

§§ 510.600 and 524.1580b (21 CFR 510.600 and 524.1580b) are amended to reflect the approval.

In addition, FDA has found that the pioneer sponsor's drug labeler code (DLC) was inadvertently omitted from § 524.1580b during format changes in 2005 (70 FR 50181; August 26, 2005). At this time, § 524.1580b is amended to include Squire Laboratories, Inc.'s DLC. Section 524.1580b is also amended to reflect current food safety warnings.

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.

FDA has determined under 21 CFR 25.33(a)(1) 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.

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

21 CFR Part 510

Administrative practice and procedure, Animal drugs, Labeling, Reporting and recordkeeping requirements.

21 CFR Part 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 510 and 524 are amended as follows:

PART 510—NEW ANIMAL DRUGS

■ 1. The authority citation for 21 CFR part 510 continues to read as follows:

Authority: 21 U.S.C. 321, 331, 351, 352, 353, 360b, 371, 379e.

§ 510.600 [Amended]

■ 2. In § 510.600, in the table in paragraph (c)(1), in the entry for "First Priority, Inc." and in the table in paragraph (c)(2), in the entry for

"058829", remove "1585 Todd Farm Dr." and in its place add "1590 Todd Farm Dr."

PART 524—OPHTHALMIC AND TOPICAL DOSAGE FORM NEW ANIMAL DRUGS

■ 3. The authority citation for 21 CFR part 524 continues to read as follows:

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

■ 4. In § 524.1580b, add paragraph (b)(3) and revise paragraph (d)(3) to read as follows:

§ 524.1580b Nitrofurazone ointment.

* * * * *

(b) * * *

(3) See Nos. 017153 and 058829 for use on horses.

* * * * *

(d) * * *

(3) *Limitations.* For use only on dogs, cats, and horses. Do not use in horses intended for human consumption. Federal law prohibits the use of this product in food-producing animals. In case of deep or puncture wounds or serious burns, use only as recommended by veterinarian. If redness, irritation, or swelling persists or increases, discontinue use; consult veterinarian.

Dated: July 28, 2009.

Bernadette Dunham,

Director, Center for Veterinary Medicine.

[FR Doc. E9-18337 Filed 7-31-09; 8:45 am]

BILLING CODE 4160-01-S

DEPARTMENT OF STATE

22 CFR Parts 123, 124, 126, and 129

[Public Notice: 6716]

Amendment to the International Traffic in Arms Regulations: Congressional Certification Regarding South Korea

AGENCY: Department of State.

ACTION: Final rule.

SUMMARY: The Department of State is amending the International Traffic in Arms Regulations (ITAR) regarding Congressional certification for the Republic of Korea (also referred to as South Korea). South Korea is now in the same category as the countries in the North Atlantic Treaty Organization (NATO), Japan, Australia, and New Zealand concerning certification to Congress, requiring such certification prior to granting any license for export of major defense equipment sold under a contract in the amount of \$25,000,000 or more, or for defense articles or defense services sold under a contract in the amount of \$100,000,000 or more,

provided the transfer does not include any other countries. The ITAR is being amended at numerous sections to reflect these statutory changes and to update two provisions.

DATES: *Effective Date:* This rule is effective August 3, 2009.

FOR FURTHER INFORMATION CONTACT:

Director Charles B. Shotwell, Office of Defense Trade Controls Policy, Department of State, Telephone (202) 663-2792 or Fax (202) 261-8199; E-mail DDTCResponseTeam@state.gov. ATTN: Regulatory Change, South Korea.

SUPPLEMENTARY INFORMATION:

Section 203 of the Public Law 110-429 amended, *inter alia*, Sections 3(d)(3)(A)(i), 36(c), and 36(d)(2)(A) of the Arms Export Control Act by inserting "Republic of Korea" before "New Zealand." This amendment added South Korea to the category of countries for which higher dollar thresholds apply for mandatory certification to Congress in advance of approving the export or transfer of defense articles and defense services. South Korea is now in the same category as the countries in the North Atlantic Treaty Organization (NATO), Japan, Australia, and New Zealand concerning certification to Congress, requiring such certification prior to granting any license for export of major defense equipment sold under a contract in the amount of \$25,000,000 or more, or for defense articles or defense services sold under a contract in the amount of \$100,000,000 or more, provided the transfer does not include any other countries. The ITAR is being amended at numerous sections, as described below, to reflect these statutory changes and to update two provisions.

Section 123.9(e) of the ITAR is being amended to add "South Korea." This section is also being amended to correct outdated information regarding the dollar limits for sales without prior written approval and to add New Zealand to the list of countries eligible for certain reexports or retransfers without prior written approval.

Section 123.15 of the ITAR entitled "Congressional certification pursuant to Section 36(c) of the Arms Export Control Act" is being amended to add "South Korea" at sections 123.15(a)(1), 123.15(a)(2), and 123.15(b).

Section 124.11 of the ITAR entitled "Congressional certification pursuant to Section 36(d) of the Arms Export Control Act" is being amended to add "South Korea" at section 124.11(b).

Section 126.8 of the ITAR entitled "Proposals to foreign persons relating to significant military equipment" is being

amended to add “South Korea” at section 126.8(a)(ii).

Part 129 of the ITAR regarding brokering activities is being amended at section 129.6(b)(2) to add “South Korea” to the category of NATO, Japan, Australia, and New Zealand for purposes of an exemption from prior written approval.

Sections 129.7(a)(1)(vii) and 129.7(a)(2) are being amended to add “South Korea” to the category of NATO, Japan, Australia, and New Zealand or purposes of defining brokering activities requiring prior written approval.

Regulatory Analysis and Notices

Administrative Procedure Act

This amendment involves a foreign affairs function of the United States and, therefore, is not subject to the procedures contained in 5 U.S.C. 553 and 554.

Regulatory Flexibility Act

Since this amendment is not subject to the notice-and-comment procedures of 5 U.S.C. 553, it does not require analysis under the Regulatory Flexibility Act.

Unfunded Mandates Reform Act of 1995

This amendment does not involve a mandate that will result in the expenditure by State, local, and Tribal governments, in the aggregate, or by the private sector, of \$100 million or more in any year and it will not significantly or uniquely affect small governments. Therefore, no actions were deemed necessary under the provisions of the Unfunded Mandates Reform Act of 1995.

Small Business Regulatory Enforcement Fairness Act of 1996

This amendment has been found not to be a major rule within the meaning of the Small Business Regulatory Enforcement Fairness Act of 1996.

Executive Orders 12372 and 13132

This amendment will not have substantial direct effects on the States, on the relationship between the national government and the States, or on the distribution of power and responsibilities among the various levels of government. Therefore, in accordance with Executive Order 13132, it is determined that this amendment does not have sufficient federalism implications to require consultations or warrant the preparation of a federalism summary impact statement. The regulations implementing Executive Order 12372 regarding intergovernmental consultation on

Federal programs and activities do not apply to this amendment.

Executive Order 12866

This amendment is exempt from review under Executive Order 12866, but has been reviewed internally by the Department of State to ensure consistency with the purposes thereof.

Paperwork Reduction Act

This rule does not impose any new reporting or recordkeeping requirements subject to the Paperwork Reduction Act, 44 U.S.C. Chapter 35.

List of Subjects

22 CFR Parts 123 and 126

Arms and munitions, Exports.

22 CFR Parts 124 and 129

Arms and munitions, Exports, Technical assistance.

■ Accordingly, for the reasons set forth above, Title 22, Chapter I, Subchapter M, parts 123, 124, 126, and 129 are amended as follows:

PART 123—LICENSES FOR THE EXPORT OF DEFENSE ARTICLES

■ 1. The authority citation for part 123 continues to read as follows:

Authority: Secs. 2, 38, and 71, Pub. L. 90–629, 90 Stat. 744 (22 U.S.C. 2752, 2778, 2797); 22 U.S.C. 2753; E.O. 11958, 42 FR 4311; 3 CFR, 1977 Comp. p. 79; 22 U.S.C. 2651a; 22 U.S.C. 2776; Pub. L. 105–261, 112 Stat. 1920; Sec. 1205(a), Pub. L. 107–228.

■ 2. Section 123.9 is amended by revising paragraphs (e) introductory text and (e)(2) to read as follows:

§ 123.9 Country of ultimate destination and approval of reexports or retransfers.

* * * * *

(e) Reexports or retransfers of U.S.-origin components incorporated into a foreign defense article to NATO, NATO agencies, a government of a NATO country, or the governments of Australia, Japan, New Zealand, or South Korea, are authorized without the prior written approval of the Directorate of Defense Trade Controls, provided:

* * * * *

(2) The U.S.-origin components are not significant military equipment, the items are not major defense equipment sold under contract in the amount of \$25,000,000 (\$25 million) or more; the articles are not defense articles or defense services sold under a contract in the amount of \$100,000,000 (\$100 million) or more; and are not identified in part 121 of this subchapter as Missile Technology Control Regime (MTCR) items; and

* * * * *

■ 3. Section 123.15 is amended by revising paragraphs (a)(1), (a)(2), and (b) to read as follows:

§ 123.15 Congressional certification pursuant to Section 36(c) of the Arms Export Control Act.

(a) * * *

(1) A license for the export of major defense equipment sold under a contract in the amount of \$14,000,000 or more, or for defense articles and defense services sold under a contract in the amount of \$50,000,000 or more to any country that is not a member country of the North Atlantic Treaty Organization (NATO), or Australia, Japan, New Zealand, or South Korea that does not authorize a new sales territory; or

(2) A license for export to a country that is a member country of the North Atlantic Treaty Organization (NATO), or Australia, Japan, New Zealand, or South Korea of major defense equipment sold under a contract in the amount of \$25,000,000 or more, or for defense articles and defense services sold under a contract in the amount of \$100,000,000 or more and provided the transfer does not include any other countries; or

* * * * *

(b) Unless an emergency exists which requires the proposed export in the national security interests of the United States, approval may not be granted for any transaction until at least 15 calendar days have elapsed after receipt by the Congress of the certification required by 22 U.S.C. 2776(c)(1) involving the North Atlantic Treaty Organization, any member country of the Organization, or Australia, Japan, New Zealand, or South Korea or at least 30 calendar days have elapsed for any other country; in the case of a license for an export of a commercial communications satellite for launch from, and by nationals of, the Russian Federation, Ukraine, or Kazakhstan, until at least 15 calendar days after the Congress receives such certification.

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PART 124—AGREEMENTS, OFF-SHORE PROCUREMENT AND OTHER DEFENSE SERVICES

■ 4. The authority citation for part 124 continues to read as follows:

Authority: Secs. 2, 38, and 71, Pub. L. 90–629, 90 Stat. 744 (22 U.S.C. 2752, 2778, 2797); E.O. 11958, 42 FR 4311; 3 CFR 1977 Comp. p. 79; 22 U.S.C. 2651a; 22 U.S.C. 2776; Pub. L. 105–261.

■ 5. Section 124.11 is amended by revising paragraph (b) to read as follows:

§ 124.11 Congressional certification pursuant to Section 36(d) of the Arms Export Control Act.

* * * * *

(b) Unless an emergency exists which requires the immediate approval of the agreement in the national security interests of the United States, approval may not be granted until at least 15 calendar days have elapsed after receipt by the Congress of the certification required by 22 U.S.C. 2776(d)(1) involving the North Atlantic Treaty Organization, any member country of that Organization, or Australia, Japan, New Zealand, or South Korea or at least 30 calendar days have elapsed for any other country. Approvals may not be granted when the Congress has enacted a joint resolution prohibiting the export.

* * * * *

PART 126—GENERAL POLICIES AND PROVISIONS

■ 6. The authority citation for part 126 continues to read as follows:

Authority: Secs. 2, 38, 40, 42, and 71, Pub. L. 90–629, 90 Stat. 744 (22 U.S.C. 2752, 2778, 2780, 2791, and 2797); E.O. 11958, 42 FR 4311; 3 CFR 1977 Comp. p. 79; 22 U.S.C. 2651a; 22 U.S.C. 287c; E.O. 12918, 59 FR 28205, 3 CFR, 1994 Comp. p. 899.

■ 7. Section 126.8 is amended by revising paragraph (a)(1)(ii) to read as follows:

§ 126.8 Proposals to foreign persons relating to significant military equipment.

(a) * * *

(1) * * *

(ii) The equipment is intended for use by the armed forces of any foreign country other than a member of the North Atlantic Treaty Organization, Australia, Japan, New Zealand, or South Korea; and

* * * * *

PART 129—REGISTRATION AND LICENSING OF BROKERS

■ 8. The authority citation for part 129 continues to read as follows:

Authority: Sec. 38, Pub. L. 104–164, 110 Stat. 1437, (22 U.S.C. 2778).

■ 9. Section 129.6 is amended by revising paragraph (b)(2) to read as follows:

§ 129.6 Requirements for license/approval.

(b) * * *

(1) * * *

(2) Brokering activities that are arranged wholly within and destined exclusively for the North Atlantic Treaty Organization, any member country of that Organization, Australia, Japan, New

Zealand, or South Korea, except in the case of the defense articles or defense services specified in § 129.7(a) of this subchapter, for which prior approval is always required.

■ 10. Section 129.7 is amended by revising paragraphs (a)(1)(vii) and (a)(2) introductory text to read as follows:

§ 129.7 Prior approval (license).

(a) * * *

(1) * * *

(vii) Foreign defense articles or defense services (other than those that are arranged wholly within and destined exclusively for the North Atlantic Treaty Organization, Australia, Japan, New Zealand, or South Korea (see §§ 129.6(b)(2) and 129.7(a)).

(2) Brokering activities involving defense articles or defense services covered by, or of a nature described by Part 121, of this subchapter, in addition to those specified in § 129.7(a), that are designated as significant military equipment under this subchapter, for or from any country not a member of the North Atlantic Treaty Organization, Australia, Japan, New Zealand, or South Korea whenever any of the following factors are present:

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Dated: June 19, 2009.

Rose E. Gottemoeller,

Assistant Secretary, Verification, Compliance and Implementation, Department of State.

[FR Doc. E9–18332 Filed 7–31–09; 8:45 am]

BILLING CODE 4710–25–P

ENVIRONMENTAL PROTECTION AGENCY

40 CFR Part 62

[EPA–R03–OAR–2009–0482; FRL–8938–6]

Approval and Promulgation of State Air Quality Plans For Designated Facilities and Pollutants, West Virginia; Control of Emissions From Commercial and Industrial Solid Waste Incinerator Units, Plan Revision

AGENCY: Environmental Protection Agency (EPA).

ACTION: Direct final rule.

SUMMARY: EPA is taking direct final action to approve a revision to the West Virginia (WV) commercial and industrial solid waste incinerator (CISWI) 111(d)/129 plan (the “plan”). The revision contains a modified WV Department of Environmental Protection, Division of Air Quality (DAQ) rule that streamlines and consolidates the state’s regulatory structure (WV45CSR6, 18 and 24) for

incinerator units and incorporates applicable Clean Air Act (CAA), section 129, requirements into one rule, WV45CSR18. This approval action relates only to CISWI units. The streamlining of the state’s regulatory structure of its incinerator rules is not an EPA requirement.

DATES: This rule is effective October 2, 2009 without further notice, unless EPA receives adverse written comment by September 2, 2009. If EPA receives such comments, it will publish a timely withdrawal of the direct final rule in the **Federal Register** and inform the public that the rule will not take effect.

ADDRESSES: Submit your comments, identified by Docket ID Number EPA–R03–OAR–2009–0482 by one of the following methods:

A. *http://www.regulations.gov*. Follow the on-line instructions for submitting comments.

B. *E-mail:* http://wilkie.walter@epa.gov.

C. *Mail:* EPA–R03–OAR–2009–0482, Walter Wilkie, Chief, Air Quality Analysis Branch, Mailcode 3AP22, U.S. Environmental Protection Agency, Region III, 1650 Arch Street, Philadelphia, Pennsylvania 19103.

D. *Hand Delivery:* At the previously-listed EPA Region III address. Such deliveries are only accepted during the Docket’s normal hours of operation, and special arrangements should be made for deliveries of boxed information.

Instructions: Direct your comments to Docket ID No. EPA–R03–OAR–2009–0482 EPA’s policy is that all comments received will be included in the public docket without change, and may be made available online at <http://www.regulations.gov>, including any personal information provided, unless the comment includes information claimed to be Confidential Business Information (CBI) or other information whose disclosure is restricted by statute. Do not submit information that you consider to be CBI or otherwise protected through <http://www.regulations.gov> or e-mail. The <http://www.regulations.gov> Web site is an “anonymous access” system, which means EPA will not know your identity or contact information unless you provide it in the body of your comment. If you send an e-mail comment directly to EPA without going through <http://www.regulations.gov>, your e-mail address will be automatically captured and included as part of the comment that is placed in the public docket and made available on the Internet. If you submit an electronic comment, EPA recommends that you include your name and other contact information in