

Commission declines to grant the requested clarification, then it should grant rehearing on this issue and on rehearing amend Order No. 717–A to state that such disclosure is unlawful.

Commission Determination:

31. We deny APGA's request for clarification or rehearing of Order No. 717–A. The Commission previously denied APGA's request for rehearing in Order No. 717–A and affirmed the adoption of the exclusion in Order No. 717. Now, for the first time, APGA asks that the Commission adopt a per se rule that, notwithstanding any exclusion, a natural gas transmission provider's disclosure of non-public transmission function information to its gas sales employees or its affiliated producers, gatherers and processors constitutes the granting of an "undue preference or advantage" under section 4 of the Natural Gas Act. As an initial matter, we note that APGA raises this request for rehearing for the first time in this proceeding. We have held repeatedly that it is inappropriate for a protestor to raise new issues in a request for rehearing because this practice is disruptive to the administrative process and denies parties the opportunity to respond.³⁴

32. We also find that APGA's request for clarification or rehearing is beyond the scope of this proceeding. Although APGA describes its filing as a request for clarification or rehearing of Order No. 717–A, in fact, APGA requests that the Commission clarify section 4 of the Natural Gas Act.³⁵ The appropriate forum to raise this request for an interpretation of section 4 of the Natural Gas Act would be in either a complaint proceeding or a petition for declaratory order. Accordingly, we deny APGA's request for clarification or rehearing in this proceeding concerning section 4 of the Natural Gas Act.

33. Although we deny APGA's request for rehearing and clarification, we note that the exclusion must be read in the context of the whole of the Standards of Conduct. For example, section 358.2(a) of the Commission's regulations specifies that "A transmission provider must treat all transmission customers, affiliated and non-affiliated, on a non-discriminatory basis and must not make or grant any undue preference or

advantage to any person or subject any person to any undue prejudice or disadvantage with respect to any transportation of natural gas. * * *", while section 358.2(d) further provides that "A transmission provider must provide equal access to non-public transmission function information to all its transmission customers, affiliated and non-affiliated, except in the case of confidential customer information or Critical Energy Infrastructure Information."

IV. Document Availability

34. In addition to publishing the full text of this document in the **Federal Register**, the Commission provides all interested persons an opportunity to view and/or print the contents of this document via the Internet through FERC's Home Page (<http://www.ferc.gov>) and in FERC's Public Reference Room during normal business hours (8:30 a.m. to 5 p.m. Eastern time) at 888 First Street, NE., Room 2A, Washington, DC 20426.

35. From FERC's Home Page on the Internet, this information is available on eLibrary. The full text of this document is available on eLibrary in PDF and Microsoft Word format for viewing, printing, and/or downloading. To access this document in eLibrary, type the docket number excluding the last three digits of this document in the docket number field.

36. User assistance is available for eLibrary and the FERC's Web site during normal business hours from FERC Online Support at 202–502–6652 (toll free at 1–866–208–3676) or e-mail at ferconlinesupport@ferc.gov, or the Public Reference Room at (202) 502–8371, TTY (202) 502–8659. E-mail the Public Reference Room at public.referenceroom@ferc.gov.

V. Effective Date

37. Changes to Order No. 717–A adopted in this order on rehearing and clarification are effective July 21, 2010.

By the Commission.

Nathaniel J. Davis, Sr.,

Deputy Secretary.

[FR Doc. 2010–9264 Filed 4–21–10; 8:45 am]

BILLING CODE 6717–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

21 CFR Parts 1, 801, 803, 807, 812, 814, 820, 822, 860, 900, 1002, and 1040

[Docket No. FDA–2010–N–0010]

Center for Devices and Radiological Health; New Address Information

AGENCY: Food and Drug Administration, HHS.

ACTION: Final rule; technical amendments.

SUMMARY: The Food and Drug Administration (FDA) is amending procedural regulations that pertain to obtaining, submitting, executing, and filing certain documents to reflect new address information for the Center for Devices and Radiological Health (CDRH). All filings and other documents that are subject to these regulations must be directed to the new addresses. This action is being taken to provide accuracy and clarity to the agency's regulations.

DATES: This regulation is effective April 22, 2010.

FOR FURTHER INFORMATION CONTACT:

Domini Bean, Food and Drug Administration, Center for Devices and Radiological Health, 10903 New Hampshire Ave., Bldg. 66, rm. 4422, Silver Spring, MD 20993–0002, 301–796–5733.

SUPPLEMENTARY INFORMATION: FDA is amending its regulations in 21 CFR parts 1, 801, 803, 807, 812, 814, 820, 822, 860, 900, 1002, and 1040 to reflect new address information for certain components of the agency's CDRH. The changes are the result of the relocation of these offices to FDA's White Oak campus.

Publication of this document constitutes final action under the Administrative Procedures Act (5 U.S.C. 553). FDA has determined that notice and public comment are unnecessary because this amendment to the regulations provides only technical changes to update mailing addresses and other information, and is nonsubstantive.

List of Subjects

21 CFR Part 1

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

³⁴ *Baltimore Gas and Electric Company*, 91 FERC ¶ 61,270, at 61,922 (2000); *Baltimore Gas and Electric Company*, 92 FERC ¶ 61,043, at 61,114 (2000); *New York Independent System Operator, Inc.*, 97 FERC ¶ 61,006, at 61,015 (2001); *Carolina Power & Light Company*, 106 FERC ¶ 61,141, at P 15 (2004); *CARE v. Calpine Energy Services, LP*, 107 FERC ¶ 61,238, at P 7 (2004); *PJM Interconnection, LLC*, 126 FERC ¶ 61,030, at P 15 (2009).

³⁵ 15 U.S.C. § 717c (2009).

21 CFR Part 801

Incorporation by reference, Labeling, Medical devices, Reporting and recordkeeping requirements.

21 CFR Part 803

Imports, Medical devices, Reporting and recordkeeping requirements.

21 CFR Part 807

Confidential business information, Imports, Medical devices, Reporting and recordkeeping requirements.

21 CFR Part 812

Health records, Medical devices, Medical research, Reporting and recordkeeping requirements.

21 CFR Part 814

Administrative practice and procedure, Confidential business information, Medical devices, Medical research, Reporting and recordkeeping requirements.

21 CFR Parts 820 and 822

Medical devices, Reporting and recordkeeping requirements.

21 CFR Part 860

Administrative practice and procedure, Medical devices.

21 CFR Part 900

Electronic products, Health facilities, Medical devices, Radiation protection, Reporting and recordkeeping requirements, X-rays.

21 CFR Part 1002

Electronic products, Radiation protection, Reporting and recordkeeping requirements.

21 CFR Part 1040

Electronic products, Labeling, Lasers, Medical devices, Radiation protection, Reporting and recordkeeping requirements.

■ Therefore, under the Federal Food, Drug, and Cosmetic Act and under authority delegated to the Commissioner of Food and Drugs, 21 CFR Chapter I is amended as follows:

PART 1—GENERAL ENFORCEMENT REGULATIONS

■ 1. The authority citation for 21 CFR part 1 continues to read as follows:

Authority: 15 U.S.C. 1453, 1454, 1455; 19 U.S.C. 1490, 1491; 21 U.S.C. 321, 331, 332, 333, 334, 335a, 343, 350c, 350d, 352, 355, 360b, 362, 371, 374, 381, 382, 393; 42 U.S.C. 216, 241, 243, 262, 264.

■ 2. Section 1.101 is amended by revising paragraph (d)(2)(iii) to read as follows:

§ 1.101 Notification and recordkeeping.

* * * * *

(d) * * *

(2) * * *

(iii) For devices—Food and Drug Administration, Center for Devices and Radiological Health, Division of Program Operations, 10903 New Hampshire Ave., Bldg. 66, rm. 5429, Silver Spring, MD 20993-0002.

* * * * *

PART 801—LABELING

■ 3. The authority citation for 21 CFR part 801 continues to read as follows:

Authority: 21 U.S.C. 321, 331, 351, 352, 360i, 360j, 371, 374.

■ 4. Section 801.430 is amended by revising the text of footnote number 1 in paragraph (f)(2) to read as follows:

§ 801.430 User labeling for menstrual tampons.

* * * * *

(f) * * *

(2) * * *

¹The Director of the Federal Register approves this incorporation by reference in accordance with 5 U.S.C. 552(a) and 1 CFR part 51. You may obtain a copy from the American Society for Testing and Materials International, 100 Barr Harbor Dr., P.O. Box C700, West Conshohocken, PA 19428-2959, 610-832-9578, www.astm.org. You may inspect a copy at the FDA Main Library, 10903 New Hampshire Ave., Bldg. 2, 3d floor, Silver Spring, MD 20993-0002, 301-796-2039, or at the National Archives and Records Administration (NARA). For information on the availability of this material at NARA, call 202-741-2139, or go to: http://www.archives.gov/federal_register/code_of_federal_regulations/ibr_locations.html.

* * * * *

PART 803—MEDICAL DEVICE REPORTING

■ 5. The authority citation for 21 CFR part 803 continues to read as follows:

Authority: 21 U.S.C. 352, 360, 360i, 360j, 371, 374.

■ 6. Section 803.11 is amended by revising paragraph (c) to read as follows:

§ 803.11 What form should I use to submit reports of individual adverse events and where do I obtain these forms?

* * * * *

(c) Food and Drug Administration, Center for Devices and Radiological Health, Division of Small Manufacturers, International and Consumer Assistance, 10903 New

Hampshire Ave., Bldg. 66, rm. 4521, Silver Spring, MD 20993-0002.

* * * * *

■ 7. Section 803.21 is amended by revising paragraph (a) to read as follows:

§ 803.21 Where can I find the reporting codes for adverse events that I use with medical device reports?

(a) The MEDWATCH Medical Device Reporting Code Instruction Manual contains adverse event codes for use with FDA Form 3500A. You may obtain the coding manual from CDRH's Web site at <http://www.fda.gov/Safety/MedWatch/HowToReport/DownloadForms/ucm149238.htm>.

* * * * *

PART 807—ESTABLISHMENT REGISTRATION AND DEVICE LISTING FOR MANUFACTURERS AND INITIAL IMPORTERS OF DEVICES

■ 8. The authority citation for 21 CFR part 807 continues to read as follows:

Authority: 21 U.S.C. 321, 331, 351, 352, 360, 360c, 360e, 360i, 360j, 371, 374, 381, 393; 42 U.S.C. 264, 271.

■ 9. Section 807.22 is amended by revising paragraph (a) to read as follows:

§ 807.22 How and where to register establishments and list devices.

(a) The first registration of a device establishment shall be on Form FDA-2891 (Initial Registration of Device Establishment). Forms are available upon request from the Food and Drug Administration, Center for Devices and Radiological Health, Office of Compliance, 10903 New Hampshire Ave., Bldg. 66, rm. 3521, Silver Spring, MD 20993-0002, or from Food and Drug Administration district offices. Subsequent annual registration shall be accomplished on Form FDA-2891a (Annual Registration of Device Establishment), which will be furnished by FDA to establishments whose registration for that year was validated under § 807.35(a). The forms will be mailed to the owner or operators of all establishments by the official correspondent in accordance with the schedule as described in § 807.21(a). The completed form shall be mailed to the address designated in this paragraph 30 days after receipt from FDA.

* * * * *

■ 10. Section 807.37 is amended by revising paragraphs (a) and (b)(2) to read as follows:

§ 807.37 Inspection of establishment registration and device listings.

(a) A copy of the forms FDA-2891 and FDA-2891a filed by the registrant will be available for inspection in

accordance with section 510(f) of the act, at the Food and Drug Administration, Center for Devices and Radiological Health, Office of Compliance, 10903 New Hampshire Ave., Bldg. 66, rm. 3521, Silver Spring, MD 20993-0002. In addition, there will be available for inspection at each of the Food and Drug Administration district offices the same information for firms within the geographical area of such district office. Upon request, verification of registration number or location of a registered establishment will be provided.

(b) * * *

(2) Requests for device listing information identified in paragraph (b)(1) of this section should be directed to the Food and Drug Administration, Center for Devices and Radiological Health, Office of Compliance, 10903 New Hampshire Ave., Bldg. 66, rm. 3521, Silver Spring, MD 20993-0002.

* * * * *

■ 11. Section 807.90 is amended by revising paragraph (a)(1) to read as follows:

§ 807.90 Format of a premarket notification submission.

* * * * *

(a)(1) For devices regulated by the Center for Devices and Radiological Health, be addressed to the Food and Drug Administration, Center for Devices and Radiological Health, Document Mail Center, 10903 New Hampshire Ave., Bldg. 66, rm. G609, Silver Spring, MD 20993-0002.

* * * * *

PART 812—INVESTIGATIONAL DEVICE EXEMPTIONS

■ 12. The authority citation for 21 CFR part 812 continues to read as follows:

Authority: 21 U.S.C. 331, 351, 352, 353, 355, 360, 360c–360f, 360h–360j, 371, 372, 374, 379e, 381, 382, 383; 42 U.S.C. 216, 241, 262, 263b–263n.

■ 13. Section 812.19 is amended by revising paragraph (a)(1) to read as follows:

§ 812.19 Address for IDE correspondence.

(a) * * *

(1) For devices regulated by the Center for Devices and Radiological Health, send it to Food and Drug Administration, Center for Devices and Radiological Health, Document Mail Center, 10903 New Hampshire Ave., Bldg. 66, rm. G609, Silver Spring, MD 20993-0002.

* * * * *

PART 814—PREMARKET APPROVAL OF MEDICAL DEVICES

■ 14. The authority citation for 21 CFR part 814 continues to read as follows:

Authority: 21 U.S.C. 351, 352, 353, 360, 360c–360j, 371, 372, 373, 374, 375, 379, 379e, 381.

■ 15. Section 814.20 is amended by revising paragraph (h)(1) to read as follows:

§ 814.20 Application.

* * * * *

(h) * * *

(1) For devices regulated by the Center for Devices and Radiological Health, Food and Drug Administration, Center for Devices and Radiological Health, Document Mail Center, 10903 New Hampshire Ave., Bldg. 66, rm. G609, Silver Spring, MD 20993-0002.

* * * * *

■ 16. Section 814.104 is amended by revising paragraph (d)(1) to read as follows:

§ 814.104 Original applications.

* * * * *

(d) * * *

(1) For devices regulated by the Center for Devices and Radiological Health, send to Document Mail Center, 10903 New Hampshire Ave., Bldg. 66, rm. G609, Silver Spring, MD 20993-0002.

* * * * *

PART 820—QUALITY SYSTEM REGULATION

■ 17. The authority citation for 21 CFR part 820 continues to read as follows:

Authority: 21 U.S.C. 351, 352, 360, 360c, 360d, 360e, 360h, 360i, 360j, 360l, 371, 374, 381, 383; 42 U.S.C. 216, 262, 263a, 264.

■ 18. Section 820.1 is amended by revising paragraph (e)(1) to read as follows:

§ 820.1 Scope.

* * * * *

(e) * * * (1) Any person who wishes to petition for an exemption or variance from any device quality system requirement is subject to the requirements of section 520(f)(2) of the act. Petitions for an exemption or variance shall be submitted according to the procedures set forth in § 10.30 of this chapter, the FDA's administrative procedures. Guidance is available from the Food and Drug Administration, Center for Devices and Radiological Health, Division of Small Manufacturers, International and Consumer Assistance, 10903 New Hampshire Ave., Bldg. 66, rm. 4613, Silver Spring, MD 20993-0002, 1-800-

638-2041 or 301-796-7100, FAX: 301-847-8149.

* * * * *

PART 822—POSTMARKET SURVEILLANCE

■ 19. The authority citation for 21 CFR part 822 continues to read as follows:

Authority: 21 U.S.C. 331, 352, 360i, 360l, 371, 374.

■ 20. Section 822.8 is revised to read as follows:

§ 822.8 When, where, and how must I submit my postmarket surveillance plan?

You must submit your plan to conduct postmarket surveillance within 30 days of the date you receive the postmarket surveillance order. For devices regulated by the Center for Biologics Evaluation and Research, send three copies of your submission to the Document Control Center (HFM-99), Center for Biologics Evaluation and Research, Food and Drug Administration, 1401 Rockville Pike, suite 200N, Rockville, MD 20852-1448. For devices regulated by the Center for Drug Evaluation and Research, send three copies of your submission to the Central Document Room, Center for Drug Evaluation and Research, Food and Drug Administration, 5901-B, Ammendale Rd., Beltsville, MD 20705-1266. For devices regulated by the Center for Devices and Radiological Health, send three copies of your submission to the Document Mail Center, 10903 New Hampshire Ave., Bldg. 66, rm. G609, Silver Spring, MD 20993-0002. When we receive your original submission, we will send you an acknowledgment letter identifying the unique document number assigned to your submission. You must use this number in any correspondence related to this submission.

■ 21. Section 822.12 is revised to read as follows:

§ 822.12 Do you have any information that will help me prepare my submission or design my postmarket surveillance plan?

Guidance documents that discuss our current thinking on preparing a postmarket surveillance submission and designing a postmarket surveillance plan are available on the Center for Devices and Radiological Health's Web site and from the Food and Drug Administration, Center for Devices and Radiological Health, Office of Surveillance and Biometrics, 10903 New Hampshire Ave., Bldg. 66, rm. 3219, Silver Spring, MD 20993-0002. Guidance documents represent our current interpretation of, or policy on, a regulatory issue. They do not establish

legally enforceable rights or responsibilities and do not legally bind you or FDA. You may choose to use an approach other than the one set forth in a guidance document, as long as your alternative approach complies with the relevant statutes (laws) and regulations. If you wish, we will meet with you to discuss whether an alternative approach you are considering will satisfy the requirements of the act and regulations.

PART 860—MEDICAL DEVICE CLASSIFICATION PROCEDURES

- 22. The authority citation for 21 CFR part 860 continues to read as follows:

Authority: 21 U.S.C. 360c, 360d, 360e, 360i, 360j, 371, 374.

- 23. Section 860.123 is amended by revising paragraph (b)(1) to read as follows:

§ 860.123 Reclassification petition: Content and form.

* * * * *

(b) * * *

(1) For devices regulated by the Center for Devices and Radiological Health, addressed to the Food and Drug Administration, Center for Devices and Radiological Health, Regulations Staff, 10903 New Hampshire Ave., Bldg. 66, rm. 4425, Silver Spring, MD 20993–0002; for devices regulated by the Center for Biologics Evaluation and Research, addressed to the Document Control Center (HFM–99), Center for Biologics Evaluation and Research, Food and Drug Administration, 1401 Rockville Pike, suite 200N, Rockville, MD 20852–1448; for devices regulated by the Center for Drug Evaluation and Research, addressed to the Central Document Control Room, Center for Drug Evaluation and Research, Food and Drug Administration, 5901–B Ammendale Rd., Beltsville, MD 20705–1266, as applicable.

* * * * *

PART 900—MAMMOGRAPHY

- 24. The authority citation for 21 CFR part 900 continues to read as follows:

Authority: 21 U.S.C. 360i, 360nn, 374(e); 42 U.S.C. 263b.

- 25. Section 900.15 is amended by revising paragraph (d)(3)(i) to read as follows:

§ 900.15 Appeals of adverse accreditation or reaccreditation decisions that preclude certification or recertification.

* * * * *

(d) * * *

(3) * * *

(i) A facility must request reconsideration by DMQRP within 60

days of the accreditation body's adverse appeals decision, at the following address: Food and Drug Administration, Center for Devices and Radiological Health, Division of Mammography Quality and Radiation Programs, Attn: Facility Accreditation Review Committee, 10903 New Hampshire Ave., Bldg. 66, rm. 4521, Silver Spring, MD 20993–0002.

* * * * *

- 26. Section 900.18 is amended by revising paragraph (c) introductory text to read as follows:

§ 900.18 Alternative requirements for § 900.12 quality standards.

* * * * *

(c) *Applications for approval of an alternative standard.* An application for approval of an alternative standard or for an amendment or extension of the alternative standard shall be submitted in an original and two copies to the Food and Drug Administration, Center for Devices and Radiological Health, Director, Division of Mammography Quality and Radiation Programs, 10903 New Hampshire Ave., Bldg. 66, rm. 4521, Silver Spring, MD 20993–0002. The application for approval of an alternative standard shall include the following information:

* * * * *

- 27. Section 900.21 is amended by revising paragraph (b)(1) to read as follows:

§ 900.21 Application for approval as a certification agency.

* * * * *

(b) * * * (1) An applicant seeking FDA approval as a certification agency shall inform the Food and Drug Administration, Center for Devices and Radiological Health, Director, Division of Mammography Quality and Radiation Programs, Attn: States as Certifiers Coordinator, 10903 New Hampshire Ave., Bldg. 66, rm. 4521, Silver Spring, MD 20993–0002, in writing, of its desire to be approved as a certification agency.

* * * * *

PART 1002—RECORDS AND REPORTS

- 28. The authority citation for 21 CFR part 1002 continues to read as follows:

Authority: 21 U.S.C. 352, 360, 360i, 360j, 360hh–360ss, 371, 374.

- 29. Section 1002.7 is amended by revising the introductory text to read as follows:

§ 1002.7 Submission of data and reports.

All submissions such as reports, test data, product descriptions, and other

information required by this part, or voluntarily submitted to the Director, Center for Devices and Radiological Health, shall be filed with the number of copies as prescribed by the Director, Center for Devices and Radiological Health, and shall be signed by the person making the submission. The submissions required by this part shall be addressed to the Food and Drug Administration, Center for Devices and Radiological Health, ATTN: Electronic Product Reports, Document Mail Center, 10903 New Hampshire Ave., Bldg. 66, rm. G609, Silver Spring, MD 20993–0002.

* * * * *

- 30. Section 1002.10 is amended by revising the introductory text to read as follows:

§ 1002.10 Product reports.

Every manufacturer of a product or component requiring a product report as set forth in table 1 of § 1002.1 shall submit a product report to the Food and Drug Administration, Center for Devices and Radiological Health, ATTN: Electronic Product Reports, Document Mail Center, 10903 New Hampshire Ave., Bldg. 66, rm. G609, Silver Spring, MD 20993–0002, prior to the introduction of such product into commerce. The report shall be distinctly marked “Radiation Safety Product Report of (name of manufacturer)” and shall:

* * * * *

- 31. Section 1002.20 is amended by revising paragraph (b) introductory text to read as follows:

§ 1002.20 Reporting of accidental radiation occurrences.

* * * * *

(b) Such reports shall be addressed to Food and Drug Administration, Center for Devices and Radiological Health, ATTN: Accidental Radiation Occurrence Reports, Document Mail Center, 10903 New Hampshire Ave., Bldg. 66, rm. G609, Silver Spring, MD 20993–0002, and the reports and their envelopes shall be distinctly marked “Report on 1002.20” and shall contain all of the following information where known to the manufacturer:

* * * * *

- 32. Section 1002.50 is amended by revising paragraph (c)(3) to read as follows:

§ 1002.50 Special exemptions.

* * * * *

(c) * * *

(3) Such conditions as are deemed necessary to protect the public health and safety. Copies of exemptions shall

be available upon request from the Food and Drug Administration, Center for Devices and Radiological Health, Division of Mammography Quality and Radiation Programs, 10903 New Hampshire Ave., Bldg. 66, rm. 4521, Silver Spring, MD 20993-0002.

* * * * *

PART 1040—PERFORMANCE STANDARDS FOR LIGHT-EMITTING PRODUCTS

- 33. The authority citation for 21 CFR part 1040 continues to read as follows:

Authority: 21 U.S.C. 351, 352, 360, 360e–360j, 371, 381; 42 U.S.C. 263B–263n.

- 34. Section 1040.10 is amended by revising paragraph (a)(3)(i) to read as follows:

§ 1040.10 Laser products.

(a) * * *

(3) * * *

(i) Registers, and provides a listing by type of such laser products manufactured that includes the product name, model number and laser medium or emitted wavelength(s), and the name and address of the manufacturer. The manufacturer must submit the registration and listing to the Food and Drug Administration, Center for Devices and Radiological Health, Director, Office of Compliance, 10903 New Hampshire Ave., Bldg. 66, rm. 3521, Silver Spring, MD 20993-0002.

* * * * *

- 35. Section 1040.20 is amended by revising paragraph (d)(3)(iii) to read as follows:

§ 1040.20 Sunlamp products and ultraviolet lamps intended for use in sunlamp products.

* * * * *

(d) * * *

(3) * * *

(iii) If the size, configuration, design, or function of the sunlamp product or ultraviolet lamp would preclude compliance with the requirements for any required label or would render the required wording of such label inappropriate or ineffective, or would render the required label unnecessary, the Director, Office of Communication, Education, and Radiation Programs 10903 New Hampshire Ave., Bldg. 66, rm. 4312, Silver Spring, MD 20993-0002, Center for Devices and Radiological Health, on the center's own initiative or upon written application by the manufacturer, may approve alternate means of providing such label(s), alternate wording for such label(s), or deletion, as applicable.

* * * * *

Dated: April 12, 2010.

Leslie Kux,

Acting Assistant Commissioner for Policy.

[FR Doc. 2010-8863 Filed 4-21-10; 8:45 am]

BILLING CODE 4160-01-S

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

21 CFR Part 558

[Docket No. FDA-2010-N-0002]

New Animal Drugs for Use in Animal Feeds; Melengestrol, Monensin, and Ractopamine

AGENCY: Food and Drug Administration, HHS.

ACTION: Final rule.

SUMMARY: The Food and Drug Administration (FDA) is amending the animal drug regulations to reflect approval of a supplemental abbreviated new animal drug application (ANADA) filed by Ivy Laboratories, Div. of Ivy Animal Health, Inc. The supplemental NADA provides for an increased level of monensin in three-way combination Type C medicated feeds containing ractopamine, melengestrol, and monensin for heifers fed in confinement for slaughter.

DATES: This rule is effective April 22, 2010.

FOR FURTHER INFORMATION CONTACT: John K. Harshman, Center for Veterinary Medicine (HFV-170), Food and Drug Administration, 7500 Standish Pl., Rockville, MD 20855, 240-276-8197, e-mail: john.harshman@fda.hhs.gov.

SUPPLEMENTARY INFORMATION: Ivy Laboratories, Div. of Ivy Animal Health, Inc., 8857 Bond St., Overland Park, KS 66214, filed a supplement to ANADA 200-448 that provides for use of HEIFERMAX 500 (melengestrol acetate) Liquid Premix, OPTAFLEXX (ractopamine hydrochloride), and RUMENSIN (monensin, USP) single-ingredient Type A medicated articles to make dry and liquid, three-way combination drug Type C medicated feeds for heifers fed in confinement for slaughter. The supplemental ANADA provides for an increased level of monensin. The supplemental ANADA is approved as of February 16, 2010, and the regulations are amended in 21 CFR 558.500 to reflect the approval.

In accordance with the freedom of information provisions of 21 CFR part 20 and 21 CFR 514.11(e)(2)(ii), a summary of safety and effectiveness data and information submitted to

support approval of this application may be seen in the Division of Dockets Management (HFA-305), Food and Drug Administration, 5630 Fishers Lane, rm. 1061, Rockville, MD 20852, between 9 a.m. and 4 p.m., Monday through Friday.

The agency has determined under 21 CFR 25.33 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.

This rule does not meet the definition of “rule” in 5 U.S.C. 804(3)(A) because it is a rule of “particular applicability.” Therefore, it is not subject to the congressional review requirements in 5 U.S.C. 801–808.

List of Subjects in 21 CFR Part 558

Animal drugs, Animal feeds.

- Therefore, under the Federal Food, Drug, and Cosmetic Act and under authority delegated to the Commissioner of Food and Drugs and redelegated to the Center for Veterinary Medicine, 21 CFR part 558 is amended as follows:

PART 558—NEW ANIMAL DRUGS FOR USE IN ANIMAL FEEDS

- 1. The authority citation for 21 CFR part 558 continues to read as follows:

Authority: 21 U.S.C. 360b, 371.

§ 558.500 [Amended]

- 2. In § 558.500, in paragraph (e)(2)(viii), in the “Limitations” column, remove “000009” and add in its place “000009 or 021641”, and in the “Sponsor” column, remove “No. 000986” and add in its place “000986, 021641”; and remove paragraph (e)(2)(xii).

Dated: April 19, 2010.

Elizabeth Rettie,

Deputy Director, Office of New Animal Drug Evaluation, Center for Veterinary Medicine.

[FR Doc. 2010-9304 Filed 4-21-10; 8:45 am]

BILLING CODE 4160-01-S