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## DEPARTMENT OF HEALTH AND HUMAN SERVICES

### Food and Drug Administration

#### 21 CFR Part 522

#### Implantation or Injectable Dosage Form New Animal Drugs; Florfenicol Solution

**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 Schering-Plough Animal Health Corp. The supplemental NADA provides for use of florfenicol injectable solution in cattle for treatment of foot rot (bovine interdigital phlegmon).

**EFFECTIVE DATE:** February 26, 1999.

**FOR FURTHER INFORMATION CONTACT:** William T. Flynn, Center for Veterinary Medicine (HFV-133), Food and Drug Administration, 7500 Standish Pl., Rockville, MD 20855, 301-827-7570.

**SUPPLEMENTARY INFORMATION:** Schering-Plough Animal Health Corp., 1095 Morris Ave., P.O. Box 1982, Union, NJ 07083-1982, filed supplemental NADA 141-063 that provides for veterinary prescription use of Nuflor® Injectable Solution (florfenicol) for treatment of cattle for bovine interdigital phlegmon (foot rot, acute interdigital necrobacillosis, infectious pododermatitis) associated with *Fusobacterium necrophorum* and *Bacteroides melaninogenicus*. The supplemental NADA is approved as of January 14, 1999, and the regulations are amended by revising 21 CFR 522.955(d)(1) to reflect the approval. The basis of approval is discussed in the freedom of information summary.

In accordance with the freedom of information provisions of 21 CFR part 20 and 514.11(e)(2)(ii), a summary of safety and effectiveness data and information submitted to support approval of this supplement may be seen in the Dockets Management Branch (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 21 U.S.C. 360b(c)(2)(F)(iii), this supplemental approval for food-producing animals qualifies for 3 years of marketing exclusivity beginning January 14, 1999, because the supplemental application contains substantial evidence of the effectiveness of the drug involved, any studies of animal safety or, in the case of food-producing animals, human food safety studies (other than bioequivalence or residue studies) required for approval and conducted or sponsored by the applicant. Three years marketing exclusivity is limited to use of the drug for treatment of bovine interdigital phlegmon associated with *F. necrophorum* and *B. melaninogenicus*.

The agency has determined under 21 CFR 25.33(d)(5) 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.

#### 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.

2. Section 522.955 is amended by revising paragraph (d)(1)(i)(B) to read as follows:

#### § 522.955 Florfenicol solution.

- \* \* \* \* \*
- (d) \* \* \*
- (1) \* \* \*

(i) \* \* \*

(B) *Indications for use.* For treatment of bovine respiratory disease (BRD) associated with *Pasteurella haemolytica*, *P. multocida*, and *Haemophilus somnus*. For treatment of bovine interdigital phlegmon (foot rot, acute interdigital necrobacillosis, infectious pododermatitis) associated with *Fusobacterium necrophorum* and *Bacteroides melaninogenicus*.

\* \* \* \* \*

Dated: February 1, 1999.

**Andrew J. Beaulieu,**

*Acting Director, Office of New Animal Drug Evaluation, Center for Veterinary Medicine.*

[FR Doc. 99-4762 Filed 2-25-99; 8:45 am]

BILLING CODE 4160-01-F

## DEPARTMENT OF STATE

### 22 CFR Part 95

[Public Notice 2991]

#### Office of the Secretary; Implementation of Torture Convention in Extradition Cases

**AGENCY:** Department of State.

**ACTION:** Final rule.

**SUMMARY:** The Department of State issues these regulations implementing the Convention Against Torture and Other Cruel, Inhuman, or Degrading Treatment or Punishment, as required by section 2242 of the Foreign Affairs Reform and Restructuring Act of 1998, Public Law 105-277.

Article 3 of the Torture Convention prohibits, among other things, the extradition of a person to a State if there are "substantial grounds for believing" that the individual "would be in danger of being subjected to torture" in that State. In its instrument of ratification to the Torture Convention, the United States included an understanding that the Article 3 standard means that the person would be "more likely than not" to be tortured if extradited to that requesting State. This rule records procedures currently in place for considering the question of torture in appropriate cases when the Secretary of State determines whether to sign a warrant surrendering a fugitive for extradition.

**DATES:** *Effective date:* February 26, 1999.

**FOR FURTHER INFORMATION CONTACT:**

Samuel L. Witten, Assistant Legal Officer, Office of Law Enforcement and Intelligence, Office of the Legal Adviser, Department of State, 202-647-7324.

**SUPPLEMENTARY INFORMATION:** This rule implements certain obligations in the context of extradition undertaken by the United States as party to the Convention Against Torture and Other Cruel, Inhuman, or Degrading Treatment or Punishment ("Torture Convention"). Article 3 of the Torture Convention provides that no State party "shall expel, return ('refouler') or extradite a person to another State where there are substantial grounds for believing that he would be in danger of being subjected to torture." Promulgation of the rule is required by section 2242 of the Foreign Affairs Reform and Restructuring Act of 1998, P.L. 105-277, which provides that, not later than 120 days after the date of enactment of that Act, "the heads of the appropriate agencies shall prescribe regulations to implement the obligations of the United States under Article 3 of the [Torture Convention], subject to any reservations, understandings, declarations, and provisos contained in the United States Senate resolution of ratification of the Convention."

Pursuant to sections 3184 and 3186 of Title 18 of the United States Criminal Code, the Secretary of State is the U.S. official responsible for determining whether to surrender a fugitive to a foreign country by means of extradition. In order to implement the obligation assumed by the United States pursuant to Article 3 of the Convention when making this determination, the Department considers, when appropriate, the question of whether a person facing extradition from the U.S. "is more likely than not" to be tortured in the State requesting extradition. These regulations record the already existing procedures followed in this consideration.

Section 95.1 provides definitions for key terms. Subsection (b) defines "torture," incorporating the definition from the Torture Convention and the understandings included in the Instrument of Ratification.

The definition set forth in subparagraph (b)(1) provides that torture includes the intentional infliction of severe pain or suffering on a person, whether physical or mental, for purposes such as obtaining from that person or a third person information or a confession; punishing that person for an act he or a third person has committed or is suspected of having committed; or intimidating or coercing

that person or a third person; or for any reason based on discrimination of any kind.

The definition also limits torture to situations where the treatment is inflicted by or at the instigation of or with the consent or acquiescence of a public official or other person acting in an official capacity. Subparagraph (4) further provides in this respect that torture applies only to acts directed against persons in the offender's custody or physical control; the term "acquiescence" is further defined in subparagraph (5) to mean that the public official, prior to the treatment at issue, must be aware of the activity and thereafter breach his or her legal responsibility to intervene to prevent such activity.

The final sentence in subparagraph (1) provides that torture does not include pain or suffering arising only from, inherent in or incidental to lawful sanctions. The term "lawful sanctions" is further defined in subparagraph (6) which provides that it includes judicially imposed sanctions and other enforcement actions authorized by law, provided that such sanctions or actions were not adopted in order to defeat the object and purpose of the Convention to prohibit torture.

Subparagraph (b)(2) requires that the act be specifically intended to inflict severe physical or mental pain or suffering and provides that mental pain or suffering refers to prolonged mental harm caused by or resulting from certain enumerated actions. Subparagraph (3) provides that noncompliance with applicable legal procedural standards does not per se constitute torture.

Subparagraph (7) makes clear that the term "torture" refers to an extreme form of cruel and inhuman treatment. As reflected in the title to the Convention, torture does not include lesser forms of cruel, inhuman or degrading treatment or punishment.

On the standard established in Article 3 of the Torture Convention, paragraph (c) records the U.S. understanding from the Instrument of Ratification that "[w]here there are substantial grounds for believing that [a fugitive] would be in danger of being subjected to torture" means "if it is more likely than not that the fugitive would be tortured."

Paragraph (d) reflects the fact that all decisions on extradition are made by the Secretary (including an Acting Secretary in the Secretary's absence) or the Deputy Secretary, by delegation. For ease of reference, the term Secretary as used in the rule includes the Deputy Secretary.

Subsection 95.2 entitled "Application" sets forth the relevant

provisions of the Convention and describes the Secretary's authority under 18 U.S.C. 3184 and 3186 to determine whether to surrender a fugitive for extradition to a foreign country. It also explains that it is in the context of making this decision that the Department considers the question of likelihood that a given individual will be tortured.

Subsection 95.3 reflects the statutory framework in which decisions on extradition are presented to the Secretary only after a fugitive has been found extraditable by a United States judicial officer. This subsection explains that appropriate policy and legal offices in the Department review and analyze relevant information in cases where allegations relating to torture are made or the issue is otherwise brought to the Department's attention in preparing a recommendation to the Secretary as to whether or not to sign the surrender warrant. Once this analysis is complete, the Secretary may decide to surrender the fugitive to the requesting State, to deny surrender of the fugitive, or to surrender the fugitive subject to conditions.

Subsection 95.4 sets forth the fact that decisions of the Secretary concerning surrender of fugitives for extradition are matters of executive discretion not subject to judicial review. The statute requiring publication of this rule also provides that, notwithstanding any other provision of law, no court shall have jurisdiction to review these regulations, and nothing in that statute shall be construed as providing any court jurisdiction to consider or review claims raised under the Torture Convention or that statute, or any other determination made with respect to the application of the policy set forth in that statute. The statute provides for two exceptions to this lack of jurisdiction, neither of which is relevant here. The first is for review of a final order of removal pursuant to section 22 of the Immigration and Nationality Act, which is not applicable to extradition. The second allows for the possibility that the regulations themselves might provide for review; this rule does not do so.

This rule involves a foreign affairs function of the United States and thus is excluded from the procedures of Executive Order 12866 (58 FR 51735) and 5 U.S.C. 553 and 554, but has been reviewed internally by the Department to ensure consistency with the purposes thereof.

**List of Subjects in 22 CFR Part 95**

Extradition, Torture Treaties

For the reasons set out in the preamble, 22 CFR part 95 is added to subchapter J as follows:

## **PART 95—IMPLEMENTATION OF TORTURE CONVENTION IN EXTRADITION CASES**

Sec.

95.1 Definitions.

95.2 Application.

95.3 Procedures.

95.4 Review and construction.

**Authority:** 18 U.S.C. 3181 *et seq.*; Convention Against Torture and Other Cruel, Inhuman or Degrading Treatment or Punishment.

### **§ 95.1. Definitions.**

(a) *Convention* means the United Nations Convention Against Torture and Other Forms of Cruel, Inhuman or Degrading Treatment or Punishment, done at New York on December 10, 1984, entered into force for the United States on November 10, 1994. Definitions provided below in paragraphs (b) and (c) of this section reflect the language of the Convention and understandings set forth in the United States instrument of ratification to the Convention.

(b) *Torture* means:

(1) Any act by which severe pain or suffering, whether physical or mental, is intentionally inflicted on a person for such purposes as obtaining from him or a third person information or a confession, punishing him for an act he or a third person has committed or is suspected of having committed, or intimidating or coercing him or a third person, or for any reason based on discrimination of any kind, when such pain or suffering is inflicted by or at the instigation of or with the consent or acquiescence of a public official or other person acting in an official capacity. It does not include pain or suffering arising only from, inherent in or incidental to lawful sanctions.

(2) In order to constitute torture, an act must be specifically intended to inflict severe physical or mental pain or suffering and that mental pain or suffering refers to prolonged mental harm caused by or resulting from:

- (i) The intentional infliction or threatened infliction of severe physical pain or suffering;
- (ii) The administration or application, or threatened administration or application, of mind altering substances or other procedures calculated to disrupt profoundly the senses or the personality;
- (iii) The threat of imminent death; or
- (iv) The threat that another person will imminently be subjected to death, severe physical pain or suffering, or the

administration or application of mind altering substances or other procedures calculated to disrupt profoundly the senses or personality.

(3) Noncompliance with applicable legal procedural standards does not per se constitute torture.

(4) This definition of torture applies only to acts directed against persons in the offender's custody or physical control.

(5) The term "acquiescence" as used in this definition requires that the public official, prior to the activity constituting torture, have awareness of such activity and thereafter breach his or her legal responsibility to intervene to prevent such activity.

(6) The term "lawful sanctions" as used in this definition includes judicially imposed sanctions and other enforcement actions authorized by law, provided that such sanctions or actions were not adopted in order to defeat the object and purpose of the Convention to prohibit torture.

(7) Torture is an extreme form of cruel and inhuman treatment and does not include lesser forms of cruel, inhuman or degrading treatment or punishment.

(c) *Where there are substantial grounds for believing that [a fugitive] would be in danger of being subjected to torture* means if it is more likely than not that the fugitive would be tortured.

(d) *Secretary* means Secretary of State and includes, for purposes of this rule, the Deputy Secretary of State, by delegation.

### **§ 95.2 Application.**

(a) Article 3 of the Convention imposes on the parties certain obligations with respect to extradition. That Article provides as follows:

(1) No State party shall expel, return ("refouler") or extradite a person to another State where there are substantial grounds for believing that he would be in danger of being subjected to torture.

(2) For the purpose of determining whether there are such grounds, the competent authorities shall take into account all relevant considerations including, where applicable, the existence in the State concerned of a consistent pattern of gross, flagrant or mass violations of human rights.

(b) Pursuant to sections 3184 and 3186 of Title 18 of the United States Criminal Code, the Secretary is the U.S. official responsible for determining whether to surrender a fugitive to a foreign country by means of extradition. In order to implement the obligation assumed by the United States pursuant to Article 3 of the Convention, the Department considers the question of

whether a person facing extradition from the U.S. "is more likely than not" to be tortured in the State requesting extradition when appropriate in making this determination.

### **§ 95.3. Procedures.**

(a) Decisions on extradition are presented to the Secretary only after a fugitive has been found extraditable by a United States judicial officer. In each case where allegations relating to torture are made or the issue is otherwise brought to the Department's attention, appropriate policy and legal offices review and analyze information relevant to the case in preparing a recommendation to the Secretary as to whether or not to sign the surrender warrant.

(b) Based on the resulting analysis of relevant information, the Secretary may decide to surrender the fugitive to the requesting State, to deny surrender of the fugitive, or to surrender the fugitive subject to conditions.

### **§ 95.4 Review and construction.**

Decisions of the Secretary concerning surrender of fugitives for extradition are matters of executive discretion not subject to judicial review. Furthermore, pursuant to section 2242(d) of the Foreign Affairs Reform and Restructuring Act of 1998, P.L. 105-277, notwithstanding any other provision of law, no court shall have jurisdiction to review these regulations, and nothing in section 2242 shall be construed as providing any court jurisdiction to consider or review claims raised under the Convention or section 2242, or any other determination made with respect to the application of the policy set forth in section 2242(a), except as part of the review of a final order of removal pursuant to section 242 of the Immigration and Nationality Act (8 U.S.C. 1252), which is not applicable to extradition proceedings.

Dated: February 18, 1999.

**Strobe Talbott,**

*Deputy Secretary of State.*

[FR Doc. 99-4560 Filed 2-25-99; 8:45 am]

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## **ENVIRONMENTAL PROTECTION AGENCY**

### **40 CFR Part 261**

[SW-FRL-6305-2]

### **Hazardous Waste Management System; Identification and Listing of Hazardous Waste; Final Exclusion**

**AGENCY:** Environmental Protection Agency (EPA).