

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.

[FR Doc. 2010–24254 Filed 9–27–10; 8:45 am]

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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.

[FR Doc. 2010–23638 Filed 9–27–10; 8:45 am]

BILLING CODE 4160–01–S

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

Divestment Act of 2010 (Pub. L. 111–195) (“CISADA”). Subsection 103(a) of CISADA provides that, in addition to any other sanction in effect, the economic sanctions described in subsection 103(b) of CISADA shall apply with respect to Iran beginning 90 days after the date of CISADA’s enactment. The economic sanctions described in subsections 103(b)(1) and (b)(2) include prohibitions on the importation of goods or services of Iranian origin directly or indirectly into the United States and on the exportation of U.S.-origin goods, services, or technology from the United States or by a United States person, wherever located, to Iran. OFAC will implement these prohibitions through an amendment to the Iranian Transactions Regulations, 31 CFR Part 560 (the “ITR”), which already implement, pursuant to, *inter alia*, the International Emergency Economic Powers Act (50 U.S.C. 1701–1706) (“IEEPA”), prohibitions similar to those set forth in subsections 103(b)(1) and (b)(2) of CISADA. Consequently, OFAC is amending the ITR by adding CISADA to the ITR’s authority citations.

Notwithstanding the ITR’s prohibitions of imports and exports, OFAC authorizes certain otherwise prohibited transactions through general licenses set forth in the ITR and specific licenses issued pursuant to the ITR. In addition, the ITR contain certain exemptions from its prohibitions of imports and exports. Similarly, subsections 103(b)(1) and (b)(2) of CISADA include a number of exceptions to CISADA’s prohibitions of imports and exports, respectively. The exceptions to CISADA’s prohibitions differ in some cases from the exemptions and authorizations contained in or issued pursuant to the ITR.

To the extent that the ITR exemptions and licenses authorize import and export transactions beyond CISADA’s exceptions, subsection 103(d)(1) of CISADA provides the authority to resolve these differences. That subsection authorizes the President to prescribe regulations to carry out section 103 and specifically states that these regulations may include regulatory exceptions to the sanctions described in subsection 103(b). Therefore, except with respect to sections 560.534 and 560.535 of the ITR, which are being removed (*see below*), OFAC is relying on the authority of subsection 103(d)(1) of CISADA to maintain in effect the general and specific licenses set forth in or issued pursuant to the ITR, and to treat those licenses as regulatory exceptions to the

import and export prohibitions in subsection 103(b) of CISADA. This extends to general and specific licenses authorizing transactions that are beyond those specified in the exceptions set forth in subsections 103(b)(1) and (b)(2) of CISADA and that otherwise would be prohibited by CISADA.

Conversely, to the extent that the transactions described in CISADA’s exceptions are neither exempt from nor authorized in or pursuant to the ITR, those transactions will remain prohibited pursuant to the ITR and, *inter alia*, IEEPA. In an explanatory statement, the Committee of Conference on CISADA stated that notwithstanding the exceptions in CISADA, any requirement under IEEPA to seek a license for the transactions described in those exceptions remains in effect. CISADA states in subsection 103(a) that the sanctions imposed by subsection 103(b) are “in addition to any other sanction in effect.” Accordingly, a specific license from OFAC is required to engage in transactions described in CISADA’s exceptions if such transactions are neither exempt from nor authorized in or pursuant to the ITR.

Subsection 103(d)(2) of CISADA strengthens the current trade embargo against Iran by providing that no exception to the import prohibition in subsection 103(b)(1) of CISADA may be made for the commercial importation of an Iranian-origin good described in section 560.534(a) of the ITR, *i.e.*, foodstuffs intended for human consumption that are classified under chapters 2–23 of the Harmonized Tariff Schedule of the United States and carpets and other textile floor coverings and carpets used as wall hangings that are classified under chapter 57 or heading 9706.00.0060 of the Harmonized Tariff Schedule of the United States. Accordingly, as of September 29, 2010 (*i.e.*, the date that is 90 days after the date of CISADA’s enactment), sections 560.534 and 560.535 of the ITR will be revoked, and OFAC will no longer authorize, by general or specific license, the commercial importation into the United States of these foodstuffs and carpets of Iranian-origin. Any such goods imported into the United States pursuant to sections 560.534 and 560.535 of the ITR must be entered for consumption prior to that date.

In addition, section 560.306 of the ITR defines the terms *goods of Iranian origin* and *Iranian-origin goods* to include: (1) Goods grown, produced, manufactured, extracted, or processed in Iran and (2) goods which have entered into Iranian commerce. Based on this definition,

foodstuffs and carpets of third-country origin that are transshipped through Iran become goods of Iranian-origin. Therefore, the revocation of the general licenses in sections 560.534 and 560.535 of the ITR also will affect the specified foodstuffs and carpets of third-country origin that are transshipped through Iran for importation into the United States.

Section 560.534 of the ITR authorized both the commercial and noncommercial importation into the United States of certain foodstuffs and carpets of Iranian origin. As a result of the revocation of sections 560.534 and 560.535 of the ITR, the noncommercial importation of certain foodstuffs and carpets of Iranian origin into the United States and related services would also be prohibited by section 560.201 of the ITR, unless otherwise authorized or exempt. One such authorization is the general license for the importation of Iranian-origin household goods and personal effects set forth in section 560.524(b) of the ITR. That general license continues in effect. OFAC notes that U.S. Customs and Border Protection (CBP) Form 3299, “Declaration for Free Entry of Unaccompanied Articles,” is used to enter Iranian-origin household and personal effects into the United States.

Public Participation

Because the Regulations involve a foreign affairs function, the provisions of Executive Order 12866 and the Administrative Procedure Act (5 U.S.C. 553) requiring notice of proposed rulemaking, opportunity for public participation, and delay in effective date are inapplicable. Because no notice of proposed rulemaking is required for this rule, the Regulatory Flexibility Act (5 U.S.C. 601–612) does not apply.

Paperwork Reduction Act

The collections of information related to the Regulations are contained in 31 CFR part 501 (the “Reporting, Procedures and Penalties Regulations”). Pursuant to the Paperwork Reduction Act of 1995 (44 U.S.C. 3507), those collections of information have been approved by the Office of Management and Budget under control number 1505–0164. An agency may not conduct or sponsor, and a person is not required to respond to, a collection of information unless the collection of information displays a valid control number.

List of Subjects in 31 CFR Part 560

Administrative practice and procedure, Banks, Banking, Brokers, Foreign trade, Investments, Loans, Securities, Iran.

■ For the reasons set forth in the preamble, the Department of the Treasury's Office of Foreign Assets Control amends 31 CFR part 560 as follows:

PART 560—IRANIAN TRANSACTIONS REGULATIONS

■ 1. Revise the authority citation to part 560 to read as follows:

Authority: 3 U.S.C. 301; 18 U.S.C. 2339B, 2332d; 22 U.S.C. 2349aa-9; 22 U.S.C. 7201-7211; 31 U.S.C. 321(b); 50 U.S.C. 1601-1651, 1701-1706; Pub. L. 101-410, 104 Stat. 890 (28 U.S.C. 2461 note); Pub. L. 110-96, 121 Stat. 1011 (50 U.S.C. 1705 note); Pub. L. 111-195, 124 Stat. 1312 (22 U.S.C. 8501-8551); E.O. 12613, 52 FR 41940, 3 CFR, 1987 Comp., p. 256; E.O. 12957, 60 FR 14615, 3 CFR, 1995 Comp., p. 332; E.O. 12959, 60 FR 24757, 3 CFR, 1995 Comp., p. 356; E.O. 13059, 62 FR 44531, 3 CFR, 1997 Comp., p. 217.

Subpart E—License, Authorizations, and Statements of Licensing Policy

§§ 560.534 and 560.535 [Removed and reserved]

■ 2. Remove and reserve §§ 560.534 and 560.535.

Dated: September 22, 2010.

Adam J. Szubin,

Director, Office of Foreign Assets Control.

[FR Doc. 2010-24211 Filed 9-27-10; 8:45 am]

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DEPARTMENT OF DEFENSE

Department of the Air Force

32 CFR Part 865

[Docket No. USAF-2008-0002]

RIN 0701-AA74

Personnel Review Boards

AGENCY: Department of the Air Force, DoD.

ACTION: Final rule.

SUMMARY: The Department of the Air Force is amending its regulations concerning the Air Force Board for Correction of Military Records. The regulations being revised establish procedures for the consideration of applications for the correction of military records and provides guidance to applicants and others interested in the process. This revision incorporates format changes and clarifies various minor provisions of the subpart.

DATES: *Effective Date:* This rule is effective October 28, 2010.

FOR FURTHER INFORMATION CONTACT: Mr Algie Walker Jr. at (240) 857-5380, *al.walker@afncr.af.mil*.

SUPPLEMENTARY INFORMATION: The proposed rule was published in the **Federal Register** on July 15, 2009 (74 FR 34279-34283). No comments were received.

Executive Order 12866, "Regulatory Planning and Review"

It has been determined that 32 CFR part 865 is not a significant regulatory action. This rule does not:

(1) Have an annual effect on the economy of \$100 million or more or adversely affect in a material way the economy, a sector of the economy, productivity, competition, jobs, the environment, public health or safety, or state, local, or tribal governments or communities;

(2) Create a serious inconsistency or otherwise interfere with an action taken or planned by another agency;

(3) Materially alter the budgetary impact of entitlements, grants, user fees, or loan programs, or the rights and obligations of the recipients thereof; or

(4) Raise novel legal or policy issues arising out of legal mandates, the President's priorities, or the principles set forth in this Executive Order.

Unfunded Mandates Reform Act (Sec. 202, Pub. L. 104-4)

It has been certified the 32 CFR part 865 does not contain a Federal Mandate that may result in the expenditure by State, local and tribal governments, in aggregate, or by the private sector, of \$100 million or more in any one year.

Public Law 96-354, "Regulatory Flexibility Act" (5 U.S.C. 601)

It has been determined that this rule is not subject to the Regulatory Flexibility Act (5 U.S.C. 601) because it would not, if promulgated, have a significant economic impact on a substantial number of small entities.

Public Law 95-511, "Paperwork Reduction Act" (44 U.S.C. Chapter 35)

It has been certified that 32 CFR part 865 does not impose any additional reporting or recordkeeping requirements under the Paperwork Reduction Act of 1995 (44 U.S.C. Chapter 35). Existing reporting and recordkeeping requirements approved under OMB Control Number 0704-0003, Application for Correction of Military Record Under the Provisions of Title 10, U.S. Code, Section 1552, will be used.

Federalism (Executive Order 13132)

It has been certified that 32 CFR part 865 does not have federalism implications, as set forth in Executive Order 13132. This rule does not have substantial direct effects on:

- (1) The States;
- (2) The relationship between the National Government and the States; or
- (3) The distribution of power and responsibilities among the various levels of government.

List of Subjects in 32 CFR Part 865

Administrative practices and procedures, Military personnel, Records.

■ Accordingly, 32 CFR part 865 is amended as follows:

PART 865—PERSONNEL REVIEW BOARDS

■ 1. The authority citation for 32 CFR part 865 continues to read as follows:

Authority: 10 U.S.C. 1034, 1552.2.

■ 2. Revise Subpart A to read as follows:

Subpart A—Air Force Board for Correction of Military Records

Sec.

- 865.0 Purpose.
- 865.1 Setup of the Board.
- 865.2 Board responsibilities.
- 865.3 Application procedures.
- 865.4 Board actions.
- 865.5 Decision of the Secretary of the Air Force.
- 865.6 Reconsideration of applications.
- 865.7 Action after final decision.
- 865.8 Miscellaneous provisions.

Subpart A—Air Force Board for Correction of Military Records

§ 865.0 Purpose.

This subpart sets up procedures for correction of military records to remedy error or injustice. It tells how to apply for correction of military records and how the Air Force Board for Correction of Military Records (AFBCMR, or the Board) considers applications. It defines the Board's authority to act on applications. It directs collecting and maintaining information subject to the Privacy Act of 1974 authorized by 10 U.S.C. 1034 and 1552. System of Records notice F035 SAFCB A, Military Records Processed by the Air Force Correction Board, applies.

§ 865.1 Setup of the Board.

The AFBCMR operates within the Office of the Secretary of the Air Force according to 10 U.S.C. 1552. The Board consists of civilians in the executive part of the Department of the Air Force who are appointed and serve at the pleasure of the Secretary of the Air Force. Three members constitute a quorum of the Board.

§ 865.2 Board responsibilities.

(a) *Considering applications.* The Board considers all individual