

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

21 CFR Part 522

DMB
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Certifier S. Reese

Implantation or Injectable Dosage Form New Animal Drugs; Dexamethasone Injection

AGENCY: Food and Drug Administration, HHS.

ACTION: Final rule.

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 Cross Vetpharm Group, Ltd. The ANADA provides for the veterinary prescription use of dexamethasone injectable solution in dogs, cats, cattle, and 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: Cross Vetpharm Group Ltd., Broomhill Rd., Tallaght, Dublin 24, Ireland, filed ANADA 200-312 that provides for use of DEXIUM (dexamethasone) Solution for the treatment of primary bovine ketosis and as an anti-inflammatory agent in dogs, cats, cattle, and horses. Cross Vetpharm Group's DEXIUM Solution is approved as a generic copy of Schering-Plough Animal Health's AZIUM Solution 2 milligrams, approved under NADA 12-559. The ANADA is approved as of October 20, 2003, and

the regulations are amended in 21 CFR 522.540 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 Division of Dockets Management (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 Subject 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.

§ 522.540 [Amended]

■ 2. Section 522.540 *Dexamethasone injection* is amended in paragraph (a)(2)(i) by removing “and 059130” and by adding in its place [“] 059130, and 061623”.

LB
11/10/03

Dated: 11/3/03
November 3, 2003.

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

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

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