

DMB

Display Date	8-5-99
Publication Date	8-6-99
Certifier	S. N. Reese

DEPARTMENT OF HEALTH AND HUMAN RESOURCES

Food and Drug Administration

21 CFR Part 522

Implantation and Injectable Dosage Form New Animal Drugs; Oxytetracycline Injection; Technical Amendment

AGENCY: Food and Drug Administration, HHS.

ACTION: Final rule; technical amendment.

SUMMARY: The Food and Drug Administration (FDA) is amending the animal drug regulations to include a limitation in the approval of Pliva d.d.'s abbreviated new animal drug application (ANADA). The regulation did not state that use of Pliva d.d.'s oxytetracycline injection in cattle is limited to use in nonlactating dairy cattle. At this time, the regulation is amended to reflect the limitation.

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: In the **Federal Register** of April 30, 1999 (64 FR 23186), FDA published a document reflecting approval of Pliva d.d.'s ANADA 200-232 for use of Geomycin 200 (oxytetracycline injection) in cattle and swine. The amendment to the regulation did not state that the product is not for use in lactating dairy cattle. At this time, the regulations in 21 CFR 522.1660(d)(1)(iii) are amended to reflect the limitation in the approval.

This rule does not meet the definition of "rule" in 5 U.S.C. 804(3)(A) because it is a rule of "particular applicability." Therefore, it is not subject to the congressional review requirements in 5 U.S.C. 801-808.

List of Subjects in 21 CFR Part 522

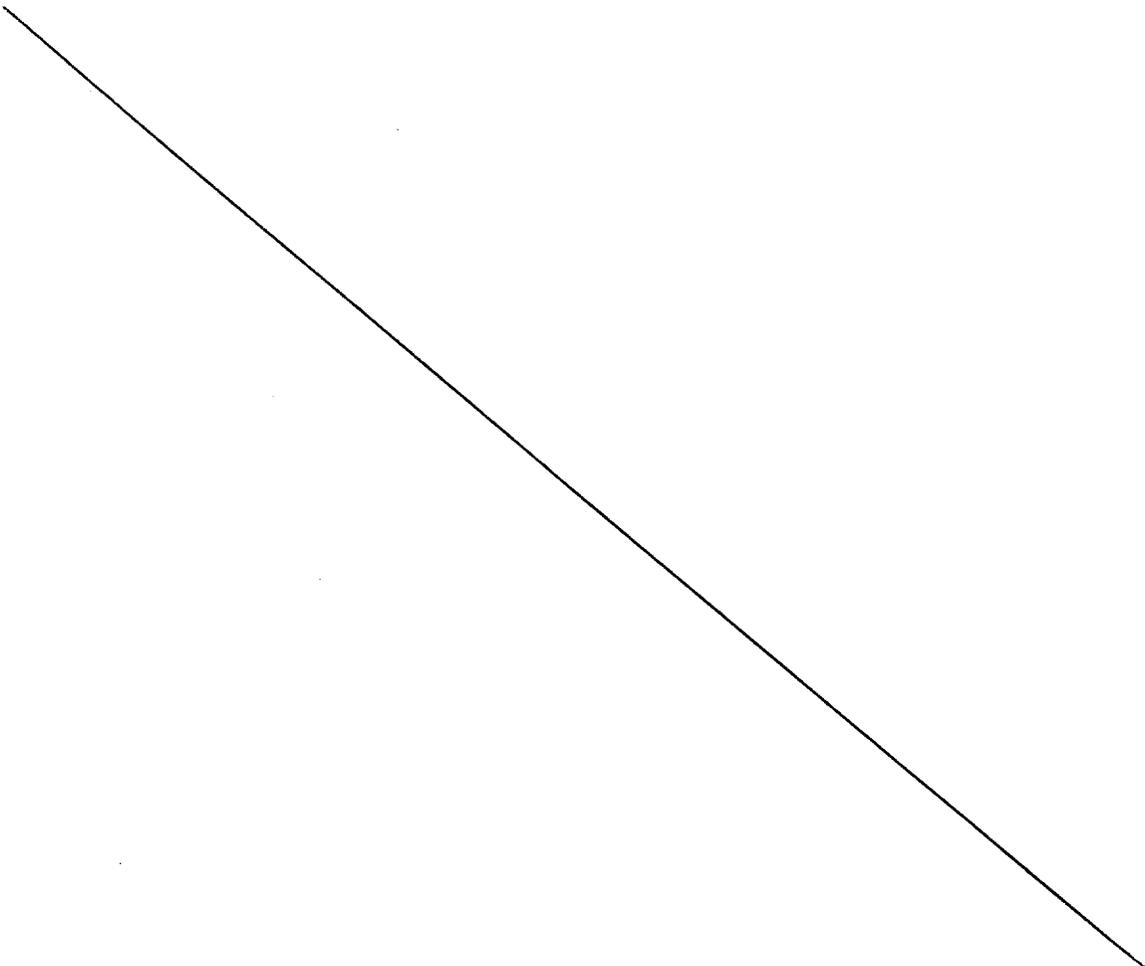
Animal drugs.

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.



§ 522.1660 [Amended]

2. Section 522.1660 *Oxytetracycline injection* is amended in paragraph (d)(1)(iii) by adding in the eighth sentence the number "011722," after the number "000010,".

Dated: 29 June 99
June 29, 1999



George A. Mitchell
Acting Deputy Director
Center for Veterinary Medicine

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

BILLING CODE 4160-01-F

CERTIFIED TO BE A TRUE COPY OF THE ORIGINAL

