introductory text in §§ 946.143 and 946.336. Authority for the change in the order's rules and regulations is provided for in §§ 946.70 and 946.52, respectively.

This action is not expected to increase costs associated with the order requirements. Rather, this action represents a cost savings for handlers and has the potential to increase industry returns. This change extends the one-year suspension of minimum quality, maturity, pack, marking, and inspection requirements indefinitely. Though inspections will not be mandated for russet potatoes handled under the order, handlers may at their discretion choose to have their potatoes inspected. Handlers are thus able to control costs—which are generally passed on to producers—based on the demands of their customers. The opportunities and benefits of this rule are equally available to all Washington potato handlers and growers, regardless of their size.

In accordance with the Paperwork Reduction Act of 1995 (44 U.S.C. Chapter 35), the order's information collection requirements have been previously approved by the Office of Management and Budget (OMB) and assigned OMB No. 0581–0178 (Vegetable and Specialty Crop Marketing Orders). No changes in those requirements as a result of this action are necessary. Should any changes become necessary, they would be submitted to OMB for approval.

This change continues the monthly reporting requirement for russet potato handlers. The reports provide the Committee with information necessary to track shipments and collect assessments. As with all Federal marketing order programs, reports and forms are periodically reviewed to reduce information requirements and duplication by industry and public sector agencies. In addition, USDA has not identified any relevant Federal rules that duplicate, overlap or conflict with this rule.

Further, the Committee's meeting was widely publicized throughout the Washington potato industry and all interested persons were invited to participate in Committee deliberations. Like all Committee meetings, the January 26, 2011, meeting was a public meeting, and all entities, both large and small, were able to express views on this issue.

Comments on the interim rule were required to be received on or before July 12, 2011. No comments were received. Therefore, for the reasons given in the interim rule, we are adopting the interim rule as a final rule, without change.

To view the interim rule, go to: *http://www.regulations.gov/#!documentDetail;D=AMS-FV-11-0024-0001.*

This action also affirms information contained in the interim rule concerning Executive Orders 12866 and 12988, the Paperwork Reduction Act (44 U.S.C. Chapter 35), and the E-Gov Act (44 U.S.C. 101).

After consideration of all relevant material presented, it is found that finalizing the interim rule, without change, as published in the **Federal Register** (76 FR 27850, May 13, 2011) will tend to effectuate the declared policy of the Act.

List of Subjects in 7 CFR Part 946

Marketing agreements, Potatoes, Reporting and recordkeeping requirements.

Accordingly, the interim rule that amended 7 CFR 946.143 and 946.336 and that was published at 76 FR 27850 on May 13, 2011, is adopted as a final rule, without change.

Dated: August 3, 2011.

David R. Shipman,

Acting Administrator, Agricultural Marketing Service.

[FR Doc. 2011–20124 Filed 8–8–11; 8:45 am]

BILLING CODE 3410–02–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

21 CFR Parts 520, 522, and 524

[Docket No. FDA–2011–N–0003]

New Animal Drugs; Change of Sponsor; Moxidectin

AGENCY: Food and Drug Administration, HHS.

ACTION: Final rule.

SUMMARY: The Food and Drug Administration (FDA) is amending the animal drug regulations to reflect a change of sponsor for three approved new animal drug applications (NADAs) for dosage form products containing moxidectin from Fort Dodge Animal Health, Division of Wyeth, a wholly owned subsidiary of Pfizer, Inc., to Boehringer Ingelheim Vetmedica, Inc.

DATES: This rule is effective August 9, 2011.

FOR FURTHER INFORMATION CONTACT: Steven D. Vaughn, Center for Veterinary Medicine (HFV–100), Food and Drug Administration, 7520 Standish Pl., Rockville, MD 20855, 240–276–8300, e-mail: *steven.vaughn@fda.hhs.gov.*

SUPPLEMENTARY INFORMATION: Fort Dodge Animal Health, Division of Wyeth, a wholly owned subsidiary of Pfizer, Inc., 235 East 42d St., New York, NY 10017 has informed FDA that it has transferred ownership of, and all rights and interest in, the following three approved NADAs for dosage form products containing moxidectin to Boehringer Ingelheim Vetmedica, Inc., 2621 North Belt Highway, St. Joseph, MO 64506–2002: NADA 141–099, NADA 141–220, and NADA 141–247. Accordingly, the Agency is amending the regulations in 21 CFR parts 520, 522, and 524 to reflect the transfer of ownership.

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 Parts 520, 522, and 524

Animal drugs.

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 parts 520, 522, and 524 are amended as follows:

PART 520—ORAL DOSAGE FORM NEW ANIMAL DRUGS

■ 1. The authority citation for 21 CFR part 520 continues to read as follows:

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

■ 2. In § 520.1454, revise paragraphs (b) and (d) to read as follows:

§ 520.1454 Moxidectin solution.

* * * * *

(b) *Sponsor.* See No. 000010 in § 510.600(c) of this chapter.

* * * * *

(d) *Special considerations.* See § 500.25 of this chapter.

* * * * *

PART 522—IMPLANTATION OR INJECTABLE DOSAGE FORM NEW ANIMAL DRUGS

■ 3. The authority citation for 21 CFR part 522 continues to read as follows:

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

■ 4. In § 522.1450, redesignate paragraph (d) as paragraph (e); add new paragraph (d); and revise paragraph (b)

and newly redesignated paragraphs (e)(1) and (e)(3) to read as follows:

§ 522.1450 Moxidectin solution.

* * * * *

(b) *Sponsor.* See No. 000010 in § 510.600(c) of this chapter.

* * * * *

(d) *Special considerations.* See § 500.25 of this chapter.

(e) * * *

(1) *Amount.* Administer 0.2 mg/kg of body weight (0.2 mg/2.2 pound) as a single, subcutaneous injection.

* * * * *

(3) *Limitations.* Do not slaughter cattle within 21 days of treatment. Because a withholding time for milk has not been established, do not use in female dairy cattle 20 months of age and older. A withdrawal period has not been established for pre-ruminating calves. Do not use in calves to be processed for veal.

PART 524—OPHTHALMIC AND TOPICAL DOSAGE FORM NEW ANIMAL DRUGS

■ 5. The authority citation for 21 CFR part 524 continues to read as follows:

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

§ 524.1451 [Redesignated as § 524.1450 and Amended]

■ 6. Redesignate § 524.1451 as § 524.1450 and revise paragraphs (a), (b), and (e)(1) to read as follows:

§ 524.1450 Moxidectin.

(a) *Specifications.* Each milliliter contains 5 milligrams (mg) moxidectin (0.5 percent solution).

(b) *Sponsor.* See No. 000010 in § 510.600(c) of this chapter.

* * * * *

(e) * * *

(1) *Amount.* Administer topically 0.5 mg per kilogram of body weight.

* * * * *

Dated: August 3, 2011.

Elizabeth Rettie,

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

[FR Doc. 2011–20182 Filed 8–8–11; 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–2010–N–0429]

Immunology and Microbiology Devices; Reclassification of the Herpes Simplex Virus Serological Assay Device

AGENCY: Food and Drug Administration, HHS.

ACTION: Final rule.

SUMMARY: The Food and Drug Administration (FDA) is amending the special controls for the herpes simplex virus (HSV) serological assay device type, which is classified as class II (special controls). These device types are devices that consist of antigens and antisera used in various serological tests to identify antibodies to herpes simplex virus in serum, and the devices that consist of herpes simplex virus antisera conjugated with a fluorescent dye (immunofluorescent assays) used to identify herpes simplex virus directly from clinical specimens or tissue culture isolates derived from clinical specimens.

DATES: This rule is effective September 8, 2011.

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. Regulatory Authorities

The Federal Food, Drug, and Cosmetic Act (the FD&C Act) (21 U.S.C. 301 *et seq.*), as amended by the Medical Device Amendments of 1976 (the 1976 amendments) (Pub. L. 94–295), Safe Medical Devices Act (SMDA) (Pub. L. 101–629), Food and Drug Administration Modernization Act (FDAMA) (Pub. L. 105–115), and the Medical Device User Fee and Modernization Act (MDUFMA) (Pub. L. 107–250), established a comprehensive system for the regulation of medical devices intended for human use. Section 513 of the FD&C Act (21 U.S.C. 360c) established three categories (classes) of devices, defined by the regulatory controls needed to provide reasonable assurance of their safety and effectiveness. The three categories of devices are class I (general controls), class II (special controls), and class III (premarket approval).

Under section 513 of the FD&C Act, FDA refers to devices that were in commercial distribution before May 28, 1976 (the date of enactment of the 1976 amendments), as preamendments devices. FDA classifies these devices after it takes the following steps: (1) Receives a recommendation from a device classification panel (an FDA advisory committee); (2) publishes the panel's recommendation for comment, along with a proposed regulation classifying the device; and (3) publishes a final regulation classifying the device. FDA has classified most preamendments devices under these procedures.

Devices that were not in commercial distribution before May 28, 1976, generally referred to as postamendments devices are classified automatically by statute (section 513(f) of the FD&C Act) into class III without any FDA rulemaking process. Those devices remain in class III until FDA does the following: (1) Reclassifies the device into class I or II; (2) issues an order classifying the device into class I or II in accordance with section 513(f)(2) of the FD&C Act; or (3) issues an order finding the device to be substantially equivalent, in accordance with section 513(i) of the FD&C Act, to a legally marketed device that has been classified into class I or class II. The agency determines whether new devices are substantially equivalent to previously marketed devices by means of premarket notification procedures in section 510(k) of the FD&C Act (21 U.S.C. 360(k)) and 21 CFR part 807 of the regulations.

Under the 1976 amendments, class II devices were defined as devices for which there was insufficient information to show that general controls themselves would provide reasonable assurance of safety and effectiveness, but for which there was sufficient information to establish performance standards to provide such assurance. SMDA broadened the definition of class II devices to mean those devices for which the general controls by themselves are insufficient to provide reasonable assurance of safety and effectiveness, but for which there is sufficient information to establish special controls to provide such assurance, including performance standards, postmarket surveillance, patient registries, development and dissemination of guidelines, recommendations, and any other appropriate actions the agency deems necessary (section 513(a)(1)(B) of the FD&C Act).

Elsewhere in this issue of the **Federal Register**, FDA is announcing the