

PART 422—ORGANIZATION AND PROCEDURES

Subpart F—[Amended]

■ 3. The authority citation for subpart F continues to read as follows:

Authority: Secs. 205 and 702(a)(5) of the Social Security Act (42 U.S.C. 405 and 902(a)(5)).

§ 422.505 [Amended]

■ 4. In the list of forms in paragraph (b) of § 422.505, remove the form SSA—1388 and its description.

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

21 CFR Parts 1, 25, 26, 99, 201, 203, 206, 310, 312, 314, 600, 601, 606, 607, 610, 640, 660, 680, 807, and 822

Food and Drug Administration Regulations; Drug and Biological Product Consolidation; Addresses; Technical Amendment

AGENCY: Food and Drug Administration, HHS.

ACTION: Final rule; technical amendment.

SUMMARY: The Food and Drug Administration (FDA) is amending certain regulations regarding biological products to include references to the Center for Drug Evaluation and Research (CDER) or the Director, CDER, and to include CDER address information or updated CDER address information, where appropriate. FDA is also amending the regulations to update mailing address information including mailing codes for the Center for Biologics Evaluation and Research (CBER), and to place the current mailing addresses for certain biologics regulations in a single location. These changes, among others, are being taken to reflect the reorganization between CBER and CDER due to the transfer of responsibility for certain products from CBER to CDER, and to ensure the consistency and accuracy of the regulations.

DATES: This rule is effective March 24, 2005.

FOR FURTHER INFORMATION CONTACT: Stephen M. Ripley, Center for Biologics Evaluation and Research (HFM–17), Food and Drug Administration, 1401 Rockville Pike, suite 200N, Rockville, MD 20852–1448, 301–827–6210.

SUPPLEMENTARY INFORMATION:

I. Background

A. Transfer of Regulatory Responsibility from the Center for Biologics Evaluation and Research to the Center for Drug Evaluation and Research

In a letter dated June 20, 2003, FDA notified sponsors that the regulatory responsibility, review, and continuing oversight for many biological products would be transferred from CBER to CDER. This change in regulatory responsibility resulted in the transfer of applications for the affected product classes (see section I.B of this document). This consolidation initiative was undertaken to provide greater opportunities to further develop and coordinate scientific and regulatory activities between CBER and CDER, leading to a more efficient, effective, and consistent review program for human drugs and biologics.

In the **Federal Register** of June 26, 2003 (68 FR 38067), we published a notice announcing the transfer of certain product oversight from CBER to CDER. On June 30, 2003, the responsibility for regulating most therapeutic biologics, with certain exceptions (e.g., cell and gene therapy products and therapeutic vaccines) was transferred from the Office of Therapeutics Research and Review (OTRR), CBER, to the Office of New Drugs (OND) and the Office of Pharmaceutical Science (OPS), CDER. Initially, this transfer of products was effected when the divisions of OTRR formerly within CBER were detailed to offices within CDER. On October 1, 2003, those CBER offices detailed to CDER were incorporated into CDER's organizational structure. Throughout these transitions, the staff that was formerly with OTRR, CBER, maintained responsibility for the therapeutic biologic products.

The two new CDER offices established for review of the therapeutic biologics include the OND, Office of Drug Evaluation VI (ODE VI), and the OPS, Office of Biotechnology Products (OBP). Within ODE VI, the following divisions were established: Division of Therapeutic Biological Oncology Products, Division of Therapeutic Biological Internal Medicine Products, and Division of Review Management and Policy. Within OBP, the following divisions were established: Division of Monoclonal Antibodies and Division of Therapeutic Proteins. The delegations of authority for CBER and CDER, which give officials in the Centers the legal authority needed to take substantive actions and perform certain functions of the Commissioner of Food and Drugs,

have been revised to reflect these changes.

B. Products Transferred to CDER and Products Remaining in CBER

The change in regulatory responsibility resulted in the transfer of applications to CDER for products belonging to the following product classes:

- Monoclonal antibodies for in-vivo use;
 - Proteins intended for therapeutic use, including cytokines (e.g., interferons), enzymes (e.g., thrombolytics), and other novel proteins, except for those that are specifically assigned to CBER (e.g., vaccines and blood products). This category includes therapeutic proteins derived from plants, animals, or microorganisms, and recombinant versions of these products;
 - Immunomodulators (nonvaccine and nonallergenic products intended to treat disease by inhibiting or modifying a preexisting immune response); and
 - Growth factors, cytokines, and monoclonal antibodies intended to mobilize, stimulate, decrease or otherwise alter the production of hematopoietic cells in vivo.¹
- The following biological product classes remain at CBER:
- Cellular products, including products composed of human, bacterial or animal cells (such as pancreatic islet cells for transplantation), or from physical parts of those cells (such as whole cells, cell fragments, or other components intended for use as preventative or therapeutic vaccines);
 - Allergenic extracts used for the diagnosis and treatment of allergic diseases and allergen patch tests;
 - Antitoxins, antivenoms, and venoms;
 - Vaccines (products intended to induce or increase an antigen specific immune response for prophylactic or therapeutic immunization, regardless of the composition or method of manufacture);
 - Blood, blood components, plasma derived products (e.g., albumin, immunoglobulins, clotting factors, fibrin sealants, proteinase inhibitors), including recombinant and transgenic versions of plasma derivatives (e.g., clotting factors), blood substitutes,

¹ Growth factors, cytokines, and monoclonal antibodies intended to mobilize, stimulate, decrease or otherwise alter the production of hematopoietic cells in vivo, for the purpose of being harvested for use in the production of a therapeutic cellular or blood product, may be regulated in combination with the therapeutic cellular or blood product, as appropriate. Sponsors of products that fit this description should contact the center jurisdiction officers for guidance on appropriate center assignment.

plasma volume expanders, human or animal polyclonal antibody preparations including radiolabeled or conjugated forms, and certain fibrinolytics such as plasma-derived plasmin, and red cell reagents.

The lists above contain some combination products comprised of a biological product component with a device and/or drug component, though such products are not specifically identified. Combination products are assigned to a Center for review and regulation in accordance with the products' primary mode of action.² When a product's primary mode of action is attributable to a type of biological product assigned to CDER, the product will be assigned to CDER. Similarly, when a product's primary mode of action is attributable to a type of biological product assigned to CBER, the product will be assigned to CBER. For further information about combination products, see <http://www.fda.gov/oc/combo>, or contact the Office of Combination Products at 301-827-9229, or combination@fda.gov.

II. Organizational and Mailing Address Changes

As a result of this product consolidation and the resulting changes to the organizational structure of CBER and CDER, certain technical amendments are necessary to the regulations in title 21 of the Code of Federal Regulations, chapter I. These amendments include adding references to CDER or the CDER Director, and the CDER address information or updated CDER address information where appropriate. CDER has announced through the Internet new mailing addresses for certain therapeutic biological product submissions.

We are also amending the biologics regulations in parts 600 through 680 (21 CFR parts 600 through 680) to update the mailing address information including mailing codes for the various submissions to CBER, and are amending these regulations to place the current mailing addresses in a single location in part 600.

The various CBER mailing addresses currently listed in the biologics regulations under parts 600 through 680, as applicable, are being moved to one location under new § 600.2. The creation of § 600.2 will ensure the consistency and accuracy of the regulations in part 600 by providing one central location to obtain CBER's mailing addresses and will expedite the mail flow system throughout CBER.

Section 600.2 will provide the public with direct and easy access to CBER's mailing addresses for various CBER submissions. The specific biologics regulations will continue to identify the appropriate recipient and specific submission requirements for the various CBER submissions. Section 600.2 will include the addresses for submissions such as biologics license applications and the amendments and supplements to these applications, samples and protocols for licensed biological products, biological product deviation reports, adverse experience reports, fatality reports, Vaccine Adverse Event Reporting System (VAERS) reports, and other correspondence.

The CDER addresses for some of the various submissions under parts 600 through 680, related to the transferred biological products regulated by CDER, have also been included in § 600.2.

In the amendments to parts 1, 99, 201, 203, 206, 310, 312, and 314 (21 CFR parts 1, 99, 201, 203, 206, 310, 312, and 314), the updated CBER mailing address and other related information will continue to be located directly in the applicable regulations so as to minimize the need for cross-referencing across different volumes of the Code of Federal Regulations.

Section 610.12(e)(2)(ii) is amended to include the updated address for obtaining American Type Culture Collection (ATCC) strains of microorganisms described in that regulation and available from the ATCC.

III. Other Changes as a Result of the Drug and Biological Product Consolidation

The revised address information for the submission of investigational new drug applications is included in § 312.140(a). We are revising § 312.140(b), by removing the currently listed products, and removing § 312.140(c), biological products for human use which are also radioactive drugs, because these products will be submitted to the appropriate Center in accordance with revised § 312.140(a). As a result of the removal of current § 312.140(c), we are redesignating current § 312.140(d) as § 312.140(c).

We are removing current § 314.440(b)(2), urokinase products, because this product is now regulated by CDER. As a result, we are redesignating current § 314.440(b)(3) as § 314.440(b)(2). We are also clarifying § 314.440(b) by adding as paragraphs (b)(3) and (b)(4), two additional products that are submitted to CBER as new drug applications.

We have also removed and reserved § 601.2(b), radioactive biological

products, because these products will be submitted in accordance with revised § 601.2(a). In addition, we have removed any reference to § 601.2(b) under § 601.2.

Finally, we have also included the appropriate CDER information under 21 CFR 807.90 and 822.8. This reflects the fact that authority to use the device authorities has already been delegated to CDER officials. One investigational device exemption product was transferred from CBER to CDER in this product consolidation initiative.

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 are unnecessary because this amendment to the regulations provides only a technical change to update information and addresses, and is nonsubstantive.

List of Subjects

21 CFR Part 1

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

21 CFR Part 25

Environmental impact statements, Foreign relations, 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 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.

² See section 503(g) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 353(g)).

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 Part 610

Biologics, Labeling, Reporting and recordkeeping requirements.

21 CFR Part 640

Blood, Labeling, Reporting and recordkeeping requirements.

21 CFR Part 660

Biologics, Labeling, Reporting and recordkeeping requirements.

21 CFR Part 680

Biologics, Blood, Reporting and recordkeeping requirements.

21 CFR Part 807

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

21 CFR Part 822

Medical devices, Reporting and recordkeeping requirements.

■ Therefore, under the Federal Food, Drug, and Cosmetic Act, and Public Health Service Act, and under authority delegated to the Commissioner of Food and Drugs, 21 CFR parts 1, 25, 26, 99, 201, 203, 206, 310, 312, 314, 600, 601, 606, 607, 610, 640, 660, 680, 807, and 822 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. 1453, 1454, 1455; 19 U.S.C. 1490, 1491; 21 U.S.C. 321, 331, 332, 333, 334, 335a, 343, 350c, 350d, 352, 355, 360b, 362, 371, 374, 381, 382, 393; 42 U.S.C. 216, 241, 243, 262, 264.

■ 2. Section 1.101 is amended by revising paragraphs (d)(2)(i) and (d)(2)(ii) to read as follows:

§ 1.101 Notification and recordkeeping.

* * * * *

(d) * * *

(2) * * *

(i) For biological products and devices regulated by the Center for Biologics Evaluation and Research—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.

(ii) For human drug products, biological products, and devices regulated by the Center for Drug Evaluation and Research—Division of New Drugs and Labeling Compliance (HFD-310), Center for Drug Evaluation and Research, Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857.

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PART 25—ENVIRONMENTAL IMPACT CONSIDERATIONS

■ 3. The authority citation for 21 CFR part 25 continues to read as follows:

Authority: 21 U.S.C. 321-393; 42 U.S.C. 262, 263b-264; 42 U.S.C. 4321, 4332; 40 CFR parts 1500-1508; E.O. 11514, 35 FR 4247, 3 CFR, 1971 Comp., p. 531-533 as amended by E.O. 11991, 42 FR 26967, 3 CFR, 1978 Comp., p. 123-124 and E.O. 12114, 44 FR 1957, 3 CFR, 1980 Comp., p. 356-360.

§ 25.31 [Amended]

■ 4. Section 25.31 is amended in paragraph (f) by removing the words “Center for Biologics Evaluation and Research” and adding in their place the words “Food and Drug Administration”.

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

■ 5. 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.

§ 26.4 [Amended]

■ 6. Section 26.4 is amended in paragraph (b) by adding in the last sentence the words “or Center for Drug Evaluation and Research” after the words “Center for Biologics Evaluation and Research”.

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

■ 7. 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.

■ 8. Section 99.201 is amended by revising paragraphs (c)(1) and (c)(2) to read as follows:

§ 99.201 Manufacturer’s submission to the agency.

* * * * *

(c) * * *

(1) For biological products and devices regulated by the Center for Biologics Evaluation and Research, 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;

(2) For human drug products, biological products, and devices regulated by the Center for Drug Evaluation and Research, the Division of Drug Marketing, Advertising, and Communications (HFD-42), Center for Drug Evaluation and Research, Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857; or

* * * * *

PART 201—LABELING

■ 9. 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.

§ 201.58 [Amended]

■ 10. Section 201.58 is amended in the first sentence by removing the zip code “20587” and adding in its place “20857”, and by removing the words “8800 Rockville Pike, Bethesda, MD 20892” and adding in their place the words “Food and Drug Administration, 1401 Rockville Pike, suite 200N, Rockville, MD 20852-1448”.

PART 203—PRESCRIPTION DRUG MARKETING

■ 11. 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.

§ 203.12 [Amended]

■ 12. Section 203.12 is amended at the end of the last sentence by adding the words “or the Office of Compliance

(HFD-300), Center for Drug Evaluation and Research, Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857, depending on the Center responsible for regulating the product”.

- 13. 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 prescription human drugs and biological products regulated by the Center for Drug Evaluation and Research shall be made to the Division of Compliance Risk Management and Surveillance (HFD-330), Office of Compliance, Center for Drug Evaluation and Research, Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857. Notifications and reports concerning prescription human biological products regulated by the Center for Biologics Evaluation and Research shall be made to the Division of Inspections and Surveillance (HFM-650), Office of Compliance and Biologics Quality, Center for Biologics Evaluation and Research, Food and Drug Administration, 1401 Rockville Pike, suite 200N, Rockville, MD 20852.

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.

- 15. Section 206.7 is amended by revising paragraph (b)(1)(i) to read as follows:

§ 206.7 Exemptions.

* * * * *

(b) * * *

(1) * * *

(i) Exemption requests for products with approved applications shall be made in writing to the appropriate review division in the Center for Drug Evaluation and Research (CDER), Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857 or the Center for Biologics Evaluation and Research (CBER), Food and Drug Administration, 1401 Rockville Pike, suite 200N, Rockville, MD 20852-1448. If FDA denies the request, the holder of the approved application will have 1 year after the date of an agency denial to imprint the drug product.

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PART 310—NEW DRUGS

- 16. 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.

§ 310.4 [Amended]

- 17. Section 310.4 is amended in paragraph (b) by removing “601.2(b)” and adding in its place “§ 601.2(a)”.

PART 312—INVESTIGATIONAL NEW DRUG APPLICATION

- 18. The authority citation for 21 CFR part 312 continues to read as follows:

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

- 19. Section 312.140 is revised to read as follows:

§ 312.140 Address for correspondence.

(a) A sponsor must send an initial IND submission to the Center for Drug Evaluation and Research (CDER) or to the Center for Biologics Evaluation and Research (CBER), depending on the Center responsible for regulating the product as follows:

(1) *For drug products regulated by CDER.* Send the IND submission to the Central Document Room, Center for Drug Evaluation and Research, Food and Drug Administration, 5901-B Ammendale Rd., Beltsville, MD 20705-1266.

(2) *For biological products regulated by CDER.* Send the IND submission to the CDER Therapeutic Biological Products Document Room, Center for Drug Evaluation and Research, Food and Drug Administration, 12229 Wilkins Ave., Rockville, MD 20852.

(3) *For biological products regulated by CBER.* Send the IND submission to the Document Control Center (HFM-99), Center for Biologics Evaluation and Research, Food and Drug Administration, 1401 Rockville Pike, suite 200N, Rockville, MD 20852-1448.

(b) On receiving the IND, the responsible Center will inform the sponsor which one of the divisions in CDER or CBER is responsible for the IND. Amendments, reports, and other correspondence relating to matters covered by the IND should be directed to the appropriate Center and division. The outside wrapper of each submission shall state what is contained in the submission, for example, “IND Application”, “Protocol Amendment”, etc.

(c) All correspondence relating to export of an investigational drug under § 312.110(b)(2) shall be submitted to the

International Affairs Staff (HFY-50), Office of Health Affairs, Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857.

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

- 20. The authority citation for 21 CFR part 314 continues to read as follows:

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

- 21. Section 314.440 is amended by revising paragraph (b) 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 Document Control Center (HFM-99), Center for Biologics Evaluation and Research, 1401 Rockville Pike, suite 200N, Rockville, MD 20852-1448, except applicants shall send a request for an opportunity for a hearing under § 314.110 or § 314.120 on the question of whether there are grounds for denying approval of an application to the Director, Center for Biologics Evaluation and Research (HFM-1), at the same address.

(1) Ingredients packaged together with containers intended for the collection, processing, or storage of blood and blood components;

(2) Plasma volume expanders and hydroxyethyl starch for leukapheresis;

(3) Blood component processing solutions and shelf life extenders; and

(4) Oxygen carriers.

PART 600—BIOLOGICAL PRODUCTS: GENERAL

- 22. 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.

- 23. Section 600.2 is added to subpart A to read as follows:

§ 600.2 Mailing addresses.

(a) *Licensed biological products regulated by the Center for Biologics Evaluation and Research (CBER).* Unless otherwise stated in paragraphs (c) or (d) of this section, or as otherwise prescribed by FDA regulation, all submissions to CBER referenced in parts 600 through 680 of this chapter, as applicable, must be sent to: Document Control Center (HFM-99), Center for Biologics Evaluation and Research, Food and Drug Administration, 1401 Rockville Pike, suite 200N, Rockville,

MD 20852–1448. Examples of such submissions include: Biologics license applications (BLAs) and their amendments and supplements, adverse experience reports, biological product deviation reports, fatality reports, and other correspondence. Biological products samples must not be sent to this address but must be sent to the address in paragraph (c) of this section.

(b) *Licensed biological products regulated by the Center for Drug Evaluation and Research (CDER)*. Unless otherwise stated in paragraphs (b)(1), (b)(2), (b)(3), or (c) of this section, or as otherwise prescribed by FDA regulation, all submissions to CDER referenced in parts 600, 601, and 610 of this chapter, as applicable, must be sent to: CDER Therapeutic Biological Products Document Room, Center for Drug Evaluation and Research, Food and Drug Administration, 12229 Wilkins Ave., Rockville, MD 20852. Examples of such submissions include: BLAs and their amendments and supplements, and other correspondence.

(1) *Biological Product Deviation Reporting (CDER)*. All biological product deviation reports required under § 600.14 must be sent to: Division of Compliance Risk Management and Surveillance (HFD–330), Office of Compliance, Center for Drug Evaluation and Research, Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857.

(2) *Postmarketing Adverse Experience Reporting (CDER)*. All postmarketing reports required under § 600.80 must be sent to: Central Document Room, Center for Drug Evaluation and Research, Food and Drug Administration, 5901–B Ammendale Rd., Beltsville, MD 20705–1266.

(3) *Advertising and Promotional Labeling (CDER)*. All advertising and promotional labeling supplements required under § 601.12(f) of this chapter must be sent to: Division of Drug Marketing, Advertising and Communication (HFD–42), Center for Drug Evaluation and Research, Food and Drug Administration, 5600 Fishers Lane, rm. 8B45, Rockville, MD 20857.

(c) *Samples and Protocols for licensed biological products regulated by CBER or CDER*. (1) Biological product samples and/or protocols, other than radioactive biological product samples and protocols, required under §§ 600.13, 600.22, 601.15, 610.2, 660.6, 660.36, or 660.46 of this chapter must be sent by courier service to: Sample Custodian (ATTN: HFM–672), Food and Drug Administration, Center for Biologics Evaluation and Research, Bldg: NLRG–B, rm. 113, 5516 Nicholson Lane, Kensington, MD 20895. The protocol(s)

may be placed in the box used to ship the samples to CBER. A cover letter should not be included when submitting the protocol with the sample unless it contains pertinent information affecting the release of the lot.

(2) Radioactive biological products required under § 610.2 of this chapter must be sent by courier service to: 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.

(d) *Vaccine Adverse Event Reporting System (VAERS)*. All VAERS reports as specified in § 600.80(c) must be sent to: Vaccine Adverse Event Reporting System (VAERS), P.O. Box 1100, Rockville, MD 20849–1100.

(e) Address information for submissions to CBER and CDER other than those listed in parts 600 through 680 of this chapter are included directly in the applicable regulations.

(f) Obtain updated mailing address information for biological products regulated by CBER at <http://www.fda.gov/cber/pubinquire.htm>, or for biological products regulated by CDER at <http://www.fda.gov/cder/biologics/default.htm>.

§ 600.3 [Amended]

■ 24. Section 600.3 is amended in paragraph (gg) by removing the words “to the Director, Center for Biologics Evaluation and Research,”.

§ 600.11 [Amended]

■ 25. Section 600.11 is amended in paragraph (f)(6) by adding at the end of the paragraph the words “or the Director, Center for Drug Evaluation and Research (see mailing addresses in § 600.2)”.

§ 600.12 [Amended]

■ 26. Section 600.12 is amended in paragraph (b)(2) by adding the words “or the Director, Center for Drug Evaluation and Research” after the words “Director, Center for Biologics Evaluation and Research”, and in paragraph (b)(3) by adding the words “or the Director, Center for Drug Evaluation and Research” after the words “Director, Center for Biologics Evaluation and Research”.

■ 27. Section 600.13 is amended by revising the last two sentences to read as follows:

§ 600.13 Retention samples.

* * * Samples retained as required in this section shall be in addition to samples of specific products required to be submitted to the Center for Biologics Evaluation and Research or the Center

for Drug Evaluation and Research (see mailing addresses in § 600.2). Exceptions may be authorized by the Director, Center for Biologics Evaluation and Research or the Director, Center for Drug Evaluation and Research, when the lot yields relatively few final containers and when such lots are prepared by the same method in large number and in close succession.

■ 28. Section 600.14 is amended by revising paragraph (e) 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 Director, Office of Compliance and Biologics Quality (HFM–600) (see mailing addresses in § 600.2), or an electronic filing through CBER’s Web site at <http://www.fda.gov/cber/biodev/biodev.htm>.

(2) For biological products regulated by the Center for Drug Evaluation and Research (CDER), send the completed Form FDA–3486 to the Division of Compliance Risk Management and Surveillance (HFD–330) (see mailing addresses in § 600.2). CDER does not currently accept electronic filings.

(3) If you make a paper filing, you should identify on the envelope that a biological product deviation report (BPDR) is enclosed.

* * * * *

§ 600.22 [Amended]

■ 29. Section 600.22 is amended in paragraph (e) by adding the words “or the Director, Center for Drug Evaluation and Research (see mailing addresses in § 600.2) after the words “Director, Center for Biologics Evaluation and Research”.

■ 30. Section 600.80 is amended by revising paragraphs (c) introductory text and (f)(4) to read as follows:

§ 600.80 Postmarketing reporting of adverse experiences.

* * * * *

(c) *Reporting requirements*. The licensed manufacturer shall report to FDA adverse experience information, as described in this section. The licensed manufacturer shall submit two copies of each report described in this section for nonvaccine biological products to the Center for Biologics Evaluation and Research (HFM–210), or to the Center for Drug Evaluation and Research (see mailing addresses in § 600.2). Submit all vaccine adverse experience reports to: Vaccine Adverse Event Reporting

System (VAERS) (see mailing addresses in § 600.2). FDA may waive the requirement for the second copy in appropriate instances.

* * * * *

(f) * * *

(4) Copies of the reporting form designated by FDA (FDA-3500A) for nonvaccine biological products may be obtained from <http://www.fda.gov/medwatch/getforms.htm>. Additional supplies of the form may be obtained from the Consolidated Forms and Publications Distribution Center, 3222 Hubbard Rd., Landover, MD 20785. Supplies of the VAERS form may be obtained from VAERS by calling 1-800-822-7967.

* * * * *

■ 31. Section 600.81 is amended by revising the first sentence to read as follows:

§ 600.81 Distribution reports.

The licensed manufacturer shall submit to the Center for Biologics Evaluation and Research or the Center for Drug Evaluation and Research (see mailing addresses in § 600.2), information about the quantity of the product distributed under the biologics license, including the quantity distributed to distributors. * * *

PART 601—LICENSING

■ 32. 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).

■ 33. Section 601.2 is amended by revising the first and fourth sentences and removing the sixth sentence of paragraph (a), by removing and reserving paragraph (b), and by revising paragraph (c)(2) to read as follows:

§ 601.2 Applications for biologics licenses; procedures for filing.

(a) *General.* To obtain a biologics license under section 351 of the Public Health Service Act for any biological product, the manufacturer shall submit an application to the Director, Center for Biologics Evaluation and Research or the Director, Center for Drug Evaluation and Research (see mailing addresses in § 600.2 of this chapter), on forms prescribed for such purposes, and shall submit data derived from nonclinical laboratory and clinical studies which demonstrate that the manufactured product meets prescribed requirements of safety, purity, and potency; with respect to each nonclinical laboratory

study, either a statement that the study was conducted in compliance with the requirements set forth in part 58 of this chapter, or, if the study was not conducted in compliance with such regulations, a brief statement of the reason for the noncompliance; statements regarding each clinical investigation involving human subjects contained in the application, that it either was conducted in compliance with the requirements for institutional review set forth in part 56 of this chapter; or was not subject to such requirements in accordance with § 56.104 or § 56.105, and was conducted in compliance with requirements for informed consent set forth in part 50 of this chapter. * * * An application for a biologics license shall not be considered as filed until all pertinent information and data have been received by the Food and Drug Administration. * * *

(b) [Reserved]

(c) * * *

(2) To the extent that the requirements in this paragraph (c) conflict with other requirements in this subchapter, this paragraph (c) shall supersede other requirements.

* * * * *

§ 601.4 [Amended]

■ 34. Section 601.4 is amended in the first sentence of paragraph (a) by adding the words “or the Director, Center for Drug Evaluation and Research” after the words “Director, Center for Biologics Evaluation and Research”.

■ 35. Section 601.6 is amended by revising paragraph (a)(2) to read as follows:

§ 601.6 Suspension of license.

(a) * * *

(2) Furnish to the Center for Biologics Evaluation and Research or the Center for Drug Evaluation and Research, complete records of such deliveries and notice of suspension.

* * * * *

§ 601.9 [Amended]

■ 36. Section 601.9 is amended in paragraph (a) by adding at the end of the paragraph the words “or the Director, Center for Drug Evaluation and Research”.

■ 37. Section 601.12 is amended by revising the first sentence of paragraph (a)(1), by revising the second sentence of paragraph (d)(1), and by revising paragraph (f)(4) to read as follows:

§ 601.12 Changes to an approved application.

(a)(1) *General.* As provided by this section, an applicant must inform the

Food and Drug Administration (FDA) (see mailing addresses in § 600.2 of this chapter) about each change in the product, production process, quality controls, equipment, facilities, responsible personnel, or labeling established in the approved license application(s). * * *

* * * * *

(d) * * *

(1) * * * The Director, Center for Biologics Evaluation and Research or the Director, Center for Drug Evaluation and Research, may approve a written request for an alternative date to combine annual reports for multiple approved applications into a single annual report submission.

* * * * *

(f) * * *

(4) *Advertisements and promotional labeling.* Advertisements and promotional labeling shall be submitted to the Center for Biologics Evaluation and Research or Center for Drug Evaluation and Research in accordance with the requirements set forth in § 314.81(b)(3)(i) of this chapter, except that Form FDA-2567 (Transmittal of Labels and Circulars) or an equivalent form shall be used.

* * * * *

■ 38. Section 601.15 is revised to read as follows:

§ 601.15 Foreign establishments and products: samples for each importation.

Random samples of each importation, obtained by the District Director of Customs and forwarded to the Director, Center for Biologics Evaluation and Research or the Director, Center for Drug Evaluation and Research (see mailing addresses in § 600.2 of this chapter) must be at least two final containers of each lot of product. A copy of the associated documents which describe and identify the shipment must accompany the shipment for forwarding with the samples to the Director, Center for Biologics Evaluation and Research or the Director, Center for Drug Evaluation and Research (see mailing addresses in § 600.2). For shipments of 20 or less final containers, samples need not be forwarded, provided a copy of an official release from the Center for Biologics Evaluation and Research or Center for Drug Evaluation and Research accompanies each shipment.

§ 601.20 [Amended]

■ 39. Section 601.20 is amended in paragraph (c) by adding the words “or the Director, Center for Drug Evaluation and Research” after the words “Director, Center for Biologics Evaluation and Research”.

■ 40. Section 601.28 is amended by revising the introductory paragraph to read as follows:

§ 601.28 Annual reports of postmarketing pediatric studies.

Sponsors of licensed biological products shall submit the following information each year within 60 days of the anniversary date of approval of each product under the license to the Director, Center for Biologics Evaluation and Research or the Director, Center for Drug Evaluation and Research (see mailing addresses in § 600.2 of this chapter):

* * * * *

§ 601.29 [Amended]

■ 41. Section 601.29 is amended in paragraph (b) by removing the words “, 1401 Rockville Pike, Rockville, MD 20852-1448” and adding in their place “(see mailing addresses in § 600.2 of this chapter)”.

§ 601.43 [Amended]

■ 42. Section 601.43 is amended in paragraph (b) by adding in the first sentence the words “or the Director of the Center for Drug Evaluation and Research” after the words “Director of the Center for Biologics Evaluation and Research”.

§ 601.51 [Amended]

■ 43. Section 601.51 is amended in last sentence of paragraph (b) by removing the words “Director of the Center for Biologics Evaluation and Research” and adding in their place the words “Food and Drug Administration”.

■ 44. Section 601.70 is amended by revising paragraph (d) to read as follows:

§ 601.70 Annual progress reports of postmarketing studies.

* * * * *

(d) Where to report. Submit two copies of the annual progress report of postmarketing studies to the Center for Biologics Evaluation and Research or Center for Drug Evaluation and Research (see mailing addresses in § 600.2 of this chapter).

* * * * *

■ 45. Section 601.92 is amended by revising the first sentence of paragraph (b) to read as follows:

§ 601.92 Withdrawal procedures.

* * * * *

(b) Notice of opportunity for a hearing. The Director of the Center for Biologics Evaluation and Research or the Director of the Center for Drug Evaluation and Research will give the applicant notice of an opportunity for a hearing on the proposal to withdraw the

approval of an application approved under this subpart. * * *

* * * * *

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

■ 46. 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.

§ 606.121 [Amended]

■ 47. Section 606.121 is amended in the introductory text of paragraph (d), and paragraphs (d)(4) and (d)(5) by removing the mail code “(HFB-1)”.

§ 606.171 [Amended]

■ 48. Section 606.171 is amended in the introductory text in paragraph (e) by removing the words “, 1401 Rockville Pike, suite 200N, Rockville, MD 20852-1448” and adding in their place “(see mailing addresses in § 600.2 of this chapter)”.

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

■ 49. 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]

■ 50. Section 607.7 is amended in paragraphs (b) and (c) by removing the words “, 1401 Rockville Pike, suite 200N, Rockville, MD 20852-1448” and adding in their place “(see mailing addresses in § 600.2 of this chapter)”.

§ 607.22 [Amended]

■ 51. Section 607.22 is amended in the first sentence in paragraph (a) by removing the words “1401 Rockville Pike, suite 200N, Rockville, MD 20852-1448” and adding in their place “(see mailing addresses in § 600.2 of this chapter)”.

§ 607.37 [Amended]

■ 52. Section 607.37 is amended in the first sentence of paragraph (a), and in paragraph (b) by removing the words “, 1401 Rockville Pike, suite 200N, Rockville, MD 20852-1448” and adding in their place “(see mailing addresses in § 600.2 of this chapter)”.

PART 610—GENERAL BIOLOGICAL PRODUCTS STANDARDS

■ 53. 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.

■ 54. Section 610.2 is amended by revising the paragraph heading and first sentence of paragraph (a) and by revising the heading and paragraph (b) to read as follows:

§ 610.2 Requests for samples and protocols; official release.

(a) Licensed biological products regulated by CBER. Samples of any lot of any licensed product together with the protocols showing results of applicable tests, may at any time be required to be sent to the Director, Center for Biologics Evaluation and Research (see mailing addresses in § 600.2 of this chapter). * * *

(b) Licensed biological products regulated by CDER. Samples of any lot of any licensed product together with the protocols showing results of applicable tests, may at any time be required to be sent to the Director, Center for Drug Evaluation and Research (see mailing addresses in § 600.2) for official release. Upon notification by the Director, Center for Drug Evaluation and Research, a manufacturer shall not distribute a lot of a biological product until the lot is released by the Director, Center for Drug Evaluation and Research: Provided, That the Director, Center for Drug Evaluation and Research shall not issue such notification except when deemed necessary for the safety, purity, or potency of the product.

§ 610.9 [Amended]

■ 55. Section 610.9 is amended in paragraph (b) by removing the words “, Food and Drug Administration, 1401 Rockville Pike, Rockville, MD 20852-1448” and adding in their place the words “or the Director, Center for Drug Evaluation and Research.”

■ 56. Section 610.11 is amended by revising the first sentence in paragraphs (c)(2) and (c)(3), and by revising the first and last sentences of paragraph (g)(2) to read as follows:

§ 610.11 General safety.

* * * * *

(c) * * * (2) Freeze-dried product for which the volume of reconstitution is not indicated on the label. The route of administration, test dose, and diluent shall be as approved in accordance with § 610.9. * * *

(3) *Nonliquid products other than freeze-dried product.* The route of administration, test dose, and diluent shall be as in accordance with § 610.9. * * *

(g) * * *

(2) For products other than those identified in paragraph (g)(1) of this section, a manufacturer may request from the Director, Center for Biologics Evaluation and Research or the Director, Center for Drug Evaluation and Research (see mailing addresses in § 600.2 of this chapter), an exemption from the general safety test. * * * The Director, Center for Biologics Evaluation and Research or the Director, Center for Drug Evaluation and Research, upon finding that the manufacturer's request justifies an exemption, may exempt the product from the general safety test subject to any condition necessary to assure the safety, purity, and potency of the product.

■ 57. Section 610.12 is amended by revising the last sentence of paragraph (e)(2)(i), by revising the first sentence of the text appearing after the table in paragraph (e)(2)(ii), and by revising paragraph (g)(4)(ii) to read as follows:

§ 610.12 Sterility.

* * * * *

(e) * * *

(2) * * *

(i) * * * When using a single batch of dehydrated culture medium, a manufacturer need not perform growth-promoting tests on each lot of prepared liquid medium, provided that a validation program exists for autoclaves used to sterilize the culture medium, and the manufacturer has received approval for this practice from the Director, Center for Biologics Evaluation and Research or the Director, Center for Drug Evaluation and Research.

(ii) * * *

ATCC strains of microorganisms described in this section are available from the American Type Culture Collection, 10801 University Blvd., Manassas, VA 20110. * * *

* * * * *

(g) * * *

(4) * * *

(ii) Where a manufacturer submits data which the Director, Center for Biologics Evaluation and Research or the Director, Center for Drug Evaluation and Research, finds adequate to establish that the mode of administration, the method of preparation, or the special nature of the product precludes or does not require a sterility test or that the sterility of the lot is not necessary to assure the safety, purity, and potency of the product, the

Director may exempt a product from the sterility requirements of this section subject to any conditions necessary to assure the safety, purity, and potency of the product.

* * * * *

§ 610.13 [Amended]

■ 58. Section 610.13 is amended in the last sentence of paragraph (a)(1) by adding the words “or the Director, Center for Drug Evaluation and Research” after the words “Director, Center for Biologics Evaluation and Research”.

§ 610.15 [Amended]

■ 59. Section 610.15 is amended in paragraph (a)(3) by adding at the end of the last sentence the words “or the Director, Center for Drug Evaluation and Research (see mailing addresses in § 600.2 of this chapter)”.

§ 610.18 [Amended]

■ 60. Section 610.18 is amended in paragraph (c)(2) by adding at the end of the last sentence the words “or the Director, Center for Drug Evaluation and Research”.

§ 610.53 [Amended]

■ 61. Section 610.53 is amended in paragraph (d) by adding at the end of the last sentence the words “or the Director of the Center for Drug Evaluation and Research”.

PART 640—ADDITIONAL STANDARDS FOR HUMAN BLOOD AND BLOOD PRODUCTS

■ 62. The authority citation for 21 CFR part 640 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.

§ 640.55 [Amended]

■ 63. Section 640.55 is amended by removing the words “Food and Drug Administration,” and adding in their place “(HFM-407) (see mailing addresses in § 600.2 of this chapter)”.

PART 660—ADDITIONAL STANDARDS FOR DIAGNOSTIC SUBSTANCES FOR LABORATORY TESTS

■ 64. 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]

■ 65. Section 660.3 is amended by adding the words “(HFM-407) (see mailing addresses in § 600.2 of this

chapter)” after the words “Center for Biologics Evaluation and Research”.

§ 660.6 [Amended]

■ 66. Section 660.6 is amended in paragraph (a)(2) by removing the words “(HFB-1), 8800 Rockville Pike, Bethesda, MD 20892” and adding in their place “(see mailing addresses in § 600.2 of this chapter)”.

§ 660.21 [Amended]

■ 67. Section 660.21 is amended in paragraph (b) by removing the words “(HFN-830), Food and Drug Administration, 8800 Rockville Pike, Bethesda, MD 20892”.

§ 660.22 [Amended]

■ 68. Section 660.22 is amended in paragraph (b) by removing the words “(HFN-890), Food and Drug Administration, 8800 Rockville Pike, Bethesda, MD 20892” and adding in their place “(HFM-407) (see mailing addresses in § 600.2 of this chapter)”.

§ 660.25 [Amended]

■ 69. Section 660.25 is amended in the introductory paragraph and paragraph (a) introductory text by removing the words “(HFN-830), Food and Drug Administration, 8800 Rockville Pike, Bethesda, MD 20892”.

§ 660.26 [Amended]

■ 70. Section 660.26 is amended by removing the words “(HFN-830), Food and Drug Administration, 8800 Rockville Pike, Bethesda, MD 20892”.

§ 660.28 [Amended]

■ 71. Section 660.28 is amended in the first sentence of paragraph (a)(1) by removing the words “(HFN-830), Food and Drug Administration, 8800 Rockville Pike, Bethesda, MD 20892”.

§ 660.36 [Amended]

■ 72. Section 660.36 is amended in paragraph (a) by removing the words “Office of Biological Product Review Sample Custodian (ATTN: HFB-215), Bldg. 29A, Rm. 1C02, Food and Drug Administration, 8800 Rockville Pike, Bethesda, MD 20892” and adding in their place the words “Center for Biologics Evaluation and Research Sample Custodian (ATTN: HFM-672) (see mailing addresses in § 600.2 of this chapter)”.

§ 660.46 [Amended]

■ 73. Section 660.46 is amended in paragraph (a)(2) introductory text by removing the words “(HFB-1), 8800 Rockville Pike, Bethesda, MD 20892” and adding in their place “(see mailing addresses in § 600.2 of this chapter)”.

§ 660.52 [Amended]

■ 74. Section 660.52 is amended by removing the words “(HFB–221), Food and Drug Administration, 8800 Rockville Pike, Bethesda, MD 20892” and adding in their place “(HFM–407) (see mailing addresses in § 600.2 of this chapter)”.

§ 660.53 [Amended]

■ 75. Section 660.53 is amended by removing the words “(HFB–1), Food and Drug Administration, 8800 Rockville Pike, Bethesda, MD 20892”.

§ 660.54 [Amended]

■ 76. Section 660.54 is amended in the introductory paragraph by removing the words “(HFB–1), Food and Drug Administration, 8800 Rockville Pike, Bethesda, MD 20892”.

§ 660.55 [Amended]

■ 77. Section 660.55 is amended in the first sentence of paragraph (a)(3) by removing the mail code “(HFB–1)”.

PART 680—ADDITIONAL STANDARDS FOR MISCELLANEOUS PRODUCTS

■ 78. 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]

■ 79. Section 680.1 is amended in the last sentence of paragraph (b)(2)(iii), in paragraph (b)(3)(iv), and in the first sentence of paragraph (c) by removing the mail code “(HFB–1)” and adding in its place “(see mailing addresses in § 600.2)”, and in paragraph (d)(1) by removing the mail code “(HFB–1)”.

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

■ 80. 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.

■ 81. Section 807.90 is amended by revising the first sentence of paragraph (a)(2) to read as follows:

§ 807.90 Format of a premarket notification submission.

(a) * * *

(2) For devices regulated by the Center for Biologics Evaluation and Research, be addressed to the Document Control Center (HFM–99), Center for Biologics Evaluation and Research, Food and Drug Administration, 1401

Rockville Pike, suite 200N, Rockville, MD 20852–1448; or for devices regulated by the Center for Drug Evaluation and Research, be addressed to the Central Document Room, Center for Drug Evaluation and Research, Food and Drug Administration, 5901–B Ammendale Rd., Beltsville, MD 20705–1266. * * *

* * * * *

PART 822—POSTMARKET SURVEILLANCE

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

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

■ 83. Section 822.8 is amended by revising the second and third sentences to read as follows:

§ 822.8 When, where, and how must I submit my postmarket surveillance plan?

* * * For devices regulated by the Center for Biologics Evaluation and Research, send three copies of your submission to the Document Control Center (HFM–99), Center for Biologics Evaluation and Research, Food and Drug Administration, 1401 Rockville Pike, suite 200N, Rockville, MD 20852–1448. For devices regulated by the Center for Drug Evaluation and Research, send three copies of your submission to the Central Document Room, Center for Drug Evaluation and Research, Food and Drug Administration, 5901–B Ammendale Rd., Beltsville, MD 20705–1266. * * *

Dated: March 15, 2005.

Jeffrey Shuren,

Assistant Commissioner for Policy.

[FR Doc. 05–5780 Filed 3–23–05; 8:45 am]

BILLING CODE 4160–01–S

DEPARTMENT OF THE INTERIOR**Office of Surface Mining Reclamation and Enforcement****30 CFR Part 906**

[CO–033–FOR]

Colorado Regulatory Program

AGENCY: Office of Surface Mining Reclamation and Enforcement, Interior.

ACTION: Final rule; approval of amendment.

SUMMARY: We are approving an amendment to the Colorado regulatory program (the “Colorado program”) under the Surface Mining Control and Reclamation Act of 1977 (SMCRA or the Act). Colorado proposed revisions to its

rules concerning prime farmland, revegetation, hydrology, enforcement, topsoil, historic properties, bond release and permit requirements. The State intends to revise its program to be consistent with the corresponding Federal regulations, provide additional safeguards, clarify ambiguities, and improve operational efficiency.

EFFECTIVE DATE: March 24, 2005.

FOR FURTHER INFORMATION CONTACT:

James F. Fulton, Telephone: (303) 844–1400, extension 1424; Internet address: JFulton@osmre.gov.

SUPPLEMENTARY INFORMATION:

- I. Background on the Colorado Program
- II. Submission of the Amendment
- III. Office of Surface Mining Reclamation and Enforcement’s (OSM) Findings
- IV. Summary and Disposition of Comments
- V. OSM’s Decision
- VI. Procedural Determinations

I. Background on the Colorado Program

Section 503(a) of the Act permits a State to assume primacy for the regulation of surface coal mining and reclamation operations on non-Federal and non-Indian lands within its borders by demonstrating that its State program includes, among other things, “a State law which provides for the regulation of surface coal mining and reclamation operations in accordance with the requirements of this Act * * *; and rules and regulations consistent with regulations issued by the Secretary pursuant to this Act.” See 30 U.S.C. 1253(a)(1) and (7). On the basis of these criteria, the Secretary of the Interior conditionally approved the Colorado program on December 15, 1980. You can find background information on the Colorado program, including the Secretary’s findings, the disposition of comments, and conditions of approval in the December 15, 1980, **Federal Register** (45 FR 82173). You can also find later actions concerning Colorado’s program and program amendments at 30 CFR 906.10, 906.15, 906.16, and 906.30.

II. Submission of the Amendment

By letter dated March 27, 2003, Colorado sent us an amendment to its program (Administrative Record No. CO–696–1) under SMCRA (30 U.S.C. 1201 *et seq.*). Colorado sent the amendment in response to May 7, 1986, June 9, 1987, and March 22, 1990, letters that we sent to it in accordance with 30 CFR 732.17(c), as well as to include changes made at its own initiative. On April 4, 2003, Colorado sent us an addition to its March 27, 2003, amendment. Finally, Colorado submitted to us further revisions to its March 27, 2003, amendment on July 23, 2003.