

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

21 CFR Parts 520, 522, and 558

New Animal Drugs; Limitations of Use

AGENCY: Food and Drug Administration, HHS.

ACTION: Final rule.

SUMMARY: The Food and Drug Administration (FDA) is amending the animal drug regulations to reflect the limitations to conditions of use for products approved under 22 new animal drug applications (NADAs) and 5 abbreviated new animal drug applications (ANADAs). In error, a label statement warning against the use of these products in calves to be processed for veal was not codified at the time supplemental NADAs or ANADAs were approved. FDA is also amending the animal drug regulations to reflect the approved preslaughter withdrawal periods and milk withholding period in cattle following use of penicillin G procaine aqueous suspension. This action is being taken to improve the accuracy of the animal drug regulations.

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

FOR FURTHER INFORMATION CONTACT: Jeffrey Punderson, Center for Veterinary Medicine (HFV-6), Food and Drug Administration, 7519 Standish Pl., Rockville, MD 20855, 301-827-4109, e-mail: jpunders@cvm.fda.gov.

SUPPLEMENTARY INFORMATION: Over the past decade, FDA's Center for Veterinary Medicine (CVM) asked sponsors of certain products approved for use in cattle to place this warning on their labels: "A withdrawal period has not been established for this product in preruminating calves. Do not use in

calves to be processed for veal.” This was done to reduce the frequency of unsafe residues of animal drugs in veal. While many sponsors complied and filed applications to change their labels, CVM did not always codify this limitation to approved conditions of use when the supplemental application was approved. At this time, FDA is amending the animal drug regulations to reflect the limitations to conditions of use for the following products:

Application No.	21 CFR Section	Trade Name
NADA 011-060	520.1660c	TERRAMYCIN Scour Tablets
NADA 012-350	558.55	AMPROVINE 25%; AMPROL 25%
NADA 012-350	520.100c	CORID 1.25% Crumbles
NADA 012-965	522.2640a	TYLAN Injection 50 mg; TYLAN Injection 200 mg
NADA 013-149	520.100a	CORID 9.6% Solution
NADA 030-434	520.540a	AZIUM Powder
NADA 030-435	520.540b	AZIUM Boluses 10 mg
NADA 031-715	520.2220b	ALBON; AGRIBON Boluses-2.5, -5.0, and -15.0
NADA 033-127	520.2200a	PRINZONE, PYRADAN, and VETISULID Boluses
NADA 033-165	520.100b	CORID 20% Soluble Powder
NADA 033-373	520.2200b	PRINZONE, PYRADAN, and VETISULID Powder
NADA 033-318	522.2200	PRINZONE, PYRADAN, and VETISULID Injection
NADA 041-245	522.2220	AGRIBON Injection 40%; ALBON
NADA 065-010	522.1696b	AGRICILLIN Pen Aqueous; AQUA-CILLIN; Penicillin G Co-op
NADA 065-110	522.1696b	PRO-PEN G in Aqueous Suspension
NADA 065-140	520.2345d	TET-SOL 10 and TET-SOL 324
NADA 065-269	520.2345d	POLYOTIC Soluble Powder
NADA 065-441	520.2345d	POLYOTIC Soluble Powder Concentrate
NADA 065-493	522.1696b	Penicillin G Procaine Aqueous Suspension
NADA 065-496	520.2345d	Tetracycline Soluble Powder
NADA 093-107	520.2220b	ALBON S.R.
NADA 138-955	522.2640a	Tylosin Injection
NADA 141-002	520.1660c	OXY 500 and 1000 Calf Boluses
ANADA 200-038	522.2220	DI-METHOX Injection 40%; Sulfadimethoxine Injection 40%
ANADA 200-049	520.2345d	TETRA-BAC 324 Soluble Powder; Tetracycline Hydrochloride Soluble Powder-324.
ANADA 200-136	520.2345d	Tetracycline HCL Powder; Tetracycline Hydrochloride Soluble Powder-324.
ANADA 200-177	522.2220	Sulfadimethoxine Injection 40%
ANADA 200-234	520.2345d	TETRASOL Soluble Powder

Accordingly, the agency is amending the regulations in 21 CFR 520.100a, 520.100b, 520.100c, 520.540a, 520.540b, 520.1660c, 520.2200a, 520.2200b, 520.2220b, 520.2345d, 522.1696b, 522.2200, 522.2220, 522.2640a, and 558.55.

In addition, FDA has found that the animal drug regulations do not reflect the approved preslaughter withdrawal period for cattle, sheep, and swine for PRO-PEN G in Aqueous Suspension sponsored by Phoenix Scientific, Inc., approved under NADA 065-110. FDA has also found that the animal drug regulations do not reflect the approved milk withholding period for Penicillin G Procaine Aqueous Suspension sponsored by G.C. Hanford Manufacturing Co. (NADA 065-493) and AGRICILLIN Pen Aqueous, AQUA-CILLIN, and Penicillin G Co-op sponsored by Norbrook Laboratories Ltd. (NADA 065-010). At this time, the regulations are being amended in 21 CFR 522.1696b to correct these errors.

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

21 CFR Parts 520 and 522

Animal drugs.

21 CFR Part 558

Animal drugs, Animal feeds.

■ 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 parts 520, 522, and 558 are amended as follows:

PART 520—ORAL DOSAGE FORM NEW ANIMAL DRUGS

■ 1. The authority citation for 21 CFR part 520 continues to read as follows:

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

§ 520.100a [Amended]

■ 2. Section 520.100a is amended in paragraphs (d)(2)(i)(b) and (d)(2)(ii)(b) by adding “A withdrawal period has not been established for this product in preruminating calves. Do not use in calves to be processed for veal.” at the end of the paragraph.

§ 520.100b [Amended]

■ 3. Section 520.100b is amended in paragraphs (d)(1)(ii) and (d)(2)(ii) by adding “A withdrawal period has not been established for this product in preruminating calves. Do not use in calves to be processed for veal.” at the end of the paragraph.

§ 520.100c [Amended]

■ 4. Section 520.100c is amended in paragraphs (d)(1)(ii) and (d)(2)(ii) by adding “A withdrawal period has not been established for this product in preruminating calves. Do not use in calves to be processed for veal.” at the end of the paragraph.

§ 520.540a [Amended]

■ 5. Section 520.540a is amended in paragraph (c)(4) by adding “A withdrawal period has not been established for this product in preruminating calves. Do not use in calves to be processed for veal.” at the end of the paragraph.

§ 520.540b [Amended]

■ 6. Section 520.540b is amended in paragraph (a)(3)(vi) by adding “A withdrawal period has not been established for this product in preruminating calves. Do not use in calves to be processed for veal.” at the end of the paragraph.

§ 520.1660c [Amended]

■ 7. Section 520.1660c is amended in paragraph (d)(3) by adding “A withdrawal period has not been established for this product in preruminating calves. Do not use in calves to be processed for veal.” at the end of the paragraph.

§ 520.2200a [Amended]

■ 8. Section 520.2200a is amended in paragraph (e)(3) by adding “A withdrawal period has not been established for this product in preruminating calves. Do not use in calves to be processed for veal.” at the end of the paragraph.

§ 520.2200b [Amended]

■ 9. Section 520.2200b is amended in paragraph (e)(1)(iii) by adding “A withdrawal period has not been established for this product in preruminating calves. Do not use in calves to be processed for veal.” at the end of the paragraph.

§ 520.2220b [Amended]

■ 10. Section 520.2220b is amended in paragraph (d)(1)(iii) by adding “A withdrawal period has not been established for this product in preruminating calves. Do not use in calves to be processed for veal.” at the end of the paragraph.

§ 520.2345d [Amended]

■ 11. Section 520.2345d is amended in paragraph (d)(1)(iii) by adding “A withdrawal period has not been established for this product in preruminating calves. Do not use in calves to be processed for veal.” at the end of the paragraph.

PART 522—IMPLANTATION OR INJECTABLE DOSAGE FORM NEW ANIMAL DRUGS

■ 12. The authority citation for 21 CFR part 522 continues to read as follows:

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

■ 13. Section 522.1696b is amended by revising paragraph (d)(2)(iii) to read as follows:

§ 522.1696b Penicillin G procaine aqueous suspension.

* * * * *

(d) * * *

(2) * * *

(iii) *Limitations*. Not for use in horses intended for food. Milk that has been taken during treatment and for 48 hours after the last treatment must not be used for food.

(A) For Nos. 053501 and 061623: Do not exceed 7 days of treatment in nonlactating dairy and beef cattle, sheep, and swine, or 5 days in lactating cattle. Discontinue treatment for the following number of days before slaughter: Nonruminating cattle (calves)—7; all other cattle—4; sheep—8; and swine—6.

(B) For Nos. 010515, 055529, and 059130: Treatment should not exceed 4 consecutive days. Discontinue treatment for the following number of days before slaughter: Cattle—10; sheep—9; and swine—7. A withdrawal period has not been established for this product in preruminating calves. Do not use in calves to be processed for veal.

§ 522.2200 [Amended]

■ 14. Section 522.2200 is amended in paragraph (e)(3) by adding “A withdrawal period has not been established for this product in preruminating calves. Do not use in calves to be processed for veal.” at the end of the paragraph.

§ 522.2220 [Amended]

■ 15. Section 522.2220 is amended in paragraph (a)(3)(iii)(c) by adding “A withdrawal period has not been established for this product in preruminating calves. Do not use in calves to be processed for veal.” at the end of the paragraph.

§ 522.2640a [Amended]

■ 16. Section 522.2640a is amended in paragraph (e)(1)(iii) by adding “A withdrawal period has not been established for this product in preruminating calves. Do not use in calves to be processed for veal.” at the end of the paragraph.

PART 558—NEW ANIMAL DRUGS FOR USE IN ANIMAL FEEDS

■ 17. The authority citation for 21 CFR part 558 continues to read as follows:

Authority: 21 U.S.C. 360b, 371.

§ 558.55 [Amended]

■ 18. Section 558.55 is amended in paragraphs (d)(1)(i)(b) and (d)(1)(ii)(b) by adding “A withdrawal period has not been established for this product in preruminating calves. Do not use in calves to be processed for veal.” at the end of the paragraph.

Dated: March 25, 2005.

Daniel G. McChesney,

Director, Office of Surveillance and Compliance, Center for Veterinary Medicine.

[FR Doc. 05-????? Filed ??-??-05; 8:45 am]

BILLING CODE 4160-01-S