

Material Incorporated by Reference

(i) You must use Bombardier Service Bulletin 670BA-27-051, dated May 14, 2009, to do the actions required by this AD, unless the AD specifies otherwise.

(1) The Director of the Federal Register approved the incorporation by reference of this service information under 5 U.S.C. 552(a) and 1 CFR part 51.

(2) For service information identified in this AD, contact Bombardier, Inc., 400 Côte Vertu Road West, Dorval, Québec H4S 1Y9, Canada; telephone 514-855-5000; fax 514-855-7401; e-mail thd.crj@aero.bombardier.com; Internet <http://www.bombardier.com>.

(3) You may review copies of the service information at the FAA, Transport Airplane Directorate, 1601 Lind Avenue, SW., Renton, Washington. For information on the availability of this material at the FAA, call 425-227-1221 or 425-227-1152.

(4) You may also review copies of the service information that is incorporated by reference at the National Archives and Records Administration (NARA). For information on the availability of this material at NARA, call 202-741-6030, or go to: http://www.archives.gov/federal_register/code_of_federal_regulations/ibr_locations.html.

Issued in Renton, Washington, on October 16, 2009.

Ali Bahrami,

Manager, Transport Airplane Directorate, Aircraft Certification Service.

[FR Doc. E9-25917 Filed 10-28-09; 8:45 am]

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DEPARTMENT OF ENERGY

Federal Energy Regulatory Commission

18 CFR Part 35

[Docket No. RM01-5-000; Order No. 714]

Electronic Tariff Filings; Correction

October 23, 2009.

AGENCY: Federal Energy Regulatory Commission, DOE.

ACTION: Correcting amendments.

SUMMARY: This document contains corrections to the final regulations, which were published in the **Federal Register** of Wednesday, October 3, 2008 (73 FR 57515). The regulations relate to the obligation to file rate schedules, tariffs and certain service agreements and to the withdrawals and amendments of rate schedules, and tariff or service agreement filings.

DATES: Effective on October 29, 2009.

FOR FURTHER INFORMATION CONTACT: Andre Goodson, 888 First St., NE., Washington, DC 20426, (202) 502-8560, Andre.Goodson@ferc.gov.

SUPPLEMENTARY INFORMATION:

Background

The final regulations that are the subject of these corrections concern the filing of rate schedules, tariffs, and service agreements under the Federal Power Act.

Need for Correction

In Order No. 714, the instructions for the amendatory language contained errors that resulted in the publication of incorrect language in the **Federal Register** for sections 35.1 and 35.17. In particular, the published regulations do not reflect that they are applicable to rate schedules, tariffs, and service agreements.

List of Subjects in 18 CFR Part 35

Electric power rates, Electric utilities, Reporting and recordkeeping requirements, Electricity, Incorporation by reference.

■ Accordingly, 18 CFR part 35 is corrected by making the following correcting amendments:

PART 35—FILING OF RATE SCHEDULES AND TARIFFS

■ 1. The authority citation for part 35 continues to read as follows:

Authority: 16 U.S.C. 791A-825R, 2601-2645; 31 U.S.C. 9701; 42 U.S.C. 7101-7352.

■ 2. In § 35.1, paragraphs (b) and (c) are revised to read as follows:

§ 35.1 Application; obligation to file rate schedules, tariffs and certain service agreements.

* * * * *

(b) A rate schedule, tariff, or service agreement applicable to a transmission or sale of electric energy, other than that which proposes to supersede, cancel or otherwise change the provisions of a rate schedule, tariff, or service agreement required to be on file with this Commission, shall be filed as an initial rate in accordance with § 35.12.

(c) A rate schedule, tariff, or service agreement applicable to a transmission or sale of electric energy which proposes to supersede, cancel or otherwise change any of the provisions of a rate schedule, tariff, or service agreement required to be on file with this Commission (such as providing for other or additional rates, charges, classifications or services, or rules, regulations, practices or contracts for a particular customer or customers) shall be filed as a change in rate in accordance with § 35.13, except cancellation or termination which shall be filed as a change in accordance with § 35.15.

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■ 3. In § 35.17, the heading and paragraphs (c) and (d) are revised to read as follows:

§ 35.17 Withdrawals and amendments of rate schedule, tariff or service agreement filings.

* * * * *

(c) *Withdrawal of suspended rate schedules, tariffs, or service agreements, or parts thereof.* Where a rate schedule, tariff, or service agreement, or part thereof has been suspended by the Commission, it may be withdrawn during the period of suspension only by special permission of the Commission granted upon application therefor and for good cause shown. If permitted to be withdrawn, any such rate schedule, tariff, or service agreement may be refiled with the Commission within a one-year period thereafter only with special permission of the Commission for good cause shown.

(d) *Changes in suspended rate schedules, tariffs, or service agreements, or parts thereof.* A public utility may not, within the period of suspension, file any change in a rate schedule, tariff, or service agreement, or part thereof, which has been suspended by order of the Commission except by special permission of the Commission granted upon application therefor and for good cause shown.

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Kimberly D. Bose,

Secretary.

[FR Doc. E9-25972 Filed 10-28-09; 8:45 am]

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

21 CFR Part 312

[Docket No. FDA-2009-N-0464]

Investigational New Drug Applications; Technical Amendment

AGENCY: Food and Drug Administration, HHS.

ACTION: Final rule; technical amendment.

SUMMARY: The Food and Drug Administration (FDA) is amending its investigational new drug application (IND) regulations to add an address for applicants to submit INDs for in vivo bioavailability and bioequivalence studies in humans. INDs for these studies that are intended to support abbreviated new drug applications (ANDAs) should be sent directly to the

Office of Generic Drugs. This action is being taken to ensure accuracy and clarity in the agency's regulations.

DATES: This rule is effective October 29, 2009.

FOR FURTHER INFORMATION CONTACT:

Peter Chen, Center for Drug Evaluation and Research (HFD-615), Food and Drug Administration, 7500 Standish Pl., Rockville, MD 20855, 240-276-8436.

SUPPLEMENTARY INFORMATION: FDA is amending its regulations in part 312 (21 CFR part 312) to clarify where ANDA applicants should submit INDs for in vivo bioavailability and bioequivalence studies in humans. This document adds the address for the Office of Generic Drugs in § 312.140(a)(1).

Publication of this document constitutes final action on 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 add an address for the submission of INDs related to ANDAs.

List of Subjects in 21 CFR Part 312

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

■ Therefore, under the Federal Food, Drug, and Cosmetic Act and under authority delegated to the Commissioner of Food and Drugs, 21 CFR part 312 is amended as follows:

PART 312—INVESTIGATIONAL NEW DRUG APPLICATION

■ 1. 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.

■ 2. Section 312.140 is amended by revising paragraph (a)(1) to read as follows:

§ 312.140 Address for correspondence.

(a) * * *

(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; except send an IND submission for an in vivo bioavailability or bioequivalence study in humans to support an abbreviated new drug application to the Office of Generic Drugs (HFD-600), Center for Drug Evaluation and Research, Food and Drug Administration, Metro Park North II, 7500 Standish Pl., Rockville, MD 20855.

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Dated: October 23, 2009.

David Horowitz,

Assistant Commissioner for Policy.

[FR Doc. E9-26095 Filed 10-28-09; 8:45 am]

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DEPARTMENT OF DEFENSE

Office of the Secretary

[DOD-2006-HA-0149; RIN 0720-AB01]

32 CFR Part 199

Civilian Health and Medical Program of the Uniformed Services (CHAMPUS); TRICARE; Implementation of Changes to the Pharmacy Benefits Program; Double Coverage With Medicare Part D

AGENCY: Department of Defense.

ACTION: Final rule.

SUMMARY: TRICARE eligible beneficiaries, who are entitled to Medicare Part A on the basis of age, disability, or end-stage renal disease, maintain their TRICARE eligibility when they are enrolled in the supplementary medical insurance program under Part B of Medicare. In general, in the case of medical or dental care provided to these individuals for which payment may be made under both Medicare and TRICARE, Medicare is the primary payer and TRICARE will normally pay the actual out-of-pocket costs incurred by the person. This final rule prescribes double coverage payment procedures and makes revisions to TRICARE rules to accommodate beneficiaries who are eligible under both Medicare and TRICARE, and who participate in Medicare's outpatient prescription drug program under Medicare Part D. These revisions are necessary because of the requirements contained in the Centers for Medicare and Medicaid Services (CMS) final rule for the Medicare Prescription Drug Benefit, Part D plans with other prescription drug coverage.

This final rule also establishes requirements and procedures for implementation of the improvements to the TRICARE Pharmacy Benefits Program directed by section 714 of the Ronald W. Reagan National Defense Authorization Act (NDAA) for Fiscal Year (FY) 2005 (NDAA FY 05) (Pub. L. 108-365). The rule clarifies that the cost-sharing requirements for Medicare-eligible beneficiaries may not be in excess of the cost-sharing requirements applicable to other retirees, their dependents, former spouses and survivors. Additionally, the rule authorizes the Department of Defense (DoD) Pharmacy and Therapeutics

Committee (P&T) to make a separate and additional determination of the relative clinical and cost effectiveness of pharmaceutical agents that provide greater value than other uniform formulary agents in that therapeutic class. This rule also describes the transition process that will occur as the uniform formulary is developed and uniform service facilities move to a uniform formulary, consistent with their scope of practice.

DATES: *Effective Date:* This final rule is effective November 30, 2009.

FOR FURTHER INFORMATION CONTACT:

RADM Thomas McGinnis, TRICARE Management Activity, Pharmaceutical Operations Directorate, telephone (703) 681-2890.

SUPPLEMENTARY INFORMATION:

I. Double Coverage With Medicare Part D

Section 101 of the Medicare Prescription Drug, Improvement, and Modernization Act of 2003 (MMA), (Pub. L. 108-173), amended Title XVIII of the Social Security Act by establishing a new Part D: the Voluntary Prescription Drug Benefit Program (henceforth, Medicare Part D). The Department of Health and Human Services, CMS, published their Final Rule on January 28, 2005 (70 FR 4193-4585). The addition of a prescription drug benefit to Medicare represents a landmark change to the Medicare program, and became available to beneficiaries beginning on January 1, 2006.

The Floyd D. Spence NDAA for FY 2001 (Pub. L. 106-398), established the TRICARE Senior Pharmacy Program under section 711 (which was effective April 1, 2001). The Act, also under section 712 (which was effective October 1, 2001), continued TRICARE eligibility for beneficiaries entitled to Medicare Part A on the basis of age, provided they also are enrolled in Medicare Part B. This program has come to be known as TRICARE for Life (TFL). Under section 701 of the National Defense Authorization Act for Fiscal Year 2000 (Pub. L. 106-65), codified at Title 10, U.S.C., Section 1074g, the Department established its new pharmacy benefits program for all TRICARE beneficiaries (as implemented by 32 CFR 199.21). The full implementation of the pharmacy benefit program was not effective until May 3, 2004; however, changes in pharmacy cost shares were effective with the implementation of TRICARE Senior Pharmacy on April 1, 2001.

In implementing TRICARE Senior Pharmacy, DoD stated that the double