



DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

21 CFR Parts 14 and 20

[Docket No. FDA-2015-N-2103]

Removal of Review and Reclassification Procedures for Biological Products Licensed Prior to July 1, 1972; Technical Amendment

AGENCY: Food and Drug Administration, HHS.

ACTION: Final rule; technical amendment.

SUMMARY: The Food and Drug Administration (FDA or Agency) is amending the Agency's regulations by removing certain regulations that include obsolete references. FDA is taking this action to improve the accuracy of the regulations.

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

FOR FURTHER INFORMATION CONTACT: Jessica T. Walker, Center for Biologics Evaluation and Research, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 71, rm. 7301, Silver Spring, MD 20993-0002, 240-402-7911.

SUPPLEMENTARY INFORMATION: In the Federal Register of February 12, 2016 (81 FR 7445), FDA published a final rule entitled "Removal of Review and Reclassification Procedures for Biological Products Licensed Prior to July 1, 1972" (February 2016 final rule). In the February 2016 final rule, FDA, in part, removed § 601.25 (21 CFR 601.25), which prescribed procedures for FDA's review of biological products licensed before July 1, 1972.

Under § 14.1(a)(2) (21 CFR 14.1(a)(2)), specific provisions are provided for a matter that is subject to a hearing before an advisory committee. Under § 20.100(c) (21 CFR 20.100(c)), in addition to the provisions of 21 CFR part 20, rules on the availability of specific categories of FDA records are established by regulations under Chapter I of Title 21 of the Code of Federal Regulations. Sections 14.1(a)(2)(v) and 20.100(c)(22) include a reference to § 601.25. In the February 2016 final rule, FDA inadvertently did not remove these sections (§§ 14.1(a)(2)(v) and 20.100(c)(22)) that referenced § 601.25. Accordingly, FDA is removing and reserving §§ 14.1(a)(2)(v) and 20.100(c)(22).

Publication of this document constitutes final action under the Administrative Procedure Act (5 U.S.C. 553). FDA has determined that notice and public comment is unnecessary because the amendments to the regulations are nonsubstantive.

List of Subjects

21 CFR Part 14

Administrative practice and procedure, Advisory committees, Color additives, Drugs, Radiation protection.

21 CFR Part 20

Confidential business information, Courts, Freedom of information, Government employees.

Therefore, under the Federal Food, Drug, and Cosmetic Act, the Public Health Service Act, and under authority delegated to the Commissioner of Food and Drugs, 21 CFR parts 14 and 20 are amended as follows:

PART 14--PUBLIC HEARING BEFORE A PUBLIC ADVISORY COMMITTEE

1. The authority citation for 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.

§ 14.1 [Amended]

2. In § 14.1, remove and reserve paragraph (a)(2)(v).

PART 20--PUBLIC INFORMATION

3. The authority citation for part 20 continues to read as follows:

Authority: 5 U.S.C. 552; 18 U.S.C. 1905; 19 U.S.C. 2531-2582; 21 U.S.C. 321-393, 1401-1403; 42 U.S.C. 241, 242, 242a, 2421, 242n, 243, 262, 263, 263b-263n, 264, 265, 300u-300u-5, 300aa-1.

§ 20.100 [Amended]

4. In § 20.100, remove and reserve paragraph (c)(22).

Dated: July 8, 2016.

Leslie Kux,

Associate Commissioner for Policy.

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