

adding new § 522.930 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.

Under section 512(c)(2)(F)(ii) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 360b(c)(2)(F)(ii)), this approval qualifies for 3 years of marketing exclusivity beginning on the date of approval.

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 522

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 part 522 is amended as follows:

PART 522—IMPLANTATION OR INJECTABLE DOSAGE FORM NEW ANIMAL DRUGS

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

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

■ 2. Add § 522.930 to read as follows:

§ 522.930 Firocoxib.

(a) *Specifications.* Each milliliter of solution contains 20 milligrams (mg) firocoxib.

(b) *Sponsors.* See No. 050604 in § 510.600(c) of this chapter.

(c) *Conditions of use in horses*—(1) *Amount.* Administer 0.04 mg/pound (lb) (0.09 mg/kilogram (kg)) of body weight (BW) intravenously, once daily, for up to 5 days. If further treatment is needed, firocoxib oral paste can be administered at a dosage of 0.045 mg/lb (0.1 mg/kg) of BW for up to an additional 9 days of treatment.

(2) *Indications for use.* For the control of pain and inflammation associated with osteoarthritis.

(3) *Limitations.* Do not use in horses intended for human consumption. Federal law restricts this drug to use by or on the order of a licensed veterinarian.

Dated: September 21, 2010.

Bernadette Dunham,

Director, Center for Veterinary Medicine.

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

21 CFR Part 866

[Docket No. FDA-2009-N-0344]

Microbiology Devices; Reclassification of Herpes Simplex Virus Types 1 and 2 Serological Assays; Confirmation of Effective Date

AGENCY: Food and Drug Administration, HHS.

ACTION: Direct final rule; confirmation of effective date.

SUMMARY: The Food and Drug Administration (FDA) is confirming the effective date of December 7, 2009, for the direct final rule that appeared in the **Federal Register** of August 25, 2009 (74 FR 42773). The direct final rule corrects the regulation classifying herpes simplex virus (HSV) serological assays by removing the reference to HSV serological assays other than type 1 and type 2. This document confirms the effective date of the direct final rule.

DATES: Effective date confirmed: December 7, 2009.

FOR FURTHER INFORMATION CONTACT: Scott McFarland, Center for Devices and Radiological Health, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 66, rm. 5543, Silver Spring, MD 20993-0002, 301-796-6217.

SUPPLEMENTARY INFORMATION: In the **Federal Register** of August 25, 2009 (74 FR 42773), FDA solicited comments concerning the direct final rule for a 44-day period ending October 8, 2009. FDA stated that the effective date of the direct final rule would be on December 7, 2009, 60 days after the end of the comment period, unless any significant adverse comment was submitted to FDA during the comment period. FDA did not receive any significant adverse comments.

■ **Authority:** 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. Accordingly, the amendments issued thereby are effective.

Dated: September 16, 2010.

Leslie Kux,

Acting Assistant Commissioner for Policy.

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DEPARTMENT OF THE TREASURY

Office of Foreign Assets Control

31 CFR Part 560

Iranian Transactions Regulations

AGENCY: Office of Foreign Assets Control, Treasury.

ACTION: Final rule.

SUMMARY: The Department of the Treasury's Office of Foreign Assets Control (“OFAC”) is amending the Iranian Transactions Regulations in the Code of Federal Regulations to remove general licenses authorizing the importation into the United States of, and dealings in, certain foodstuffs and carpets of Iranian origin and related services, and to implement the import and export prohibitions in section 103 of the Comprehensive Iran Sanctions, Accountability, and Divestment Act of 2010.

DATES: *Effective Date:* September 29, 2010.

FOR FURTHER INFORMATION CONTACT:

Assistant Director for Compliance, Outreach & Implementation, tel.: 202/622-2490, Assistant Director for Licensing, tel.: 202/622-2480, Assistant Director for Policy, tel.: 202/622-4855, Office of Foreign Assets Control, or Chief Counsel (Foreign Assets Control), tel.: 202/622-2410, Office of the General Counsel, Department of the Treasury (not toll free numbers).

SUPPLEMENTARY INFORMATION:

Electronic and Facsimile Availability

This document and additional information concerning OFAC are available from OFAC's Web site (<http://www.treas.gov/ofac>). Certain general information pertaining to OFAC's sanctions programs also is available via facsimile through a 24-hour fax-on-demand service, tel.: 202/622-0077.

Background

On July 1, 2010, the President signed into law the Comprehensive Iran Sanctions, Accountability, and