

Issued in Washington, DC on October 22, 2004.
Anthony F. Fazio,
Director, Office of Rulemaking.
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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

21 CFR Part 14

Advisory Committee: Change of Name and Function; Technical Amendment

AGENCY: Food and Drug Administration, HHS.
ACTION: Final rule; technical amendment.

SUMMARY: The Food and Drug Administration (FDA) is amending the standing advisory committees' regulations to change the name and function of the Biological Response Modifiers Advisory Committee. This action is being taken to reflect changes made to the charter for this advisory committee.

DATES: This rule is effective October 28, 2004.

FOR FURTHER INFORMATION CONTACT: Theresa Green, Advisory Committee Oversight Management Staff (HF-4), Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857, 301-827-1220.

SUPPLEMENTARY INFORMATION: FDA is announcing that the name of the Biological Response Modifiers Advisory Committee, which was established on October 28, 1988, has been changed. The name "Cellular, Tissue and Gene Therapies Advisory Committee" more accurately describes the subject areas for which the committee is responsible. The committee reviews and evaluates available data relating to the safety, effectiveness, and appropriate use of human cells, human tissues, gene transfer therapies, and xenotransplantation products which are intended for transplantation, implantation, infusion, and transfer in the prevention and treatment of a broad spectrum of human diseases, and in the reconstruction, repair or replacement of tissues for various conditions. The Committee also considers the quality and relevance of FDA's research

program which provides scientific support for the regulation of these products, and makes appropriate recommendations to the Commissioner of Food and Drugs.

The Biological Response Modifiers Advisory Committee name was changed and its functions expanded in the charter renewal dated October 28, 2004. FDA is revising 21 CFR 14.100(b)(2) to reflect these changes. In this document, FDA is hereby formally changing the name and the function of the committee by revising 21 CFR 14.100(b)(2).

Publication of this final rule constitutes a final action on this change under the Administrative Procedure Act. Under 5 U.S.C. 553(b)(B) and (d) and 21 CFR 10.40(d) and (e), the agency finds good cause to dispense with notice and public procedure and to proceed to an immediately effective regulation. Such notice and procedures are unnecessary and are not in the public interest, because the final rule is merely codifying the new name and expanded function of the advisory committee to reflect the current committee charter.

List of Subjects in 21 CFR Part 14

Administrative practice and procedure, Advisory committees, Color additives, Drugs, Radiation protection.
■ Therefore, under the Federal Food, Drug, and Cosmetic Act and under authority delegated to the Commissioner of Food and Drugs, 21 CFR part 14 is amended as follows:

PART 14—PUBLIC HEARING BEFORE A PUBLIC ADVISORY COMMITTEE

■ 1. The authority citation for 21 CFR part 14 continues to read as follows:

Authority: 5 U.S.C. App. 2; 15 U.S.C. 1451-1461, 21 U.S.C. 41-50, 141-149, 321-394, 467f, 679, 821, 1034; 28 U.S.C. 2112; 42 U.S.C. 201, 262, 263b, 264; Pub. L. 107-109; Pub. L. 108-155.

■ 2. Section 14.100 is amended by revising the heading of paragraph (b)(2) and paragraph (b)(2)(ii) to read as follows:

§ 14.100 List of standing advisory committees.

* * * * *

(b) * * *
(2) Cellular, Tissue and Gene Therapies Advisory Committee.

* * * * *

(ii) Function: Reviews and evaluates available data relating to the safety, effectiveness, and appropriate use of

human cells, human tissues, gene transfer therapies and xenotransplantation products which are intended for transplantation, implantation, infusion, and transfer in the prevention and treatment of a broad spectrum of human diseases and in the reconstruction, repair or replacement of tissues for various conditions. The Committee also considers the quality and relevance of FDA's research program which provides scientific support for the regulation of these products, and makes appropriate recommendations to the Commissioner of Food and Drugs.

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Dated: October 21, 2004.
Sheila Dearybury Walcott,
Associate Commissioner for External Relations.
[FR Doc. 04-24065 Filed 10-27-04; 8:45 am]
BILLING CODE 4160-01-S

DEPARTMENT OF HEALTH AND HUMAN SERVICES

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 October 28, 2004.

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

Application Number	21 CFR Section	Trade Name
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.

Steven D. Vaughn,

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

[FR Doc. 04-24112 Filed 10-27-04; 8:45 am]

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FEDERAL COMMUNICATIONS COMMISSION

47 CFR Part 64

[CC Docket No. 96-115; FCC 04-206]

Telecommunications Carriers' Use of Customer Proprietary Network Information and Other Customer Information

AGENCY: Federal Communications Commission.

ACTION: Final rule.

SUMMARY: In this document, the Federal Communications Commission addresses the petitions for reconsideration of the *Subscriber List Information Order*, which adopted rules to implement section 222(e) of the Communications Act of 1934, as amended (Communications Act or Act). The Commission denies requests for modification of certain aspects of the complaint procedures, notification requirements, and unbundling requirements established in the *Subscriber List Information Order*. The Commission eliminates the requirement for carriers to provide requesting directory publishers with notice of changes in subscriber list information in circumstances where customers choose to cease having their numbers listed, and modifies the contract disclosure requirement to allow carriers to withhold from disclosure those portions of their contracts that are unrelated to the provision of subscriber list information and to subject such disclosures to confidentiality agreements.

DATES: The amendments to § 64.2341 are effective November 29, 2004.

ADDRESSES: Federal Communications Commission, 445 12th Street, SW., Washington, DC 20554. See Supplementary Information for further filing instructions.

FOR FURTHER INFORMATION CONTACT:

William Kehoe, Senior Attorney, Competition Policy Division, Wireline Competition Bureau, at (202) 418-7122, or at William.Kehoe@fcc.gov.

SUPPLEMENTARY INFORMATION: This is a summary of the Commission's *Memorandum Opinion and Order on Reconsideration (Reconsideration Order)* in CC Docket No. 96-114, FCC 04-206, adopted August 25, 2004, and released September 13, 2004. The complete text of this Reconsideration Order is available for inspection and copying during normal business hours in the FCC Reference Information Center, Portals II, 445 12th Street, SW., Room CY-A257, Washington, DC, 20554. This document may also be purchased from the Commission's duplicating contractor, Best Copy and Printing Inc., Portals II, 445 12th Street, SW., Room CY-B402, Washington, DC 20554, telephone 202-863-2893,