Drug labeler code	Firm Name and address
* * *	* * * *
060951	Endo Pharmaceuticals, Inc., 223 Wilmington West Chester Pike, Chadds Ford, PA 19317.
* * *	* * * *

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.

§ 522.1462 [Amended]

4. Section 522.1462 *Naloxone hydrochloride injection* is amended in paragraph (b) by removing ''000056'' and adding in its place ''060951''.

§ 522.1642 [Amended]

5. Section 522.1642 *Oxymorphone hydrochloride injection* is amended in paragraph (b) by removing ''000056'' and adding in its place ''060951''.

Dated: January 28, 1998.

Andrew J. Beaulieau,

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

[FR Doc. 98–3902 Filed 2–13–98; 8:45 am]

BILLING CODE 4160–01–F

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

21 CFR Part 522

Implantation or Injectable Dosage Form New Animal Drugs; Tilmicosin Phosphate Injection

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 Elanco Animal Health, A Division of Eli Lilly and Co. The supplemental NADA provides for removal of the label warnings concerning subcutaneous use of tilmicosin phosphate injection in preruminating (veal) calves. Removal of the warning is based on a tissue residue depletion study in calves less than 1 month of age.

EFFECTIVE DATE: February 17, 1998.

FOR FURTHER INFORMATION CONTACT: Naba K. Das, Center for Veterinary Medicine (HFV–133), Food and Drug Administration, 7500 Standish Pl., Rockville, MD 20855, 301–594–1659.

SUPPLEMENTARY INFORMATION: Elanco Animal Health, A Division of Eli Lilly and Co., Lilly Corporate Center, Indianapolis, IN 46285, is sponsor of NADA 140–929 that provides for the subcutaneous use of Micotil® 300 (tilmicosin phosphate) Injection for the treatment of cattle with bovine respiratory disease (BRD) associated with *Pasteurella haemolytica*. The drug is limited to use by or on the order of a licensed veterinarian. The firm filed a supplemental NADA providing for removal of the warning statements regarding use of the product in preruminating (veal) calves. The supplemental NADA is approved as of December 23, 1997, and the regulations are amended in 21 CFR 522.2471(d)(1)(iii) 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.

The agency has determined under 21 CFR 25.33(a)(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.

§ 522.2471 [Amended]

2. Section 522.2471 *Tilmicosin phosphate injection* is amended in paragraph (d)(1)(iii) by removing the 13th and 14th sentences.

Dated: January 30, 1998.

Stephen F. Sundlof,

Director, Center for Veterinary Medicine.

[FR Doc. 98–3897 Filed 2–13–98; 8:45 am]

BILLING CODE 4160–01–F

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

21 CFR Parts 522 and 556

Implantation or Injectable Dosage Form New Animal Drugs; Ivermectin

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 Merial Ltd. The supplemental NADA provides for use of 1 percent ivermectin injection for treatment and control of grubs in American bison and a tolerance for residues of ivermectin and its metabolites in edible tissues.

EFFECTIVE DATE: February 17, 1998.

FOR FURTHER INFORMATION CONTACT: Estella Z. Jones, Center for Veterinary Medicine (HFV–135), Food and Drug Administration, 7500 Standish Pl., Rockville, MD 20855, 301–594–1643.

SUPPLEMENTARY INFORMATION: Merial Ltd., 2100 Ronson Rd., Ilesin, NJ 08830–3077, is sponsor of NADA 128–409, which provides for the use of Ivomec® Injection (1 percent ivermectin) for cattle, swine, and reindeer. The firm filed a supplement that provides for use

of 1 percent ivermectin injection for treatment and control of grubs (*Hypoderma bovis*) in American bison. The supplemental NADA is approved as of December 19, 1997, and the regulations are amended in 21 CFR 522.1192 in paragraph (a)(2) and by adding new paragraph (d)(6) to reflect the approval. The basis of approval is discussed in the freedom of information summary.

A tolerance for residues of ivermectin in the edible tissues of bison has not previously been established. At this time, a tolerance for residues of ivermectin and its metabolites in American bison is established in § 556.344 (21 CFR 556.344). Also, § 556.344 is revised to reflect a newer format.

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.

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

21 CFR Part 522

Animal drugs.

21 CFR Part 556

Animal drugs, Foods.

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 522 and 556 are 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 522.1192 is amended in paragraph (a)(2) by revising the heading and by adding new paragraph (d)(6) to read as follows:

§ 522.1192 Ivermectin injection.

(a) * * *

(2) *Cattle, reindeer, swine, and American bison.* * * *

(d) * * *

(6) *American bison*—(i) *Amount.* 200 micrograms per kilogram (10 milligrams per 110 pounds) of body weight.

(ii) *Indications for use.* It is used in American bison for the treatment and control of grubs (*Hypoderma bovis*).

(iii) *Limitations.* For subcutaneous use. Do not slaughter within 56 days of last treatment. Consult your veterinarian for assistance in the diagnosis, treatment, and control of parasitism.

PART 556—TOLERANCES FOR RESIDUES OF NEW ANIMAL DRUGS IN FOOD

3. The authority citation for 21 CFR part 556 continues to read as follows:

Authority: 21 U.S.C. 342, 360b, 371.

4. Section 556.344 is revised to read as follows:

§ 556.344 Ivermectin.

The marker residue used to monitor the total residues of ivermectin and its metabolites in American bison is 22,23-dihydroavermectin B_{1a}. The target tissue is liver. A tolerance is established for 22,23-dihydroavermectin B_{1a} in liver as follows:

(a) *Cattle*: 100 parts per billion.
(b) *Swine*: 20 parts per billion.
(c) *Sheep*: 30 parts per billion.
(d) *Reindeer*: 15 parts per billion.
(e) *American bison*. 15 parts per billion.

Dated: January 30, 1998.

Stephen F. Sundlof,

Director, Center for Veterinary Medicine.

[FR Doc. 98–3896 Filed 2–13–98; 8:45 am]

BILLING CODE 4160–01–F

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

21 CFR Part 529

Certain Other Dosage Form New Animal Drugs; Tricaine Methanesulfonate

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 an abbreviated new animal drug application (ANADA) filed by Western Chemical, Inc. The ANADA provides for the use of tricaine methanesulfonate in the water of fish and other cold-blooded aquatic animals for temporary immobilization.

EFFECTIVE DATE: February 17, 1998

FOR FURTHER INFORMATION CONTACT: Lonnie W. Luther, Center for Veterinary Medicine (HFV–102), Food and Drug Administration, 7500 Standish Pl., Rockville, MD 20855, 301–827–0209.

SUPPLEMENTARY INFORMATION: Western Chemical, Inc., 1269 Lattimore Rd., Ferndale, WA 98248, is the sponsor of ANADA 200–226, which provides for the use of tricaine methanesulfonate powder to be mixed in the water of fish and other cold-blooded animals to be used for anesthesia and tranquilization. Western Chemical's ANADA 200–226 is approved as a generic copy of Argent Chemical Laboratories' NADA 42–427 Finquel®. The ANADA is approved as of November 21, 1997, and the regulations are amended in 21 CFR 529.2503(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. to 4 p.m., Monday through Friday.

The agency has determined under 21 CFR 25.33(a)(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 529

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 529 is amended as follows:

PART 529—CERTAIN OTHER DOSAGE FORM NEW ANIMAL DRUGS

1. The authority citation for 21 CFR part 529 continues to read as follows:

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

§ 529.2503 [Amended]

2. Section 529.2503 *Tricaine methanesulfonate* is amended in paragraph (b) by removing ''No.