4160-01-P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

21 CFR Part 14

[Docket No. FDA-2013-N-1687]

Advisory Committee; Pharmacy Compounding Advisory Committee

AGENCY: Food and Drug Administration, HHS.

ACTION: Final rule.

SUMMARY: The Food and Drug Administration (FDA) is amending its regulations to update information regarding the Pharmacy Compounding Advisory Committee in FDA's Center for Drug Evaluation and Research in the Agency's list of standing advisory committees. This updated information regarding the Committee includes changes to its charter to reflect the recent enactment of the Drug Quality and Security Act.

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

FOR FURTHER INFORMATION CONTACT: Jayne E. Peterson, Center for Drug Evaluation and Research, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 31, rm. 2417, Silver Spring, MD 20993-0002, 301-796-9001, FAX 301-847-8533, email: PCAC@fda.hhs.gov.

SUPPLEMENTARY INFORMATION: FDA announced the original establishment of the Pharmacy Compounding Advisory Committee (the Committee) and amended the regulations at § 14.100 (21 CFR 14.100) to add the Committee to the Agency's standing list of advisory committees in the Federal Register of March 10, 1998 (63 FR 11596). The Committee was established under authorities that included the Federal Advisory Committee Act (Pub. L. 92-

463), section 1004 of the Federal Food, Drug, and Cosmetic Act (the FD&C Act) (21 U.S.C. 394), and section 503A of the FD&C Act (21 U.S.C. 353a), as enacted as part of the Food and Drug Administration Modernization Act of 1997 (FDAMA) (Pub. L. 105-115), which exempted drugs compounded by pharmacies from the FD&C Act's new drug approval, adequate directions for use, and good manufacturing practice requirements if specified conditions, including two restrictions on commercial speech, were met. Section 503A of the FD&C Act as added by FDAMA also required the Agency to convene and consult with an advisory committee on compounding before issuing specified regulations.

In 2002, FDA terminated the Committee in response to the Supreme Court's decision in Thompson, et al. v. Western States Medical Center Pharmacy, et al. (535 U.S. 357 (2002)). That decision affirmed a decision of the U.S. Court of Appeals for the Ninth Circuit that held the speech related provisions of section 503A of the FD&C Act, as added by FDAMA, were unconstitutional. The Supreme Court held that the speech related restrictions in section 503A of the FD&C Act violated the First Amendment. The Ninth Circuit had also concluded that the unconstitutional speech restriction could not be severed from the other provisions of section 503A of the FD&C Act. The Supreme Court did not reach this issue. Therefore, the Ninth Circuit's opinion invalidating section 503A of the FD&C Act in its entirety remained intact. FDA stated its view at the time, which was that the underlying authority in section 503A of the FD&C Act to establish the Pharmacy Compounding Advisory Committee was invalidated and without a statutory basis for the Committee, the Agency terminated the Committee (67 FR 70227, November 21, 2002).

Subsequently, in 2008, the U.S. Court of Appeals for the Fifth Circuit decided Medical Center Pharmacy v. Mukasey (536 F.3d 383 (5th Cir. 2008)), in which that court disagreed with

the Ninth Circuit's holding regarding the severability of section 503A of the FD&C Act as added by FDAMA. The Fifth Circuit found the unconstitutional provisions of section 503A of the FD&C Act to be severable and that the other provisions could remain in effect. Based on this decision, FDA reestablished the Pharmacy Compounding Advisory Committee in 2012.

On November 27, 2013, the President signed into law the Drug Quality and Security Act (Pub. L. 113-54). This law removed the unconstitutional provisions from section 503A and added a new section 503B to the FD&C Act (21 U.S.C. 353b) that also requires FDA to consult with a Pharmacy Compounding Advisory Committee before issuing certain regulations pertaining to outsourcing facilities. As a result, FDA has amended the charter of the Pharmacy Compounding Advisory Committee to reflect the relevant statutory changes.

Under the amended charter, the Committee provides advice on scientific, technical, and medical issues concerning drug compounding under sections 503A and 503B of the FD&C Act and, as required, any other product for which FDA has regulatory responsibility, and makes appropriate recommendations to the Commissioner of Food and Drugs (the Commissioner).

The Committee will be composed of a core of 12 voting members including the Chair. Members and the Chair are selected by the Commissioner or designee from among authorities knowledgeable in the fields of pharmaceutical compounding, pharmaceutical manufacturing, pharmacy, medicine, and related specialties. Membership also includes representatives from the National Association of Boards of Pharmacy and the United States Pharmacopoeia, and representatives of patient and public health advocacy organizations. Members will be invited to serve for overlapping terms of up to 4 years. Almost all non-Federal members of this committee will serve as special Government employees. The core of voting members may include one qualified member, selected by the Commissioner or designee, who is identified with consumer

interests and is recommended by either a consortium of consumer-oriented organizations or other interested persons. In addition to the voting members, the Committee may include one or more non-voting members who are identified with industry interests.

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 updates information regarding the function of the Committee already set out in the charter, and updates information regarding the dates related to the Committee establishment in the list of standing advisory committees in § 14.100. Therefore, the Agency is amending § 14.100.

Elsewhere in this issue of the Federal Register, FDA is publishing a notice requesting nominations for voting members of the Committee, a notice for industry organizations to participate in the nominations for and selection of industry representatives for the Committee, and a notice for consumer organizations to participate in the nominations for and selection of the consumer representative for the 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 is revised 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 paragraph (c)(18) to read as follows:

§ 14.100 List of standing advisory committees.

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(c) * * *

(18) Pharmacy Compounding Advisory Committee.

(i) Date re-established: April 25, 2012.

(ii) Function: Provides advice on scientific, technical, and medical issues concerning drug compounding under sections 503A and 503B of the Federal Food, Drug, and Cosmetic Act and, as required, any other product for which the Food and Drug Administration has regulatory responsibility, and makes appropriate recommendations to the Commissioner of Food and Drugs.

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Dated: January 7, 2014.

Jill Hartzler Warner,

Acting Associate Commissioner for Special Medical Programs.

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