Drug labeler code	Firm name and address
* * *	* * * *
012579	Roussel-UCLAF SA, Animal Health Division, 102 Route de Noisy, 93235 Romainville Cedex, France.
* * *	* * * *

Dated: August 20, 1996.

Robert C. Livingston,

Director, Office of New Animal Drug Evaluation, Center for Veterinary Medicine.

[FR Doc. 96–22486 Filed 9–3–96; 8:45 am]

BILLING CODE 4160–01–F

21 CFR Part 522

Implantation or Injectable Dosage Form New Animal Drugs; Xylazine 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 Chanelle Pharmaceuticals Manufacturing Ltd. The ANADA provides for intravenous, intramuscular, or subcutaneous use of xylazine injection in dogs and cats to produce sedation accompanied by a shorter period of analgesia.

EFFECTIVE DATE: September 4, 1996.

FOR FURTHER INFORMATION CONTACT: Sandra K. Woods, Center For Veterinary Medicine (HFV–114), Food and Drug Administration, 7500 Standish Pl., Rockville, MD 20855, 301–594–1617.

SUPPLEMENTARY INFORMATION: Chanelle Pharmaceuticals Manufacturing Ltd., Loughrea, County Galway, Ireland, filed ANADA 200–184, which provides for intravenous, intramuscular, and subcutaneous use of Chanazine® (20 milligrams/milliliter (mg/mL)) Injectable (xylazine hydrochloride equivalent to 20 mg xylazine per mL) in dogs and cats to produce sedation accompanied by a shorter period of analgesia. The drug is limited to use by or on the order of a licensed veterinarian.

Approval of ANADA 200–184 for Chanelle's Chanazine® (xylazine 20 mg/mL) Injectable is as a generic copy of Bayer's NADA 47–955 for Rompun® (xylazine 20 mg/mL) injectable. The ANADA is approved as of July 12, 1996, and the regulations are amended by revising 21 CFR 522.2662(b) 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 part 20 (21 CFR part 20) and § 514.11(e)(2)(ii) (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, 12420 Parklawn Dr., rm. 1–23, Rockville, MD 20857, between 9 a.m. and 4 p.m., Monday through Friday.

The agency has determined under 21 CFR 25.24(d)(1)(i) 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.

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: Sec. 512 of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 360b).

2. Section 522.2662 is amended by revising the first two sentences in paragraph (b) to read as follows:

§ 522.2662 Xylazine hydrochloride injection.

* * * * *

(b) *Sponsor.* See 000856 in § 510.600(c) of this chapter for use in horses, wild deer, and elk. See 000859 and 061651 in § 510.600(c) of this chapter for use in horses, wild deer, elk, dogs, and cats. * * *

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Dated: August 20, 1996.

Stephen F. Sundlof,

Director, Center for Veterinary Medicine.

[FR Doc. 96–22487 Filed 9–3–96; 8:45 am]

BILLING CODE 4160–01–F

DEPARTMENT OF THE INTERIOR

Office of Surface Mining Reclamation and Enforcement

30 CFR Part 935

[OH–238–FOR, #72]

Ohio Regulatory Program

AGENCY: Office of Surface Mining Reclamation and Enforcement (OSM), Interior.

ACTION: Final rule; approval of amendment.

SUMMARY: OSM is approving a proposed amendment to the Ohio regulatory program (hereinafter referred to as the ''Ohio program'') under the Surface Mining Control and Reclamation Act of 1977 (SMCRA). Ohio proposed revisions to rules pertaining to underground mining. The amendment is intended to revise the Ohio program to be consistent with the corresponding Federal regulations.

EFFECTIVE DATE: September 4, 1996.

FOR FURTHER INFORMATION CONTACT: George Rieger, Field Branch Chief, Appalachian Regional Coordinating Center, OSM, 3 Parkway Center, Pittsburgh, PA 15220, Telephone: (412) 937–2153.

SUPPLEMENTARY INFORMATION:

I. Background on the Ohio Program

On August 16, 1982, the Secretary of the Interior conditionally approved the Ohio program. Background information on the Ohio program, including the Secretary's findings, the disposition of comments, and the conditions of