further notice. An amendment, published in the Federal Register of October 20, 2011, further modified the rule. This action is the result of satisfactory flight inspections for the Federal airways affected by the relocation of the Anchorage VHF Omnidirectional Range (VOR). DATES: Effective date 0901 UTC. This announcement is effective February 9, 2012. The effective date of FR Doc. 2011-10240, published on April 28, 2011 (FR 76 23687), delayed by FR Doc. 2011-14711, published on June 16, 2011, and amended by FR Doc. 2011-27118, published October 20, 2011 (FR 76 65106) is February 9, 2012. The Director of the Federal Register

The FAA subsequently published a rule

in the Federal Register of June 16, 2011

that delayed the effective date until

#### FOR FURTHER INFORMATION CONTACT:

the annual revision of FAA Order

Colby Abbott, Airspace, Regulations and ATC Procedures Group, Office of Mission Support Services, Federal Aviation Administration, 800 Independence Avenue SW., Washington, DC 20591; telephone: (202) 267–8783.

approves this incorporation by reference

action under 1 CFR part 51, subject to

7400.9 and publication of conforming

#### SUPPLEMENTARY INFORMATION:

## Background

amendments.

Federal Register Document FAA-2011-0010, Airspace Docket No. 11-AAL-1, published on April 28, 2011 (76 FR 23687), amends all Federal airways affected by the relocation of the Anchorage VOR navigation aid effective June 30, 2011. Due to a failed flight inspection, the FAA subsequently published in the Federal Register of June 16, 2011 a rule delaying the effective date from June 30, 2011, until further notice (76 FR 35097). Upon further inspection, the FAA removed two Federal airways in an amendment published in the Federal Register of October 20, (76 FR 65106). Two Federal airways were removed to be reworked as a separate rulemaking action. Satisfactory flight inspection results for the remaining Federal airways contained in the rule, as delayed and amended, have been accomplished the effective date is now established.

The FAA has determined that this regulation only involves an established body of technical regulations for which frequent and routine amendments are necessary to keep them operationally current. Therefore, this regulation (1) Is not a significant regulatory action under Executive Order 12866; (2) is not a

"significant rule" under DOT
Regulatory Policies and Procedures (44
FR 11034; February 26, 1979); and (3)
does not warrant preparation of a
Regulatory Evaluation as the anticipated
impact is so minimal. Since this is a
routine matter that will only affect air
traffic procedures and air navigation, it
is certified that this rule will not have
a significant economic impact on a
substantial number of small entities
under the criteria of the Regulatory
Flexibility Act.

The FAA's authority to issue rules regarding aviation safety is found in Title 49 of the United States Code. Subtitle I, section 106 describes the authority of the FAA Administrator. Subtitle VII, Aviation Programs, describes in more detail the scope of the agency's authority.

This rulemaking is promulgated under the authority described in subtitle VII, part A, subpart I, section 40103. Under that section, the FAA is charged with prescribing regulations to assign the use of the airspace necessary to ensure the safety of aircraft and the efficient use of airspace. This regulation is within the scope of that authority as it modifies federal airways in Alaska.

## List of Subjects in 14 CFR Part 71

Airspace, Incorporation by reference, Navigation (air).

### **PART 71—AMENDED**

## **Announcement of Effective Date**

■ The effective date of Airspace Docket No. 11–AAL–1, published on April 28, 2011 (76 FR 23687), delayed on June 16, 2011 (76 FR 35097), and amended on October 20, 2011 (76 FR 65106) is hereby established as February 9, 2012.

**Authority:** 49 U.S.C. 106(g), 40103, 40113, 40120; E.O. 10854, 24 FR 9565, 3 CFR, 1959–1963 Comp., p. 389.

Issued in Washington, DC, on November 30, 2011.

#### Gary A. Norek,

Acting Manager, Airspace, Regulations and ATC Procedures Group.

[FR Doc. 2011–31461 Filed 12–8–11; 8:45 am]

BILLING CODE 4910-13-P

## **DEPARTMENT OF COMMERCE**

**Bureau of Industry and Security** 

15 CFR Parts 730, 734, 736, 742, 744, and 745

[Docket No. 111031662-1691-01] RIN 0694-AF44

Updated Statements of Legal Authority To Reflect Continuation of Emergency Declared in Executive Order 12938

**AGENCY:** Bureau of Industry and Security, Commerce.

ACTION: Final rule.

SUMMARY: This rule updates the Code of Federal Regulations (CFR) legal authority citations for the Export Administration Regulations (EAR) to replace citations to the President's Notice of November 4, 2010, Continuation of Emergency Regarding Weapons of Mass Destruction, with citations to the President's Notice of November 9, 2011 on the same subject. BIS is making these changes to keep the CFR's legal authority citations for the EAR current.

DATES: Effective Date: December 9, 2011.

ADDRESSES: Comments concerning this rule should be sent to publiccomments@bis.doc.gov, or to Regulatory Policy Division, Bureau of Industry and Security, Room H2099B, U.S. Department of Commerce, Washington, DC 20230. Please refer to regulatory identification number (RIN) 0694—AF44 in all comments, and in the subject line of email comments.

## FOR FURTHER INFORMATION CONTACT:

William Arvin, Regulatory Policy Division, Bureau of Industry and Security, telephone: (202) 482–2440.

### SUPPLEMENTARY INFORMATION:

## **Background**

In Executive Order 12938 of November 14, 1994 (59 FR 59099, 3 CFR, 1994 Comp., p. 950), the President declared a national emergency with respect to the unusual and extraordinary threat to the national security, foreign policy and economy of the United States posed by the proliferation of nuclear, biological and chemical weapons and the means of delivering such weapons. That emergency has been continued in effect through successive annual presidential notices. The authority for parts 730, 734, 736, 742, 744 and 745 of the EAR (15 CFR parts 730, 734, 736, 742, 744 and 745) rests in part on E.O. 12938, as amended, and on the successive annual notices continuing the emergency. This rule revises the authority citations in those parts of the

CFR to cite the notice of November 9, 2011, which is the most recent such annual Presidential notice, and to remove the citation to the notice of November 4, 2010 on the same topic.

BIS is making these revisions so that title 15 of the CFR will cite the current authority for the parts mentioned above. This rule is purely procedural, and makes no changes other than to revise CFR authority citations paragraphs. It does not change the text of any section of the EAR, nor does it alter any right, obligation or prohibition that applies to any person under the EAR.

## **Rulemaking Requirements**

- 1. Executive Orders 13563 and 12866 direct agencies to assess all costs and benefits of available regulatory alternatives and, if regulation is necessary, to select regulatory approaches that maximize net benefits (including potential economic, environmental, public health and safety effects, distributive impacts, and equity). This rule does not impose any regulatory burden on the public and is consistent with the goals of Executive Order 13563. This rule has been determined not to be a significant rule for purposes of Executive Order 12866.
- 2. Notwithstanding any other provision of law, no person is required to respond to, nor shall any person be subject to a penalty for failure to comply with, a collection of information subject to the requirements of the Paperwork Reduction Act of 1995 (PRA), 44 U.S.C. 3501 et seq., unless that collection of information displays a currently valid Office of Management and Budget (OMB) Control Number. This rule does not involve any collection of information.
- 3. This rule does not contain policies with Federalism implications as that term is defined under Executive Order 13132.
- 4. The Department finds that there is good cause under 5 U.S.C. 553(b)(3)(B) to waive the provisions of the Administrative Procedure Act requiring prior notice and the opportunity for public comment because they are unnecessary. This rule only updates legal authority citations and is nondiscretionary. This rule does not alter any right, obligation or prohibition that applies to any person under the EAR. Because these revisions are not substantive changes, it is unnecessary to provide notice and opportunity for public comment. In addition, the 30-day delay in effectiveness required by 5 U.S.C. 553(d) is not applicable because this rule is not a substantive rule. Because neither the Administrative Procedure Act nor any other law

requires that notice of proposed rulemaking and an opportunity for public comment be given for this rule, the analytical requirements of the Regulatory Flexibility Act (5 U.S.C. 601 *et seq.*) are not applicable.

#### List of Subjects

15 CFR Part 730

Administrative practice and procedure, Advisory committees, Exports, Reporting and recordkeeping requirements, Strategic and critical materials.

## 15 CFR Part 734

Administrative practice and procedure, Exports, Inventions and patents, Research, Science and technology.

15 CFR Part 736

Exports.

15 CFR Part 742

Exports, Terrorism.

15 CFR Part 744

Exports, Reporting and recordkeeping requirements, Terrorism.

15 CFR Part 745

Administrative practice and procedure, Chemicals, Exports, Foreign trade, Reporting and recordkeeping requirements.

Accordingly, the EAR (15 CFR parts 730–774) is amended as follows:

## PART 730—[AMENDED]

■ 1. The authority citation for 15 CFR part 730 is revised to read as follows:

Authority: 50 U.S.C. app. 2401 et seq.; 50 U.S.C. 1701 et seq.; 10 U.S.C. 7420; 10 U.S.C. 7430(e); 22 U.S.C. 287c; 22 U.S.C. 2151 note; 22 U.S.C. 3201 et seq.; 22 U.S.C. 6004; 30 U.S.C. 185(s), 185(u); 42 U.S.C. 2139a; 42 U.S.C. 6212; 43 U.S.C. 1354; 15 U.S.C. 1824a; 50 U.S.C. app. 5; 22 U.S.C. 7201 et seq.; 22 U.S.C. 7210; E.O. 11912, 41 FR 15825, 3 CFR, 1976 Comp., p. 114; E.O. 12002, 42 FR 35623, 3 CFR, 1977 Comp., p. 133; E.O. 12058, 43 FR 20947, 3 CFR, 1978 Comp., p. 179; E.O. 12214, 45 FR 29783, 3 CFR, 1980 Comp., p. 256; E.O. 12851, 58 FR 33181, 3 CFR, 1993 Comp., p. 608; E.O. 12854, 58 FR 36587, 3 CFR, 1993 Comp., p. 179; E.O. 12918, 59 FR 28205, 3 CFR, 1994 Comp., p. 899; E.O. 12938, 59 FR 59099, 3 CFR, 1994 Comp., p. 950; E.O. 12947, 60 FR 5079, 3 CFR, 1995 Comp., p. 356; E.O. 12981, 60 FR 62981, 3 CFR, 1995 Comp., p. 419; E.O. 13020, 61 FR 54079, 3 CFR, 1996 Comp., p. 219; E.O. 13026, 61 FR 58767, 3 CFR, 1996 Comp., p. 228; E.O. 13099, 63 FR 45167, 3 CFR, 1998 Comp., p. 208; E.O. 13222, 66 FR 44025, 3 CFR, 2001 Comp., p. 783; E.O. 13224, 66 FR 49079, 3 CFR, 2001 Comp., p. 786; E.O. 13338, 69 FR 26751, 3 CFR, 2004 Comp., p. 168; Notice of January 13, 2011, 76 FR 3009

(January 18, 2011); Notice of August 12, 2011, 76 FR 50661 (August 16, 2011); Notice of November 9, 2011, 76 FR 70319 (November 10, 2011).

## PART 734—[AMENDED]

■ 2. The authority citation for 15 CFR part 734 is revised to read as follows:

**Authority:** 50 U.S.C. app. 2401 *et seq.*; 50 U.S.C. 1701 *et seq.*; E.O. 12938, 59 FR 59099, 3 CFR, 1994 Comp., p. 950; E.O. 13020, 61 FR 54079, 3 CFR, 1996 Comp., p. 219; E.O. 13026, 61 FR 58767, 3 CFR, 1996 Comp., p. 228; E.O. 13222, 66 FR 44025, 3 CFR, 2001 Comp., p. 783; Notice of August 12, 2011, 76 FR 50661 (August 16, 2011); Notice of November 9, 2011, 76 FR 70319 (November 10, 2011).

## PART 736—[AMENDED]

■ 3. The authority citation for 15 CFR part 736 is revised to read as follows:

Authority: 50 U.S.C. app. 2401 et seq.; 50 U.S.C. 1701 et seq.; 22 U.S.C. 2151 note; E.O. 12938, 59 FR 59099, 3 CFR, 1994 Comp., p. 950; E.O. 13020, 61 FR 54079, 3 CFR, 1996 Comp., p. 219; E.O. 13026, 61 FR 58767, 3 CFR, 1996 Comp., p. 228; E.O. 13222, 66 FR 44025, 3 CFR, 2001 Comp., p. 783; E.O. 13338, 69 FR 26751, 3 CFR, 2004 Comp., p. 168; Notice of August 12, 2011, 76 FR 50661 (August 16, 2011); Notice of November 9, 2011, 76 FR 70319 (November 10, 2011).

## PART 742—[AMENDED]

■ 4. The authority citation for 15 CFR part 742 is revised to read as follows:

Authority: 50 U.S.C. app. 2401 et seq.; 50 U.S.C. 1701 et seq.; 22 U.S.C. 3201 et seq.; 42 U.S.C. 2139a; 22 U.S.C. 7201 et seq.; 22 U.S.C. 7210; Sec. 1503, Pub. L. 108–11, 117 Stat. 559; E.O. 12058, 43 FR 20947, 3 CFR, 1978 Comp., p. 179; E.O. 12851, 58 FR 33181, 3 CFR, 1993 Comp., p. 608; E.O. 12938, 59 FR 59099, 3 CFR, 1994 Comp., p. 950; E.O. 13026, 61 FR 58767, 3 CFR, 1996 Comp., p. 228; E.O. 13222, 66 FR 44025, 3 CFR, 2001 Comp., p. 783; Presidential Determination 2003–23 of May 7, 2003, 68 FR 26459, May 16, 2003; Notice of August 12, 2011, 76 FR 50661 (August 16, 2011); Notice of November 9, 2011, 76 FR 70319 (November 10, 2011).

## PART 744—[AMENDED]

■ 5. The authority citation for 15 CFR part 744 is revised to read as follows:

Authority: 50 U.S.C. app. 2401 et seq.; 50 U.S.C. 1701 et seq.; 22 U.S.C. 3201 et seq.; 42 U.S.C. 2139a; 22 U.S.C. 7201 et seq.; 22 U.S.C. 7210; E.O. 12058, 43 FR 20947, 3 CFR, 1978 Comp., p. 179; E.O. 12851, 58 FR 33181, 3 CFR, 1993 Comp., p. 608; E.O. 12938, 59 FR 59099, 3 CFR, 1994 Comp., p. 950; E.O. 12947, 60 FR 5079, 3 CFR, 1995 Comp., p. 356; E.O. 13026, 61 FR 58767, 3 CFR, 1996 Comp., p. 228; E.O. 13099, 63 FR 45167, 3 CFR, 1998 Comp., p. 208; E.O. 13222, 66 FR 44025, 3 CFR, 2001 Comp., p. 783; E.O. 13224, 66 FR 49079, 3 CFR, 2001 Comp., p. 786; Notice of January 13, 2011, 76 FR 3009

(January 18, 2011); Notice of August 12, 2011, 76 FR 50661 (August 16, 2011); Notice of November 9, 2011, 76 FR 70319 (November 10, 2011).

#### PART 745—[AMENDED]

■ 6. The authority citation for 15 CFR part 745 is revised to read as follows:

**Authority:** 50 U.S.C. 1701 *et seq.*; E.O. 12938, 59 FR 59099, 3 CFR, 1994 Comp., p. 950; Notice of November 9, 2011, 76 FR 70319 (November 10, 2011).

Dated: December 5, 2011.

#### Kevin J. Wolf,

Assistant Secretary for Export Administration.

[FR Doc. 2011-31687 Filed 12-8-11; 8:45 am]

BILLING CODE 3510-33-P

## DEPARTMENT OF HEALTH AND HUMAN SERVICES

#### **Food and Drug Administration**

## 21 CFR Part 558

[Docket No. FDA-2011-N-0003]

# New Animal Drugs for Use in Animal Feeds; Tilmicosin

**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 a supplemental new animal drug application (NADA) filed by Elanco Animal Health, a division of Eli Lilly & Co. The supplemental NADA provides for use of tilmicosin Type C medicated feeds by veterinary feed directive for the control of bovine respiratory disease in groups of beef and nonlactating dairy cattle.

**DATES:** This rule is effective December 9, 2011.

## FOR FURTHER INFORMATION CONTACT:

Cindy L. Burnsteel, Center for Veterinary Medicine (HFV–130), Food and Drug Administration, 7500 Standish Pl., Rockville, MD 20855, (240) 276– 8341, email:

cindy.burnsteel@fda.hhs.gov.

SUPPLEMENTARY INFORMATION: Elanco Animal Health, a division of Eli Lilly & Co., Lilly Corporate Center, Indianapolis, IN 46285, filed a supplement to NADA 141–064 for PULMOTIL 90 (tilmicosin phosphate) Type A medicated article. The supplemental NADA provides for the use of tilmicosin Type C medicated feeds by veterinary feed directive for the control of bovine respiratory disease

(BRD) associated with Mannheimia haemolytica, Pasteurella multocida, and Histophilus somni in groups of beef and nonlactating dairy cattle where active BRD has been diagnosed in at least 10 percent of the animals in the group. The supplemental NADA is approved as of August 19, 2011, and 21 CFR 558.4 and 558.618 are amended 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.

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

The Agency has carefully considered the potential environmental impact of this action and has concluded that the action will not have a significant impact on the human environment and that an environmental impact statement is not required. FDA's finding of no significant impact and the evidence supporting that finding, contained in an environmental assessment, may be seen in the Division of Dockets Management (address above) between 9 a.m. and 4 p.m., Monday through Friday.

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 558

Animal drugs, Animal feeds.

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 558 is amended as follows:

# PART 558—NEW ANIMAL DRUGS FOR USE IN ANIMAL FEEDS

■ 1. The authority citation for 21 CFR part 558 continues to read as follows:

Authority: 21 U.S.C. 360b, 371.

## § 558.4 [Amended]

■ 2. In paragraph (d) of § 558.4, in the "Category II" table, in the "Type B maximum (100x)" column, in the entry for "Tilmicosin", remove "18.2 g/lb

- (4.0%)" and in its place add "37.9 g/lb (8.35%)".
- $\blacksquare$  3. In § 558.618, revise paragraphs (a), (c), and (e) to read as follows:

#### §558.618 Tilmicosin.

- (a) Specifications. Type A medicated article containing 90.7 grams (g) per pound tilmicosin as tilmicosin phosphate (200 g per kilogram).
- (c) Special considerations—(1) Tilmicosin medicated feeds are restricted to use under a veterinary feed directive (VFD). See § 558.6 of this chapter for required label statements and other limitations.
- (2) VFDs for tilmicosin phosphate shall not be refilled.
- (3) Labeling of tilmicosin Type B or Type C medicated feeds must bear the following warnings:
- (i) Do not allow horses or other equines access to feeds containing tilmicosin.
- (ii) Use of antibacterial drugs in the absence of a susceptible bacterial infection is unlikely to provide benefit to treated animals and may increase the risk of the development of drug-resistant pathogenic bacteria.
- (4) Special considerations for use of tilmicosin medicated swine feeds include the following:
- (i) The expiration date of VFDs for tilmicosin must not exceed 90 days from the time of issuance.
- (ii) Labeling of tilmicosin Type B or Type C medicated feeds for swine must bear the following warning: "Do not use in any feeds containing bentonite. Bentonite in feeds may affect the efficacy of tilmicosin."
- (iii) Feed containing tilmicosin shall not be fed to pigs for more than 21 days during each phase of production without ceasing administration for reevaluation of antimicrobial use by a licensed veterinarian before reinitiating a further course of therapy with an appropriate antimicrobial.
- (5) Special consideration for use of tilmicosin medicated cattle feeds include the following:
- (i) The expiration date of VFDs for cattle must not exceed 45 days from the time of issuance.
- (ii) Labeling of tilmicosin Type B or Type C medicated feeds for cattle must bear the following warning: "Do not use in any feeds containing bentonite, cottonseed meal, or cottonseed hulls. Bentonite, cottonseed meal, or cottonseed hulls in feeds may affect the efficacy of tilmicosin."
- (iii) To assure both food safety and responsible use in cattle, administration of feed containing tilmicosin to cattle