

DEPARTMENT OF HEALTH AND HUMAN SERVICES**Food and Drug Administration**

21 CFR Parts 1, 26, 99, 201, 203, 206, 207, 310, 312, 314, 600, 601, 606, 607, 610, 660, 680, 801, 807, 812, 814, 822, and 1271

[Docket No. FDA-2015-N-0011]

Food and Drug Administration Regulations; Change of Addresses; Technical Amendment

AGENCY: Food and Drug Administration, HHS.

ACTION: Final rule; technical amendment.

SUMMARY: The Food and Drug Administration (FDA) is amending its regulations to update address information for the Center for Biologics Evaluation and Research (CBER) as a result of the recent relocation of CBER offices and laboratories to the FDA White Oak campus in Silver Spring, MD, as well as make other related technical revisions. These changes are being made to ensure the accuracy of the Agency's regulations.

DATES: This rule is effective April 3, 2015.

FOR FURTHER INFORMATION CONTACT: John Reilly, 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: FDA is amending its regulations in parts 1, 26, 99, 201, 203, 206, 207, 310, 312, 314, 600, 601, 606, 607, 610, 660, 680, 801, 807, 812, 814, 822, and 1271 (21 CFR parts 1, 26, 99, 201, 203, 206, 207, 310, 312, 314, 600, 601, 606, 607, 610, 660, 680, 801, 807, 812, 814, 822, and 1271) to reflect the following changes: (1) The relocation of CBER offices and laboratories from various Rockville and Bethesda, MD, locations to the FDA White Oak campus in Silver Spring, MD; (2) the change of address of CBER's Document Control Center; (3) updating the names of certain CBER organizational units referenced in the regulations; (4) revising certain cross-references to be more specific and thereby facilitate locating the appropriate mailing addresses for submissions, requests, and other correspondence relating to biological products regulated by CBER and the Center for Drug Evaluation and Research (CDER); and (5) making other minor changes to ensure accuracy. The updated addresses include locations to

which applicants must submit information related to applications or products regulated by CBER or from which the public can request information. Where appropriate, CBER Web addresses for obtaining or submitting forms and other information are added or updated, and outdated addresses are removed. In certain instances, mail previously addressed to specific CBER offices should now be addressed to the CBER Document Control Center.

The technical amendments, reflected in the regulatory text of this final rule, are as follows:

- In § 1.101(d)(2)(i), the CBER unit and address for submitting notifications regarding CBER-regulated products exported under section 802 of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 382) are updated to the CBER Document Control Center on the White Oak campus.
- In Appendix E to subpart A of part 26, the contact information provided for CBER, including its address, telephone, and fax numbers to be used in the two-way alert system established in accordance with the 1998 "Agreement on Mutual Recognition Between the United States of America and the European Community," is updated to reflect CBER's move to the White Oak campus.
- In § 99.201(c)(1), the CBER unit and address to send a submission and certification statement, or to send an application for exemption relating to the dissemination of information on an unapproved/new use regarding a biological product or device is updated to the CBER Document Control Center on the White Oak campus.
- In § 201.25(d)(2), the CBER unit and address for submitting a request for exemption from the bar code label requirement for biological products regulated by CBER are updated to the CBER Document Control Center on the White Oak campus. Several other minor changes are made to this provision for purposes of clarity and correctness in referring to products regulated by CBER or CDER.
- In § 201.58, the CBER unit and address for submitting a request for waiver from certain labeling requirements are updated to the CBER Document Control Center on the White Oak campus.
- In § 203.12, the CBER unit and address for submitting an appeal from an adverse decision relating to the reimportation of biological products regulated by CBER are updated to the CBER Document Control Center on the White Oak campus. Several other minor changes in terminology also are made to

this provision for purposes of accuracy and consistency when referring to products regulated by CBER or CDER.

- In § 203.37(e), the CBER unit and address for submitting information in notifications and reports involving human prescription biological products regulated by CBER are updated to the CBER Document Control Center on the White Oak campus. Several other minor changes in terminology also are made to this provision for purposes of accuracy and consistency when referring to products regulated by CBER or CDER.
- In § 203.70(b)(2), the CBER unit and address to apply for a reward when providing information leading to a criminal proceeding or conviction related to the sale, purchase, or trade of a drug sample are updated to the CBER Document Control Center on the White Oak campus.
- In § 206.7(b)(1)(i), the CBER unit and address for requesting an exemption from imprinting requirements involving human drug products in solid oral dosage form are updated to the CBER Document Control Center on the White Oak campus.
- In § 207.7(a), the CBER unit and address for submitting blood establishment registration and product listing information are updated to the CBER Document Control Center on the White Oak campus.
- In § 310.503(f)(3), the CBER unit and address for submitting an investigational new drug (IND) application or an application for a biologics license under section 351 of the Public Health Service Act with regard to certain radioactive drugs considered biologics are updated to the CBER Document Control Center on the White Oak campus.
- In § 312.140(a)(3), the address for submitting an IND application involving biological products regulated by CBER is updated to the White Oak campus.
- In § 312.145(b), the CBER unit and address from which to request a list of CBER guidances are updated to the Office of Communication, Outreach and Development and the White Oak campus.
- In § 312.310(d)(1), the CBER local telephone number for requesting emergency expanded access use of investigational biological drug products regulated by CBER is updated.
- In § 314.440(b), the CBER addresses for submitting new drug applications and other correspondence involving certain drug products used in the collection, processing, or storage of

blood components, as well as the address for requesting an opportunity for a hearing, are updated to the White Oak campus.

- In § 600.2(a), the CBER Document Control Center address for regulatory submissions and other correspondence pertaining to licensed biological products regulated by CBER is updated to the White Oak campus.

- In § 600.2(c)(1), the CBER Sample Custodian address for submitting samples and protocols of licensed biological products regulated by CBER or CDER is updated to the White Oak campus.

- In § 600.2(c)(2), the unit and address for submitting samples and protocols of radioactive biological products are updated to the White Oak Radiation Safety Program and the White Oak campus.

- In § 600.11(f)(6), the cross-reference “§ 600.2” is changed to “§ 600.2(a) or (b)” to provide a more specific citation to the appropriate CBER or CDER address to use when notifying FDA of certain infectious animal diseases.

- In § 600.14(e)(1), the CBER unit and address for reporting biological product deviations for products regulated by CBER are updated to the CBER Document Control Center on the White Oak campus. The specific CBER Web address for submitting such reports electronically is removed, and a more general reference for submitting such reports electronically is added in its place.

- In § 600.22(e), the cross-reference “§ 600.2” is changed to “§ 600.2(c)” to provide a more specific citation to the appropriate CBER or CDER address to use when submitting product or ingredient samples from an inspection of a licensed establishment.

- In § 601.2(a), the cross-reference “§ 600.2” is changed to “§ 600.2(a) or (b)” to provide a more specific citation to the appropriate CBER or CDER address to use when submitting an application for a biologics license.

- In § 601.12(f)(4), the reference to Form FDA 2567 (Transmittal of Labels and Circulars) is removed because the form is no longer used.

- In § 601.15, the cross-reference “§ 600.2” is changed to “§ 600.2(c)” to provide a more specific citation to the appropriate address to use when submitting samples of imported licensed biological products regulated by CBER or CDER.

- In § 601.28, the cross-reference “§ 600.2” is changed to “§ 600.2(a) or (b)” to provide a more specific citation to the appropriate CBER or CDER address to use when submitting

postmarketing pediatric studies with regard to licensed biological products.

- In § 601.29(b), the CBER unit and address from which to request a list of CBER guidances are updated to the White Oak campus.

- In § 601.70(d), the cross-reference “§ 600.2” is changed to “§ 600.2(a) or (b)” to provide a more specific citation to the appropriate CBER or CDER address to use when submitting annual progress reports of postmarketing studies.

- In § 606.170(b), the cross-reference “§ 600.2” is changed to “§ 600.2(a)” to clarify the need to use the updated CBER Document Control Center address when submitting a written report involving a fatal adverse reaction relating to blood collection or transfusion.

- In § 606.171(e), the CBER unit and address for reporting blood and blood component product deviations are updated to the CBER Document Control Center on the White Oak Campus. The specific CBER Web address for submitting such reports electronically is removed, and a more general reference for submitting such reports electronically is added in its place. Other editorial changes have been made to improve the provision's clarity without changing its meaning.

- In § 607.7(b) and (c), the cross-reference “§ 600.2” is changed to “§ 600.2(a)” and the reference to mail code “(HFM-375)” is removed to clarify using the updated CBER Document Control Center address in § 600.2(a) when requesting and submitting registration and product listing information with regard to the manufacture of blood products.

- In § 607.22(a), the cross-reference “§ 600.2” is changed to “§ 600.2(a)” and the reference to mail code “(HFM-375)” is removed to clarify using the updated CBER Document Control Center address in § 600.2(a) when requesting and submitting registration and product listing information involving the manufacture of blood products on Form FDA 2830. Reference to the “Department of Health and Human Services” as part of the address has been removed.

- Section 607.37(a) is updated to reflect that registrant and product list information filed on Form FDA 2830 for establishments manufacturing blood products, previously made available through public inspection at CBER offices, now is accessible by using CBER's Web site or by visiting FDA's Division of Dockets Management. In § 607.37(b), the name of the CBER unit and address for requesting other information regarding blood

establishment registrations and blood product listings are updated to the Office of Communication, Outreach and Development and the White Oak campus.

- In § 610.2(a) and (b), the cross-reference “§ 600.2” is changed to “§ 600.2(c)” to provide a more specific citation to the appropriate address to use when submitting samples and protocols of licensed biological products.

- In § 610.11(g)(2), the cross-reference “§ 600.2” is changed to “§ 600.2(a) or (b)” to provide a more specific citation to the appropriate CBER or CDER address to use when submitting a request for an exemption from the general safety test requirement for licensed biological products.

- In § 610.15(a)(3), the cross-reference “§ 600.2” is changed to “§ 600.2(a) or (b)” to provide a more specific citation to the appropriate CBER or CDER address to use when submitting data regarding the amount of aluminum used in individual doses of a biological product.

- In § 660.3, the CBER unit and address for obtaining a Reference Hepatitis B Surface Antigen Panel have been updated to CBER Reagents and Standards Shipping and the White Oak campus.

- In § 660.6(a)(2), the cross-reference “§ 600.2” is changed to “§ 600.2(c)” to provide a more specific citation to the appropriate address to use when submitting product samples and protocols involving Antibody to Hepatitis B Surface Antigen. Also, a misspelling of the word “Official” in the heading in § 660.6(c) is corrected.

- In § 660.22(b), the CBER unit and address for obtaining reference preparations for Reference Blood Grouping Reagents have been updated to CBER Reagents and Standards Shipping and the White Oak campus.

- In § 660.36, the cross-reference to § 600.2(c) is added to § 660.36(a) and (c), and the cross-reference to § 600.2(a) is added to § 660.36(b), to provide further specificity as to the appropriate address to use when submitting product samples and protocols relating to Reagent Red Blood Cells.

- In § 660.46(a)(2), the cross-reference “§ 600.2” is changed to “§ 600.2(c)” to provide a more specific citation to the appropriate address to use when submitting product samples and protocols relating to Hepatitis B Surface Antigen.

- In § 660.52, the CBER unit and address for obtaining reference preparations for Reference Anti-Human Globulin are updated to CBER Reagents

and Standards Shipping and the White Oak campus.

- In § 680.1(b)(2)(iii), (b)(3)(iv), and (c), the cross-reference “§ 600.2” is changed to “§ 600.2(a) of this chapter” to clarify using the updated CBER Document Control Center address when submitting the requested source material information regarding allergenic products.

- In § 801.55(b)(1), the CBER unit and address for requesting an exception or alternative to a unique device identifier for devices regulated by CBER are updated to the CBER Document Control Center on the White Oak campus.

- In § 807.90(a)(2), the address for submitting a premarket notification for devices regulated by CBER is updated to the White Oak campus; the specific CBER Web address for obtaining information about devices regulated by CBER is removed, and a more general reference for obtaining this information on the CBER’s Web site is added in its place.

- In § 812.19(a)(2), the address for sending correspondence in connection with investigational device exemptions (IDEs) involving devices regulated by CBER is updated to the White Oak campus.

- In § 814.20(h)(2), the address for submitting a premarket approval application (PMA), a PMA amendment, a PMA supplement, or correspondence involving a PMA for devices regulated by CBER is updated to the White Oak campus.

- In § 814.104(d)(2), the address for submitting an original PMA seeking a humanitarian device exemption (HDE), or related amendments or supplements, or other correspondence relating to an HDE for devices regulated by CBER is updated to the White Oak campus.

- In § 822.8, the address for submitting a postmarket surveillance plan for devices regulated by CBER is updated to the White Oak campus.

- The address for submitting a reclassification petition for devices regulated by CBER in § 860.123(b)(1) was updated to the White Oak campus in a previous FDA document published in the **Federal Register** on December 24, 2014 (79 FR 77387).

- In § 1271.22(b), the CBER address and local telephone number for requesting Form FDA 3356 involving establishment registration and listing for human cells, tissues, and cellular and tissue-based products (HCT/Ps) are updated to the Document Control Center on the White Oak campus. In § 1271.22(c)(1), the CBER unit and address for submitting Form FDA 3356 are updated to the CBER Document Control Center on the White Oak

campus. And in § 1271.22(c)(2), the specific CBER Web address for submitting Form FDA 3356 electronically is removed, and a more general reference for submitting this form electronically is added in its place.

- Section 1271.37(a) is updated to reflect that registrant and product list information filed on Form FDA 3356 for HCT/Ps, previously made available for public inspection at CBER offices, can now be accessed through CBER’s Web site or by visiting FDA’s Division of Dockets Management. In § 1271.37(b), the name of the CBER unit and address for requesting other information regarding HCT/P establishment registrations and HCT/P listings are updated to the Office of Communication, Outreach and Development and the White Oak campus.

- In § 1271.350(a)(5), the CBER unit and address for submitting adverse reaction reports involving an HCT/P have been updated to the CBER Document Control Center on the White Oak campus. In § 1271.350(b)(3), the address for obtaining and submitting Form FDA 3486 by mail has been updated to the CBER Document Control Center on the White Oak campus. The specific CBER Web addresses for obtaining and submitting the form electronically have been replaced by a more general reference to using CBER’s electronic Web-based application.

Publication of this document constitutes final action of these changes under the Administrative Procedure Act (5 U.S.C. 553). FDA has determined that notice and public comment are unnecessary because this amendment to the regulations provides only technical changes to update addresses and other information, and is nonsubstantive.

List of Subjects

21 CFR Part 1

Cosmetics, Drugs, Exports, Food labeling, Imports, Labeling, Reporting and recordkeeping requirements.

21 CFR Part 26

Animal drugs, Biologics, Drugs, Exports, Imports.

21 CFR Part 99

Administrative practice and procedure, Biologics, Drugs, Medical devices, Reporting and recordkeeping requirements.

21 CFR Part 201

Drugs, Labeling, Reporting and recordkeeping requirements.

21 CFR Part 203

Labeling, Prescription drugs, Reporting and recordkeeping requirements, Warehouses.

21 CFR Part 206

Drugs.

21 CFR Part 207

Drugs, Reporting and recordkeeping requirements.

21 CFR Part 310

Administrative practice and procedure, Drugs, Labeling, Medical devices, Reporting and recordkeeping requirements.

21 CFR Part 312

Drugs, Exports, Imports, Investigations, Labeling, Medical research, Reporting and recordkeeping requirements, Safety.

21 CFR Part 314

Administrative practice and procedure, Confidential business information, Drugs, Reporting and recordkeeping requirements.

21 CFR Part 600

Biologics, Reporting and recordkeeping requirements.

21 CFR Part 601

Administrative practice and procedure, Biologics, Confidential business information.

21 CFR Part 606

Blood, Labeling, Laboratories, Reporting and recordkeeping requirements.

21 CFR Part 607

Blood.

21 CFR Parts 610 and 660

Biologics, Labeling, Reporting and recordkeeping requirements.

21 CFR Part 680

Biologics, Blood, Reporting and recordkeeping requirements.

21 CFR Part 801

Labeling, Medical devices, Reporting and recordkeeping requirements.

21 CFR Part 807

Confidential business information, Imports, Medical devices, Reporting and recordkeeping requirements.

21 CFR Part 812

Health records, Medical devices, Medical research, Reporting and recordkeeping requirements.

21 CFR Part 814

Administrative practice and procedure, Confidential business information, Medical devices, Medical research, Reporting and recordkeeping requirements.

21 CFR Part 822

Medical devices, Reporting and recordkeeping requirements.

21 CFR Part 1271

Biologics, Drugs, Human cells and tissue-based products, Medical devices, Reporting and recordkeeping requirements.

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 1, 26, 99, 201, 203, 206, 207, 310, 312, 314, 600, 601, 606, 607, 610, 660, 680, 801, 807, 812, 814, 822, and 1271 are amended as follows:

PART 1—GENERAL ENFORCEMENT REGULATIONS

- 1. The authority citation for 21 CFR part 1 continues to read as follows:

Authority: 15 U.S.C. 1333, 1453, 1454, 1455, 4402; 19 U.S.C. 1490, 1491; 21 U.S.C. 321, 331, 332, 333, 334, 335a, 343, 350c, 350d, 352, 355, 360b, 360ccc, 360ccc-1, 360ccc-2, 362, 371, 374, 381, 382, 387, 387a, 387c, 393; 42 U.S.C. 216, 241, 243, 262, 264.

§ 1.101 [Amended]

- 2. Section 1.101 is amended in paragraph (d)(2)(i) by removing the words “Division of Case Management (HFM-610), Office of Compliance and Biologics Quality, Center for Biologics Evaluation and Research, Food and Drug Administration, 1401 Rockville Pike, Suite 200N, Rockville, MD 20852-1448” and by adding in their place “Food and Drug Administration, Center for Biologics Evaluation and Research, Document Control Center, 10903 New Hampshire Ave., Bldg. 71, Rm. G112, Silver Spring, MD 20993-0002”.

PART 26—MUTUAL RECOGNITION OF PHARMACEUTICAL GOOD MANUFACTURING PRACTICE REPORTS, MEDICAL DEVICE QUALITY SYSTEM AUDIT REPORTS, AND CERTAIN MEDICAL DEVICE PRODUCT EVALUATION REPORTS: UNITED STATES AND THE EUROPEAN COMMUNITY

- 3. The authority citation for 21 CFR part 26 continues to read as follows:

Authority: 5 U.S.C. 552; 15 U.S.C. 1453, 1454, 1455; 18 U.S.C. 1905; 21 U.S.C. 321, 331, 351, 352, 355, 360, 360b, 360c, 360d,

360e, 360f, 360g, 360h, 360i, 360j, 360l, 360m, 371, 374, 381, 382, 383, 393; 42 U.S.C. 216, 241, 242l, 262, 264, 265.

- 4. Appendix E to subpart A of part 26 is amended under the heading “B. For the United States:” in the entry for “Biologics” by removing the words “Director, Office of Compliance and Biologics Quality (HFM-600), 1401 Rockville Pike, Rockville, MD 20852, phone: 301-827-6190, fax: 301-594-1944” and by adding in their place “Food and Drug Administration, Center for Biologics Evaluation and Research, Document Control Center, 10903 New Hampshire Ave., Bldg. 71, Rm. G112, Silver Spring, MD 20993-0002, telephone: 240-402-9153, FAX: 301-595-1302”.

PART 99—DISSEMINATION OF INFORMATION ON UNAPPROVED/ NEW USES FOR MARKETING DRUGS, BIOLOGICS, AND DEVICES

- 5. The authority citation for 21 CFR part 99 continues to read as follows:

Authority: 21 U.S.C. 321, 331, 351, 352, 355, 360, 360c, 360e, 360aa-360aaa-6, 371, and 374; 42 U.S.C. 262.

§ 99.201 [Amended]

- 6. Section 99.201 is amended in paragraph (c)(1) by removing the words “the Advertising and Promotional Labeling Staff (HFM-602), Center for Biologics Evaluation and Research, Food and Drug Administration, 1401 Rockville Pike, Suite 200N, Rockville, MD 20852-1448” and by adding in their place “Food and Drug Administration, Center for Biologics Evaluation and Research, Document Control Center, 10903 New Hampshire Ave., Bldg. 71, Rm. G112, Silver Spring, MD 20993-0002”.

PART 201—LABELING

- 7. The authority citation for 21 CFR part 201 continues to read as follows:

Authority: 21 U.S.C. 321, 331, 351, 352, 353, 355, 358, 360, 360b, 360gg-360ss, 371, 374, 379e; 42 U.S.C. 216, 241, 262, 264.

§ 201.25 [Amended]

- 8. Section 201.25 is amended in paragraph (d)(2) by removing the words “(requests involving a drug product) or to the Office of Compliance and Biologics Quality (HFM-600), Center for Biologics Evaluation and Research, Food and Drug Administration, 1401 Rockville Pike, Rockville, MD 20852 (requests involving a biological product)” and by adding in their place “(requests involving a drug product or biological product regulated by the Center for Drug Evaluation and

Research) or to the Food and Drug Administration, Center for Biologics Evaluation and Research, Document Control Center, 10903 New Hampshire Ave., Bldg. 71, Rm. G112, Silver Spring, MD 20993-0002 (requests involving a biological product regulated by the Center for Biologics Evaluation and Research)”.

§ 201.58 [Amended]

- 9. Section 201.58 is amended in the second sentence by removing the words “Center for Biologics Evaluation and Research, Food and Drug Administration, 1401 Rockville Pike, Suite 200 North, Rockville, MD 20852-1448” and by adding in their place “Food and Drug Administration, Center for Biologics Evaluation and Research, Document Control Center, 10903 New Hampshire Ave., Bldg. 71, Rm. G112, Silver Spring, MD 20993-0002”.

PART 203—PRESCRIPTION DRUG MARKETING

- 10. The authority citation for 21 CFR part 203 continues to read as follows:

Authority: 21 U.S.C. 331, 333, 351, 352, 353, 360, 371, 374, 381.

- 11. Section 203.12 is revised to read as follows:

§ 203.12 An appeal from an adverse decision by the district office.

An appeal from an adverse decision by the district office involving insulin-containing drugs or human prescription drugs or biological products regulated by the Center for Drug Evaluation and Research may be made to the Office of Compliance, Center for Drug Evaluation and Research, Food and Drug Administration, 10903 New Hampshire Ave., Silver Spring, MD 20993-0002. An appeal from an adverse decision by the district office involving human prescription biological products regulated by the Center for Biologics Evaluation and Research may be made to the Food and Drug Administration, Center for Biologics Evaluation and Research, Document Control Center, 10903 New Hampshire Ave., Bldg. 71, Rm. G112, Silver Spring, MD 20993-0002.

- 12. Section 203.37 is amended by revising paragraph (e) to read as follows:

§ 203.37 Investigation and notification requirements.

* * * * *

(e) *Whom to notify at FDA.*

Notifications and reports concerning human prescription drugs or biological products regulated by the Center for Drug Evaluation and Research shall be made to the Division of Compliance

Risk Management and Surveillance, Office of Compliance, Center for Drug Evaluation and Research, Food and Drug Administration, 10903 New Hampshire Ave., Silver Spring, MD 20993-0002. Notifications and reports concerning human prescription biological products regulated by the Center for Biologics Evaluation and Research shall be made to the Food and Drug Administration, Center for Biologics Evaluation and Research, Document Control Center, 10903 New Hampshire Ave., Bldg. 71, Rm. G112, Silver Spring, MD 20993-0002.

■ 13. Section 203.70 is amended by revising paragraph (b)(2) to read as follows:

§ 203.70 Application for a reward.

* * * * *

(b) * * *

(2) Food and Drug Administration, Center for Biologics Evaluation and Research, Office of Compliance and Biologics Quality (ATTN: Director), Document Control Center, 10903 New Hampshire Ave., Bldg. 71, Rm. G112, Silver Spring, MD 20993-0002, as appropriate.

PART 206—IMPRINTING OF SOLID ORAL DOSAGE FORM DRUG PRODUCTS FOR HUMAN USE

■ 14. The authority citation for 21 CFR part 206 continues to read as follows:

Authority: 21 U.S.C. 321, 331, 351, 352, 355, 371; 42 U.S.C. 262.

§ 206.7 [Amended]

■ 15. Section 206.7 is amended in the first sentence of paragraph (b)(1)(i) by removing the words “Center for Biologics Evaluation and Research (CBER), Food and Drug Administration, 1401 Rockville Pike, Suite 200N, Rockville, MD 20852-1448” and by adding in their place “Food and Drug Administration, Center for Biologics Evaluation and Research, Document Control Center, 10903 New Hampshire Ave., Bldg. 71, Rm. G112, Silver Spring, MD 20993-0002”.

PART 207—REGISTRATION OF PRODUCERS OF DRUGS AND LISTING OF DRUGS IN COMMERCIAL DISTRIBUTION

■ 16. The authority citation for 21 CFR part 207 continues to read as follows:

Authority: 21 U.S.C. 321, 331, 351, 352, 355, 360, 360b, 371, 374, 381, 393; 42 U.S.C. 262, 264, 271.

§ 207.7 [Amended]

■ 17. Section 207.7 is amended in the first sentence of paragraph (a) by

removing the words “Center for Biologics Evaluation and Research (HFM-375), 1401 Rockville Pike, Suite 200N, Rockville, MD 20852-1448” and by adding in their place “Food and Drug Administration, Center for Biologics Evaluation and Research, Document Control Center, 10903 New Hampshire Ave., Bldg. 71, Rm. G112, Silver Spring, MD 20993-0002”.

PART 310—NEW DRUGS

■ 18. The authority citation for 21 CFR part 310 continues to read as follows:

Authority: 21 U.S.C. 321, 331, 351, 352, 353, 355, 360b-360f, 360j, 361(a), 371, 374, 375, 379e; 42 U.S.C. 216, 241, 242(a), 262, 263b-263n.

§ 310.503 [Amended]

■ 19. Section 310.503 is amended in the last sentence of paragraph (f)(3) by removing the words “Center for Biologics Evaluation and Research, Food and Drug Administration, 8800 Rockville Pike, Bethesda, MD 20014” and by adding in their place “Food and Drug Administration, Center for Biologics Evaluation and Research, Document Control Center, 10903 New Hampshire Ave., Bldg. 71, Rm. G112, Silver Spring, MD 20993-0002”.

PART 312—INVESTIGATIONAL NEW DRUG APPLICATION

■ 20. The authority citation for 21 CFR part 312 continues to read as follows:

Authority: 21 U.S.C. 321, 331, 351, 352, 353, 355, 360bbb, 371; 42 U.S.C. 262.

§ 312.140 [Amended]

■ 21. Section 312.140 is amended in paragraph (a)(3) by removing the words “Document Control Center (HFM-99), Center for Biologics Evaluation and Research, Food and Drug Administration, 1401 Rockville Pike, Suite 200N, Rockville, MD 20852-1448” and by adding in their place “Food and Drug Administration, Center for Biologics Evaluation and Research, Document Control Center, 10903 New Hampshire Ave., Bldg. 71, Rm. G112, Silver Spring, MD 20993-0002”.

§ 312.145 [Amended]

■ 22. Section 312.145 is amended in the last sentence of paragraph (b) by removing the words “Office of Communication, Training, and Manufacturers Assistance (HFM-40), Center for Biologics Evaluation and Research, Food and Drug Administration, 1401 Rockville Pike, Rockville, MD 20852-1448” and by adding in their place “Food and Drug Administration, Center for Biologics

Evaluation and Research, Office of Communication, Outreach and Development, 10903 New Hampshire Ave., Bldg. 71, Rm. 3103, Silver Spring, MD 20993-0002”.

§ 312.310 [Amended]

■ 23. Section 312.310 is amended in the second sentence of paragraph (d)(1) by removing “301-827-1800” and by adding in its place “240-402-8010”.

PART 314—APPLICATIONS FOR FDA APPROVAL TO MARKET A NEW DRUG

■ 24. The authority citation for 21 CFR part 314 continues to read as follows:

Authority: 21 U.S.C. 321, 331, 351, 352, 353, 355, 356, 356a, 356b, 356c, 371, 374, 379e.

■ 25. Section 314.440 is amended by revising paragraph (b) introductory text to read as follows:

§ 314.440 Addresses for applications and abbreviated applications.

* * * * *

(b) Applicants shall send applications and other correspondence relating to matters covered by this part for the drug products listed below to the Food and Drug Administration, Center for Biologics Evaluation and Research, Document Control Center, 10903 New Hampshire Ave., Bldg. 71, Rm. G112, Silver Spring, MD 20993-0002, except applicants shall send a request for an opportunity for a hearing under § 314.110 on the question of whether there are grounds for denying approval of an application to the Center for Biologics Evaluation and Research, ATTN: Director, at the same address.

* * * * *

PART 600—BIOLOGICAL PRODUCTS: GENERAL

■ 26. The authority citation for 21 CFR part 600 continues to read as follows:

Authority: 21 U.S.C. 321, 351, 352, 353, 355, 360, 360i, 371, 374; 42 U.S.C. 216, 262, 263, 263a, 264, 300aa-25.

§ 600.2 [Amended]

■ 27. Section 600.2 is amended as follows:

■ a. In the first sentence of paragraph (a) by removing the words “Document Control Center (HFM-99), Center for Biologics Evaluation and Research, Food and Drug Administration, 1401 Rockville Pike, Suite 200N, Rockville, MD 20852-1448” and by adding in their place “Food and Drug Administration, Center for Biologics Evaluation and Research, Document Control Center, 10903 New Hampshire Ave., Bldg. 71,

Rm. G112, Silver Spring, MD 20993–0002”.

■ b. In the first sentence of paragraph (c)(1) by removing the words “Sample Custodian (ATTN: HFM–672), Food and Drug Administration, Center for Biologics Evaluation and Research, Bldg. NLRC–B, Rm. 113, 5516

Nicholson Lane, Kensington, MD 20895” and by adding in their place “Food and Drug Administration, Center for Biologics Evaluation and Research, ATTN: Sample Custodian, 10903 New Hampshire Ave., Bldg. 75, Rm. G707, Silver Spring, MD 20993–0002”; and

■ c. In paragraph (c)(2), by removing the words “Sample Custodian (ATTN: HFM–672), Food and Drug Administration, Center for Biologics Evaluation and Research, Nicholson Lane Research Center, c/o Radiation Safety Office, National Institutes of Health, 21 Wilson Dr., Rm. 107, Bethesda, MD 20892–6780” and by adding in their place “Food and Drug Administration, Center for Biologics Evaluation and Research, ATTN: Sample Custodian, c/o White Oak Radiation Safety Program, 10903 New Hampshire Ave., Bldg. 52–72, Rm. G406A, Silver Spring, MD 20993–0002”.

§ 600.11 [Amended]

■ 28. Section 600.11 is amended in paragraph (f)(6) by removing “§ 600.2” and by adding in its place “§ 600.2(a) or (b)”.

■ 29. Section 600.14 is amended by revising paragraph (e)(1) to read as follows:

§ 600.14 Reporting of biological product deviations by licensed manufacturers.

* * * * *

(e) *Where do I report under this section?* (1) For biological products regulated by the Center for Biologics Evaluation and Research (CBER), send the completed Form FDA 3486 to the CBER Document Control Center (see mailing address in § 600.2(a)), or submit electronically using CBER’s electronic Web-based application.

* * * * *

§ 600.22 [Amended]

■ 30. Section 600.22 is amended in paragraph (e) by removing “§ 600.2” and by adding in its place “§ 600.2(c)”.

PART 601—LICENSING

■ 31. The authority citation for 21 CFR part 601 continues to read as follows:

Authority: 15 U.S.C. 1451–1561; 21 U.S.C. 321, 351, 352, 353, 355, 356b, 360, 360c–360f, 360h–360j, 371, 374, 379e, 381; 42 U.S.C. 216, 241, 262, 263, 264; sec 122, Pub.

L. 105–115, 111 Stat. 2322 (21 U.S.C. 355 note).

§ 601.2 [Amended]

■ 32. Section 601.2 is amended in the first sentence of paragraph (a) by removing “§ 600.2” and by adding in its place “§ 600.2(a) or (b)”.

§ 601.12 [Amended]

■ 33. Section 601.12 is amended in paragraph (f)(4) by removing the words “, except that Form FDA–2567 (Transmittal of Labels and Circulars) or an equivalent form shall be used”.

§ 601.15 [Amended]

■ 34. Section 601.15 is amended by removing “§ 600.2” in both places it appears and by adding in each place “§ 600.2(c)”.

§ 601.28 [Amended]

■ 35. The introductory text of § 601.28 is amended by removing “§ 600.2” and by adding in its place “§ 600.2(a) or (b)”.

§ 601.29 [Amended]

■ 36. Section 601.29 is amended in the last sentence of paragraph (b) by removing the words “Office of Communication, Training, and Manufacturers Assistance (HFM–40), Center for Biologics Evaluation and Research, Food and Drug Administration (see mailing addresses in § 600.2 of this chapter)” and by adding in their place “Food and Drug Administration, Center for Biologics Evaluation and Research, Office of Communication, Outreach and Development, 10903 New Hampshire Ave., Bldg. 71, Rm. 3103, Silver Spring, MD 20993–0002”.

§ 601.70 [Amended]

■ 37. Section 601.70 is amended in paragraph (d) by removing “§ 600.2” and by adding in its place “§ 600.2(a) or (b)”.

PART 606—CURRENT GOOD MANUFACTURING PRACTICE FOR BLOOD AND BLOOD COMPONENTS

■ 38. The authority citation for 21 CFR part 606 continues to read as follows:

Authority: 21 U.S.C. 321, 331, 351, 352, 355, 360, 360j, 371, 374; 42 U.S.C. 216, 262, 263a, 264.

§ 606.170 [Amended]

■ 39. Section 606.170 is amended in the last sentence of paragraph (b) by removing the words “(for mailing addresses, see § 600.2 of this chapter)” and by adding in their place “(for mailing address, see § 600.2(a) of this chapter)”.

■ 40. Section 606.171 is amended by revising paragraph (e) to read as follows:

§ 606.171 Reporting of product deviations by licensed manufacturers, unlicensed registered blood establishments, and transfusion services.

* * * * *

(e) *Where do I report under this section?* You must send the completed Form FDA 3486 to the Center for Biologics Evaluation and Research (CBER), either in paper or electronic format.

(1) If you make a paper filing, send the completed form to the CBER Document Control Center (see mailing address in § 600.2(a) of this chapter), and identify on the envelope that a BPDR (biological product deviation report) is enclosed; or

(2) If you make an electronic filing, send the completed Form FDA3486 electronically using CBER’s electronic Web-based application.

* * * * *

PART 607—ESTABLISHMENT REGISTRATION AND PRODUCT LISTING FOR MANUFACTURERS OF HUMAN BLOOD AND BLOOD PRODUCTS

■ 41. The authority citation for 21 CFR part 607 continues to read as follows:

Authority: 21 U.S.C. 321, 331, 351, 352, 355, 360, 371, 374, 381, 393; 42 U.S.C. 262, 264, 271.

§ 607.7 [Amended]

■ 42. Section 607.7 is amended in paragraphs (b) and (c) by removing both times it appears “(HFM–375) (see mailing addresses in § 600.2 of this chapter)” and by adding in their place “(see mailing address in § 600.2(a) of this chapter)”.

§ 607.22 [Amended]

■ 43. Section 607.22 is amended in the first sentence of paragraph (a) by removing the words “Department of Health and Human Services, Food and Drug Administration, Center for Biologics Evaluation and Research (HFM–375), (see mailing addresses in § 600.2 of this chapter),” and by adding in their place “Food and Drug Administration, Center for Biologics Evaluation and Research (see mailing address in § 600.2(a) of this chapter),”.

■ 44. Section 607.37 is revised to read as follows:

§ 607.37 Inspection of establishment registrations and blood product listings.

(a) Any registration on Form FDA 2830 (Blood Establishment Registration and Product Listing) filed in paper or electronic format by the registrant will

be available for inspection under section 510(f) of the act, through the Center for Biologics Evaluation and Research Blood Establishment Registration Database Web site by using the CBER electronic Web-based application or by going in person to the Food and Drug Administration, Division of Dockets Management Public Reading Room (see address in § 20.120(a) of this chapter). The following information submitted under the blood product listing requirements is illustrative of the type of information that will be available for public disclosure when it is compiled:

- (1) A list of all blood products.
- (2) A list of all blood products manufactured by each establishment.
- (3) A list of blood products discontinued.
- (4) All data or information that has already become a matter of public knowledge.

(b) Other requests for information regarding blood establishment registrations and blood product listings should be directed to the Food and Drug Administration, Center for Biologics Evaluation and Research, Office of Communication, Outreach and Development, 10903 New Hampshire Ave., Bldg. 71, Rm. 3103, Silver Spring, MD 20993-0002.

PART 610—GENERAL BIOLOGICAL PRODUCTS STANDARDS

■ 45. The authority citation for 21 CFR part 610 continues to read as follows:

Authority: 21 U.S.C. 321, 331, 351, 352, 353, 355, 360, 360c, 360d, 360h, 360i, 371, 372, 374, 381; 42 U.S.C. 216, 262, 263, 263a, 264.

§ 610.2 [Amended]

■ 46. Section 610.2 is amended in the first sentence of paragraph (a) by removing “§ 600.2” and by adding in its place “§ 600.2(c)” and in the first sentence of paragraph (b) by removing “§ 600.2” and by adding in its place “§ 600.2(c) of this chapter”.

§ 610.11 [Amended]

■ 47. Section 610.11 is amended in the first sentence of paragraph (g)(2) by removing “§ 600.2” and by adding in its place “§ 600.2(a) or (b)”.

§ 610.15 [Amended]

■ 48. Section 610.15 is amended in paragraph (a)(3) by removing “§ 600.2” and by adding in its place “§ 600.2(a) or (b)”.

PART 660—ADDITIONAL STANDARDS FOR DIAGNOSTIC SUBSTANCES FOR LABORATORY TESTS

■ 49. The authority citation for 21 CFR part 660 continues to read as follows:

Authority: 21 U.S.C. 321, 331, 351, 352, 353, 355, 360, 360c, 360d, 360h, 360i, 371, 372; 42 U.S.C. 216, 262, 263, 263a, 264.

§ 660.3 [Amended]

■ 50. Section 660.3 is amended by removing the words “Center for Biologics Evaluation and Research (HFM-407) (see mailing addresses in § 600.2 of this chapter)” and by adding in their place “Food and Drug Administration, Center for Biologics Evaluation and Research, Reagents and Standards Shipping, 10903 New Hampshire Ave., Bldg. 75, Rm. G704, Silver Spring, MD 20993-0002”.

§ 660.6 [Amended]

■ 51. Section 660.6 is amended in paragraph (a)(2) by removing “§ 600.2” and by adding in its place “§ 600.2(c)” and in the heading of paragraph (c) by removing the word “Official” and by adding in its place “Official”.

§ 660.22 [Amended]

■ 52. Section 660.22 is amended in paragraph (b) by removing the words “Center for Biologics Evaluation and Research (HFM-407) (see mailing addresses in § 600.2 of this chapter)” and by adding in their place “Food and Drug Administration, Center for Biologics Evaluation and Research, Reagents and Standards Shipping, 10903 New Hampshire Ave., Bldg. 75, Rm. G704, Silver Spring, MD 20993-0002”.

§ 660.36 [Amended]

■ 53. Section 660.36 is amended as follows:

■ a. In paragraph (a) introductory text by removing the words “(ATTN: HFM-672) (see mailing addresses in § 600.2 of this chapter)” and by adding in their place “(see mailing addresses in § 600.2(c) of this chapter)”.

■ b. In paragraph (b) by adding the words “(see mailing addresses in § 600.2(a) of this chapter)” immediately following the words “Director, Center for Biologics Evaluation and Research”.

■ c. In paragraph (c) by adding the words “(see mailing addresses in § 600.2(c) of this chapter)” immediately following the words “Director, Center for Biologics Evaluation and Research”.

§ 660.46 [Amended]

■ 54. Section 660.46 is amended in paragraph (a)(2) introductory text by

removing “§ 600.2” and by adding in its place “§ 600.2(c)”.

§ 660.52 [Amended]

■ 55. Section 660.52 is amended by removing the words “Center for Biologics Evaluation and Research (HFM-407) (see mailing addresses in § 600.2 of this chapter)” and by adding in their place “Food and Drug Administration, Center for Biologics Evaluation and Research, Reagents and Standards Shipping, 10903 New Hampshire Ave., Bldg. 75, Rm. G704, Silver Spring, MD 20993-0002”.

PART 680—ADDITIONAL STANDARDS FOR MISCELLANEOUS PRODUCTS

■ 56. The authority citation for 21 CFR part 680 continues to read as follows:

Authority: 21 U.S.C. 321, 351, 352, 353, 355, 360, 371; 42 U.S.C. 216, 262, 263, 263a, 264.

§ 680.1 [Amended]

■ 57. Section 680.1 is amended as follows:

■ a. In the last sentence of paragraph (b)(2)(iii) by removing the words “addresses in § 600.2” and by adding in their place “address in § 600.2(a) of this chapter”.

■ b. In paragraph (b)(3)(iv) by removing the word “allergenic” and by adding in its place the word “Allergenic” and by removing the words “addresses in § 600.2” and by adding in their place “address in § 600.2(a) of this chapter”.

■ c. In paragraph (c) by removing the words “addresses in § 600.2” and by adding in their place “address in § 600.2(a) of this chapter”.

PART 801—LABELING

■ 58. The authority citation for 21 CFR part 801 continues to read as follows:

Authority: 21 U.S.C. 321, 331, 351, 352, 360i, 360j, 371, 374.

§ 801.55 [Amended]

■ 59. Section 801.55 is amended in paragraph (b)(1) by removing the words “Office of Communication, Outreach and Development (HFM-40), Center for Biologics Evaluation and Research, Food and Drug Administration, 1401 Rockville Pike, Suite 200N, Rockville, MD 20852-1448” and by adding in their place “Food and Drug Administration, Center for Biologics Evaluation and Research, Document Control Center, 10903 New Hampshire Ave., Bldg. 71, Rm. G112, Silver Spring, MD 20993-0002”.

PART 807—ESTABLISHMENT REGISTRATION AND DEVICE LISTING FOR MANUFACTURERS AND INITIAL IMPORTERS OF DEVICES

■ 60. The authority citation for 21 CFR part 807 continues to read as follows:

Authority: 21 U.S.C. 321, 331, 351, 352, 360, 360c, 360e, 360i, 360j, 371, 374, 381, 393; 42 U.S.C. 264, 271.

§ 807.90 [Amended]

■ 61. Section 807.90 is amended in paragraph (a)(2) by removing in the first sentence the words “Document Control Center (HFM–99), Center for Biologics Evaluation and Research, Food and Drug Administration, 1401 Rockville Pike, Suite 200N, Rockville, MD 20852–1448” and by adding in their place “Food and Drug Administration, Center for Biologics Evaluation and Research, Document Control Center, 10903 New Hampshire Ave., Bldg. 71, Rm. G112, Silver Spring, MD 20993–0002” and by removing in the second sentence “at <http://www.fda.gov/cber/dap/devlst.htm>” and by adding in its place “by using the Center for Biologics Evaluation and Research electronic Web-based application”.

PART 812—INVESTIGATIONAL DEVICE EXEMPTIONS

■ 62. The authority citation for 21 CFR part 812 continues to read as follows:

Authority: 21 U.S.C. 331, 351, 352, 353, 355, 360, 360c–360f, 360h–360j, 371, 372, 374, 379e, 381, 382, 383; 42 U.S.C. 216, 241, 262, 263b–263n.

§ 812.19 [Amended]

■ 63. Section 812.19 is amended in paragraph (a)(2) by removing the words “Document Control Center (HFM–99), Center for Biologics Evaluation and Research, Food and Drug Administration, 1401 Rockville Pike, Suite 200N, Rockville, MD 20852–1448” and by adding in their place “Food and Drug Administration, Center for Biologics Evaluation and Research, Document Control Center, 10903 New Hampshire Ave., Bldg. 71, Rm. G112, Silver Spring, MD 20993–0002”.

PART 814—PREMARKET APPROVAL OF MEDICAL DEVICES

■ 64. The authority citation for 21 CFR part 814 continues to read as follows:

Authority: 21 U.S.C. 351, 352, 353, 360, 360c–360j, 371, 372, 373, 374, 375, 379, 379e, 381.

§ 814.20 [Amended]

■ 65. Section 814.20 is amended in paragraph (h)(2) by removing the words “Document Control Center (HFM–99),

Center for Biologics Evaluation and Research, Food and Drug Administration, 1401 Rockville Pike, Suite 200N, Rockville, MD 20852–1448” and by adding in their place “Food and Drug Administration, Center for Biologics Evaluation and Research, Document Control Center, 10903 New Hampshire Ave., Bldg. 71, Rm. G112, Silver Spring, MD 20993–0002”.

§ 814.104 [Amended]

■ 66. Section 814.104 is amended in paragraph (d)(2) by removing the words “Document Control Center (HFM–99), Center for Biologics Evaluation and Research, Food and Drug Administration, 1401 Rockville Pike, Suite 200N, Rockville, MD 20852–1448” and by adding in their place “Food and Drug Administration, Center for Biologics Evaluation and Research, Document Control Center, 10903 New Hampshire Ave., Bldg. 71, Rm. G112, Silver Spring, MD 20993–0002”.

PART 822—POSTMARKET SURVEILLANCE

■ 67. The authority citation for 21 CFR part 822 continues to read as follows:

Authority: 21 U.S.C. 331, 352, 360i, 360l, 371, 374.

§ 822.8 [Amended]

■ 68. Section 822.8 is amended by removing the words “Document Control Center (HFM–99), Center for Biologics Evaluation and Research, Food and Drug Administration, 1401 Rockville Pike, Suite 200N, Rockville, MD 20852–1448” and by adding in their place “Food and Drug Administration, Center for Biologics Evaluation and Research, Document Control Center, 10903 New Hampshire Ave., Bldg. 71, Rm. G112, Silver Spring, MD 20993–0002”.

PART 1271—HUMAN CELLS, TISSUES, AND CELLULAR AND TISSUE-BASED PRODUCTS

■ 69. The authority citation for 21 CFR part 1271 continues to read as follows:

Authority: 42 U.S.C. 216, 243, 263a, 264, 271.

§ 1271.22 [Amended]

■ 70. Section 1271.22 is amended as follows:

■ a. In paragraph (b)(1) by removing the words “Center for Biologics Evaluation and Research (HFM–775), Food and Drug Administration, 1401 Rockville Pike, Rockville, MD 20852–1448, Attention: Tissue Establishment Registration Coordinator” and by adding in their place “Food and Drug Administration, Center for Biologics

Evaluation and Research, Document Control Center, 10903 New Hampshire Ave., Bldg. 71, Rm. G112, Silver Spring, MD 20993–0002, ATTN: Tissue Establishment Registration Coordinator”.

■ b. In paragraph (b)(3) by removing “301–827–1800” and by adding in its place “240–402–8010”.

■ c. In paragraph (c)(1) by removing the words “Center for Biologics Evaluation and Research (HFM–775), Food and Drug Administration, 1401 Rockville Pike, Rockville, MD 20852–1448, Attention: Tissue Establishment Registration Coordinator” and by adding in their place the words “Food and Drug Administration, Center for Biologics Evaluation and Research, Document Control Center, 10903 New Hampshire Ave., Bldg. 71, Rm. G112, Silver Spring, MD 20993–0002, ATTN: Tissue Establishment Registration Coordinator”.

■ d. In paragraph (c)(2) by removing “at <http://www.fda.gov/cber/tissue/tisreg.htm>” and by adding in its place the words “using the CBER electronic Web-based application”.

■ 71. Section 1271.37 is revised to read as follows:

§ 1271.37 Will establishment registrations and HCT/P listings be available for inspection, and how do I request information on registrations and listings?

(a) Any registration on Form FDA 3356 filed in paper or electronic format by each establishment will be available for public inspection through the Center for Biologics Evaluation and Research Human Cell and Tissue Establishment Registration—Public Query Web site by using the CBER electronic Web-based application or by going in person to the Food and Drug Administration, Division of Dockets Management Public Reading Room (see address in § 20.120(a) of this chapter). The following information submitted under the HCT/P requirements is illustrative of the type of information that will be available for public disclosure when it is compiled:

- (1) A list of all HCT/P’s;
- (2) A list of all HCT/P’s manufactured by each establishment;
- (3) A list of all HCT/P’s discontinued; and
- (4) All data or information that has already become a matter of public record.

(b) You should direct your other requests for information regarding HCT/P establishment registrations and HCT/P listings to the Food and Drug Administration, Center for Biologics Evaluation and Research, Office of Communication, Outreach and Development, 10903 New Hampshire

Ave., Bldg. 71, Rm. 3103, Silver Spring, MD 20993-0002.

■ 72. Section 1271.350 is amended:

- a. In the first sentence of paragraph (a)(5) by removing the words “Center for Biologics Evaluation and Research (HFM-210), Food and Drug Administration, 1401 Rockville Pike, Suite 200N, Rockville, MD 20852-1448” and by adding in their place “Food and Drug Administration, Center for Biologics Evaluation and Research, Document Control Center, 10903 New Hampshire Ave., Bldg. 71, Rm. G112, Silver Spring, MD 20993-0002”; and
- b. By revising paragraph (b)(3) to read as follows:

§ 1271.350 Reporting.

* * * * *

(b) * * *

(3) You must report each such HCT/P deviation that relates to a core CGTP requirement on Form FDA 3486 within 45 days of the discovery of the event either electronically using the Center for Biologics Evaluation and Research electronic Web-based application or by mail to the Food and Drug Administration, Center for Biologics Evaluation and Research, Document Control Center, 10903 New Hampshire Ave., Bldg. 71, Rm. G112, Silver Spring, MD 20993-0002.

Dated: March 23, 2015.

Leslie Kux,

Associate Commissioner for Policy.

[FR Doc. 2015-07268 Filed 4-2-15; 8:45 am]

BILLING CODE 4164-01-P

DEPARTMENT OF HOUSING AND URBAN DEVELOPMENT

24 CFR Parts 200 and 235

[Docket No. FR-5829-F-01]

Federal Housing Administration (FHA): Removal of Section 235 Home Ownership Program Regulations

AGENCY: Office of the Assistant Secretary for Housing, Federal Housing Commissioner, HUD.

ACTION: Final rule.

SUMMARY: Through this rule, HUD removes the regulations for its Section 235 Program, which authorized HUD to provide mortgage subsidy payments to lenders to assist lower-income families who are unable to meet the credit requirements generally applicable to FHA mortgage insurance programs. Authority to provide insurance to mortgagees under this program was terminated under the Housing and Community Development Act of 1987

and HUD has not provided new mortgage subsidy payments under this program since then. Because the regulations governing this program are no longer operative, they are being removed by this final rule. To the extent that any Section 235 mortgages remain in existence, or second mortgages for the recapture of subsidy payment pursuant to HUD's regulations governing the Section 235 Program (which was reserved by regulatory streamlining in 1995), the removal of these regulations does not affect the requirements for transactions entered into when Section 235 Program regulations were in effect. Assistance made available under the Section 235 Program will continue to be governed by the regulations that existed immediately before the effective date of this final rule.

DATES: Effective May 4, 2015.

FOR FURTHER INFORMATION CONTACT:

Camille E. Acevedo, Associate General Counsel for Legislation and Regulations, Office of General Counsel, Department of Housing and Urban Development, 451 7th Street SW., Room 10276, Washington, DC 20410; telephone 202-708-1793 (this is not a toll-free number). Persons with hearing or speech impairments may access this number through TTY by calling the toll-free Federal Relay Service at 800-877-8389.

SUPPLEMENTARY INFORMATION:

I. Background

On August 1, 1968, the Housing and Urban Development Act of 1968 (Pub. L. 90-448) amended the National Housing Act to add a new section 235 (12 U.S.C. 1715z) (Section 235 Program). This provision authorized the Secretary to provide subsidies to reduce mortgage interest rates to as low as 1 percent and authorized a new credit assistance homeownership program for lower-income families who were unable to meet the credit requirements generally applicable to FHA mortgage insurance programs. HUD promulgated regulations implementing the Section 235 Program on January 6, 1976 (see 41 FR 1176) and codified these regulations in part 235 of title 24 of the Code of Federal Regulations (CFR). However, on February 5, 1988, the Section 235 Program was terminated under section 401(d) of the Housing and Community Development Act of 1987 (Pub. L. 100-242) and HUD ceased to make mortgage subsidy payments available under this program beginning October 1, 1989.¹ In

¹ Although the Section 235 Program was terminated, section 401(d) of the Housing and Community Development Act of 1987 permitted the Secretary to continue to refinance mortgages

1995, HUD removed much of part 235 from the CFR as part of HUD's effort to eliminate outdated, obsolete, or unutilized regulations, leaving only the parts that were necessary to regulate outstanding loans assisted or insured under the program. (See 60 FR 56498.) As of the date of this publication, there are only two outstanding loans remaining that were assisted or insured under this program.

This Final Rule

Since authority for HUD to provide assistance or insurance to low-income borrowers under the Section 235 Homeownership Program expired on October 1, 1989, HUD is proceeding to remove Section 235 Program regulations codified in 24 CFR part 235.

Loans issued with assistance provided under Section 235 that are still outstanding will continue to be governed by the regulations in effect on May 3, 2015. Accordingly, this rule amends § 1301 (Expiring Programs—Savings Clause) of 24 CFR 200, subpart W (Administrative Matters), and adds a new paragraph (g) to § 200.1301, which preserves the Section 235 Program regulations as in effect prior to the effective date of this final rule, and continues to govern any assistance provided under the Section 235 Program before May 4, 2015.

II. Justification for Final Rulemaking

HUD generally publishes a rule for public comment before issuing a final rule for effect, in accordance with HUD's own regulations on rulemaking in 24 CFR part 10. However, part 10 provides for exceptions to the general rule if the agency finds good cause to omit advance notice and public participation. The good cause requirement is satisfied when prior public procedure is impracticable, unnecessary, or contrary to the public interest. (See 24 CFR 10.1.)

HUD finds that public notice and comment are not necessary for this rulemaking because assistance is no longer being provided under this program and, therefore, the regulations are no longer operative. For these reasons, HUD has determined that it is unnecessary to delay the effectiveness of this rule in order to solicit prior public comment.

insured previously under section 235(r) of the National Housing Act. However, no insurance or assistance for new loans has been provided by HUD since October 1, 1989.