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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 Walcoff,

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