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 4310–02–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

21 CFR Parts 520, 522, and 524


New Animal Drugs; Change of Sponsor; Moxidectin

AGENCY: Food and Drug Administration, HHHS.

ACTION: Final rule.

SUMMARY: The Food and Drug Administration (FDA) is amending the new 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., 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:


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:


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