

ACTION: Final rule; technical amendment.

SUMMARY: The Food and Drug Administration (FDA) is amending the animal drug regulations to reflect a change of sponsor for two new animal drug applications (NADAs) for injectable iron supplements used in baby pigs from Boehringer Ingelheim Vetmedica, Inc., to Animal Health Pharmaceuticals, LLC. In addition, FDA is taking this opportunity to consolidate injectable iron supplements in a single section of the Code of Federal Regulations (CFR). This is being done to simplify and clarify the regulations.

DATES: This rule is effective March 10, 2008.

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:

Boehringer Ingelheim Vetmedica, Inc., 2621 North Belt Highway, St. Joseph, MO 64506-2002, has informed FDA that it has transferred ownership of, and all rights and interest in, NADA 106-772 for Iron-GARD Injection 100 milligrams/milliliter (mg/mL) and NADA 134-708 for Iron-GARD Injection 200 mg/mL to Animal Health Pharmaceuticals, LLC, 1805 Oak Ridge Circle, suite 101, St. Joseph, MO 64506. Accordingly, the regulations are amended in 21 CFR 522.1182 to reflect these changes of sponsorship.

In addition, FDA is taking this opportunity to consolidate such injectable iron supplements in a single section of the CFR. This is being done to simplify and clarify the regulations.

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 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 part 522 is 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.

§ 522.940 [Removed]

■ 2. Remove § 522.940.

§ 522.1055 [Removed]

■ 3. Remove § 522.1055.

■ 4. Revise § 522.1182 to read as follows:

§ 522.1182 Iron injection.

(a) *Specifications.* See § 510.440 of this chapter. Each milliliter (mL) of solution contains the equivalent of:

(1) 100 milligrams (mg) of elemental iron derived from:

- (i) Ferric hydroxide;
- (ii) Ferric oxide; or
- (iii) Elemental iron.

(2) 200 mg of elemental iron derived from ferric hydroxide.

(b) *Sponsors and conditions of use.* It is used in baby pigs by sponsors in § 510.600(c) of this chapter as follows:

(1) Nos. 059130 and 068718 for use of product described in paragraph (a)(1)(i) of this section as follows:

(i) For prevention of iron deficiency anemia, inject 100 mg (1 mL) by intramuscular injection at 2 to 4 days of age.

(ii) For treatment of iron deficiency anemia, inject 100 mg (1 mL) by intramuscular injection. Dosage may be repeated in approximately 10 days.

(2) No. 000856 for use of product described in paragraph (a)(1)(i) of this section as follows:

(i) For the prevention of anemia due to iron deficiency, administer an initial intramuscular injection of 100 mg at 2 to 4 days of age. Dosage may be repeated in 14 to 21 days.

(ii) For the treatment of anemia due to iron deficiency, administer an intramuscular injection of 200 mg.

(3) Nos. 000061 and 062408 for use of product described in paragraph (a)(1)(i) of this section as follows:

(i) For the prevention of iron deficiency anemia, administer intramuscularly an amount of drug containing 100 to 150 mg of elemental iron to animals from 1 to 3 days of age.

(ii) For the treatment of iron deficiency anemia, administer intramuscularly an amount of drug containing 100 to 200 mg of elemental iron per animal. Dosage may be repeated in 10 days to 2 weeks.

(4) Nos. 051311 and 053501 for use of product described in paragraph (a)(1)(ii) of this section as follows:

(i) For prevention of iron deficiency anemia, administer 1 mL by intramuscular injection at 2 to 5 days of age. Dosage may be repeated at 2 weeks of age.

(ii) For treatment of iron deficiency anemia, administer 1 to 2 mL by

intramuscular injection at 5 to 28 days of age.

(5) No. 053501 for use of product described in paragraph (a)(1)(iii) of this section as follows:

(i) For prevention of anemia due to iron deficiency, administer 100 mg by intramuscular or subcutaneous injection at 2 to 4 days of age.

(ii) For treatment of anemia due to iron deficiency, administer 100 mg by intramuscular or subcutaneous injection up to 4 weeks of age.

(6) Nos. 058005 and 059130 for use of product described in paragraph (a)(1)(iii) of this section as follows:

(i) For prevention of anemia due to iron deficiency, administer 100 mg by intramuscular injection at 2 to 4 days of age.

(ii) For treatment of anemia due to iron deficiency, administer 100 mg by intramuscular injection. Treatment may be repeated in 10 days.

(7) Nos. 059130 and 068718 for use of product described in paragraph (a)(2) of this section as follows:

(i) For prevention of baby pig anemia due to iron deficiency, intramuscularly inject 200 mg of elemental iron (1 mL) at 1 to 3 days of age.

(ii) For treatment of baby pig anemia due to iron deficiency, intramuscularly inject 200 mg of elemental iron at the first sign of anemia.

(8) No. 062408 for use of product described in paragraph (a)(2) of this section as follows:

(i) For prevention of iron deficiency anemia, administer 200 mg intramuscularly on or before 3 days of age.

(ii) For treatment of iron deficiency anemia, administer 200 mg intramuscularly.

§ 522.1183 [Removed]

■ 5. Remove § 522.1183.

Dated: February 27, 2008.

Bernadette Dunham,

Director, Center for Veterinary Medicine.

[FR Doc. E8-4603 Filed 3-7-08; 8:45 am]

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DEPARTMENT OF JUSTICE

United States Parole Commission

28 CFR Part 2

Paroling, Recommitting, and Supervising Federal Prisoners: Prisoners Serving Sentences Under the United States and District of Columbia Codes

AGENCY: United States Parole Commission, Justice.

ACTION: Final rule.

SUMMARY: The Parole Commission's regulation regarding the Commission's transfer treaty function describes the procedures and policies for making release date and supervised release term decisions for prisoners transferred under treaty to the custody of the United States for service of the remainder of their foreign sentences. The Commission is amending this regulation to: add a policy statement that the Commission, like a federal district judge in imposing a sentence, uses the U.S. Sentencing Guidelines as advisory guidelines in making decisions for a transfer treaty prisoner; and eliminate the requirement that a certified court reporter record a transfer treaty hearing.

DATES: Effective date: April 9, 2008.

FOR FURTHER INFORMATION CONTACT: Office of General Counsel, U. S. Parole Commission, 5550 Friendship Blvd., Chevy Chase, Maryland 20815, telephone (301) 492-5959. Questions about this publication are welcome, but inquiries concerning individual cases cannot be answered over the telephone.

SUPPLEMENTARY INFORMATION: The statute at 18 U.S.C. 4106A grants the Parole Commission the authority to set a release date and a term and conditions of supervised release for a prisoner transferred by treaty to the United States for service of a foreign prison term. The Commission is instructed to make these determinations "as though the offender were convicted in a United States district court" of an offense similar to that of the foreign offense. 18 U.S.C. 4106A(b)(1)(A). The Commission's regulation at 28 CFR 2.68 implements the statute, and contains a statement regarding decision-making criteria and the procedures used at a transfer treaty hearing. Commission decisions for transferred prisoners may be appealed to a federal court of appeals. See 18 U.S.C. 4106A(b)(2).

Before the Supreme Court's decision in *United States v. Booker*, 543 U.S. 220 (2005), the Commission, like a federal district judge imposing a criminal sentence, made the decisions for a transfer treaty prisoner in accordance with the U.S. Sentencing Guidelines unless it found good cause for departure. After *Booker*, the Commission considered the sentencing guidelines as advisory guidelines for its decision-making under 18 U.S.C. 4106A. Appellate courts have made it clear that the Commission should apply the holding in *Booker* to transfer treaty prisoner determinations. *Odili v. U.S. Parole Commission*, 474 F.3d 1255 (11th

Cir. 2007); *Austin v. U.S. Parole Commission*, 448 F.3d 197 (2d Cir. 2006). The first amendment to § 2.68 sets forth an explicit policy statement that the Commission makes decisions for transferred offenders under 18 U.S.C. 4106A using the sentencing guidelines as advisory guidelines.

The second amendment eliminates the procedural requirement that a transfer treaty hearing must be recorded by a certified court reporter. When the Commission initially promulgated the regulation on transfer treaty determinations, the Commission decided, as a matter of policy, to adopt some of the procedures that were normally found in sentencing proceedings, e.g., prehearing disclosure of the probation officer's post-sentence report, representation by counsel and the use of a court reporter to record the proceeding.

The Commission did not interpret the statute at section 4106A to require the Commission, an administrative agency, to adopt identical procedures for judicial proceedings in conducting its administrative hearings. In addition to the recording of the hearing by the court reporter, after the transfer treaty hearing, the hearing examiner prepares a written summary of the proceeding for the review of other decision-makers in the case.

For parole release and revocation hearings, Commission hearing examiners use digital recorders to record the hearings verbatim, and dictate hearing summaries that are transcribed for inclusion in the file. Under the amendment, the hearing examiner will follow these same procedures in transfer treaty hearings. The Commission is facing severe budget constraints in the current fiscal year, and this procedural change will be one small step in cutting costs for the agency. If an appeal is filed and a review of the verbatim record is necessary, the Commission will prepare a transcription of the hearing, or provide the digital recording for review by the court.

The Commission is promulgating these amendments as a final rule without the need for public comment because the amended policy statement only implements a legal requirement and the elimination of the court reporter provision changes only a procedural rule.

Implementation

The amended rules will take effect April 9, 2008, and will apply to transfer treaty hearings held on or after the effective date.

Executive Order 12866

The U. S. Parole Commission has determined that the final rule does not constitute a significant rule within the meaning of Executive Order 12866.

Executive Order 13132

The regulation 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. Under Executive Order 13132, the rule does not have sufficient federalism implications requiring a Federalism Assessment.

Regulatory Flexibility Act

The rule will not have a significant economic impact upon a substantial number of small entities within the meaning of the Regulatory Flexibility Act, 5 U.S.C. 605(b).

Unfunded Mandates Reform Act of 1995

The rule will not cause State, local, or tribal governments, or the private sector, to spend \$100,000,000 or more in any one year, and will not significantly or uniquely affect small governments. No action under the Unfunded Mandates Reform Act of 1995 is necessary.

Small Business Regulatory Enforcement Fairness Act of 1996 (Subtitle E—Congressional Review Act)

The rule is not a "major rule" as defined by Section 804 of the Small Business Regulatory Enforcement Fairness Act of 1996 (Subtitle E—Congressional Review Act), now codified at 5 U.S.C. 804(2). The rule will not result in an annual effect on the economy of \$100,000,000 or more; a major increase in costs or prices; or significant adverse effects on the ability of United States-based companies to compete with foreign-based companies. Moreover, this is a rule of agency procedure or practice that does not substantially affect the rights or obligations of non-agency parties, and does not come within the meaning of the term "rule" as used in Section 804(3)(C), now codified at 5 U.S.C. 804(3)(C). Therefore, the reporting requirement of 5 U.S.C. 801 does not apply.

List of Subjects in 28 CFR Part 2

Administrative practice and procedure, Prisoners, Probation and Parole.

The Final Rule

■ Accordingly, the U. S. Parole Commission is adopting the following amendment to 28 CFR part 2.

PART 2—[AMENDED]

1. The authority citation for 28 CFR part 2 continues to read as follows:

Authority: 18 U.S.C. 4203(a)(1) and 4204(a)(6).

■ 2. Amend § 2.68 by revising the first sentence of paragraph (g) and the second sentence of paragraph (h) to read as follows:

§ 2.68 Prisoners transferred pursuant to treaty.

* * * * *

(g) *The decisionmaking criteria.* The Commission will consider the United States Sentencing Guidelines as advisory guidelines in making its decisions, as though the transferee were convicted in a United States District Court of a statutory offense most nearly similar to the offense of which the transferee was convicted in the foreign court. * * *

(h) *Hearing procedures.* * * * Each special transferee hearing shall be recorded by the hearing examiner. * * *

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Dated: February 6, 2008.

Edward F. Reilly, Jr.,

Chairman, U. S. Parole Commission.

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DEPARTMENT OF HOMELAND SECURITY

Coast Guard

33 CFR Part 165

[Docket No. USCG-2008-0083]

RIN 1625-AA00

Safety Zone; Molokini Crater, Maui, HI

AGENCY: Coast Guard, DHS.

ACTION: Temporary final rule; request for comments.

SUMMARY: The Coast Guard is establishing a temporary safety zone around Molokini Crater, in waters south of the island of Maui, HI. This zone is necessary to protect rescue and security assets, air crews, and the general public from hazards associated with an explosive ordnance disposal (EOD) process scheduled to take place on Molokini Crater. Entry of persons or vessels into this safety zone would be

prohibited unless authorized by the Captain of the Port (COTP) Honolulu.

DATES: This rule is effective from March 1, 2008, through March 31, 2008. The Coast Guard will accept comments on this rule through March 31, 2008.

ADDRESSES: You may submit comments and related material, identified by Coast Guard docket number USCG-2008-0083, by any of the four methods listed below. To avoid duplication, please use only one of the following methods:

(1) *Online:* <http://www.regulations.gov>.

(2) *Mail:* Docket Management Facility (M-30), U.S. Department of Transportation, West Building Ground Floor, Room W12-140, 1200 New Jersey Avenue, SE., Washington, DC 20590-0001.

(3) *Hand delivery:* Room W12-140 on the Ground Floor of the West Building, 1200 New Jersey Avenue, SE., Washington, DC 20590, between 9 a.m. and 5 p.m., Monday through Friday, except Federal holidays. The telephone number is 202-366-9329.

(4) *Fax:* 202-493-2251.

Documents indicated in this preamble as being available in the docket are part of docket # USCG-2008-0083 and are available for inspection and copying at U.S. Coast Guard Sector Honolulu between 7 a.m. and 3:30 p.m., Monday through Friday, except Federal holidays.

FOR FURTHER INFORMATION CONTACT: Lieutenant (Junior Grade) Jasmin Parker, U.S. Coast Guard Sector Honolulu at (808) 842-2600.

SUPPLEMENTARY INFORMATION:

Regulatory Information

On January 28, 2008, we published a temporary final rule entitled Safety Zone; Molokini Crater, Maui, HI in the **Federal Register** (73 FR 4695), docket number USCG-2007-0128. We intended that safety zone to safeguard the same EOD that this rule addresses. Adverse weather prevented the EOD from occurring within the effective period of that first safety zone, so this rule is now necessary. We received no comments on the first safety zone. No public meeting was requested, and none was held.

We did not publish a notice of proposed rulemaking (NPRM) for this temporary rule. Under 5 U.S.C. 553(b)(B), the Coast Guard finds that good cause exists for not publishing an NPRM. It would be contrary to the public interest to delay implementing this temporary rule, as any delay might result in damage or injury to the public, vessels, and facilities in the area of Molokini Crater. For the same reasons, under 5 U.S.C. 553(d)(3), the Coast Guard finds that good cause exists for

making this temporary rule effective less than 30 days after publication in the **Federal Register**.

Although the Coast Guard has good cause to issue this temporary rule without first publishing a proposed rule, you are invited to submit post-promulgation comments and related material regarding this rule through March 31, 2008. All comments will be reviewed as they are received. Your comments will assist us in drafting future rules should they be necessary, and may cause us to change this temporary final rule before it expires.

All comments received will be posted, without change, to <http://www.regulations.gov> and will include any personal information you have provided. We have an agreement with the Department of Transportation (DOT) for their Docket Management Facility to process online submissions to Coast Guard dockets. You may review the Department of Transportation's Privacy Act Statement in the **Federal Register** published on April 11, 2000 (65 FR 19477), or you may visit <http://DocketsInfo.dot.gov>.

Background and Purpose

During a site survey on Molokini Crater, surveyors discovered three pieces of unexploded ordnance requiring disposal. The Coast Guard, in consultation with the U.S. Fish and Wildlife Service, the State of Hawaii, the City and County of Maui, the U.S. Navy, and the Federal Aviation Administration, has determined it is necessary to close the area in the vicinity of Molokini Crater in order to minimize the dangers that fragmentation, explosive arcs, and possible fires may present to persons and vessels. Should such an incident occur, or in the event that EOD personnel would require emergency assistance, rescuers must have immediate and unencumbered access to the area. Also, vessels operating in the area might otherwise distract EOD and rescue personnel. The Coast Guard, through this action, intends to promote the safety of personnel, vessels, and facilities in the area of Molokini Crater.

Discussion of Rule

This temporary safety zone encompasses all waters up to and within one nautical mile of the shoreline of Molokini Crater, from the surface of the water to the ocean floor. It is effective from March 1, through March 31, 2008, but will be enforced for periods of 10 hours or less on the effective dates. Unpredictable weather and sea states make a broad date and time range necessary to safely complete