

within the scope of that authority as it revises Colored Federal Airways in Alaska.

Environmental Review

The FAA has determined that this action qualifies for categorical exclusion under the National Environmental Policy Act in accordance with FAA Order 1050.1E, Environmental Impacts: Policies and Procedures, paragraph 311a. This airspace action is not expected to cause any potentially significant environmental impacts, and no extraordinary circumstances exist that warrant preparation of an environmental assessment.

List of Subjects in 14 CFR Part 71

Airspace, Incorporation by reference, Navigation (air).

Adoption of the Amendment

■ In consideration of the foregoing, the Federal Aviation Administration amends 14 CFR part 71 as follows:

PART 71—DESIGNATION OF CLASS A, B, C, D, AND E AIRSPACE AREAS; AIR TRAFFIC SERVICE ROUTES; AND REPORTING POINTS

■ 1. The authority citation for part 71 continues to read as follows:

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

§ 71.1 [Amended]

■ 2. The incorporation by reference in 14 CFR 71.1 of FAA Order 7400.9T, Airspace Designations and Reporting Points, signed August 27, 2009, and effective September 15, 2009, is to be amended as follows:

Paragraph 6009(a) Green Federal Airways.
* * * * *

G–16 [Revised]

From Point Lay, AK, NDB; Wainwright Village, AK, NDB; Browerville, AK, NDB; Nuiqsut Village, AK, NDB; to Put River, AK, NDB.

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Paragraph 6009(d) Blue Federal Airways.
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B–26 [Revised]

From Chena, AK, NDB, to Yukon River, AK, NDB.

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Issued in Washington, DC, December 3, 2009.

Kenneth L. McElroy,
Acting Manager, Airspace and Rules Group.
[FR Doc. E9–29396 Filed 12–10–09; 8:45 am]
BILLING CODE 4910–13–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

21 CFR Parts 510 and 522

[Docket No. FDA–2009–N–0665]

New Animal Drugs; Change of Sponsor; Azaperone

AGENCY: Food and Drug Administration, HHS.

ACTION: Final rule.

SUMMARY: The Food and Drug Administration (FDA) is amending the animal drug regulations to reflect a change of sponsor for a new animal drug application (NADA) from Schering-Plough Animal Health Corp. to Janssen Pharmaceutica NV.

DATES: This rule is effective December 11, 2009.

FOR FURTHER INFORMATION CONTACT:

David R. Newkirk, Center for Veterinary Medicine (HFV–100), Food and Drug Administration, 7500 Standish Pl., Rockville, MD 20855, 240–276–8307, e-mail: david.newkirk@fda.hhs.gov.

SUPPLEMENTARY INFORMATION: Schering-Plough Animal Health Corp., 556 Morris Ave., Summit, NJ 07901, has informed FDA that it has transferred ownership of, and all rights and interest in, approved NADA 115–732 for STRESNIL (azaperone) Injection to Janssen Pharmaceutica NV, Turnhoutseweg 30, B–2340 Beerse, Belgium. Accordingly, the agency is amending the regulations in 21 CFR 522.150 to reflect the transfer of ownership and a current format.

In addition, Janssen Pharmaceutica NV is not currently listed in the animal drug regulations as a sponsor of an approved application. Accordingly, 21 CFR 510.600(c) is being amended to add entries for this sponsor.

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 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 parts 510 and 522 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.

■ 2. In § 510.600, in the table in paragraph (c)(1), alphabetically add an entry for “Janssen Pharmaceutica NV”; and in the table in paragraph (c)(2), numerically add an entry for “012578” to read as follows:

§ 510.600 Names, addresses, and drug labeler codes of sponsors of approved applications.

* * * * *
(c) * * *
(1) * * *

Firm name and address	Drug labeler code
* * *	* * *
Janssen Pharmaceutica NV, Turnhoutseweg 30, B–2340 Beerse, Belgium	012578
* * *	* * *
(2) * * *	
Drug labeler code	Firm name and address
* * *	* * *
012578	Janssen Pharmaceutica NV, Turnhoutseweg 30, B–2340 Beerse, Belgium
* * *	* * *
* * *	* * *

PART 522—IMPLANTATION OR INJECTABLE DOSAGE FORM NEW ANIMAL DRUGS

■ 3. The authority citation for 21 CFR part 522 continues to read as follows:

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

■ 4. Revise § 522.150 to read as follows:

§ 522.150 Azaperone.

(a) *Specifications.* Each milliliter of solution contains 40 milligrams (mg) azaperone.

(b) *Sponsor.* See No. 012578 in § 510.600(c) of this chapter.

(c) *Conditions of use—(1) Indications for use.* For control of aggressiveness when mixing or regrouping weanling or feeder pigs weighing up to 80 pounds.

(2) *Dosage.* 2.2 mg per kilogram (1 mg per pound) by deep intramuscular injection.

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

Dated: December 7, 2009.

Bernadette Dunham,

Director, Center for Veterinary Medicine.

[FR Doc. E9-29494 Filed 12-10-09; 8:45 am]

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DEPARTMENT OF HOMELAND SECURITY

Coast Guard

33 CFR Part 165

[Docket No. USCG-2009-0484]

RIN 1625-AA00

Safety Zone; San Diego Parade of Lights Fireworks; San Diego Bay, CA

AGENCY: Coast Guard, DHS.

ACTION: Temporary final rule.

SUMMARY: The Coast Guard proposes a safety zone upon the navigable waters of San Diego Bay in San Diego, CA in support of the San Diego Parade of Lights Fireworks. This safety zone is necessary to provide for the safety of the participants, crew, spectators, participating vessels, and other users of the waterway. Persons and vessels are prohibited from entering into, transiting through, or anchoring within this safety zone unless authorized by the Captain of the Port or his designated representative.

DATES: This rule is effective from 5:30 p.m. to 10 p.m., each day, on December 13, 2009, and December 20, 2009.

ADDRESSES: Comments and material received from the public, as well as documents mentioned in this preamble as being available in the docket, are part of docket USCG-2009-0484 and are available online by going to <http://www.regulations.gov>, inserting USCG-2009-0484 in the "Keyword" box, and then clicking "Search." This material is also available for inspection or copying at the Docket Management Facility (M-30), U.S. Department of Transportation, West Building Ground Floor, Room W12-140, 1200 New Jersey Avenue, SE., Washington, DC 20590, between 9 a.m. and 5 p.m., Monday through Friday, except Federal holidays.

FOR FURTHER INFORMATION CONTACT: If you have questions on this temporary rule, call or e-mail Petty Officer Shane Jackson, Waterways Management, U.S. Coast Guard Sector San Diego at telephone 619-278-7262, E-mail Shane.E.Jackson@uscg.mil. If you have

questions on viewing the docket, call Renee V. Wright, Program Manager, Docket Operations, telephone 202-366-9826.

SUPPLEMENTARY INFORMATION:

Regulatory Information

On September 29, 2009 we published a notice of proposed rulemaking (NPRM) entitled Safety Zone; San Diego Parade of Lights Fireworks; San Diego, CA in the **Federal Register** (74 FR 49831). We received no comments on the proposed rule. Additionally, no public meeting was requested, and none was held.

Background and Purpose

Fireworks & Stage FX Inc is sponsoring the San Diego Parade of Lights Fireworks, which will include a fireworks presentation from a barge in San Diego Bay. This temporary safety zone is necessary to provide for the safety of the crew, spectators, participants, and other vessels and users of the waterway.

Discussion of Comments and Changes

No comments were submitted in response to the NPRM. After publication of the NPRM, the sponsor informed the Coast Guard that changes to the fireworks show plans required enlargement of the safety zone. The NPRM described a *safety zone extending in a 400 foot radius around a barge in approximate position 32°43'23" N, 117°11'57" W. Instead, in order to protect members of the public from the hazards associated with fireworks displays, the zone will extend in a 600 foot radius from the same approximate position. Vessel traffic will continue to be able to pass safely around the zone, and no other negative impacts are expected to result from this change.*

Regulatory Analyses

We developed this rule after considering numerous statutes and executive orders related to rulemaking. Below we summarize our analyses based on 13 of these statutes or executive orders.

Regulatory Planning and Review

This rule is not a significant regulatory action under section 3(f) of Executive Order 12866, Regulatory Planning and Review, and does not require an assessment of potential costs and benefits under section 6(a)(3) of that Order. The Office of Management and Budget has not reviewed it under that Order.

We expect the economic impact of this proposed rule to be so minimal that

a full Regulatory Evaluation is unnecessary. This determination is based on the size and location of the safety zone. Commercial vessels will not be hindered by the safety zone. Recreational vessels will not be allowed to transit through the designated safety zone during the specified times unless authorized to do so by the Captain of the Port or his designated representative.

Small Entities

Under the Regulatory Flexibility Act (5 U.S.C. 601-612), we have considered whether this rule would have a significant economic impact on a substantial number of small entities. The term "small entities" comprises small businesses, not-for-profit organizations that are independently owned and operated and are not dominant in their fields, and governmental jurisdictions with populations of less than 50,000.

The Coast Guard certifies under 5 U.S.C. 605(b) that this rule will not have a significant economic impact on a substantial number of small entities.

This rule will affect the following entities, some of which may be small entities: The owners or operators of vessels intending to transit or anchor in a portion of the San Diego Bay from 5:30 p.m. to 10 p.m. on December 13 and 20, 2009.

This safety zone will not have a significant economic impact on a substantial number of small entities for the following reasons. Vessel traffic can pass safely around the zone. Additionally, before the effective period, the Coast Guard will publish a local notice to mariners (LNM).

Assistance for Small Entities

Under section 213(a) of the Small Business Regulatory Enforcement Fairness Act of 1996 (Pub. L. 104-121), in the NPRM we offered to assist small entities in understanding the rule so that they could better evaluate its effects on them and participate in the rulemaking process.

Small businesses may send comments on the actions of Federal employees who enforce, or otherwise determine compliance with, Federal regulations to the Small Business and Agriculture Regulatory Enforcement Ombudsman and the Regional Small Business Regulatory Fairness Boards. The Ombudsman evaluates these actions annually and rates each agency's responsiveness to small business. If you wish to comment on actions by employees of the Coast Guard, call 1-888-REG-FAIR (1-888-734-3247). The Coast Guard will not retaliate against small entities that question or