

Aviation Programs,” describes in more detail the scope of the Agency’s authority.

We are issuing this rulemaking under the authority described in “Subtitle VII, Part A, Subpart III, Section 44701: General requirements.” Under that section, Congress charges the FAA with promoting safe flight of civil aircraft in air commerce by prescribing regulations for practices, methods, and procedures the Administrator finds necessary for safety in air commerce. This regulation is within the scope of that authority because it addresses an unsafe condition that is likely to exist or develop on product(s) identified in this rulemaking action.

Regulatory Findings

We determined that this AD will not have federalism implications under Executive Order 13132. This AD will not have a substantial direct effect 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, I certify this AD:

1. Is not a “significant regulatory action” under Executive Order 12866;
2. Is not a “significant rule” under the DOT Regulatory Policies and Procedures (44 FR 11034, February 26, 1979); and
3. Will not have a significant economic impact, positive or negative, on a substantial number of small entities under the criteria of the Regulatory Flexibility Act.

We prepared an economic evaluation of the estimated costs to comply with this AD and placed it in the AD docket.

List of Subjects in 14 CFR Part 39

Air transportation, Aircraft, Aviation safety, Safety.

Adoption of the Amendment

■ Accordingly, under the authority delegated to me by the Administrator, the FAA amends 14 CFR part 39 as follows:

PART 39—AIRWORTHINESS DIRECTIVES

■ 1. The authority citation for part 39 continues to read as follows:

Authority: 49 U.S.C. 106(g), 40113, 44701.

§ 39.13 [Amended]

■ 2. The FAA amends § 39.13 by adding the following new AD:

2009–15–15 Bell Helicopter Textron

Canada (BHTC): Amendment 39–15978; Docket No. FAA–2009–0227; Directorate Identifier 2007–SW–65–AD.

Effective Date

(a) This airworthiness directive (AD) becomes effective on September 8, 2009.

Other Affected ADs

(b) None.

Applicability

(c) This AD applies to Model 427 helicopters, serial numbers 56001 through 56057, 58001, and 58002, certificated in any category.

Reason

(d) Transport Canada states in the mandatory continuing airworthiness information (MCAI) that it has been determined that the existing hardware connecting the vertical fin to the tail rotor gearbox needs to be upgraded to prevent the vertical fin from becoming loose. BHTC has received reports of loose vertical fins discovered during inspections. Investigation revealed that the current vertical fin attachment hardware may not provide adequate clamp-up. If not corrected, the vertical fin could become loose and cause vibration, which could lead to subsequent loss of control of the helicopter.

Actions and Compliance

(e) Within the next 150 hours time-in-service, unless already done, do the following:

(1) Remove the vertical fin and visually inspect the inboard and outboard surfaces of the vertical fin where it attaches to the tail rotor gearbox support for a crack, an elongated bolt hole, fretting, distortion and corrosion.

(2) Visually inspect the tail rotor gearbox support attachment legs for a crack, fretting and corrosion.

(f) If a crack, elongated bolt hole, fretting, distortion or corrosion is detected, repair or replace the part with an airworthy part before further flight.

(g) Reinstall the vertical fin.

Differences Between This AD and the MCAI AD

(h) This AD differs from the MCAI AD as follows:

(1) We do not require compliance “no later than November 27, 2007”, because that date has passed.

(2) We refer to the compliance time as “hours time-in-service” rather than “air time hours.”

Other Information

(i) Alternative Methods of Compliance (AMOCs): The Manager, Safety Management Group, FAA, has the authority to approve AMOCs for this AD, if requested using the procedures found in 14 CFR 39.19. Send information to ATTN: Sharon Miles, Aviation Safety Engineer, FAA, Rotorcraft Directorate, Regulations and Guidance Group, 2601 Meacham Blvd., Fort Worth, Texas 76137, telephone (817) 222–5122, fax (817) 222–5961.

Related Information

(j) Mandatory Continuing Airworthiness Information (MCAI) Transport Canada Airworthiness Directive CF–2007–22, dated

September 14, 2007, and Bell Helicopter Textron Alert Service Bulletin No. 427–06–15, dated December 14, 2006, contain related information.

Subject

(k) Joint Aircraft System/Component (JASC) Code: 5553, Vertical Stabilizer, Attach Fittings.

Issued in Fort Worth, Texas, on July 14, 2009.

Judy I. Carl,

Acting Manager, Rotorcraft Directorate, Aircraft Certification Service.

[FR Doc. E9–18431 Filed 7–31–09; 8:45 am]

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

21 CFR Parts 510 and 524

[Docket No. FDA–2009–N–0665]

New Animal Drugs; Nitrofurazone Ointment

AGENCY: Food and Drug Administration, HHS.

ACTION: Final rule; technical amendment.

SUMMARY: The Food and Drug Administration (FDA) is amending the animal drug regulations to reflect approval of an original abbreviated new animal drug application (ANADA) filed by First Priority, Inc. The ANADA provides for use of nitrofurazone ointment on horses for prevention or treatment of superficial bacterial infections.

DATES: This rule is effective August 3, 2009.

FOR FURTHER INFORMATION CONTACT: John K. Harshman, Center for Veterinary Medicine (HFV–104), Food and Drug Administration, 7500 Standish Pl., Rockville, MD 20855, 240–276–8197, e-mail: john.harshman@fda.hhs.gov.

SUPPLEMENTARY INFORMATION: First Priority, Inc., 1585 Todd Farm Dr., Elgin, IL 60123, filed ANADA 200–425 for use of Nitrofurazone Soluble Dressing in horses for prevention or treatment of superficial bacterial infections of wounds, burns, and cutaneous ulcers. First Priority, Inc.’s Nitrofurazone Soluble Dressing is approved as a generic copy of FURA–ZONE (nitrofurazone) ointment, sponsored by Squire Laboratories, Inc., under NADA 132–427. In addition, First Priority, Inc., has informed FDA of a change of address. The ANADA is approved as of July 13, 2009, and

§§ 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