

DMS

Display Date	4-17-00
Publication Date	4-18-00
Certifier	M. Bell

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

21 CFR Part 526

**Intramammary Dosage Form New Animal Drugs; Cephapirin Sodium for
Intramammary Infusion**

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. The supplemental NADA provides for amending the milk discard statement to state the milk discard time only (i.e., to remove reference to the number of milkings).

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

FOR FURTHER INFORMATION CONTACT: Naba K. Das, Center for Veterinary Medicine (HFV-130), Food and Drug Administration, 7500 Standish Pl., Rockville, MD 20855, 301-827-7569.

SUPPLEMENTARY INFORMATION: Fort Dodge Animal Health, Division of American Home Products Corp., 800 Fifth Street NW., P.O. Box 518, Fort Dodge, IA 50501, filed supplemental NADA 97-222 that provides for a 96-hour milk-discard time (i.e., removal of the parenthetical reference to an 8-milking milk discard time) for use of CEFA-LAK® and TODAY® (cephapirin sodium) intramammary infusion products for treatment of lactating cows for bovine mastitis. The supplemental NADA is approved as of February 4, 2000, and the regulations are amended in 21 CFR 526.365(d)(3) to reflect the approval.

Approval of this supplemental NADA conforms to the requirements of 21 CFR 510.105. Approval does not require review of the safety or effectiveness data required for approval of the NADA. 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 526

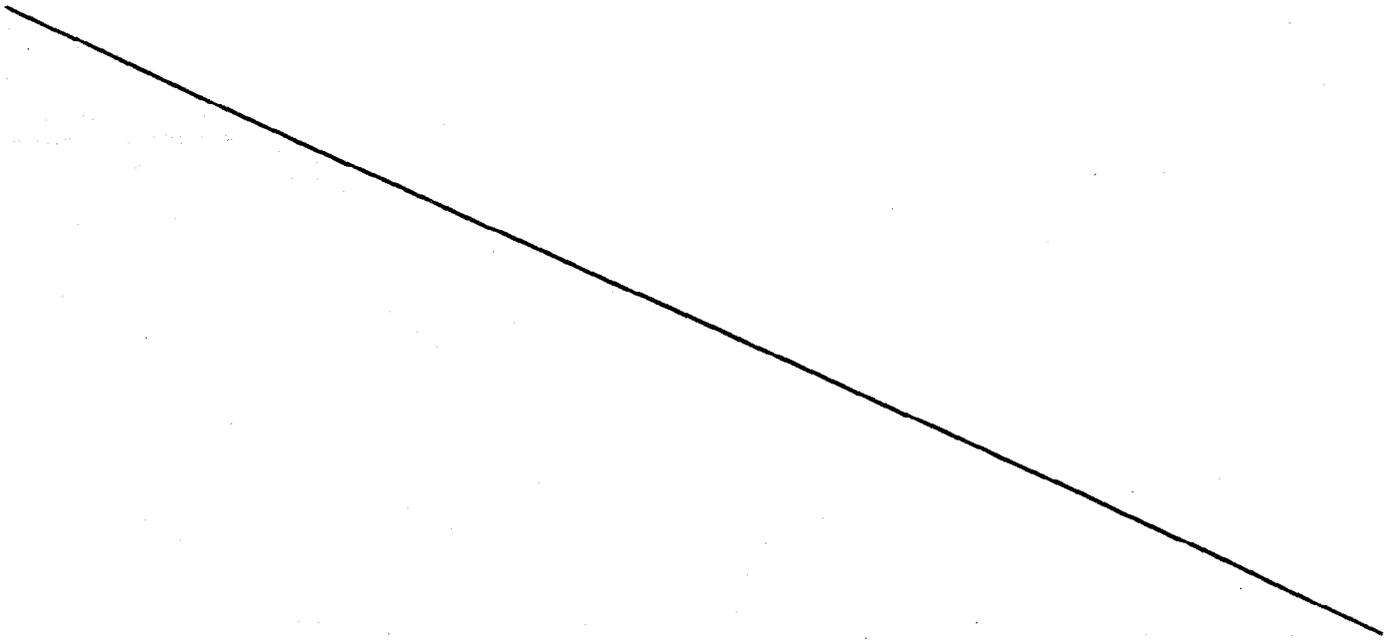
Animal drugs.

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:

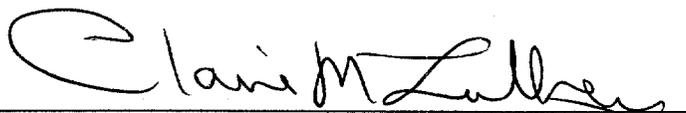
Authority: 21 U.S.C. 360b.



§ 526.365 [Amended]

2. Section 526.365 *Cephapirin sodium for intramammary infusion* is amended in paragraph (d)(3) by removing "(8 milkings)".

Dated: 3/17/2000
March 17, 2000



Claire M. Lathers
Director
Office of New Animal Drug Evaluation
Center for Veterinary Medicine

[FR Doc. 00-???? Filed ??-??-00; 8:45 am]

BILLING CODE 4160-01-F

CERTIFIED TO BE A TRUE COPY OF THE ORIGINAL

