

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

21 CFR Part 526

Intramammary Dosage Forms; Cephapirin Benzathine

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 Fort Dodge Animal Health, Division of Wyeth. The supplemental NADA provides for a revision to the labeling of cephapirin benzathine intramammary infusion administered to dairy cows entering their dry period for the treatment of mastitis.

DATES: This rule is effective [insert date of publication in the FEDERAL REGISTER].

FOR FURTHER INFORMATION CONTACT: Cindy L. Burnsteel, Center for Veterinary Medicine (HFV-130), Food and Drug Administration, 7500 Standish Pl., Rockville, MD 20855, 240-276-8341, e-mail: cindy.burnsteel@fda.hhs.gov.

SUPPLEMENTARY INFORMATION: Fort Dodge Animal Health, Division of Wyeth, 800 Fifth St. NW., Fort Dodge, IA 50501, filed a supplement to NADA 108-114 that revises labeling of CEFA-DRI (cephapirin benzathine) Intramammary Infusion administered to dairy cows entering their dry period for the treatment of mastitis. The application is approved as of February 7, 2008, and the regulations are amended in 21 CFR 526.363 to reflect the approval, an editorial change, and a current format.

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.

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2008-108-114

NFR

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FDA 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 526

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 526 is amended as follows:

PART 526--INTRAMAMMARY DOSAGE FORMS

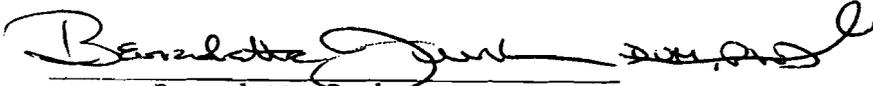
- 1. The authority citation for 21 CFR part 526 continues to read as follows:

Authority: 21 U.S.C. 360b.

§ 526.363 [Amended]

- 2. In § 526.363, at the end of paragraph (d)(2), add “, including penicillin-resistant strains”; and in the second sentence of paragraph (d)(3), remove “use” and add in its place “used”.

Dated: 02/27/2008
February 27, 2008.



Bernadette Dunham,
Director,
Center for Veterinary Medicine.

gd
3/3/08

[FR Doc. 08-????? Filed ??-??-08; 8:45 am].
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