

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

21 CFR Part 526

DMF Display Date 7-30-03
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Certifier R. LEDEGMA

Intramammary Dosage Forms; Change of Sponsor

AGENCY: Food and Drug Administration, HHS.

ACTION: Final rule.

SUMMARY: The Food and Drug Administration (FDA) is amending the animal drug regulations to reflect a change of sponsor for three approved new animal drug applications (NADAs) from Pfizer, Inc., to Schering-Plough Animal Health Corp.

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

FOR FURTHER INFORMATION CONTACT: David R. Newkirk, Center for Veterinary Medicine (HFV-100), Food and Drug Administration, 7500 Standish Pl., Rockville, MD 20855, 301-827-6967, e-mail: dnewkirk@cvm.fda.gov.

SUPPLEMENTARY INFORMATION: Pfizer, Inc., 235 East 42d St., New York, NY 10017, has informed FDA that it has transferred ownership of, and all rights and interest in, the following three approved NADAs to Schering-Plough Animal Health Corp., 1095 Morris Ave., Union, NJ 07083:

NADA No.	Trade Name
55-069	ORBENIN DC (cloxacillin benzathine)
55-070	DARICLOX (cloxacillin sodium)
55-100	AMOXI-MAST (amoxicillin trihydrate)

Accordingly, the agency is amending the regulations in 21 CFR 526.88, 526.464b, and 526.464c to reflect the transfer of ownership.

cv0370

NADA 55-069
55-070
55-100

NFR

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.

§ 526.88 [Amended]

■ 2. Section 526.88 *Amoxicillin trihydrate for intramammary infusion* is amended in paragraph (b) by removing “000069” and by adding in its place “000061”.

§ 526.464b [Amended]

■ 3. Section 526.464b *Cloxacillin benzathine for intramammary infusion, sterile* is amended in paragraph (d) by removing “000069” and by adding in its place “000061”.

§ 526.464c [Amended]

■ 4. Section 526.464c *Cloxacillin sodium for intramammary infusion, sterile* is amended in paragraph (b) by removing “000069” and by adding in its place “000061”.

Dated: July 18, 2003
July 18, 2003.

Steven D. Vaughn - DM

Steven D. Vaughn,
Director, *Animal*
Office of New Drug Evaluation, Center for Veterinary Medicine.

LB
7/24/03

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