

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

21 CFR Parts 520 and 558

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Certifier R. LEDESMA

ADM

New Animal Drugs; Change of Sponsor; Sulfaquinoxaline

AGENCY: Food and Drug Administration, HHS.

ACTION: Final rule.

SUMMARY: The Food and Drug Administration (FDA) is amending the animal drug regulations to reflect a change of sponsor for an approved new animal drug application (NADA) from Hess & Clark, Inc., to Phoenix Scientific, Inc.

DATES: This rule is effective [insert date of publication in the **Federal Register**].

FOR FURTHER INFORMATION CONTACT: David R. Newkirk, Center for Veterinary Medicine (HFV-100), Food and Drug Administration, 7500 Standish Pl., Rockville, MD 20855, 301-827-6967, e-mail: *david.newkirk@fda.gov*.

SUPPLEMENTARY INFORMATION: Hess & Clark, Inc., 944 Nandino Blvd., Lexington, KY 40511, has informed FDA that it has transferred ownership of , and all rights and interest in, the following three approved NADAs, to Phoenix Scientific, Inc., 3915 South 48th Street Ter., St. Joseph, MO 64503:

NADA Number	Trade Name
6-391	S.Q. (sulfaquinoxaline) 40% Medicated Feed
6-677	S.Q. (sulfaquinoxaline) 20% Solution
7-087	Sulfaquinoxaline Solubilized

Accordingly, the agency is amending the regulations in 21 CFR 520.2325a and 558.586 to reflect the transfer of ownership and a current format.

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 the congressional review requirements in 5 U.S.C. 801-808.

List of Subjects

21 CFR Part 520

Animal drugs.

21 CFR Part 558

Animal drugs, Animal feeds.

■ 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 520 and 558 are 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.

§ 520.2325a [Amended]

■ 2. Section 520.2325a is amended in paragraph (a)(1) by removing “050749” and by adding in its place “059130”.

PART 558—NEW ANIMAL DRUGS FOR USE IN ANIMAL FEEDS

■ 3. The authority citation for 21 CFR part 558 continues to read as follows:

Authority: 21 U.S.C. 360b, 371.

■ 4. Section 558.586 is amended by revising the section heading; by removing paragraphs (c) and (d); by redesignating paragraphs (e) and (f) as paragraphs (c) and (d); and by revising paragraphs (a) and (b) to read as follows:

§ 558.586 Sulfaquinoxaline.

(a) *Specifications.* Type A medicated articles containing 40 percent sulfaquinoxaline.

adding paragraphs
per Kent
Giles/OFR

(b) *Approvals*. See No. 059130 in § 510.600(c) of this chapter.

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Dated: September 27, 2004
September 27, 2004.

Steven D. Vaughn

Steven D. Vaughn,
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Center for Veterinary Medicine.

[FR Doc. 04-????? Filed ??-??-04; 8:45 am]

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