4160-01-P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

21 CFR Part 14

[Docket No. FDA-2014-N-0355]

Advisory Committee: Bone, Reproductive and Urologic 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 and function of the Advisory Committee for Reproductive Health Drugs. This action is being taken to reflect changes made to the charter for this advisory committee.

DATES: This rule is effective [INSERT DATE OF PUBLICATION IN THE FEDERAL REGISTER].

FOR FURTHER INFORMATION CONTACT: Teresa Hays, Committee Management Officer, Food and Drug Administration, 10903 New Hampshire Ave., Silver Spring, MD 20993, 301-796-8220.

SUPPLEMENTARY INFORMATION: FDA is announcing that the name of the Advisory Committee for Reproductive Health Drugs, which was established on March 23, 1978, has been changed. The Agency decided that the name "Bone, Reproductive and Urologic Drugs Advisory Committee" more accurately describes the subject areas for which the committee is responsible. The committee reviews and evaluates data on the safety and effectiveness of marketed and investigational human drug products for use in the practice of osteoporosis and metabolic bone

disease, obstetrics, gynecology, urology and related specialties, and makes appropriate recommendations to the Commissioner of Food and Drugs.

The Bone, Reproductive and Urologic Drugs Advisory Committee name was changed and its functions expanded in the charter renewal dated March 23, 2014. In this final rule, FDA is revising 21 CFR 14.100(c)(9) 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 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 the 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. Section 14.100 is amended by revising the heading of paragraph (c)(9) and paragraph (c)(9)(ii) to read as follows:

§ 14.100 List of standing advisory committees.

* * * * *

(c) * * *

(9) Bone, Reproductive and Urologic Drugs Advisory Committee.

(i) * * *

(ii) Function: Advises the Commissioner or designee in discharging responsibilities as they relate to helping to ensure safe and effective drugs for human use and, as required, any other product for which the Food and Drug Administration has regulatory responsibility.

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Dated: April 8, 2014.

Jill Hartzler Warner,

Acting Associate Commissioner for Special Medical Programs.

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