

2010). The regulations themselves, however, remain in place.

The Commission has now concluded that, in light of the amendments to the Smokeless Tobacco Act, the regulations in 16 CFR Part 307 no longer serve any purpose and actually conflict with the new statutory provisions. As noted above, the Family Smoking Prevention Act revised the language of the smokeless tobacco health warning statements and adopted new requirements for the format, size, and location of those statements on smokeless tobacco packaging and in ads for smokeless tobacco products. These requirements supersede those adopted by the Commission pursuant to the 1986 statute. Accordingly, the Commission concludes that its regulations implementing the Smokeless Tobacco Act should be removed. Indeed, retention of these regulations could generate confusion if some smokeless tobacco manufacturers and importers mistakenly believe that they reflect current legal requirements.

Under 5 U.S.C. 553(b)(B), an agency may promulgate a rule without prior notice and an opportunity for public comment if the agency finds for good cause that this procedure is unnecessary. *Nat'l Customs Brokers & Forwarders Ass'n v. United States*, 59 F.3d 1219, 1223-1224 (Fed. Cir. 1995). In rescinding 16 CFR Part 307, the Commission finds that public comment is unnecessary because the FTC is rescinding its regulations in response to the transfer of its underlying regulatory authority to the Secretary of DHHS. Since the FTC has no discretion in that matter, there is no reason or need for public comment on this regulatory action. The Family Smoking Prevention Act amended 15 U.S.C. 4402 by repealing the Commission's authority to promulgate rules implementing the smokeless tobacco labels and related rotational plans. That Act provides the Secretary of DHHS the authority to promulgate rules regarding the smokeless tobacco labels and the authority to approve related rotational plans. Therefore, as of June 22, 2010, the effective date of Congress's amendments, the Commission's rules under 16 CFR Part 307 were no longer authorized by statute. Although 15 U.S.C. 4404(b) continues to refer to "[r]egulations issued by the Federal Trade Commission under [15 U.S.C. 4402]," it is clear from the amendments to 15 U.S.C. 4402 that the Commission no longer has the authority to promulgate such regulations. Moreover, the Commission's rules under 16 CFR Part 307, if left intact, would conflict with the unambiguously expressed

intent of Congress to provide the Secretary with the authority to promulgate such regulations and to approve the related rotational plans. Therefore, immediate rescission of the outdated rules will help avoid confusion as to which agency has proper authority to promulgate these rules and to approve related rotational plans.<sup>2</sup> For all of these reasons, the Commission finds that public notice and comment are not necessary in rescinding 16 CFR Part 307.

In addition, the Commission finds that, under 5 U.S.C. 553(d)(1), the rescission may take effect immediately upon publication of this notice in the Federal Register. The removal of the regulations is exempt from the usual 30-day notice requirement as it merely "relieves a restriction" from FTC requirements. 5 U.S.C. 553(d)(1); *see also Indep. U.S. Tanker Owners Comm. v. Skinner*, 884 F.2d 587, 591 (D.C. Cir. 1989). The 30-day notice requirement does not apply under these circumstances, in which the Family Smoking Prevention Act has required the submission of rotational warning plans to DHHS since June 22, 2010. Therefore, affected companies do not need time to prepare for or take any action with regard to the rescission. *See Daniel Int'l Corp. v. Occupational Safety & Health Review Com.*, 656 F.2d 925, 931 (4th Cir. 1981) ("The purpose of the 30-day notice requirement in § 553(d) is to 'afford persons affected a reasonable time to prepare for the effective date of a rule or rules or to take any other action which the issuance of rules may prompt.' Administrative Procedure Act Legislative History, 79th Cong., 2d Sess. 201 (1946)").

### III. Paperwork Reduction Act

The Commission's regulations implementing the Smokeless Tobacco Act impose reporting requirements that constitute a "collection of information" under the Paperwork Reduction Act, 44 U.S.C. 3501 *et seq.* Accordingly, removal of these regulations will eliminate any burden on the public previously imposed by those requirements.

### IV. Regulatory Flexibility Act

Because the Commission has determined that it may remove these regulations without public comment, the Commission is also not required to

<sup>2</sup> Although the Commission no longer has the authority to promulgate regulations implementing the smokeless tobacco labels or to approve related rotational plans, the Commission continues to have authority to bring enforcement actions with respect to violations of 15 U.S.C. 4402 under 15 U.S.C. 4404(a).

publish any initial or final regulatory flexibility analysis under the Regulatory Flexibility Act as part of such action. *See* 5 U.S.C. 603(a), 604(b).

### List of Subjects in 16 CFR Part 307

Advertising, Labeling Smokeless Tobacco, Tobacco, Trade Practices.

■ Accordingly, for the reasons set forth above, and under the authority of 15 U.S.C. 4402 and 5 U.S.C. 553(d)(1), the Commission amends Title 16, Code of Federal Regulations, by removing and reserving part 307.

### PART 307—REMOVED AND RESERVED

By direction of the Commission.

Donald S. Clark,  
Secretary.

[FR Doc. 2010-24220 Filed 9-27-10; 8:45 am]  
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## DEPARTMENT OF HEALTH AND HUMAN SERVICES

### Food and Drug Administration

#### 21 CFR Part 522

[Docket No. FDA-2010-N-0002]

#### Implantation and Injectable Dosage Form New Animal Drugs; Firocoxib

**AGENCY:** Food and Drug Administration, HHS.

**ACTION:** Final rule.

**SUMMARY:** The Food and Drug Administration (FDA) is amending the animal drug regulations to reflect approval of an original new animal drug application (NADA) filed by Merial Ltd. The NADA provides for the veterinary prescription use of firocoxib injectable solution in horses for the control of pain and inflammation associated with osteoarthritis.

**DATES:** This rule is effective September 28, 2010.

**FOR FURTHER INFORMATION CONTACT:** Melanie R. Berson, Center for Veterinary Medicine (HFV-110), Food and Drug Administration, 7500 Standish Pl., Rockville, MD 20855, 240-276-8337, email: [melanie.berson@fda.hhs.gov](mailto:melanie.berson@fda.hhs.gov).

**SUPPLEMENTARY INFORMATION:** Merial Ltd., 3239 Satellite Blvd., Bldg. 500, Duluth, GA 30096-4640 filed NADA 141-313 that provides for veterinary prescription use of EQUIOXX (firocoxib) Injection in horses for the control of pain and inflammation associated with osteoarthritis. The NADA is approved as of August 20, 2010, and the regulations are amended in 21 CFR part 522 by

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