

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

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21 CFR Parts 510 and 522

Implantation or Injectable Dosage Form New Animal Drugs; Oxytetracycline 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 an abbreviated new animal drug application (ANADA) filed by Pliva d.d. The ANADA provides for intramuscular use of oxytetracycline injection in swine and intramuscular and intravenous use in cattle for treatment of bacterial infections susceptible to oxytetracycline.

EFFECTIVE DATE: (*Insert date of publication in the Federal Register.*)

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: Pliva d.d., Ulica grada Vukovara 49, 10000 Zagreb, Croatia, filed ANADA 200-232 that provides for the use of Geomycin 200 (oxytetracycline injection) for treatment of diseases caused by oxytetracycline susceptible organisms as follows: Intramuscular use in swine for treatment of bacterial enteritis (scours, colibacillosis) caused by *Escherichia coli*, pneumonia caused by *Pasteurella multocida*, and leptospirosis caused by *Leptospira pomona*, and in sows as an aid in the control of infectious enteritis (baby pig scours, colibacillosis) in suckling pigs caused by *E. coli*; intramuscular and intravenous use in cattle for the treatment of bacterial pneumonia and shipping fever complex associated with *Pasteurella* spp. and *Haemophilus* spp., infectious bovine keratoconjunctivitis (pinkeye) caused by *Moraxella bovis*, foot rot and diphtheria caused by *Fusobacterium necrophorum*, bacterial enteritis (scours) caused by *E. coli*, wooden

tongue caused by *Actinobacillus lignieresii*, leptospirosis caused by *L. pomona*, and wound infections and acute metritis caused by strains of streptococcal and staphylococcal organisms.

Approval of Pliva d.d.'s ANADA 200–232 for oxytetracycline injection is as a generic copy of Pfizer, Inc.'s NADA 113–232 for Liquamycin® LA–200® (oxytetracycline injection). ANADA 200–232 is approved as of February 12, 1999, and the regulations are amended in 21 CFR 522.1660(b) and (d) to reflect the approval. The basis of approval is discussed in the freedom of information summary.

Because Pliva d.d. has not been previously listed in the animal drug regulations as the sponsor of an approved application, 21 CFR 510.600 is amended in paragraphs (c)(1) and (c)(2) to add entries for the firm.

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, 5630 Fishers Lane, rm. 1061, Rockville, MD 20852, 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 510

Administrative practices and procedures, Animal drugs, Labeling, Reporting and recordkeeping requirements.

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 parts 510 and 522 are amended as follows:

PART 510—NEW ANIMAL DRUGS

1. The authority citation for 21 CFR part 510 continues to read as follows:

Authority: 21 U.S.C. 321, 331, 351, 352, 353, 360b, 371, 379e.

2. Section 510.600 is amended in the table in paragraph (c)(1) by alphabetically adding an entry for “Pliva d.d.” and in the table in paragraph (c)(2) by numerically adding an entry for “011722” to read as follows:

§ 510.600 Names, addresses, and drug labeler codes of sponsors of approved applications.

* * * * *

(c) * * *

(1) * * *

| Firm name and address | Drug labeler code |
|--|-------------------|
| Pliva d.d., Ulica grada Vukovara 49, 10000 Zagreb, Croatia | 011722 |

(2) * * *

| Drug labeler code | Firm name and address |
|-------------------|--|
| 011722 | Pliva d.d., Ulica grada Vukovara 49, 10000 Zagreb, Croatia |

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.

§ 522.1660 [Amended]

2. Section 522.1660 *Oxytetracycline injection* is amended in paragraphs (b) and (d)(2)(iii) by adding the number "011722," after "000069".

Dated: 21 April 99
April 21, 1999



George A. Mitchell
Acting Director
Center for Veterinary Medicine

[FR Doc. 99-???? Filed ??-??-99; 8:45 am]

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