Title: FERC–725R, Mandatory Reliability Standards: Reliability Standard BAL–003–1.

Action: Proposed Collection of Information.

OMB Control No: To be determined.

Respondents: Business or other for-profit, and not-for-profit institutions.

Frequency of Responses: Annual.

Necessity of the Information: The revision of NERC Reliability Standard BAL–003–1 is part of the implementation of the Congressional mandate of the Energy Policy Act of 2005 to develop mandatory and enforceable Reliability Standards to better ensure the reliability of the nation's Bulk Power System. Specifically, Reliability Standard BAL–003–1 is intended to ensure sufficient Frequency Response from balancing authorities to maintain Interconnection Frequency within predefined bounds.

Internal Review: The Commission has reviewed the revisions to the Reliability Standard and determined that its action is necessary to implement section 215 of the FPA. The Commission has assured itself, by means of its internal review, that there is specific, objective support for the burden estimate associated with the information requirements.

103. Interested persons may obtain information on the reporting requirements by contacting the following: Federal Energy Regulatory Commission, 888 First Street NE., Washington, DC 20426 [Attention: Ellen Brown, Office of the Executive Director, email: *DataClearance@ferc.gov,* phone: (202) 502–8663, fax: (202) 273–0873].

VI. Environmental Analysis

104. The Commission is required to prepare an Environmental Assessment or an Environmental Impact Statement for any action that may have a significant adverse effect on the human environment.[126] The Commission has categorically excluded certain actions from this requirement as not having a significant effect on the human environment. Included in the exclusion are rules that are clarifying, corrective, or procedural or that do not substantially change the effect of the regulations being amended.[127] The actions directed herein fall within this categorical exclusion in the Commission's regulations.

VII. Regulatory Flexibility Act

105. The Regulatory Flexibility Act of 1980 (RFA)[128] generally requires a description and analysis of proposed rules that will have significant economic impact on a substantial number of small entities. The NERC registry includes about 132 individual balancing authorities. Comparison of the NERC Compliance Registry with data submitted to the Energy Information Administration on Form EIA–861 indicates that, of these entities, 15 may qualify as small entities.[129]

106. As noted above, the Commission estimates the annual regulatory burden for compliance with the Reliability Standard to be $13,560 per balancing authority. This estimate for all balancing authorities was established using 28 events per year, but smaller entities may have fewer events which qualify for analysis,[130] and the costs for these smaller entities may be reduced. Further, while the Reliability Standard establishes a balancing authority's Frequency Response Obligation, because balancing authorities are currently providing frequency response, we do not anticipate additional compliance costs. Accordingly, we do not consider the cost of compliance with the Reliability Standard to be a significant economic impact for small entities because it should not represent a significant percentage of an affected small entity's operating budget. Accordingly, no regulatory flexibility analysis is required.

VIII. Document Availability

107. 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 the Commission's Home Page *(http://www.ferc.gov)* and in the Commission's Public Reference Room during normal business hours (8:30 a.m. to 5:00 p.m. Eastern time) at 888 First Street NE., Room 2A, Washington, DC 20426.

108. From the Commission'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.

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

IX. Effective Date and Congressional Notification

110. These regulations are effective March 24, 2014. The Commission has determined, with the concurrence of the Administrator of the Office of Information and Regulatory Affairs of OMB, that this rule is not a ''major rule'' as defined in section 351 of the Small Business Regulatory Enforcement Fairness Act of 1996.

By the Commission.

Nathaniel J. Davis, Sr.,

Deputy Secretary.

[FR Doc. 2014–01218 Filed 1–22–14; 8:45 am]

BILLING CODE 6717–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

21 CFR Part 225

[Docket No. FDA–2013–N–0002]

Current Good Manufacturing Practice for Medicated Feeds

AGENCY: Food and Drug Administration, HHS.

ACTION: Final rule, correcting amendment.

SUMMARY: The Food and Drug Administration (FDA) is amending the regulations for good manufacturing practice of animal feeds containing a new animal drug to correctly cite the applicable section of the Federal Food, Drug, and Cosmetic Act (FD&C Act). This action is being taken to improve the accuracy of the regulations.

DATES: This rule is effective January 23, 2014.

FOR FURTHER INFORMATION CONTACT: George K. Haibel, Center for Veterinary

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[126] *Regulations Implementing the National Environmental Policy Act,* Order No. 486, 52 FR 47897 (Dec. 17, 1987), FERC Stats. & Regs., Regulations Preambles 1986–1990 ¶ 30,783 (1987).

[127] 18 CFR 380.4(a)(2)(ii).

[128] 5 U.S.C. 601–612.

[129] The RFA definition of ''small entity'' refers to the definition provided in the Small Business Act (SBA), which defines a ''small business concern'' as a business that is independently owned and operated and that is not dominant in its field of operation. *See* 15 U.S.C. 632 (2006). According to the Small Business Administration, an electric utility is defined as ''small'' if, including its affiliates, it is primarily engaged in the generation, transmission, and/or distribution of electric energy for sale and its total electric output for the preceding fiscal year did not exceed 4 million megawatt hours.

[130] The Procedures establish a minimum of 20 events for analysis, and a process for identifying when fewer than 20 events are available for analysis.

Medicine (HFV–6), Food and Drug Administration, 7519 Standish Pl., Rockville, MD 20855, 240–276–9019, *ghaibel@fda.hhs.gov*.

SUPPLEMENTARY INFORMATION: FDA has noticed the regulations for good manufacturing practice of animal feeds containing a new animal drug do not correctly cite the applicable section of the FD&C Act. At this time, FDA is making a correcting amendment in 21 CFR 225.1. This action is being taken to improve the accuracy of the regulations.

List of Subjects in 21 CFR Part 225

Animal drugs, Animal feeds, Labeling, Packaging and containers, 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 part 225 is amended as follows:

PART 225—CURRENT GOOD MANUFACTURING PRACTICE FOR MEDICATED FEEDS

■ 1. The authority citation for 21 CFR part 225 continues to read as follows:

Authority: 21 U.S.C. 351, 352, 360b, 371, 374.

§ 225.1 [Amended]

■ 2. In § 225.1, in the last sentence in paragraph (b)(1), remove ''section 402(a)(2)(D) of the act'' and in its place add ''section 402(a)(2)(C)(ii) of the act''.

Dated: January 16, 2014.

Leslie Kux,

Assistant Commissioner for Policy.

[FR Doc. 2014–01299 Filed 1–22–14; 8:45 am]

BILLING CODE 4160–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

21 CFR Part 866

[Docket No. FDA–2013–N–1662]

Medical Devices; Immunology and Microbiology Devices; Classification of John Cunningham Virus Serological Reagents

AGENCY: Food and Drug Administration, HHS.

ACTION: Final order.

SUMMARY: The Food and Drug Administration (FDA) is classifying John Cunningham Virus (JCV) serological reagents into class II (special controls). The Agency is classifying the device into class II (special controls) in order to provide a reasonable assurance of safety and effectiveness of the device.

DATES: This order is effective February 24, 2014. The classification was effective January 20, 2012.

FOR FURTHER INFORMATION CONTACT: Haja Sittana El Mubarak, Center for Devices and Radiological Health, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 66, rm. 5519, Silver Spring, MD 20993–0002, 301–796–6193.

SUPPLEMENTARY INFORMATION:

I. Background

In accordance with section 513(f)(1) of the Federal Food, Drug, and Cosmetic Act (the FD&C Act) (21 U.S.C. 360c(f)(1)), devices that were not in commercial distribution before May 28, 1976 (the date of enactment of the Medical Device Amendments of 1976), generally referred to as postamendments devices, are classified automatically by statute into class III without any FDA rulemaking process. These devices remain in class III and require premarket approval, unless and until the device is classified or reclassified into class I or II, or FDA issues an order finding the device to be substantially equivalent, in accordance with section 513(i) of the FD&C Act, to a predicate device that does not require premarket approval. The Agency determines whether new devices are substantially equivalent to predicate devices by means of premarket notification procedures in section 510(k) of the FD&C Act (21 U.S.C. 360(k)) and part 807 (21 CFR part 807) of the regulations.

Section 513(f)(2) of the FD&C Act provided a procedure by which a person may request that FDA classify a device under the criteria set forth in section 513(a)(1). The person submits a premarket notification under section 510(k) of the FD&C Act for a device that has not previously been classified and, within 30 days of receiving an order classifying the device into class III under section 513(f)(1) of the FD&C Act, the person requests a classification under section 513(f)(2). In response to a request to classify a device under the procedure provided by section 513(f)(2) of the FD&C Act, FDA will classify the device by written order within 60 days. This classification will be the initial classification of the device. Within 30 days after the issuance of an order classifying the device, FDA must publish a notice in the **Federal Register** announcing this classification.

In accordance with section 513(f)(1) of the FD&C Act, FDA issued an order on December 22, 2011, classifying the STRATIFY JCV™ antibody enzyme-linked immunosorbent assay (ELISA) into class III because it was not substantially equivalent to a device that was introduced or delivered for introduction into interstate commerce for commercial distribution before May 28, 1976, or a device which was subsequently reclassified into class I or class II. On January 5, 2012, Focus Diagnostics, Inc., submitted a request for de novo classification of the STRATIFY JCV™ antibody ELISA under section 513(f)(2) of the FD&C Act. The manufacturer recommended that the device be classified into class II.

In accordance with section 513(f)(2) of the FD&C Act, FDA reviewed the request for de novo classification in order to classify the device under the criteria for classification set forth in section 513(a)(1) of the FD&C Act. FDA classifies devices into class II if general controls by themselves are insufficient to provide reasonable assurance of safety and effectiveness, but there is sufficient information to establish special controls to provide reasonable assurance of the safety and effectiveness of the device for its intended use. After review of the information submitted in the request, FDA determined that the device can be classified into class II with the establishment of special controls. FDA believes these special controls will provide reasonable assurance of the safety and effectiveness of the device.

The device is assigned the generic name John Cunningham Virus serological reagents, which are devices that consist of antigens and antisera used in serological assays to identify antibodies to JCV in serum and plasma. The identification aids in the risk stratification for the development of progressive multifocal leukoencephalopathy in multiple sclerosis and Crohn's disease patients undergoing natalizumab therapy. These devices are for adjunctive use, in the context of other clinical risk factors for the development of progressive multifocal leukoencephalopathy.

FDA has identified the following risks to health associated with this type of device and the measures required to mitigate these risks:

TABLE 1—IDENTIFIED RISKS TO HEALTH AND MITIGATION MEASURES

Identified risks to health	Mitigation measures
False positive results	Device Description Performance.
False negative results	Device Description Performance.