

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 Drug Abuse Advisory Committee. This action is being taken to reflect changes made to the charter for this advisory committee.

DATES: This rule is effective July 11, 2002.

FOR FURTHER INFORMATION CONTACT: Theresa Green, Committee Management Officer (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 Drug Abuse Advisory Committee, which was established on May 31, 1978, has been changed. The agency decided that the name "Drug Safety and Risk Management Advisory Committee" would more accurately describe the subject areas for which the committee is responsible. The mandate of the committee is being expanded to include drug specific risk management and medication errors, educational campaigns and risk communication messages, and advice on potential drug name changes to reduce potential medication errors. The committee reviews and evaluates data on risk management plans, provides active surveillance methodologies, trademark studies, methodologies for risk management communication, and related issues.

The Drug Abuse Advisory Committee name was changed and its functions expanded in the charter renewal dated May 31, 2002. FDA is revising 21 CFR 14.100(c)(7) to reflect these changes.

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 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.

2. Section 14.100 is amended by revising the heading of paragraph (c)(7) and paragraph (c)(7)(ii) to read as follows:

§ 14.100 List of standing advisory committees.

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(c) * * *

(7) *Drug Safety and Risk Management Advisory Committee.*

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(ii) Function: Reviews and evaluates data on risk management plans, provides active surveillance methodologies, trademark studies, methodologies for risk management communication, and related issues.

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Dated: July 5, 2002.

William K. Hubbard,

Senior Associate Commissioner for Policy, Planning, and Legislation.

[FR Doc. 02-17401 Filed 7-10-02; 8:45 am]

BILLING CODE 4160-01-S

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

21 CFR Part 510

New Animal Drugs; Change of Sponsor's Address

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's address for BioScience Division of Milk Specialties Co.

DATES: This rule is effective July 11, 2002.

FOR FURTHER INFORMATION CONTACT: Lonnie W. Luther, Center for Veterinary Medicine (HFV-101), Food and Drug Administration, 7500 Standish Pl., Rockville, MD 20855, 301-827-0209, e-mail: lluther@cvm.fda.gov.

SUPPLEMENTARY INFORMATION: BioScience Division of Milk Specialties Co., Illinois and Water Sts., P.O. Box 278, Dundee, IL 60118, has informed FDA of a change of sponsor's address to 1902 Tennyson Lane, Madison, WI 53704. Accordingly, the agency is amending the regulations in 21 CFR 510.600(c)(1) and (c)(2) to reflect the change.

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 in 21 CFR Part 510

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

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 is amended as follows:

1. The authority citation for 21 CFR part 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 revising the entry for "BioScience Division of Milk Specialties Co." and in the table in paragraph (c)(2) by revising the entry for "032761" to read as follows:

§ 510.600 Names, addresses, and drug labeler codes of sponsors of approved applications.

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