

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

21 CFR Part 522

OMB
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Certifier *S. Penley*

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 abbreviated new animal drug application (ANADA) filed by Pliva d.d. The supplemental ANADA provides for the subcutaneous administration of an oxytetracycline injectable solution to cattle, and for its use in lactating dairy cattle.

DATES: This rule is effective [*insert date of publication in the Federal Register*].

FOR FURTHER INFORMATION CONTACT: Lonnie W. Luther, Center for Veterinary Medicine (HFV-101), Food and Drug Administration, 7500 Standish Pl., Rockville, MD 20855, 301-827-0209, e-mail: lluther@cvm.fda.gov.

SUPPLEMENTARY INFORMATION: Pliva d.d., Ulica grada Vukovara 49, 10000 Zagreb, Croatia, filed a supplement to approved ANADA 200-232 that provides for the use of GEOMYCIN 200 (oxytetracycline) Injection as a treatment for various bacterial diseases in cattle and swine. The supplemental ANADA provides for the subcutaneous administration of this oxytetracycline injectable solution to cattle, and for its use in lactating dairy cattle. The supplemental application is approved as of April 8, 2002, and the regulations are amended

in 21 CFR 522.1660d 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, 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.

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 Subject 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:

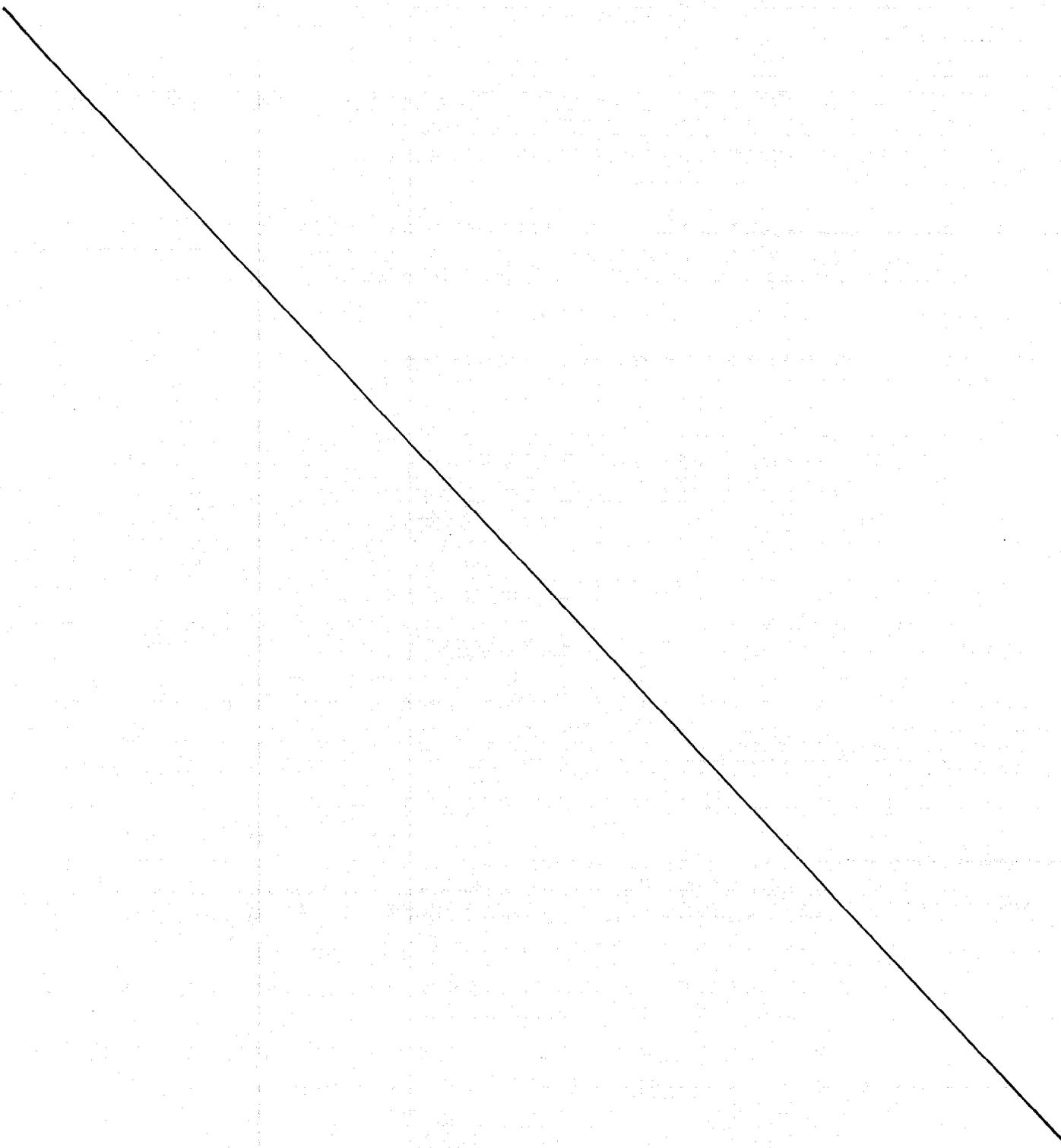
PART 522—IMPLANTATION OR INJECTABLE DOSAGE FORM NEW ANIMAL DRUGS

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) in the second sentence by numerically adding "011722,"; in the eighth sentence by removing "011722,"; and in the ninth sentence by removing "sponsor 000069" and by adding in its place "sponsors 000069 and 011722".



Dated: July 11, 2002
July 11, 2002.

Andrew J. Beaulieu

Andrew J. Beaulieu,
Acting Director,
Office of New Animal Drug Evaluation, Center for Veterinary Medicine.
[FR Doc. 02-????? Filed ??-??-02; 8:45 am]

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COPY OF THE ORIGINAL**

John Kenney