

(i) The acquiring person is not an affiliate or a principal shareholder of the divesting company, or a company controlled by such a principal shareholder; and

(ii) The acquiring person does not have any officer, director, trustee, or beneficiary in common with or subject to control by the divesting company.

* * * * *

By order of the Board of Governors of the Federal Reserve System, June 29, 1995.

William W. Wiles,

Secretary of the Board.

[FR Doc. 95-16539 Filed 7-5-95; 8:45 am]

BILLING CODE 6210-01-P

DEPARTMENT OF THE TREASURY

Customs Service

19 CFR Parts 141 to 199

Title 19 Parts 141 to 199; Republication

CFR Correction

Title 19 parts 141 to 199, revised as of April 1, 1995, is being republished in its entirety. The earlier issuance inadvertently omitted text from the Appendix to part 181. The omitted text should begin on page 411 after the second entry in the first table.

Billing Code 1505-01-D

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

21 CFR Parts 510 and 522

Animal Drugs, Feeds, and Related Products; 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 a supplemental new animal drug application (NADA) filed by Lloyd, Inc. The supplemental NADA provides for intravenous, intramuscular, or subcutaneous use of xylazine injection in cats to produce sedation accompanied by a shorter period of analgesia.

EFFECTIVE DATE: July 6, 1995.

FOR FURTHER INFORMATION CONTACT: Marcia K. Larkins, Center For Veterinary Medicine (HFV-112), Food and Drug Administration, 7500 Standish Pl., Rockville, MD 20855, 301-594-0614.

SUPPLEMENTARY INFORMATION: Lloyd, Inc., 604 W. Thomas Ave., Shenandoah, IA 51601, is sponsor of NADA 139-236, which provides for intravenous, intramuscular, or subcutaneous use of AnaSed® Xylazine Injection containing xylazine hydrochloride equivalent to 100 milligrams (mg) xylazine per milliliter (mL) in horses and 20 mg/mL in dogs to produce sedation accompanied by a shorter period of analgesia. The supplement provides for use of 20 mg/mL xylazine in cats for the same indications. The drug is limited to use by or on the order of a licensed veterinarian.

Supplemental NADA 139-236 is approved as a generic copy of Bayer's NADA 47-955 for Rompun® (xylazine 20 mg/mL) injectable. The supplemental NADA is approved as of May 16, 1995, 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.

Also, the firm has changed the name of the NADA sponsor from Vet-A-Mix, Inc., to Lloyd, Inc. Because Lloyd, Inc., has not previously been listed in the animal drug regulations as the sponsor of an approved application, the agency is amending 21 CFR 510.600(c)(1) and (c)(2) to add entries for Lloyd, Inc.

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, rm. 1-23, 12420 Parklawn Dr., Rockville, MD 20857, between 9 a.m. and 4 p.m., Monday through Friday.

The agency has carefully considered the potential environmental effects of this action. FDA has concluded that the action will not have a significant impact on the human environment, and that an environmental impact statement is not required. The agency's finding of no significant impact and the evidence supporting that finding, contained in an environmental assessment, may be seen in the Dockets Management Branch (address above) between 9 a.m. and 4 p.m., Monday through Friday.

List of Subjects

21 CFR Part 510

Administrative practice and procedure, Animal drugs, Labeling, Reporting and recordkeeping requirements.

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 parts 510 and 522 are amended as follows:

PART 510—NEW ANIMAL DRUGS

1. The authority citation for 21 CFR part 510 continues to read as follows:

Authority: Secs. 201, 301, 501, 502, 503, 512, 701, 721 of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 321, 331, 351, 352, 353, 360b, 371, 379e).

2. Section 510.600 is amended in the table in paragraph (c)(1) by alphabetically adding a new entry for Lloyd, Inc., and in the table in paragraph (c)(2) by numerically adding a new entry for "061690" to read as follows:

§ 510.600 Names, addresses, and drug labeler codes of sponsors of approved applications.

* * * * *
(c) * * *
(1) * * *

Firm name and address	Drug labeler code
* * * * *	*
Lloyd, Inc., 604 W. Thomas Ave., Shenandoah, IA 51601.	061690
* * * * *	*

(2) * * *

Drug labeler code	Firm name and address
* * * * *	*
061690	Lloyd, Inc., 604 W. Thomas Ave., Shenandoah, IA 51601

PART 522—IMPLANTATION AND INJECTABLE DOSAGE FORM NEW ANIMAL DRUGS

3. 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).

§ 522.2662 [Amended]

4. Section 522.2662 *Xylazine hydrochloride injection* is amended in paragraph (b) by revising the third sentence to read: "See 061690 in § 510.600(c) of this chapter for use in horses, dogs, and cats."