

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

availability of the revised guidance document entitled "Class II Special Controls Guidance Document: Herpes Simplex Virus Types 1 and 2 Serological Assays" that will serve as the special control for the device. Because FDA is amending the special control for this device type, the agency is publishing the final rule that designates the revised guidance document as the special control for HSV serological devices.

## II. Regulatory Background of the Device

As a preamendments device, HSV 1 and 2 serological assays were classified into class III in a final rule in the **Federal Register** of November 9, 1982 (47 FR 50823) following the receipt of a classification recommendation from a classification panel and the issuance of a proposed rule as required by section 513(b) of the FD&C Act. In the **Federal Register** of April 3, 2007 (72 FR 15829), FDA published a final rule to reclassify HSV 1 and 2 serological assays into class II. These assays are used as an aid in the clinical laboratory diagnosis of diseases caused by HSV 1 and 2. FDA identified the guidance document entitled "Class II Special Controls Guidance Document: Herpes Simplex Virus Types 1 and 2 Serological Assays" as the special control. Since April 3, 2007, FDA believed it had become aware of sufficient additional safety and efficacy profile information to justify revision of the special controls to better provide assurance of the safety and effectiveness of the device. Accordingly, in the **Federal Register** of September 28, 2010 (75 FR 59670), FDA issued a proposed rule to amend the special controls guidance for the device and replace it with a new guidance of the same name. FDA invited interested persons to comment on the proposed rule by November 29, 2010. No comments germane to this rule were received by the agency.

## III. Summary of the Reasons for Revising Special Controls

The final rule revises the special controls for HSV 1 and 2 serological assays because the new special controls, in addition to general controls, provide reasonable assurance of the safety and effectiveness of the device. FDA believes there is sufficient additional safety and efficacy profile information to justify this revision of the special controls to better provide such assurance. We revised the existing guidance by rewriting the method comparison section and the sample selection inclusion and exclusion criteria section. The revisions defined and differentiated the required studies

and the study populations for the assessment of the safety and effectiveness of the different types of HSV1 and HSV2 serological assays. Additionally, we made several corrections and clarifications throughout the document to ensure accuracy, consistency, and ease of reading.

## IV. Special Controls

In addition to general controls, FDA believes that the revised guidance document entitled "Class II Special Controls Guidance Document: Herpes Simplex Virus Types 1 and 2 Serological Assays" (the class II special controls guidance document) is a special control that is adequate to address the risks to health associated with the use of the device. FDA believes that the revised class II special controls guidance document, which incorporates voluntary consensus standards and describes labeling recommendations, in addition to general controls, provides reasonable assurance of the safety and effectiveness of the device.

Following the effective date of this final rule, any firm submitting a 510(k) for HSV 1 and 2 serological assays will need to address the issues covered in the special controls guidance. However, the firm need only show that its device meets the recommendations of the guidance or in some other way provides equivalent assurances of safety and effectiveness.

## V. FDA's Findings

As discussed previously in this document, FDA believes HSV 1 and 2 serological assays should be classified into class II because special controls, in addition to general controls, provide reasonable assurance of the safety and effectiveness of the device and because there is sufficient information to establish special controls to provide such assurance. FDA, therefore, is finalizing the establishment of the revised class II special controls guidance document as a special control for the device.

Section 510(m) of the FD&C Act provides that a class II device may be exempt from the premarket notification requirements under section 510(k) of the FD&C Act, if the agency determines that premarket notification is not necessary to provide reasonable assurance of the safety and effectiveness of the device. For this device, FDA believes that premarket notification is necessary to provide reasonable assurance of safety and effectiveness and, therefore, is not exempting the device from the premarket notification requirements.

## VI. Environmental Impact

The Agency has determined under 21 CFR 25.34(b) 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.

## VII. Analysis of Impacts

FDA has examined the impacts of the final rule under Executive Order 12866, Executive Order 13563, the Regulatory Flexibility Act (5 U.S.C. 601–612), and the Unfunded Mandates Reform Act of 1995 (Pub. L. 104–4). Executive Orders 12866 and 13563 direct Agencies to assess all costs and benefits of available regulatory alternatives and, when regulation is necessary, to select regulatory approaches that maximize net benefits (including potential economic, environmental, public health and safety, and other advantages; distributive impacts; and equity). The Agency believes that this final rule is not a significant regulatory action under Executive Order 12866.

The Regulatory Flexibility Act requires Agencies to analyze regulatory options that would minimize any significant impact of a rule on small entities. Because the changes to the guidance are minimal, the Agency certifies that the final rule will not have a significant economic impact on a substantial number of small entities.

Section 202(a) of the Unfunded Mandates Reform Act of 1995 requires that Agencies prepare a written statement, which includes an assessment of anticipated costs and benefits, before proposing "any rule that includes any Federal mandate that may result in the expenditure by State, local, and tribal governments, in the aggregate, or by the private sector, of \$100,000,000 or more (adjusted annually for inflation) in any one year." The current threshold after adjustment for inflation is \$136 million, using the most current (2010) Implicit Price Deflator for the Gross Domestic Product. FDA does not expect this final rule to result in any 1-year expenditure that would meet or exceed this amount.

The changes to the guidance include adding specific recommendations on appropriate comparators for tests for antibodies and antigens, as well as recommendations for sample selection inclusion and exclusion criteria to define the target populations for HSV 1 and HSV 2 serological assays. These recommended changes increase the usefulness of the guidance while imposing a minimal burden.

## VIII. Federalism

FDA has analyzed this final rule in accordance with the principles set forth in Executive Order 13132. Section 4(a) of the Executive order requires agencies to “construe \* \* \* a Federal statute to preempt State law only where the statute contains an express preemption provision or there is some other clear evidence that the Congress intended preemption of State law, or where the exercise of State authority conflicts with the exercise of Federal authority under the Federal statute.” Federal law includes an express preemption provision that preempts certain state requirements “different from or in addition to” certain Federal requirements applicable to devices. 21 U.S.C. 360k; See *Medtronic Inc., v. Lohr* 518 U.S. 470 (1996); *Riegel v. Medtronic, Inc.*, 552 U.S. 312 (2008). The special controls established by this final rule create “requirements” for specific medical devices under 21 U.S.C. 360k, even though products sponsors have some flexibility in how they meet those requirements. Cf. *Papike v. Tambrands, Inc.*, 107 F. 3d 737, 740–742 (9th Cir. 1991).

## IX. Paperwork Reduction Act of 1995

This final rule contains no new collections of information. Therefore, clearance by the Office of Management and Budget (OMB) under the Paperwork Reduction Act of 1995 (PRA) (44 U.S.C. 3501–3520) is not required. This final rule establishes as special controls a guidance document that refers to currently approved collections of information found in other FDA regulations. These collections of information are subject to review by OMB under the PRA. The analysis of the paperwork burden for the guidance document is included in its notice of availability.

### List of Subjects in 21 CFR Part 866

Biologics, Laboratory, Medical devices.

Therefore, under the Federal Food, Drug, and Cosmetic Act and under authority delegated to the Commissioner of Food and Drugs, 21 CFR part 866 is amended as follows:

### PART 866—IMMUNOLOGY AND MICROBIOLOGY DEVICES

■ 1. The authority citation for 21 CFR part 866 continues to read as follows:

**Authority:** 21 U.S.C. 351, 360, 360c, 360e, 360j, 371.

■ 2. Section 866.3305 is amended by revising paragraph (b) to read as follows:

### § 866.3305 Herpes simplex virus serological assays.

\* \* \* \* \*

(b) *Classification.* Class II (special controls). The device is classified as class II (special controls). The special control for the device is FDA’s revised guidance document entitled “Class II Special Controls Guidance Document: Herpes Simplex Virus Types 1 and 2 Serological Assays.” For availability of the guidance revised document, see § 866.1(e).

Dated: August 3, 2011.

**Nancy K. Stade,**

*Deputy Director for Policy, Center for Devices and Radiological Health.*

[FR Doc. 2011–20115 Filed 8–8–11; 8:45 am]

**BILLING CODE 4160–01–P**

## DEPARTMENT OF HOMELAND SECURITY

### Coast Guard

#### 33 CFR Part 117

[Docket No. USCG–2011–0759]

### Drawbridge Operation Regulations; Long Island, New York Inland Waterway From East Rockaway Inlet to Shinnecock Canal, NY

**AGENCY:** Coast Guard, DHS.

**ACTION:** Notice of temporary deviation from regulations.

**SUMMARY:** The Commander, First Coast Guard District, has issued a temporary deviation from the regulation governing the operation of the Loop Parkway Bridge, mile 0.7, across Long Creek, and the Captree State Parkway (Robert Moses Causeway) Bridge, mile 30.7, across the State Boat Channel, at Long Island, New York. This deviation is necessary to facilitate the 2011 March of Dimes Motorcycle Run. The deviation allows the two bridges listed above to remain in the closed position during this public event.

**DATES:** This deviation is effective from 10:51 a.m. through 1:49 p.m. on September 25, 2011.

**ADDRESSES:** Documents mentioned in this preamble as being available in the docket are part of docket USCG–2011–0759 and are available online at <http://www.regulations.gov>, inserting USCG–2011–0759 in the “Keyword” box and then clicking “Search”. They are also available for inspection or copying at the Docket Management Facility (M–30), U.S. Department of Transportation, West Building Ground Floor, Room W12–140, 1200 New Jersey Avenue, SE., Washington, DC 20590,

between 9 a.m. and 5 p.m., Monday through Friday, except Federal holidays.

**FOR FURTHER INFORMATION CONTACT:** If you have questions on this rule, call or e-mail Ms. Judy Leung-Yee, Project Officer, First Coast Guard District, telephone (212) 668–7165, [judy.k.leung-ye@uscg.mil](mailto:judy.k.leung-ye@uscg.mil). If you have questions on viewing the docket, call Renee V. Wright, Program Manager, Docket Operations, telephone 202–366–9826.

### SUPPLEMENTARY INFORMATION:

The Loop Parkway Bridge, mile 0.7, across Long Creek has a vertical clearance in the closed position of 21 feet at mean high water and 25 feet at mean low water. The existing drawbridge operation regulations are listed at 33 CFR 117.799(f).

The Captree State Parkway (Robert Moses Causeway) Bridge, mile 30.7, across the State Boat Channel has a vertical clearance in the closed position of 29 feet at mean high water and 31 feet at mean low water. The existing drawbridge operation regulations are listed at 33 CFR 117.799(i).

Long Creek and the State Boat Channel both are both transited by commercial fishing and recreational vessel traffic.

The owner of the two bridges, the State New York Department of Transportation, requested bridge closures to facilitate a public event, the March of Dimes Charity Motorcycle Run.

Under this temporary deviation the Loop Parkway Bridge may remain in the closed position from 10:51 a.m. through 11:49 a.m. and from 12:21 p.m. through 1:49 p.m. on September 25, 2011, and the Captree State Parkway Bridge (Robert Moses Causeway) may remain in the closed position from 11 a.m. through 1 p.m. on September 25, 2011, to facilitate a public event, the 2011 March of Dimes Motorcycle Run.

Vessels that can pass under the closed draws during each respective closure may do so at any time.

In accordance with 33 CFR 117.35(e), the bridge must return to its regular operating schedule immediately at the end of the designated time period. This deviation from the operating regulations is authorized under 33 CFR 117.35.

Dated: July 29, 2011.

**Gary Kassof,**

*Bridge Program Manager, First Coast Guard District.*

[FR Doc. 2011–20092 Filed 8–8–11; 8:45 am]

**BILLING CODE 9110–04–P**