

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

21 CFR Part 522

DMB  
Display Date 4-28-03  
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Certifier N. Hawkins

Implantation or Injectable Dosage Form New Animal Drugs; Butorphanol  
Tartrate Injection

AGENCY: Food and Drug Administration, HHS.

ACTION: Final rule.

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**SUMMARY:** The Food and Drug Administration (FDA) is amending the animal drug regulations to reflect approval of an abbreviated new animal drug application (ANADA) filed by Phoenix Scientific, Inc. The ANADA provides for the use of a butorphanol tartrate injectable solution for the relief of pain in horses.

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

**FOR FURTHER INFORMATION CONTACT:** Lonnie W. Luther, Center for Veterinary Medicine (HFV-104), Food and Drug Administration, 7519 Standish Pl., Rockville, MD 20855, 301-827-8549, e-mail: lluther@cvm.fda.gov.

**SUPPLEMENTARY INFORMATION:** Phoenix Scientific, Inc., 3915 South 48th Street Ter., St. Joseph, MO 64503, filed ANADA 200-322 that provides for the use of Butorphanol Tartrate Injection for the relief of pain associated with colic and postpartum pain in adult and yearling horses. Phoenix Scientific's Butorphanol Tartrate Injection is approved as a generic copy of Fort Dodge Animal Health's TORBUGESIC approved under NADA 135-780. The ANADA is approved as of January 22, 2003, and the regulations are amended in 21

CFR 522.246 to reflect the approval. The basis of approval is discussed in the freedom of information summary.

In accordance with the freedom of information provisions of 21 CFR part 20 and 21 CFR 514.11(e)(2)(ii), a summary of safety and effectiveness data and information submitted to support approval of this application may be seen in the Dockets Management Branch (HFA-305), Food and Drug Administration, 5630 Fishers Lane, rm. 1061, Rockville, MD 20852, between 9 a.m. and 4 p.m., Monday through Friday.

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 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**

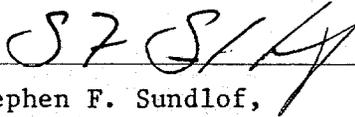
1. The authority citation for 21 CFR part 522 continues to read as follows:

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

§ 522.246 [Amended]

2. Section 522.246 *Butorphanol tartrate injection* is amended in paragraph (b)(1) by removing “No. 057926” and by adding in its place “Nos. 057926 and 059130”.

Dated: 04/01/03  
April 1, 2003.



Stephen F. Sundlof,  
Director,  
Center for Veterinary Medicine.

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

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