

6064T07P02, SNs GFFN****, GFFP****, GFFR0*** through GFFR7***, GFFR81** through GFFR89**, GFFR8A** through GFFR8G**, GFFR8H92 through GFFR8H99, and GFFR8H9A through GFFR8H9N into any engine.

Material Incorporated by Reference

(h) None.

Related Information

(i) GE CT7-TS Alert Service Bulletin 72-A0032, dated June 11, 2003, provides additional information regarding the disassembly of the gas generator turbine rotor assembly.

Issued in Burlington, Massachusetts, on July 29, 2004.

Jay J. Pardee,

Manager, Engine and Propeller Directorate, Aircraft Certification Service.

[FR Doc. 04-17755 Filed 8-5-04; 8:45 am]

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

21 CFR Part 1

[Docket No. 2003D-0545]

Guidance for Industry: Questions and Answers Regarding the Interim Final Rule on Registration of Food Facilities (Edition 4); Availability

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice of availability of guidance.

SUMMARY: The Food and Drug Administration (FDA) is announcing the availability of a revised guidance entitled "Questions and Answers Regarding the Interim Final Rule on Registration of Food Facilities (Edition 4)." The guidance responds to various questions raised about section 305 of the Public Health Security and Bioterrorism Preparedness and Response Act of 2002 (the Bioterrorism Act) and the agency's implementing regulation, which require facilities that manufacture/process, pack, or hold food for consumption in the United States to register with FDA by December 12, 2003.

DATES: Submit written or electronic comments on the agency guidance at any time.

ADDRESSES: You may submit comments, identified by Docket No. 2003D-0545, by any of the following methods:

- Federal eRulemaking Portal: <http://www.regulations.gov>. Follow the instructions for submitting comments.
- Agency Web site: <http://www.fda.gov/dockets/ecomments>.

Follow the instructions for submitting comments on the agency Web site.

- E-mail: fdadockets@oc.fda.gov. Include Docket No. 2003D-0545 in the subject line of your e-mail message.
- FAX: 301-827-6870.
- Mail/Hand delivery/Courier [For paper, disk, or CD-ROM submissions]: Division of Dockets Management, 5630 Fishers Lane, rm. 1061, Rockville, MD 20852.

Instructions: All submissions received must include the agency name and Docket No. or Regulatory Information Number (RIN) for this rulemaking. All comments received will be posted without change to <http://www.fda.gov/ohrms/dockets/default/htm>, including any personal information provided. For detailed instructions on submitting comments and additional information on the rulemaking process, see the "Comments" heading of the **SUPPLEMENTARY INFORMATION** section of this document.

Docket: For access to the docket to read background documents or comments received, go to <http://www.fda.gov/ohrms/dockets/default/htm> and insert the docket number, found in brackets in the heading of this document, into the "Search" box and follow the prompts and/or go to the Division of Dockets Management, 5630 Fishers Lane, rm. 1061, Rockville, MD 20852.

FOR FURTHER INFORMATION CONTACT:

Melissa S. Scales, Office of Regulations and Policy (HFS-24), Center for Food Safety and Applied Nutrition, Food and Drug Administration, 5100 Paint Branch Pkwy., College Park, MD 20740, 301-436-1720.

SUPPLEMENTARY INFORMATION:

I. Background

In the **Federal Register** of October 10, 2003 (68 FR 58894), FDA issued an interim final rule to implement section 305 of the Bioterrorism Act. The registration regulation requires facilities that manufacture/process, pack, or hold food (including animal feed) for consumption in the United States to register with FDA by December 12, 2003.

On December 4, 2003, FDA issued the first edition of a guidance entitled "Questions and Answers Regarding the Interim Final Rule on Registration of Food Facilities." The second edition of this guidance was issued on January 12, 2004, and the third edition on February 17, 2004. The guidance announced by this document entitled "Questions and Answers Regarding the Interim Final Rule on Registration of Food Facilities (Edition 4)" is a revision of the February

17, 2004, guidance and responds to additional questions about the interim final rule on registration. The guidance is intended to help the industry better understand and comply with the regulation in 21 CFR part 1, subpart H.

FDA wishes to highlight one issue clarified in the fourth edition of the food facility registration guidance, the appropriate designation of a U.S. agent by a foreign food facility. Since the interim final rule published, several individuals have notified FDA that, although listed in a facility's registration as its U.S. agent, the individual had not agreed to serve as the facility's U.S. agent. Question 14.20 in the fourth edition clarifies how FDA will handle the registration of a facility when the agency is notified that the individual listed as the facility's U.S. agent disagrees with that designation.

FDA is issuing the guidance entitled "Questions and Answers Regarding the Interim Final Rule on Registration of Food Facilities (Edition 4)" as a level 1 guidance. Consistent with FDA's good guidance practices (GGPs) regulation § 10.115 (21 CFR 10.115), the agency will accept comments on this guidance, but it is implementing the guidance immediately, in accordance with § 10.115(g)(2), because the agency has determined that prior public participation is not feasible or appropriate. As noted, the Bioterrorism Act requires covered facilities to be registered with FDA by December 12, 2003. Clarifying the provisions of the interim final rule will facilitate prompt registration by covered facilities and thus, complete implementation of the interim final rule.

As noted in previous notices announcing the availability of guidance for food facility registration, FDA continues to respond to requests for clarification of the registration interim final rule by providing guidance in a question-and-answer format. The agency is maintaining all responses to questions concerning food facility registration in a single document that is periodically updated as the agency responds to additional questions. The following four indicators are employed to help users of the guidance identify revisions: (1) The guidance will be identified as a revision of a previously issued document, (2) the revision date of the guidance will appear on its cover, (3) the edition number of the guidance will be included in its title, and (4) new questions and answers will be identified as such in the body of the guidance.

II. Comments

Interested persons may, at any time, submit written or electronic comments

to the Division of Dockets Management (see **ADDRESSES**) regarding this guidance. Submit a single copy of electronic comments or two paper copies of any mailed comments, except that individuals may submit one copy. Comments are to be identified with the docket number found in brackets in the heading of this document. The guidance and received comments may be seen in the Division of Dockets Management between 9 a.m. and 4 p.m., Monday through Friday.

III. Electronic Access

Persons with access to the Internet may obtain the document at <http://www/cfsan.fda.gov/guidance.html>.

Dated: August 2, 2004.

Jeffrey Shuren,

Assistant Commissioner for Policy.

[FR Doc. 04-18057 Filed 8-4-04; 8:45 am]

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DEPARTMENT OF DEFENSE

Department of the Army

32 CFR Part 519

RIN 0702-AA40-U

Publication of Rules Affecting the Public

AGENCY: Department of the Army, DOD.

ACTION: Final rule.

SUMMARY: The Department of the Army is revising our rule concerning the publication of rules affecting the public to incorporate requirements and policies required by various acts of Congress and Executive Orders. This revision also incorporates changes to program proponenty and policies within the Department of the Army. This rule finalizes the proposed rule that was published in the **Federal Register** on April 7, 2004.

DATES: *Effective Date:* September 7, 2004.

ADDRESSES: U.S. Army Records Management and Declassification Agency, ATTN: AHRC-PDD-RP, 7701 Telegraph Road, Alexandria, VA 22315-3860.

FOR FURTHER INFORMATION CONTACT: Ms. Brenda Bowen, Army Federal Register Liaison Officer, Alexandria, VA at (703) 428-6422 or Mrs. Brenda Kopitzke, Alternate Army Federal Register Liaison Officer, Alexandria, VA at (703) 428-6437.

SUPPLEMENTARY INFORMATION:

A. Background

In the April 7, 2004, issue of the **Federal Register** (69 FR 18314), the Department of the Army issued a proposed rule to revise 32 CFR 519. This final rule prescribes procedures and responsibilities for publishing applicable Department of the Army policies, practices, and procedures as required by statutes. It also delineates responsibilities for complying with this regulation, the Regulatory Flexibility Act, 5 U.S.C. 601-612 (E.O. 12866), and the Congressional Review Act (CRA, 5 U.S.C. Chapter 8), within the Department of the Army. The Department of the Army received responses from two commentors. No substantive changes were requested or made; however, we accepted and incorporated administrative changes to the final rule to put all verbs into the present tense and to adopt a consistent way of expressing requirements, recommendations, and discretionary actions.

B. Regulatory Flexibility Act

This rule has been reviewed under the Regulatory Flexibility Act, 5 U.S.C. 601-612, which requires the preparation of a regulatory flexibility analysis for any regulation that will have a significant economic impact on a substantial number of small entities (*i.e.*, small businesses and small governments). The Department of the Army has determined that this rule will have no significant economic impact on small entities.

C. Paperwork Reduction Act

The Paperwork Reduction Act does not apply because this rule does not impose any information collection requirements that require the approval of the Office of Management and Budget under 44 U.S.C. 3501, *et seq.*

D. Executive Order 12866

The Department of the Army has determined that according to the criteria defined in Executive Order 12866, this rule is not considered a significant regulatory action.

Brenda S. Bowen,

Army Federal Register Liaison Officer.

List of Subjects in 32 CFR Part 519

Administrative practices and procedures.

■ For the reasons stated in the preamble, the Department of the Army revises 32 CFR part 519 to read as follows:

PART 519—PUBLICATION OF RULES AFFECTING THE PUBLIC

Subpart A—General

Sec.

- 519.1 Purpose.
- 519.2 Explanation of terms.
- 519.3 Responsibilities.
- 519.4 Designation of Rulemaking Coordinators.
- 519.5 Statement of compliance.
- 519.6 Submission of publications for printing.
- 519.7 Regulatory review.

Subpart B—Information To Be Published in the Federal Register

- 519.8 General.
- 519.9 Information to be published.
- 519.10 Requirements pertaining to the information to be published.
- 519.11 Incorporation by reference.
- 519.12 Exceptions.
- 519.13 Procedures.
- 519.14 Effect of not publishing.

Subpart C—Inviting Public Comment on Certain Proposed Rules and Submission of Petitions

- 519.15 General.
- 519.16 Applicability.
- 519.17 Procedures when proposing rules.
- 519.18 OMB Control Number.
- 519.19 Consideration of public comment.
- 519.20 Procedures when publishing adopted rules.
- 519.21 Submission of petitions.
- 519.22 Cases in which public comment is impractical.

Authority: Sec. 3012, Pub. L. 84-1028, 70A Stat. 157, (10 U.S.C. 3013); sec. 3, Pub. L. 79-404, 60 Stat. 238, (5 U.S.C. 552).

Subpart A—General

§ 519.1 Purpose.

This part prescribes procedures and responsibilities for publishing certain Department of the Army policies, practices and procedures in the **Federal Register** as required by statute, and for inviting public comment thereon, as appropriate. This regulation implements portions of the Administrative Procedure Act (APA), 5 U.S.C. 551; Freedom of Information Act (FOIA), 5 U.S.C. 552(a)(1), as implemented by 32 CFR Part 335; Regulatory Flexibility Act (5 U.S.C. 601, *et seq.*), as implemented by 1 CFR Chapter 1; Congressional Review Act (CRA), 5 U.S.C. Chapter 8; Executive Order 12866 of September 30, 1993; and DODD 5025.1, DOD Directives System.

§ 519.2 Explanation of terms.

(a) *Rule.* The whole or a part of any Department of the Army Statement (regulation, circular, directive, or other media) of general or particular applicability and future effect, which is designed to implement, interpret, or prescribe law or policy or which