

DEPARTMENT OF HEALTH AND HUMAN RESOURCES

Display Date	9.29.98
Publication Date	9.29.98
Certifier	[Signature]

Food and Drug Administration

21 CFR Parts 522 and 556

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 a supplemental new animal drug application (NADA) filed by Pfizer, Inc. The supplemental NADA provides for intramuscular, intravenous, and subcutaneous use of oxytetracycline injection in lactating dairy cattle in addition to use in beef cattle, nonlactating dairy cattle, calves including preruminating (veal) calves, and swine.

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

FOR FURTHER INFORMATION CONTACT: William T. Flynn, Center for Veterinary Medicine (HFV-133), Food and Drug Administration, 7500 Standish Pl., Rockville, MD 20855, 301-594-1652.

SUPPLEMENTARY INFORMATION: Pfizer, Inc., 235 East 42d St., New York, NY 10017, filed supplemental NADA 113-232 that provides for intramuscular, intravenous, and subcutaneous use of Liqumycin® LA-200® (oxytetracycline injection) for treatment of lactating dairy cattle in addition to treatment of beef cattle, nonlactating dairy cattle, calves including preruminating (veal) calves, and swine as in § 522.1660(d)(1) and (d)(2) (21 CFR 522.1660(d)(1) and (d)(2)). The supplemental NADA is approved as of July 21, 1998, and the regulations in § 522.1660(d)(1) are amended to reflect the approval. The basis of approval is discussed in the freedom of information summary.

Also § 522.1660(c) is revised to cross-reference the tolerances for oxytetracycline in 21 CFR 556.500. In addition, the tolerances are amended to provide for an acceptable daily intake (ADI) (see 61 FR 67453, December 23, 1996) and for a tolerance for residues in milk. Because the December 23, 1996, publication amends tolerances for all tetracyclines (chlortetracycline, oxytetracycline, and tetracycline), this document also amends 21 CFR 556.150 and 556.720 to reflect the tetracycline ADI.

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 this approval 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 section 512(c)(2)(F)(iii) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 360b(c)(2)(F)(iii)), this supplemental approval for food-producing animals qualifies for 3 years of marketing exclusivity beginning July 21, 1998, because the supplement contains substantial evidence of 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 of the supplement and conducted or sponsored by the applicant. The 3 years of marketing exclusivity applies only to use of this drug in lactating dairy cattle for the labeled indications for which the supplemental application is approved.

The agency has carefully considered the potential environmental effects of this action. FDA has concluded that the action will not have a significant impact on the human environment, and that an environmental impact statement is not required. The agency's finding of no significant impact and the evidence supporting that finding, contained in an environmental assessment, may be seen in the Dockets Management Branch (address above) between 9 a.m. and 4 p.m., Monday through Friday.

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 522.1660 is amended by adding paragraph (c), by revising the heading in paragraph (d)(1) and the two last sentences in paragraph (d)(1)(iii) to read as follows:

§ 522.1660 Oxytetracycline injection.

* * * * *

(c) *Related tolerances.* See § 556.500 of this chapter.

(d) * * *

(1) *Beef cattle, dairy cattle, and calves including preruminating (veal) calves.* * * *

(iii) * * * For sponsors 000010, 053389, 059130, and 061623: Not for use in lactating dairy cattle. For sponsor 000069: Milk taken from animals during treatment and for 96 hours after the last treatment must not be used for food; use subcutaneously with a maximum of 10 milliliters per injection site in adult cattle as well as intramuscularly and intravenously.

* * * * *

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 556.150 is revised to read as follows:

§ 556.150 Chlortetracycline.

(a) *Acceptable daily intake (ADI)*. The ADI for total residues of tetracyclines including chlortetracycline, oxytetracycline, and tetracycline is 25 micrograms per kilogram of body weight per day.

(b) *Beef cattle, nonlactating dairy cows, calves, swine, sheep, chickens, turkeys, and ducks.*

Tolerances are established for the sum of residues of the tetracyclines including chlortetracycline, oxytetracycline, and tetracycline, in tissues as follows:

- (1) 2 parts per million (ppm) in muscle.
- (2) 6 ppm in liver.
- (3) 12 ppm in fat and kidney.

5. Section 556.500 is revised to read as follows:

§ 556.500 Oxytetracycline.

(a) *Acceptable daily intake (ADI)*. The ADI for total residues of tetracyclines including chlortetracycline, oxytetracycline, and tetracycline is 25 micrograms per kilogram of body weight per day.

(b) *Beef cattle, dairy cattle, calves, swine, sheep, chickens, turkeys, catfish, lobster, and salmonids.* Tolerances are established for the sum of residues of the tetracyclines including chlortetracycline, oxytetracycline, and tetracycline, in tissues and milk as follows:

- (1) 2 parts per million (ppm) in muscle.
- (2) 6 ppm in liver.
- (3) 12 ppm in fat and kidney.

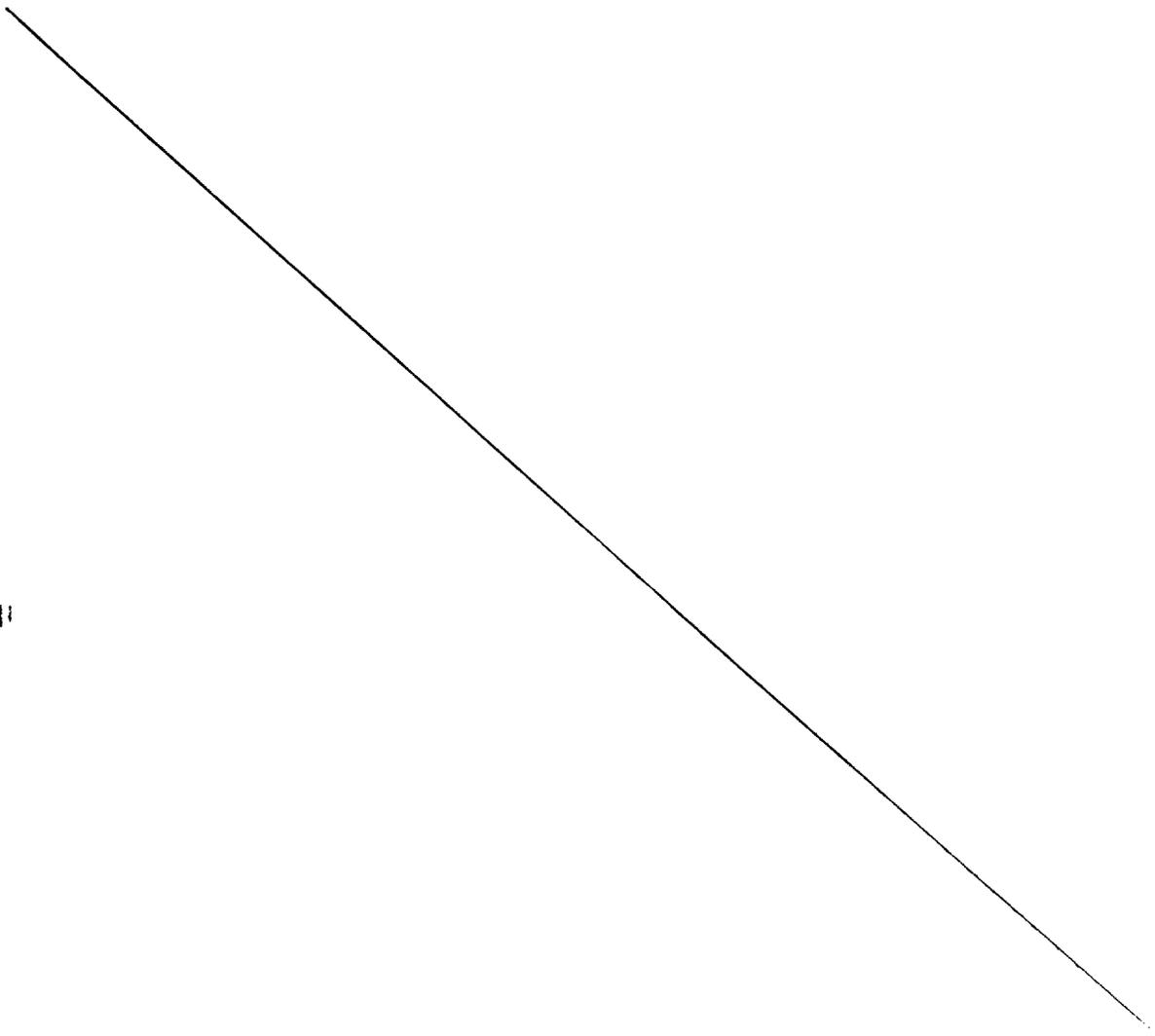
(4) 0.3 ppm in milk.

6. Section 556.720 is revised to read as follows:

§ 556.720 Tetracycline.

(a) *Acceptable daily intake (ADI)*. The ADI for total residues of tetracyclines including chlortetracycline, oxytetracycline, and tetracycline is 25 micrograms per kilogram of body weight per day.

(b) *Calves, swine, sheep, chickens, and turkeys*. Tolerances are established for the sum of residues of the tetracyclines including chlortetracycline, oxytetracycline, and tetracycline, in tissues as follows:



(1) 2 parts per million (ppm) in muscle.

(2) 6 ppm in liver.

(3) 12 ppm in fat and kidney.

Dated: Sept 8 1998
September 8, 1998

Margaret Ann Miller
Margaret Ann Miller
Acting Director
Office of New Animal Drug Evaluation
Center for Veterinary Medicine

[FR Doc. 98-???? Filed ??-??-98; 8:45 am]

BILLING CODE 4160-01-F

CERTIFIED TO BE A TRUE COPY OF THE ORIGINAL

