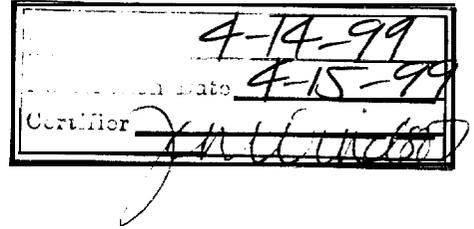


DMB



DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

21 CFR Part 520

Oral Dosage Form New Animal Drugs; Sulfadimethoxine Soluble Powder

**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 Phoenix Scientific, Inc. The ANADA provides for use of sulfadimethoxine (SDM) soluble powder to make a medicated drinking water for the treatment of chickens and turkeys and to make a drinking water or drench for treatment of dairy calves and heifers and beef cattle.

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

**FOR FURTHER INFORMATION CONTACT:** Lonnie W. Luther, Center for Veterinary Medicine (HFV-102), Food and Drug Administration, 7500 Standish Pi., Rockville, MD 20855, 301-827-0209.

**SUPPLEMENTARY INFORMATION:** Phoenix Scientific, Inc., 3915 South 48th St. Terrace, P.O. Box 6457, St. Joseph, MO 64506-0457, has filed ANADA 200-258 that provides for use of SDM soluble powder in drinking water for the treatment of disease outbreaks of coccidiosis, fowl cholera, and infectious coryza in broiler and replacement chickens; and coccidiosis and fowl cholera in meat-producing turkeys. The ANADA also provides for use of SDM soluble powder in drinking water or as a drench for the treatment of shipping fever complex and bacterial pneumonia associated with *Pasteurella* spp. sensitive to sulfadimethoxine, and for calf diphtheria and foot rot associated with *Sphaerophorus necrophorus* sensitive to sulfadimethoxine, in dairy calves, dairy heifers, and beef cattle.

**ANADA 200–258** is approved as a generic copy of Pfizer's NADA 46–285 Al bon <sup>®</sup> (sulfadimethoxine soluble powder). ANADA 200-258 is approved as of March 4, 1999, and the regulations in 21 CFR 520.2220a(a)(2) are amended 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 **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,

#### **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 redelegate 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.

§ 520.2220a [Amended]

2. Section 520,2220a *Sulfadimethoxine oral solution and soluble powder* is amended in paragraph (a)(2) by removing “and 057561” and adding in its place “057561, and 059130”.

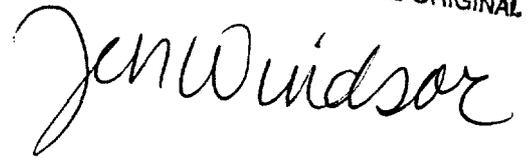
Dated: 4/1/99 —

April 1, 1999

 George A. Mitchell DVM

George A. Mitchell  
Acting Deputy Director  
Center for Veterinary Medicine

CERTIFIED TO BE A TRUE COPY OF THE ORIGINAL



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

BILLING CODE 4160-01-F