

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

21 CFR Part 522

DDM

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Certifier A. Corbin

Implantation or Injectable Dosage Form New Animal Drugs; Oxytetracycline Solution

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 Norbrook Laboratories, Ltd. The supplemental NADA provides for changing scientific nomenclature for a bovine pathogen on labeling for 300 milligrams per milliliter (mg/mL) strength oxytetracycline injectable solution.

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

FOR FURTHER INFORMATION CONTACT: Joan C. Gotthardt, Center for Veterinary Medicine (HFV-130), Food and Drug Administration, 7500 Standish Pl., Rockville, MD 20855, 240-276-8342, e-mail: joan.gotthardt@fda.hhs.gov.

SUPPLEMENTARY INFORMATION: Norbrook Laboratories, Ltd., Station Works, Newry, BT35 6JP, Northern Ireland, filed a supplement to NADA 141-143 for TETRADURE 300 (oxytetracycline) Injection used for the treatment of various bacterial diseases of cattle and swine. The supplemental NADA provides for changing a bovine pathogen genus from *Haemophilus* to *Histophilus* on product labeling. The supplemental NADA is approved as of February 8, 2008, and the regulations are amended in 21 CFR 522.1660b to reflect the approval.

Approval of this supplemental NADA did not require review of additional safety or effectiveness data or information. Therefore, a freedom of information summary is not required.

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 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.

■ 2. In § 522.1660, revise the section heading to read as follows:

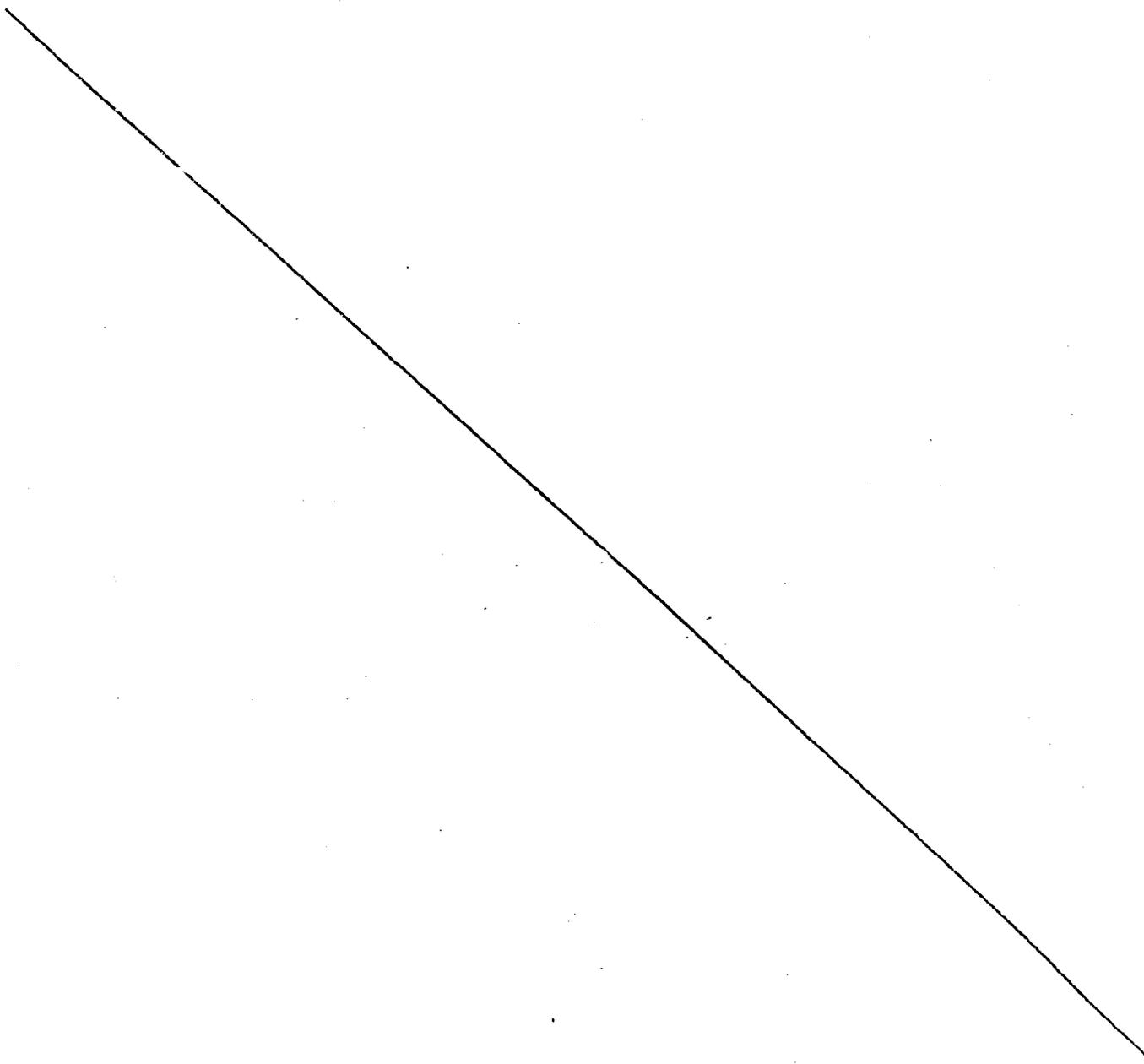
§ 522.1660 Oxytetracycline injectable dosage forms.

■ 3. In § 522.1660a, revise the section heading to read as follows:

§ 522.1660a Oxytetracycline solution, 200 milligrams/milliliter.

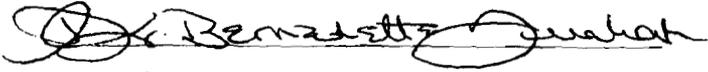
§ 522.1660b [Amended]

■ 4. In § 522.1660b, in the section heading, remove “injection, 300 milligram/milliliter” and in its place add “solution, 300 milligrams/milliliter”; in paragraph (e)(1)(i)(A), remove “*Haemophilus* spp.” and in its place add “*Histophilus* spp.”; and in the fourth sentence in paragraph (e)(1)(ii), remove “in cattle”.



Dated: 03/06/2008

March 6, 2008.



Bernadette Dunham,
Director,
Center for Veterinary Medicine.

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