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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*.

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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]

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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.