DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

21 CFR Part 522

Implantation or Injectable Dosage Form New Animal Drugs; Propofol

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 new animal drug application (NADA) filed by Abbott Laboratories. The NADA provides for veterinary prescription use of propofol emulsion for intravenous injection in dogs as an anesthetic.

EFFECTIVE DATE: May 4, 1998.

FOR FURTHER INFORMATION CONTACT: Melanie R. Berson, Center ForVeterinary Medicine (HFV–110), Food and Drug Administration, 7500 Standish Pl., Rockville, MD 20855, 301–594–1612.

SUPPLEMENTARY INFORMATION: Abbott Laboratories, 1401 Sheridan Rd., North Chicago, IL 60064–4000, filed NADA 141–098 that provides for veterinary prescription use of PropoFlo® (propofol) emulsion for intravenous injection in dogs for induction of anesthesia, maintenance of anesthesia, or induction of anesthesia where maintenance is provided by inhalation anesthetic. The NADA is approved as of March 13, 1998, and the regulations are amended in 21 CFR 522.2005(b) 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 application may be seen in the Dockets Management Branch (HFA–305), Food and Drug Administration, 12420 Parklawn Dr., rm. 1–23, Rockville, MD 20857, between 9 a.m. and 4 p.m., Monday through Friday.

Under section 512(c)(2)(F)(ii) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 360b(c)(2)(F)(ii), this approval for nonfood-producing animals qualifies for 3 years of marketing exclusivity beginning March 13, 1998, because the application contains substantial evidence of the effectiveness of the drug involved and studies of animal safety required for approval and conducted or sponsored by the applicant.

The agency has determined under 21 CFR 25.33(d)(1) 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.

§ 522.2005 [Amended]

2. Section 522.2005 *Propofol injection* is amended in paragraph (b) by removing ''No. 000061'' and adding in its place ''Nos. 000061 and 000074''.

Dated: April 22, 1998.

Stephen F. Sundlof,

Director, Center for Veterinary Medicine.

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

21 CFR Part 558

New Animal Drugs For Use In Animal Feeds; Monensin

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 two supplemental new animal drug applications (NADA's) filed by Elanco Animal Health, Division of Eli Lilly and Co. The supplemental NADA's provide a revised specification for monensin bulk drug substance used to make monensin Type A medicated articles.

EFFECTIVE DATE: May 4, 1998.

FOR FURTHER INFORMATION CONTACT: Mary G. Leadbetter, Center for Veterinary Medicine (HFV–142), Food and Drug Administration, 7500 Standish Pl., Rockville, MD 20855, 301–594–1662.

SUPPLEMENTARY INFORMATION: Elanco Animal Health, Division of Eli Lilly and Co., Lilly Corporate Center, Indianapolis, IN 46285, is the sponsor of NADA 38–878 that provides for use of monensin Type A medicated articles to make monensin Type C medicated feeds for chickens, turkeys, and quail, and NADA 95–735 that provides for use of monensin Type A medicated articles to make monensin Type B and C medicated feeds for cattle and goats. Elanco filed supplemental NADA's that provide revised assay information used in checking the specifications of the monensin bulk drug substance used in Type A medicated articles. The supplemental NADA's were approved as of March 17, 1997, and the regulations are amended in 21 CFR 558.355(a) to reflect the approval.

Approval of these supplements did not require a freedom of information summary because the approvals concern a change in specifications of the monensin bulk drug substance. This change does not affect the product's safety or effectiveness.

The agency has determined under 21 CFR 25.33(a)(3) 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 558

Animal drugs, Animal feeds.

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 558 is amended as follows:

PART 558—NEW ANIMAL DRUGS FOR USE IN ANIMAL FEEDS

1. The authority citation for 21 CFR part 558 continues to read as follows:

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

§ 558.355 [Amended]

2. Section 558.355 *Monensin* is amended in paragraph (a) after the parenthetical phrase by removing the period at the end of the second sentence, and by adding the phrase '', or, using High Performance Liquid Chromatography, the factor distribution of monensin Factor A or B is calculated as the percentage of total biopotency of all peaks.''