

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

21 CFR Part 522

DMB

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Certifier N. Hawkins

Implantation or Injectable Dosage Form New Animal Drugs; 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 two approved new animal drug applications (NADAs) from Anthony Products Co. to Cross Vetpharm Group Ltd.

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: Anthony Products Co., 5600 Peck Rd., Arcadia, CA 91006, has informed FDA that it has transferred ownership of, and all rights and interest in, the following two approved NADAs to Cross Vetpharm Group, Ltd., Broomhill Rd., Tallaght, Dublin 24, Ireland:

NADA Number	Trade Name
065-505 065-506	MICROCILLIN Injectable Suspension COMBICILLIN Injectable Suspension

Accordingly, the agency is amending the regulations in 21 CFR 522.1696a and 522.1696b to reflect the transfer of ownership.

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.

§ 522.1696a [Amended]

2. Section 522.1696a *Penicillin G benzathine and penicillin G procaine sterile suspension* is amended in paragraph (b)(1) by removing “000864, 010515, and 049185” and by adding in its place “010515, 049185, and 061623”; and in paragraph (b)(3) by removing “000864, 010515, and 059130” and by adding in its place “010515, 059130, and 061623”.

§ 522.1696b [Amended]

3. Section 522.1696b *Penicillin G procaine aqueous suspension* is amended in paragraph (b)(2) by removing “000864 and 055529” and by adding in its place “055529 and 061623”; in paragraph (d)(2)(i)(A) by removing “000864, 010515, 053501, and 059130” and by adding in its place “010515, 053501, 059130, and 061623”; and in paragraph (d)(2)(iii)(A) by

removing "000864, 010515, 053501, and 059130" and by adding in its place
"010515, 053501, and 059130".

Dated: May 19, 2003
May 19, 2003.

Steven D. Vaughn DVM

Steven D. Vaughn,
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Center for Veterinary Medicine.
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