

Dated: December 12, 1996.
 Stephen F. Sundlof,
Director, Center for Veterinary Medicine.
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21 CFR Part 556

Tolerances for Residues of New Animal Drugs in Food; Oxytetracycline

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 Animal Health. The supplemental NADA provides for revised tolerances for residues of oxytetracycline in edible tissues.

EFFECTIVE DATE: December 23, 1996.

FOR FURTHER INFORMATION CONTACT: Dianne T. McRae, Center for Veterinary Medicine (HFV-102), Food and Drug Administration, 7500 Standish Pl., Rockville, MD 20855, 301-594-1623.

SUPPLEMENTARY INFORMATION: Pfizer, Inc., 235 East 42d St., New York, NY 10017, is sponsor of NADA 113-232, which provides for the use of Liqueamycin® LA-200® (oxytetracycline) sterile suspension for injection in beef cattle, beef calves, nonlactating dairy cattle, dairy calves, and swine for the indications for use as in 21 CFR 522.1662a.

The supplement provides for a change in the tolerance levels specified in § 556.500 (21 CFR 556.500) for oxytetracycline residues in edible tissues of cattle, beef calves, nonlactating dairy cattle, dairy calves, and swine. Review of the supplement involved a reevaluation of the data and information in the original approval using criteria in the "Human Food Safety Guideline for Antimicrobial Drugs." The supplement is approved as of May 31, 1996, and the regulation in § 556.500 is revised to reflect the approval.

In evaluating this supplement, FDA's Center for Veterinary Medicine (CVM) considered the cumulative effects of all tetracyclines approved for use as new animal drugs because all tetracycline drugs have a similar end point of toxicological concern, i.e., an effect on the intestinal microflora. Based on the cumulative effect, the acceptable daily intake (ADI) was established for total tetracycline activity at 1.5 milligrams

per person per day. Forty percent of that ADI is being assigned to edible tissues and 60 percent of the ADI is reserved for milk. Based on this evaluation, CVM has established the revised tolerance for residues of all tetracycline new animal drugs (including chlortetracycline, oxytetracycline, and tetracycline) to 2 parts per million (ppm) in muscle, 6 ppm in liver, and 12 ppm in fat and kidney. As such, § 556.500 has been amended to provide that for oxytetracycline, tolerances are established for the sum of residues of the tetracyclines including chlortetracycline, oxytetracycline, and tetracycline at 2 ppm in muscle, 6 ppm in liver, and 12 ppm in kidney and fat.

Although approval of Pfizer's supplement did not require submission of new safety or effectiveness data, a summary of data and information used to support approval of this supplement as described in 21 CFR part 20 and 21 CFR 514.11(e)(2)(ii) 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)(iii) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 360b(c)(2)(F)(iii)), this supplement does not qualify for marketing exclusivity because the supplement does not contain reports of new clinical or field investigations (other than bioequivalence or residue studies) or human food safety studies (other than bioequivalence or residue studies) essential to the approval and conducted or sponsored by the applicant.

FDA has determined under 21 CFR 25.24(d)(1)(i) 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.

Because the revised tolerance approved in this supplement for oxytetracycline is based on the total tetracycline activity, it, in effect, revises the tolerances for chlortetracycline and tetracycline. Therefore, FDA has also revised 21 CFR 556.150 (chlortetracycline) and 556.720 (tetracycline) to be consistent with the new tolerance for oxytetracycline based on the total tetracycline activity.

List of Subjects in 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 part 556 is amended as follows:

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

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

Authority: Secs. 402, 512, 701 of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 342, 360b, 371).

2. Section 556.150 is revised to read as follows:

§ 556.150 Chlortetracycline.

Tolerances are established for the sum of residues of the tetracyclines including chlortetracycline, oxytetracycline, and tetracycline, in tissues of beef cattle, nonlactating dairy cows, calves, swine, sheep, chickens, turkeys, and ducks, as follows:

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

(b) 6 ppm in liver.

(c) 12 ppm in fat and kidney.

3. Section 556.500 is revised to read as follows:

§ 556.500 Oxytetracycline.

Tolerances are established for the sum of residues of the tetracyclines including chlortetracycline, oxytetracycline, and tetracycline, in tissues of cattle, beef calves, nonlactating dairy cattle, dairy calves, swine, sheep, chickens, turkeys, catfish, lobsters, and salmonids, as follows:

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

(b) 6 ppm in liver.

(c) 12 ppm in fat and kidney.

4. Section 556.720 is revised to read as follows:

§ 556.720 Tetracycline.

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

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

(b) 6 ppm in liver.

(c) 12 ppm in fat and kidney.

Dated: December 9, 1996.
 Stephen F. Sundlof,
Director, Center for Veterinary Medicine.
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