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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

21 CFR Part 520

Oral Dosage Form New Animal Drugs; Sulfamethazine Tablets

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 new animal drug application (NADA) filed by Lloyd, Inc. The NADA provides for oral use of sulfamethazine tablets for beef cattle and nonlactating dairy cattle to treat diseases caused by sulfamethazine sensitive organisms.

EFFECTIVE DATE: *(Insert date of publication in the Federal Register.)*

FOR FURTHER INFORMATION CONTACT: Dianne T. McRae, Center for Veterinary Medicine (HFV-102), Food and Drug Administration, 7500 Standish Pl., Rockville, MD 20855, 301-827-0212.

SUPPLEMENTARY INFORMATION: Lloyd, Inc., P.O. Box 86, 604 West Thomas Ave., Shenandoah, IA 51601, filed NADA 140-908 that provides for oral use of Veta-Meth (sulfamethazine) tablets for beef cattle and nonlactating dairy cattle to treat diseases caused by sulfamethazine sensitive organisms such as bacterial pneumonia and bovine respiratory disease complex (shipping fever complex) (*Pasteurella* spp.), colibacillosis (bacterial scours) (*Escherichia coli*), necrotic pododermatitis (foot rot) (*Fusobacterium necrophorum*), calf diphtheria (*F. necrophorum*), acute mastitis (*Streptococcus* spp.), acute metritis (*Streptococcus* spp.), coccidiosis (*Eimeria bovis*, *E. zurnii*).

cv954

NADA 140-908

NFR 1

The NADA is approved as of September 16, 1999, and the regulations are amended in § 520.2260a(a)(1) (21 CFR 520.2260a(a)(1)) to reflect the approval. The basis for approval is discussed in the freedom of information summary.

In addition, the regulation currently contains a paragraph reflecting that approval of NADA's were based on National Academy of Sciences/National Research Council (NAS/NRC) Drug Efficacy Study Implementation evaluations of the products and FDA's conclusions based on those evaluations. Enactment of the Generic Animal Drug and Patent Term Restoration Act of 1988 has superseded the approval of NADA's based on NAS/NRC evaluations. At this time, the NAS/NRC status paragraph is removed.

Also, the heading of § 520.2260a is revised to include tablets in addition to oblets and boluses.

In accordance with the freedom of information provisions of 21 CFR part 20 and 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 congressional review requirements in 5 U.S.C. 801-808.

List of Subjects in 21 CFR Part 520

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 520 is amended as follows:

PART 520—ORAL DOSAGE FORM NEW ANIMAL DRUGS

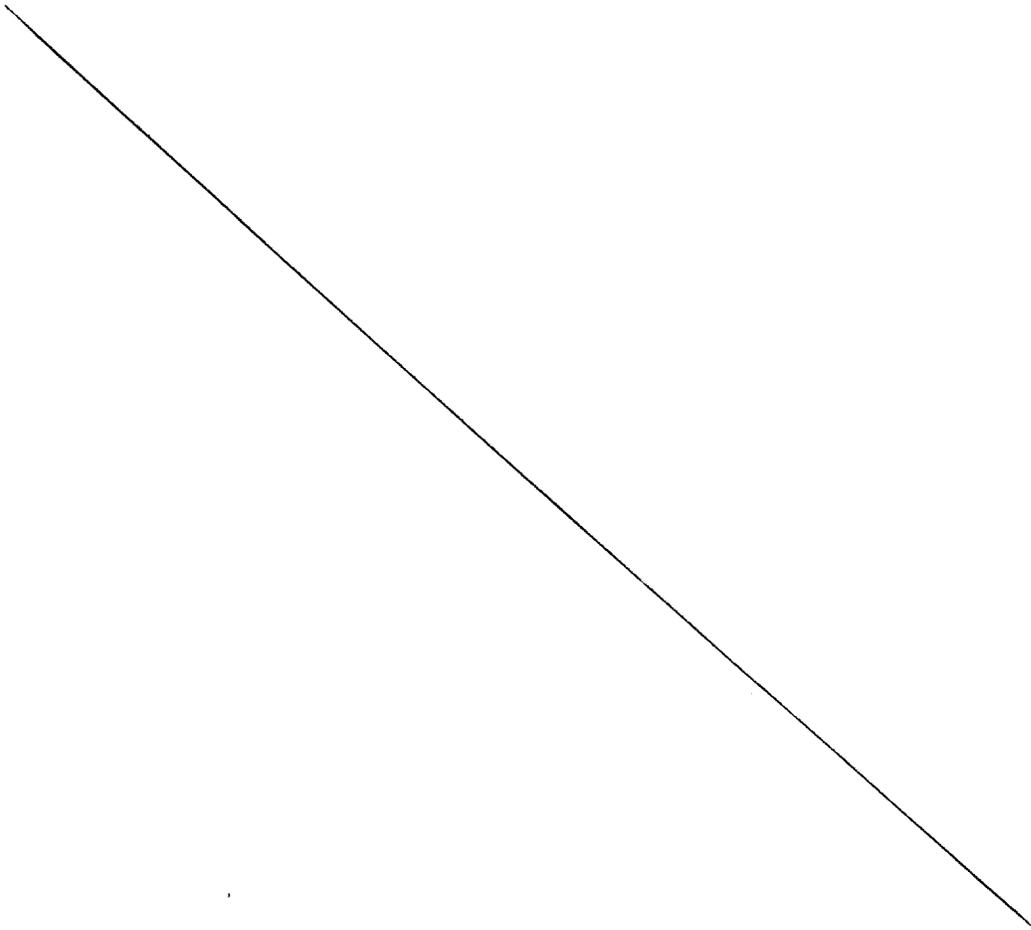
1. The authority citation for 21 CFR part 520 continues to read as follows:

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

2. Section 520.2260a is amended by revising the section heading and paragraph (a)(1), and by removing paragraph (a)(4) to read as follows:

§ 520.2260a Sulfamethazine oblet, tablet, and bolus.

(a)(1) *Sponsor.* See No. 010042 in § 510.600(c) of this chapter for use of 2.5-, 5-, and 15-gram sulfamethazine oblet in beef cattle, nonlactating dairy cattle, and horses. See No. 061690



in § 510.600(c) of this chapter for use of 5-, 15-, and 25-gram tablet in beef and nonlactating dairy cattle.

* * * * *

Dated: 11/10/99
November 10, 1999

SF SFF
Stephen F. Sundlof
Director
Center for Veterinary Medicine

[FR Doc. 99-???? Filed ??-??-99; 8:45 am]

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Michael W. Beech