commission may extend the time limit for a response to a request or appeal for up to 10 business days due to unusual circumstances, as specified in 5 U.S.C. 552(a)(6)(B)(iii). In such a case, the Commission will notify the requester in writing of the unusual circumstance causing the extension and the date by which the Commission estimates that the request can be processed.

(b) If an extension will exceed 10 business days, the Commission will:

(1) Provide the requester with an opportunity to limit the scope of the request or to arrange an alternative timeframe for processing the request or a modified request. The applicable time limits are not tolled while the Commission waits for a response from the requester under this subsection; and

(2) Make its FOIA Public Liaison available to the requester and apprise the requester of their right to seek dispute resolution services from the Office of Government Information Services.

■ 8. Amend § 3004.52 by revising paragraph (e) and adding paragraph (f) to read as follows:

§ 3004.52 Fees—general provisions.

* * * * *

(e) No requester will be charged a fee after any search or response which occurs after the applicable time limits as described in §§ 3004.43 and 3004.44, unless:

(1) The Commission extends the time limit for its response due to unusual circumstances, pursuant to § 3004.45(a), and the Commission completes its response within the extension of time provided under that section; or

(2) The Commission extends the time limit for its response due to unusual circumstances, pursuant to § 3004.45(a), and more than 5,000 pages are necessary to respond to the request and the Commission has discussed with the requester how they could effectively limit the scope of the request or made at least three good faith attempts to do so; or

(3) A court has determined that exceptional circumstances exist and excused the Commission from responding by court order.

(f) The Commission may, however, charge fees for a partial grant of a request while it reviews records that may be exempt and may be responsive to the request, if it is made within the applicable time limits.

[FR Doc. 2016–30905 Filed 12–23–16; 8:45 am]

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POSTAL REGULATORY COMMISSION

39 CFR Part 3622

[Docket No. RM2017–3; Order No. 3673]

Statutory Review of the System for Regulating Market Dominant Rates and Classifications

AGENCY: Postal Regulatory Commission.

ACTION: Advance notice of proposed rulemaking.

SUMMARY: The Commission is initiating a review to determine whether the current system of regulating rates and classes for market dominant products is achieving the objectives, taking into account the factors, established by Congress under the Postal Accountability and Enhancement Act of 2006. This advance notice informs the public of the docket's initiation, invites public comment, and takes other administrative steps.

DATES: *Comments are due:* March 20, 2017.

ADDRESSES: Submit comments electronically via the Commission's Filing Online system at <http://www.prc.gov>. Those who cannot submit comments electronically should contact the person identified in the **FOR FURTHER INFORMATION CONTACT** section by telephone for advice on filing alternatives.

FOR FURTHER INFORMATION CONTACT: David A. Trissell, General Counsel, at 202–789–6820.

SUPPLEMENTARY INFORMATION:

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I. Introduction

On December 20, 2006, the Postal Accountability and Enhancement Act (PAEA) was signed into law.¹ The PAEA required that the Commission establish a modern system of regulating rates and classes for market dominant products.² The PAEA also mandated that the Commission review this system 10 years later to determine if it is achieving the objectives, taking into account the factors, established by Congress.³ If the Commission determines that the system is not achieving the objectives, taking into account the factors, the Commission may, by regulation, make modifications or adopt an alternative system as necessary to achieve the objectives. *Id.*

In accordance with 39 U.S.C. 3622, this Notice and Order establishes the beginning of the Commission's statutory review of the ratemaking system. Based on the Commission's analysis and relevant information obtained through this proceeding, the Commission will determine if the objectives, taking into account the factors, are being achieved by the current system. If the Commission finds that the objectives, taking into account the factors, are not being achieved, the Commission may propose modifications to the system or propose to adopt an alternative system as necessary to achieve the objectives.

II. Scope of the Review⁴

The Commission intends to examine all aspects of the ratemaking system

¹ Pub. L. 109–435, 120 Stat. 3198 (2006).

² 39 U.S.C. 3622(a).

³ 39 U.S.C. 3622(d)(3).

⁴ The Postal Service previously petitioned the Commission to initiate a proceeding to clarify the scope of the statutory review. See Docket No. RM2016–9, Petition of the United States Postal