33°37′ N., longitude 86°45′ W.; thence to latitude 32°30′ N., longitude 86°25′ W.; thence to latitude 33°22′ N., longitude 85°00′ W.; thence to latitude 36°35′ N., longitude 79°20′ W.; thence to latitude 40°11′ N., longitude 76°24′ W.; thence to latitude 41°24′ N., longitude 74°30′ W.; thence to latitude 41°43′ N., longitude 72°40′ W.; thence to latitude 42°13′ N., longitude 72°44′ W.; thence to latitude 43°12′ N., longitude 71°30′ W.; thence to latitude 43°45′ N., longitude 70°30′ W.; thence to latitude 45°00′ N., longitude 69°30′ W.; thence to latitude 47°10′ N., longitude 67°55′ W., point of beginning.

* * * * *

Issued in Washington, DC, on October 23, 2008.

Pamela Hamilton-Powell,

Director, Office of Rulemaking.

[FR Doc. E8–25692 Filed 10–27–08; 8:45 am]

BILLING CODE 4910–13–P

DEPARTMENT OF ENERGY

Federal Energy Regulatory Commission

18 CFR Part 35

[Docket No. RM01–5–000, Order No. 714]

Electronic Tariff Filings

October 22, 2008.

AGENCY: Federal Energy Regulatory Commission.

ACTION: Final rule; correction.

SUMMARY: The Federal Energy Regulatory Commission published a document in the **Federal Register** on October 3, 2008 (73 FR 57515), revising Commission rules. That document inadvertently included two non-substantive errors in the instructions for the amendatory language. This document corrects those instructions.

DATES: *Effective Date:* Effective on November 3, 2008.

FOR FURTHER INFORMATION CONTACT: Andre Goodson, Office of the General Counsel, Federal Energy Regulatory Commission, 888 First Street, NE., Washington, DC 20426, (202) 502–8560, *Andre.Goodson@ferc.gov.*

SUPPLEMENTARY INFORMATION: In FR Doc. E8–22500 appearing on page 57515 in the **Federal Register** of Friday, October 3, 2008, the following corrections are made:

§ 35.13 [Corrected]

■ 1. On page 57532, in the second column, in § 35.13, instruction 14g is revised to read as follows: In paragraph (b)(3), the word ''schedule'' is removed; and the word ''mailed'' is removed, and the word ''posted'' is added in its place.

§ 35.14 [Corrected]

■ 2. On page 57532, in the third column, in § 35.14, instruction 15a is revised to read as follows: In paragraph (a), introductory text, the phrase ''(fuel clause)'' is added after the phrase ''Fuel adjustment clauses'', and the phrase '', tariffs or service agreements'' is added after the phrase ''rate schedules'' anywhere it appears in the paragraph's introductory text.

Kimberly D. Bose,

Secretary.

[FR Doc. E8–25611 Filed 10–27–08; 8:45 am]

BILLING CODE 6717–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

21 CFR Parts 201, 208, and 209

[Docket No. FDA–2003–N–0313] (formerly Docket No. 2003N–0342)

RIN 0910–AC35

Toll-Free Number for Reporting Adverse Events on Labeling for Human Drug Products

AGENCY: Food and Drug Administration, HHS.

ACTION: Final rule.

SUMMARY: The Food and Drug Administration (FDA) is issuing a final rule that confirms the interim final rule entitled ''Toll-Free Number for Reporting Adverse Events on Labeling for Human Drug Products'' (73 FR 402, January 3, 2008) (interim final rule) and responds to comments submitted in response to the request for comments in the proposed rule of the same title (69 FR 21778, April 22, 2004) (proposed rule). This final rule affirms the interim final rule's requirement for the addition of a statement to the labeling for certain human drug products for which an application is approved under section 505 of the Federal Food, Drug, and Cosmetic Act (the act). The statement includes a toll-free number and advises that the number is to be used only for reporting side effects and is not intended for medical advice (the side effects statement). This final rule also affirms the interim final rule's addition of new part 209 to the regulations requiring distribution of the side effects statement. This final rule implements provisions of the Best Pharmaceuticals for Children Act (the BPCA) and the Food and Drug Administration Amendments Act of 2007 (FDAAA).

DATES: *Effective Date*: This final rule is effective November 28, 2008.

Compliance Date: The compliance date for this final rule is July 1, 2009. For more information on the compliance date see section II of the **SUPPLEMENTARY INFORMATION** section of this document.

FOR FURTHER INFORMATION CONTACT: Carol Drew, Center for Drug Evaluation and Research, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 51, rm. 6306, Silver Spring, MD 20993–0002, 301–796–3601.

SUPPLEMENTARY INFORMATION:

I. Background

A. BPCA and Proposed Rule

The BPCA (Public Law 107–109) directed FDA to issue a final rule requiring the labeling of each human drug product for which an application is approved under section 505 of the act (21 U.S.C. 355) to include: (1) A toll-free number maintained by FDA for the purpose of receiving reports of adverse events regarding drugs and (2) a statement that the number is to be used for reporting purposes only, not to receive medical advice. Collectively, we refer to the toll-free number and reporting statement as the ''side effects statement.'' The BPCA stated that the final rule must implement the labeling requirement to reach the broadest consumer audience and minimize the cost to the pharmacy profession.

On April 22, 2004 (69 FR 21778), FDA published a proposed rule entitled ''Toll-Free Number for Reporting Adverse Events on Labeling for Human Drug Products.'' FDA received 22 comments on the proposed rule.

B. FDAAA Requirements and Interim Final Rule

On September 27, 2007, the President signed into law FDAAA (Public Law 110–85). Among other things, FDAAA reauthorized the BPCA. Section 502(f) of FDAAA stated that ''the proposed rule * * * 'Toll-Free Number for Reporting Adverse Events on Labeling for Human Drug Products' * * * shall take effect on January 1, 2008,'' unless FDA issues a final rule before that date. FDA was in the process of analyzing the comments on the proposed rule and conducting research on consumer comprehension of the proposed side effects statements when FDAAA was enacted. FDA did not issue a final rule prior to January 1, 2008. Therefore, by operation of law, the proposed rule took effect on January 1, 2008.

FDAAA mandated one change to the proposed rule. Section 502(f)(2) of