

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

Notice of Approval of Abbreviated New Animal Drug Application; Oxytocin Injection

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration's Center for Veterinary Medicine (CVM) is providing notice that it has approved an original abbreviated new animal drug application (ANADA) filed by Cross Vetpharm Group, Ltd. The ANADA provides for the veterinary prescription use of oxytocin injectable solution in ewes, sows, cows, and horses. The applicable section of the regulation did not require amendment.

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: In accordance with section 512(i) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 360b(i)) and 21 CFR 514.105(a) and 514.106(a), CVM is providing notice that it has approved original ANADA 200-328 filed by Cross Vetpharm Group, Ltd., Broomhill Rd., Tallaght, Dublin 24, Ireland. ANADA 200-328 provides for the veterinary prescription use of Oxytocin Injection in ewes, sows, cows, and horses. Cross Vetpharm Group's Oxytocin Injection is approved as a generic copy of Phoenix Scientific, Inc.'s PVL Oxytocin Injectable, approved under NADA 124-241. The ANADA is approved as of May 21, 2004. The basis of approval is discussed in the freedom

of information summary. The applicable sections of the regulation did not require amendment.

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.

Dated: June 14, 2004.

Linda Tollefson,

Acting Center Director, Center for Veterinary Medicine.

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