

action, contact Judi Citrenbaum, Office of Aerospace Medicine, Federal Aviation Administration, 800 Independence Avenue SW., Washington, DC 20591; telephone (202) 267-9689; email [Judi.M.Citrenbaum@faa.gov](mailto:Judi.M.Citrenbaum@faa.gov).

For legal questions concerning this action, contact Sabrina Jawed, Office of the Chief Counsel, Regulations Division, Federal Aviation Administration, 800 Independence Avenue SW., Washington, DC 20591; telephone (202) 267-3073; email [Sabrina.Jawed@faa.gov](mailto:Sabrina.Jawed@faa.gov).

#### SUPPLEMENTARY INFORMATION:

##### Background

Since 2008, Title 14, Code of Federal Regulations (14 CFR) § 67.401(j) has required individuals granted the Special Issuance of a Medical Certificate (Authorization) to have their letter of Authorization in their physical possession or readily accessible in the aircraft while exercising pilot privileges. The FAA published a direct final rule on March 22, 2012 (77 FR 16664) to remove this provision for several reasons. Namely, affected individuals find the standard burdensome given that other longstanding FAA operational requirements already mandate that pilots carry their medical certificate when exercising pilot privileges. In addition, the FAA is not aware of any individuals affected by the standard who have had to produce their letter of Authorization for any civil aviation authorities during the nearly 4-year period the rule has been in effect. In this regard, the FAA identified this rulemaking action as burden-relieving under Executive Order 13563 of January 18, 2011 entitled "Improving Regulation and Regulatory Review."

Once this rule becomes effective, § 67.401(j) no longer will apply. This means that the "Note" under the regulatory reference to § 67.401(j) listed under the "Conditions of Issue" on an individual's existing FAA medical certificate no longer will be necessary. This does not mean that the FAA needs or intends to re-issue medical certificates. It will be acceptable for the FAA medical certificate to reference this "Note" until an individual's medical certificate is renewed. The FAA will begin using medical certificates with updated "Conditions of Issue" that do not include reference to the removed standard as soon as possible after July 20, 2012.

##### Discussion of Comments

The FAA received nine supportive comments from individuals and one

supportive comment from the Air Line Pilots Association International regarding this action. All of the commenters believe that this regulation is unnecessary, and removing it would relieve affected pilots of an undue burden.

##### Conclusion

The FAA received no adverse comments in response to the direct final rule "Removal of the Part 67 Requirement for Individuals Granted the Special Issuance of a Medical Certificate to Carry Their Letter of Authorization While Exercising Pilot Privileges". The FAA has determined that no further rulemaking action is necessary. Therefore, the rule is adopted as amendment 67-21 and becomes effective on July 20, 2012.

##### How To Obtain Additional Information

###### A. Rulemaking Documents

An electronic copy of a rulemaking document may be obtained by using the Internet —

1. Search the Federal eRulemaking Portal (<http://www.regulations.gov>);
2. Visit the FAA's Regulations and Policies Web page at [http://www.faa.gov/regulations\\_policies/](http://www.faa.gov/regulations_policies/) or
3. Access the Government Printing Office's Web page at <http://www.gpo.gov/fdsys>.

Copies may also be obtained by sending a request (identified by notice, amendment, or docket number of this rulemaking) to the Federal Aviation Administration, Office of Rulemaking, ARM-1, 800 Independence Avenue SW., Washington, DC 20591, or by calling (202) 267-9680.

###### B. Comments Submitted to the Docket

Comments received may be viewed by going to <http://www.regulations.gov> and following the online instructions to search the docket number for this action. Anyone is able to search the electronic form of all comments received into any of the FAA's dockets by the name of the individual submitting the comment (or signing the comment, if submitted on behalf of an association, business, labor union, etc.).

Issued in Washington, DC on June 6, 2012.

**Frederick E. Tilton,**  
Federal Air Surgeon.

[FR Doc. 2012-16317 Filed 7-2-12; 8:45 am]

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## SECURITIES AND EXCHANGE COMMISSION

### 17 CFR Parts 229 and 240

[Release Nos. 33-9330; 34-67220; File No. S7-13-11]

RIN 3235-AK95

#### Listing Standards for Compensation Committees

##### Correction

In rule document 2012-15408, appearing on pages 38422-38455, in the issue of Wednesday, June 27, 2012, make the following correction:

1. On page 38422, in column one, under the heading **DATES**, Compliance Dates, thirteenth line, "June 27, 2012" should read "June 27, 2013".

[FR Doc. C1-2012-15408 Filed 7-2-12; 8:45 am]

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## DEPARTMENT OF HEALTH AND HUMAN SERVICES

### Food and Drug Administration

#### 21 CFR Parts 522 and 556

[Docket No. FDA-2012-N-0002]

#### Implantation or Injectable Dosage Form New Animal Drugs; Maropitant; Tildipirosin

**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 actions for new animal drug applications (NADAs) and abbreviated new animal drug applications (ANADAs) during May 2012. FDA is also informing the public of the availability of summaries of the basis of approval and of environmental review documents, where applicable.

**DATES:** This rule is effective July 3, 2012.

**FOR FURTHER INFORMATION CONTACT:** George K. Haibel, Center for Veterinary Medicine (HFV-6), Food and Drug Administration, 7519 Standish Pl., Rockville, MD 20855, 240-276-9019, email: [george.haibel@fda.hhs.gov](mailto:george.haibel@fda.hhs.gov).

**SUPPLEMENTARY INFORMATION:** FDA's Center for Veterinary Medicine (CVM) is adopting use of a monthly **Federal Register** document to codify approval actions for NADAs and ANADAs. CVM will no longer publish a separate rule for each action. This approach will allow a more efficient use of available resources.

In this document, FDA is amending the animal drug regulations to reflect the original and supplemental approval actions during May 2012, as listed in table 1 of this document. In addition, FDA is informing the public of the availability, where applicable, of documentation of environmental review required under the National Environmental Policy Act (NEPA) and, for actions requiring review of safety or effectiveness data, summaries of the

basis of approval (freedom of information summaries) under the Freedom of Information Act (FOIA). These public documents 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. Persons with access to the Internet may obtain these documents at the CVM FOIA Electronic Reading

Room at <http://www.fda.gov/AboutFDA/CentersOffices/OfficeofFoods/CVM/CVMFOIAElectronicReadingRoom/default.htm>.

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.

TABLE 1—ORIGINAL AND SUPPLEMENTAL NADAS AND ANADAS APPROVED DURING MAY 2012

NADA/ ANADA	Sponsor	New animal drug product name	Action	21 CFR Section	FOIA Summary	NEPA Review
141–334 .....	Intervet, Inc., 556 Morris Ave., Summit, NJ 07901.	ZUPREVO 18% (tildipirosin) Injectable Solution.	Original approval for the treatment of bovine respiratory disease (BRD) in beef and non-lactating dairy cattle; and for the control of respiratory disease in beef and non-lactating dairy cattle at high risk of developing BRD.	522.2460 556.733	yes .....	CE <sup>1</sup>
141–263 .....	Pfizer, Inc., 235 East 42d St., New York, NY 10017.	CERENIA (maropitant citrate) Injectable Solution.	Supplemental approval adding treatment of vomiting in cats.	522.1315	yes .....	CE <sup>1</sup>

<sup>1</sup> The Agency has determined under 21 CFR 25.33 that this action is categorically excluded from the requirement to submit an environmental assessment or an environmental impact statement because it is of a type that does not individually or cumulatively have a significant effect on the human environment.

### List of Subjects

#### 21 CFR Part 522

Animal drugs.

#### 21 CFR Part 556

Animal drugs, Foods.

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 522 and 556 are 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. In § 522.1315, revise paragraph (c) to read as follows:

#### § 522.1315 Maropitant.

\* \* \* \* \*

(c) *Conditions of use*—(1) *Dogs*—(i) *Amount*. Administer 1.0 mg per kilogram (mg/kg) of body weight by subcutaneous injection once daily for up to 5 consecutive days.

(ii) *Indications for use*. For the prevention and treatment of acute vomiting.

(iii) *Limitations*. Federal law restricts this drug to use by or on the order of a licensed veterinarian.

(2) *Cats*—(i) *Amount*. Administer 1.0 mg/kg of body weight by subcutaneous injection once daily for up to 5 consecutive days.

(ii) *Indications for use*. For the treatment of vomiting.

(iii) *Limitations*. Federal law restricts this drug to use by or on the order of a licensed veterinarian.

■ 3. Section 522.2460 is added to read as follows:

#### § 522.2460 Tildipirosin.

(a) *Specifications*. Each milliliter of solution contains:

(1) 180 milligrams (mg) tildipirosin.

(2) [Reserved]

(b) *Sponsor*. See No. 000061 in § 510.600(c) of this chapter.

(c) *Related tolerances*. See § 556.733 of this chapter.

(d) *Conditions of use*—(1) *Cattle*—(i) *Amount*. Administer 4 mg/kg of body weight one time by subcutaneous injection in the neck.

(ii) *Indications for use*. For the treatment of bovine respiratory disease (BRD) associated with *Mannheimia haemolytica*, *Pasteurella multocida*, and *Histophilus somni* in beef and non-lactating dairy cattle; and for the control of respiratory disease in beef and non-lactating dairy cattle at high risk of developing BRD associated with *M. haemolytica*, *P. multocida*, and *H. somni*.

(iii) *Limitations*. Cattle intended for human consumption must not be

slaughtered within 21 days from the last treatment. Do not use in female dairy cattle 20 months of age or older. A withdrawal period has not been established for this product in preruminating calves. Do not use in calves to be processed for veal. Federal law restricts this drug to use by or on the order of a licensed veterinarian.

(2) [Reserved]

### PART 556—TOLERANCES FOR RESIDUES OF NEW ANIMAL DRUGS IN FOOD

■ 4. The authority citation for 21 CFR part 556 continues to read as follows:

**Authority:** 21 U.S.C. 342, 360b, 371.

■ 5. Add § 556.733 to read as follows:

#### § 556.733 Tildipirosin.

(a) *Acceptable Daily Intake (ADI)*. The ADI for total residues of tildipirosin is 10 micrograms per kilogram of body weight per day.

(b) *Tolerances*. The tolerances for tildipirosin (the marker residue) are:

(1) *Cattle*—(i) *Liver (the target tissue)*: 10 parts per million.

(ii) [Reserved]

(2) [Reserved]

(c) *Related conditions of use*. See § 522.2460 of this chapter.

Dated: June 27, 2012.

**Bernadette Dunham,**

*Director, Center for Veterinary Medicine.*

[FR Doc. 2012-16203 Filed 7-2-12; 8:45 am]

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## DEPARTMENT OF STATE

### 22 CFR Part 126

RIN 1400-AD23

[Public Notice 7944]

#### Amendment to the International Traffic in Arms Regulations: Yemen

**AGENCY:** Department of State.

**ACTION:** Final rule.

**SUMMARY:** The Department of State is amending the International Traffic in Arms Regulations (ITAR) to update the policy toward Yemen. Licenses or other approvals for exports or imports of defense articles and defense services destined for or originating in Yemen will be reviewed, and may be issued, on a case-by-case basis.

**DATES:** *Effective Date:* This rule is effective July 3, 2012.

**FOR FURTHER INFORMATION CONTACT:** Ms. Candace M. J. Goforth, Director, Office of Defense Trade Controls Policy, U.S. Department of State, telephone (202) 663-2792, or email [DDTCResponseTeam@state.gov](mailto:DDTCResponseTeam@state.gov). ATTN: Regulatory Change, Part 126, Yemen.

**SUPPLEMENTARY INFORMATION:** The Department of State published a notice in the **Federal Register** on December 16, 1992, providing that the defense export policy for Yemen included a "presumption of denial" for proposed exports of lethal defense articles or items supporting such articles. On August 8, 2011, the Department amended the ITAR to include Yemen in § 126.1, which describes prohibited exports, imports, and sales to or from certain countries. That policy allowed for the export of non-lethal defense articles and defense services and non-lethal, safety-of-use defense articles for lethal end-items. License applications for the export of lethal defense articles and defense services were denied.

This rule removes the ITAR § 126.1 limitations on defense trade with Yemen. Less restrictive defense trade will further the national security and foreign policy interests of the United States. The Republic of Yemen has taken important steps to stabilize the country, including holding successful presidential elections in February 2012. Furthermore, the Republic of Yemen is a critical partner in the United States'

continuing efforts against terrorism. Defense assistance to the Yemeni government will be critical to increasing stability and security throughout the country and countering this threat.

Therefore, § 126.1(u) is removed, and the Department will review on a case-by-case basis all requests for licenses or other approvals for exports or temporary imports of defense articles and defense services destined for or originating in Yemen.

#### Regulatory Analysis and Notices

##### *Administrative Procedure Act*

The Department of State is of the opinion that controlling the import and export of defense articles and services is a foreign affairs function of the United States Government and that rules implementing this function are exempt from sections 553 (rulemaking) and 554 (adjudications) of the Administrative Procedure Act. Since the Department is of the opinion that this rule is exempt from 5 U.S.C. 553, it is the view of the Department of State that the provisions of § 553(d) do not apply to this rulemaking. Therefore, this rule is effective upon publication. The Department also finds that, given the national security issues surrounding U.S. policy towards Yemen, notice and public procedure on this rule would be impracticable, unnecessary, or contrary to the public interest; for the same reason, the rule will be effective immediately. *See* 5 U.S.C. 808(2).

##### *Regulatory Flexibility Act*

Since the Department is of the opinion that this rule is exempt from the rulemaking provisions of 5 U.S.C. 553, it does not require analysis under the Regulatory Flexibility Act.

##### *Unfunded Mandates 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 Orders 12866 and 13563*

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, distributed impacts, and equity). Executive Order 13563 emphasizes the importance of quantifying both costs and benefits, of reducing costs, of harmonizing rules, and of promoting flexibility. This rule has been designated a "significant regulatory action," although not economically significant, under section 3(f) of Executive Order 12866. Accordingly, the rule has been reviewed by the Office of Management and Budget (OMB).

##### *Executive Order 12988*

The Department of State has reviewed the amendment in light of sections 3(a) and 3(b)(2) of Executive Order 12988 to eliminate ambiguity, minimize litigation, establish clear legal standards, and reduce burden.

##### *Executive Order 13175*

The Department has determined that this rulemaking will not have tribal implications, will not impose substantial direct compliance costs on Indian tribal governments, and will not preempt tribal law. Accordingly, Executive Order 13175 does not apply to this rulemaking.

##### *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 in 22 CFR Part 126

Arms and munitions, Exports.

Accordingly, for the reasons set forth above, Title 22, Chapter I, Subchapter M, part 126 is amended as follows: