



4164-01-P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

21 CFR Part 14

[Docket No. FDA-2009-N-0443]

Advisory Committee; Anti-Infective Drugs Advisory Committee

AGENCY: Food and Drug Administration, HHS.

ACTION: Final rule.

SUMMARY: The Food and Drug Administration (FDA) is amending the standing advisory committees' regulations to change the name of the Anti-Infective Drugs Advisory Committee.

This action is being taken to change the name of this committee on the Agency's list of standing advisory committees.

DATES: This rule is effective [INSERT DATE OF PUBLICATION IN THE FEDERAL REGISTER]. The name change became applicable March 4, 2015.

FOR FURTHER INFORMATION CONTACT: Michael Ortwerth, Advisory Committee Oversight and Management Staff, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 32, rm. 5129, Silver Spring, MD 20993-0002, FAX: 301-847-8640, or Michael.Ortwerth@fda.hhs.gov.

SUPPLEMENTARY INFORMATION: The Anti-Infective Drugs Advisory Committee (the Committee) was established on October 7, 1980 (45 FR 79025). The Committee reviews and

evaluates available data concerning the safety and effectiveness of marketed and investigational human drug products for use in the treatment of infectious diseases and disorders.

The Committee name has been changed to the following: Antimicrobial Drugs Advisory Committee. The Agency changed the name to better reflect the products and issues that will be brought to the committee. The change became effective March 4, 2015.

Therefore, the Agency is amending 21 CFR 14.100(c) as set forth in the regulatory text of this document.

Under 5 U.S.C. 553(b)(3)(B) and (d) and 21 CFR 10.40(d) and (e), the Agency finds good cause to dispense with notice and public comment procedures and to proceed to an immediate effective date on this rule. Notice and public comment and a delayed effective date are unnecessary and are not in the public interest as this final rule merely removes the name of the Anti-Infective Drugs Advisory Committee from the list of standing advisory committees in 21 CFR 14.100 and replaces it with the Antimicrobial Drugs Advisory Committee.

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; Pub. L. 113-54.

2. Amend § 14.100 by revising paragraph (c)(2) introductory text to read as follows:

§ 14.100 List of standing advisory committees.

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(c) * * *

(2) Antimicrobial Drugs Advisory Committee.

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Dated: March 27, 2015.

Leslie Kux,

Associate Commissioner for Policy.

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