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Display Date 6-19-03  
Publication Date 6-20-03  
Certifier J. Cooke

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

21 CFR Parts 522 and 524

Dosage Form New Animal Drugs; Change of Sponsor; Technical Amendment

AGENCY: Food and Drug Administration, HHS.

ACTION: Final rule; technical amendment.

**SUMMARY:** The Food and Drug Administration (FDA) is amending the animal drug regulations to reflect a change of sponsor for four 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 four approved NADAs to Cross Vetpharm Group, Ltd., Broomhill Rd., Tallaght, Dublin 24, Ireland.

| NADA Number | Trade Name   | 21 CFR Section |
|-------------|--|----------------|
| 049-187     | PHEN-BUTA (phenylbutazone) Vet Tablets;<br>Phenylbutazone Tablets (Dogs) | 520.1720a      |
| 122-447     | FURA-SEPTIN (nitrofurazone) Soluble Dressing                             | 524.1580b      |
| 130-136     | Oxytocin Injection   | 522.1680       |
| 140-582     | BIOCYL 50, BIOCYL 100 (oxytetracycline)                                  | 522.1662a      |

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NADA 049-187 130-138  
122-447 140-582

NFR

Accordingly, the agency is amending the regulations in §§ 522.1662a, 522.1680, and 524.1580b (21 CFR 522.1662a, 522.1680, and 524.1580b) to reflect the transfer of ownership. No amendment of 21 CFR 520.1720a is necessary as each sponsor owns additional phenylbutazone products.

In addition, § 522.1662a is being revised to reflect current format. This action is being taken to improve consistency between sections of the regulations.

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 Parts 522 and 524**

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 parts 522 and 524 are 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.

#### **§ 522.1662a [Amended]**

2. Section 522.1662a *Oxytetracycline hydrochloride injection* is amended in paragraph (k)(2) by removing “000864” and by adding in its place “061623”.

3. Section 522.1680 is amended in paragraph (b) by removing “000864” and by numerically adding “061623”; in paragraph (c) by removing the

footnote; in paragraphs (c)(1)(i) and (c)(1)(ii) in the table headings by removing “ml” and by adding in its place “mL”; and by revising paragraphs (a) and (c)(3) to read as follows:

**§ 522.1680 Oxytocin injection.**

(a) *Specifications.* Each milliliter (mL) of solution contains 20 USP units oxytocin.

\* \* \* \* \*

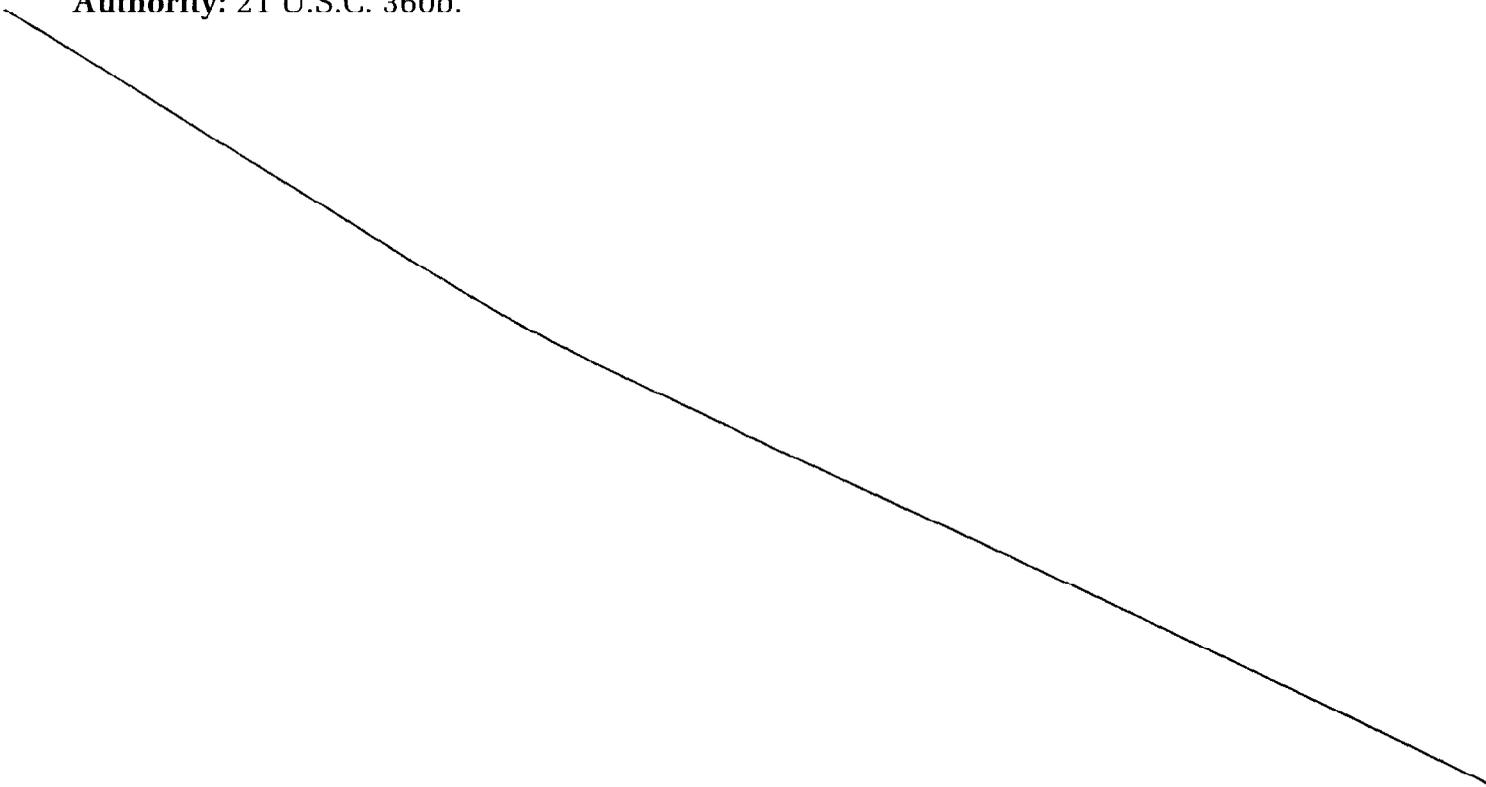
(c) \* \* \*

(3) *Limitations.* Federal law restricts this drug to use by or on the order of a licensed veterinarian.

**PART 524—OPHTHALMIC AND TOPICAL DOSAGE FORM NEW ANIMAL DRUGS**

4. The authority citation for 21 CFR part 524 continues to read as follows:

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



§ 524.1580b [Amended]

5. Section 524.1580b *Nitrofurazone ointment* is amended in paragraph (b) by removing "000864,".

Dated: June 3, 2003  
June 3, 2003.

Steven D. Vaughn  
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Center for Veterinary Medicine.

[FR Doc. 03-????? Filed ??-??-03; 8:45 am]

BILLING CODE 4160-01-S

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