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DEPARTMENT OF HEALTH AND HUMAN SERVICES

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Food and Drug Administration

21 CFR Parts 510 and 520

New Animal Drugs; Change of Sponsor

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 three new animal drug applications (NADAs) from Sweetlix LLC to Ridley U.S. Holdings, 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: Sweetlix LLC, 175 South Main St., suite 150, Salt Lake City, UT 84111, has informed FDA that it has transferred ownership of, and all rights and interest in, the following three approved NADAs to Ridley U.S. Holdings, Inc., 424 North Riverfront Dr., P.O. Box 8500, Mankato, MN 56002-8500:

Application Number	21 CFR Section	Trade Name
NADA 033-733	520.1840	Sweetlix Bloat Guard Block
NADA 109-471	520.1448a	Cattle Block M
NADA 136-214	520.1846	Enproal Bloat Blox

Accordingly, the agency is amending the regulations in 21 CFR 520.1448a, 520.1840, and 520.1846 to reflect the transfer of ownership.

Following these changes of sponsorship, Sweetlix LLC is no longer the sponsor of an approved application. In addition, Ridley U.S. Holdings, Inc., is not currently listed in the animal drug regulations as a sponsor of an approved application. Accordingly, § 510.600(c) is being amended to remove the entries for Sweetlix LLC and to add entries for Ridley U.S. Holdings, Inc.

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 510*

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

#### *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 510 and 520 are amended as follows:

### **PART 510—NEW ANIMAL DRUGS**

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

**Authority:** 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 removing the entry for “Sweetlix LLC” and by alphabetically adding an entry for “Ridley U.S. Holdings, Inc.” and in the table in paragraph (c)(2) by removing the entry for “036904” and by adding an entry for “067949” 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
Ridley U.S. Holdings, Inc., 424 North Riverfront Dr., P.O. Box 8500, Mankato, MN 56002-8500.	067949

(2) \* \* \*

Drug labeler code	Firm name and address
067949	Ridley U.S. Holdings, Inc., 424 N. Riverfront Dr., P.O. Box 8500, Mankato, MN 56002-8500

**PART 520—ORAL DOSAGE FORM NEW ANIMAL DRUGS**

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

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

**520.1448a [Amended]**

■ 4. Section 520.1448a is amended in paragraph (a)(2) by removing “036904” and by adding in its place “No. 067949.”

**520.1840 [Amended]**

■ 5. Section 520.1840 is amended in paragraph (b)(3) by removing “036904” and by adding in its place “067949.”

**520.1846 [Amended]**

■ 6. Section 520.1846 is amended in paragraph (b) by removing “050112” and by adding in its place “067949.”

Dated: October 20, 2004  
October 20, 2004.

cv0477

Steven D. Vaughn

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

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*John*