Docket	Filed	Effective	Pagination	Superseded sheet
		2/1/00	2nd Sub Fourth Rev	Sub 2nd Rev Third Rev.

Example No. 5: Retroactive Sheets. Continuing from Example 4, a subsequent tracker filing retroactive to November 1, 1999:

Docket	Filed	Effective	Pagination	Superseded sheet
ER00–77–000	4/30/00 2/1/00	11/1/99	3rd Rev Third Rev ..... 3rd Sub Fourth Rev	Sub 2nd Rev Third Rev. 3rd Rev Third Rev.

Example No. 6: Abbreviations. Abbreviate ''Fourth Revised Twenty-Third Revised Sheet No. 4'' as ''4th Rev Twenty-Third Revised Sheet No. 4''.

Example No. 7: Canceled Rate Schedules and Tariffs. To cancel Rate Schedule FERC No. 26, which consists of Original Sheet Nos. 1–39, file First Revised Sheet No. 1.

Company Name; Rate Schedule FERC No. 26.

First Revised Sheet No. 1.

Cancels FERC Electric Rate Schedule No. 26.

Notice of Cancellation

Example No. 8: Reserved Sheets. Your general terms and conditions end on page 75 and you want to reserve sheets 76 through 99 for future use:

Company Name; FERC Electric Tariff, Original Volume No. 2.

Sheet Nos. 76 through 99.

Sheet Nos. 76 through 99 are reserved for future use.

Abbreviation Conventions List

Substitute: Sub
Alternate: Alt
Revised: Rev
First, Second, etc.: 1st, 2nd, etc.
Sheet No.: (omit these words)

SAMPLE PAGE

Day and Light Power Company, FERC Electric Tariff, Original Volume No. 1.

Original Sheet No. 4

Issued by: Harriet Officer, Rates Manager.

Effective: July 1, 2000.

Issued on: June 10, 2000.

Filed to comply with order of the Federal Energy Regulatory Commission, Docket No. ER99–5374–000, issued October 27, 1999, 90 FERC ¶ 61,010 (1999).

[FR Doc. 00–8459 Filed 4–6–00; 8:45 am]

BILLING CODE 6717–01–P

DEPARTMENT OF ENERGY

Federal Energy Regulatory Commission

18 CFR Part 35

[Docket No. RM00–2–000, Order No. 612]

Time Frame for Intervening in and Protesting Federal Power Act Section 205 Filings; Correction

April 3, 2000.

AGENCY: Federal Energy Regulatory Commission.

ACTION: Final rule; correction.

SUMMARY: The Federal Energy Regulation Commission (Commission) published in the **Federal Register** of December 28, 1999, a final rule amending its regulations to provide that, absent a notice providing some other time period, a twenty-one (21) calendar day time period from the date a Federal Power Act (FPA) Section 205 rate filing is filed, amended, or supplemented will be provided for interested parties to file any protest or intervention in the proceeding. Inadvertently, § 35.8(b) contained a typographical error. This document corrects that typographical error.

DATES: Effective on April 7, 2000.

FOR FURTHER INFORMATION CONTACT: Julia A. Lake, Attorney, Federal Energy Regulatory Commission, 888 First Street, NW, Washington, DC 20426; phone: 202–208–2019; e-mail:*julia.lake@ferc.fed.us.*

SUPPLEMENTARY INFORMATION: The Federal Energy Regulatory Commission (Commission) published in the **Federal Register** of December 28, 1999, a final rule amending its regulations to provide that, absent a notice providing some other time period, a twenty-one (21) calendar day time period time from the date a Federal Power Act (FPA) Section 205 rate filing is filed, amended, or supplemented will be provided for interested parties to file any protest or intervention in the proceeding. Inadvertently, § 35.8(d) contained a typographical error. This document corrects that typographical error.

In rule FR Doc. 99–33593, published on December 28, 1999 (64 FR 72535), make the following correction. On page 72537, in the second column, last paragraph, correct the word ''§ 35.9'' to read ''§ 35.8''.

Dated: March 31, 2000.

Linwood A. Watson, Jr.,

Acting Secretary.

FR Doc. 00–8621 Filed 4–6–00; 8:45 am]

BILLING CODE 6717–01–M

DEPARTMENT OF ENERGY

Federal Energy Regulatory Commission

18 CFR Part 385

[Docket No. RM98–1–000; Order No. 607]

Regulations Governing Off-the-Record Communications; Correction

March 31, 2000.

AGENCY: Federal Energy Regulatory Commission, DOE.

ACTION: Final rule; correction.

SUMMARY: The Federal Energy Regulatory Commission (''Commission'') published in the **Federal Register** of September 22, 1999, a document revising its rules concerning communications between persons outside the Commission and the Commission and its employees. One amendatory instruction for Part 385 was incorrectly stated. This document corrects that amendatory instruction.

DATES: Effective on April 7, 2000.

FOR FURTHER INFORMATION CONTACT: Julia A. Lake, Attorney, Federal Energy Regulatory Commission, 888 First Street, NW, Washington, DC 20426; phone: 202–208–2019; e-mail: *julia.lake@ferc.fed.us.*

SUPPLEMENTARY INFORMATION: The Federal Energy Regulatory Commission (''Commission'') published in the **Federal Register** of September 22, 1999, a document revising its rules concerning communications between persons outside the Commission and the Commission and its employees. One amendatory instruction for Part 385 was incorrectly stated. This document corrects that amendatory instruction.

In rule FR Doc. 99–24616 published on September 22, 1999 (64 FR 51222), make the following correction. On page 51234, in the first column, correct amendatory instruction 2 to read as follows:

''2. In § 385.101, remove paragraph (b)(4).''

Dated: March 31, 2000.

Linwood A. Watson, Jr.,

Acting Secretary.

[FR Doc. 00–8458 Filed 4–6–00; 8:45 am]

BILLING CODE 6717–01–M

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

21 CFR Parts 809 and 864

[Docket No. 97N–0135]

Hematology and Pathology Devices; Reclassification; Restricted Devices; OTC Test Sample Collection Systems for Drugs of Abuse Testing

AGENCY: Food and Drug Administration, HHS.

ACTION: Final rule.

SUMMARY: The Food and Drug Administration (FDA) is reclassifying over-the-counter (OTC) test sample collection systems for drugs of abuse testing from class III (premarket approval) into class I (general controls) and exempting them from premarket notification (510(k)) and current good manufacturing practice (CGMP) requirements. FDA is also designating OTC test sample collection systems for drugs of abuse testing as restricted devices under the Federal Food, Drug, and Cosmetic Act (the act) and establishing restrictions intended to assure consumers that: The underlying laboratory test(s) are accurate and reliable; the laboratory performing the test(s) has adequate expertise and competency; and the product has adequate labeling and methods of communicating test results to consumers. Finally, FDA is adding a conforming amendment to the existing classification regulation for specimen transport and storage containers to clarify that it does not apply to specimen transport and storage containers that are part of an OTC test sample collection system for the purpose of testing for the presence of drugs of abuse or their metabolites in a laboratory.

DATES: This rule is effective April 9, 2001.

ADDRESSES: Comments on the burden estimates or on any other aspect of the information collection provisions should be sent to the Office of Device Evaluation (HFZ–440), Center for Devices and Radiological Health, Food and Drug Administration, 2094 Gaither Rd., Rockville, MD 20850.

FOR FURTHER INFORMATION CONTACT: Steven Gutman, Center for Devices and Radiological Health (HFZ–440), Food and Drug Administration, 2098 Gaither Rd., Rockville, MD 20850, 301–594–3084.

SUPPLEMENTARY INFORMATION:

I. Background

In the **Federal Register** of March 5, 1998 (63 FR 10792), FDA published a proposed rule to: (1) Reclassify OTC test sample collection systems for drugs of abuse testing from class III (premarket approval) into class I (general controls) and to exempt them from premarket notification (510(k)) and CGMP requirements; (2) to designate OTC test sample collection systems for drugs of abuse testing as restricted devices under the act; and (3) to establish restrictions intended to assure consumers that: The underlying laboratory test(s) are accurate and reliable, the laboratory performing the test(s) has adequate expertise and competency, and the product has adequate labeling and methods of communicating test results to consumers.

The proposed rule does not affect OTC tests for drugs of abuse that are performed in the home setting—i.e., the testing is performed in the home setting and the test results are read and interpreted directly by the consumer, without involvement or input from a health professional. These are referred to as ''point of care'' tests. When manufacturers or distributors market ''point of care'' tests, they are selling the consumers the actual test rather than a collection system that uses a laboratory to perform a test. Under these circumstances, FDA cannot determine whether the test is accurate and reliable without premarket review of the product. Accordingly, no changes are being proposed in FDA's current policy of reviewing ''point of care'' tests prior to marketing.

Interested persons were given until July 6, 1998, to submit written comments on the proposed rule. FDA received nine comments.

In the **Federal Register** of May 28, 1998 (63 FR 29174), FDA announced that on June 19, 1998, it would hold a public hearing on the proposed rule. FDA held that hearing as announced.

II. Response to Comments

FDA received nine comments on the proposed rule from individuals, manufacturers, and professional societies. The majority of comments supported FDA's proposed rule. A summary of the written comments as well as comments made at the public hearing and FDA's response is set forth in this section II.

A. General Comments

1. Six comments generally supported regulating OTC test sample collection systems for drugs of abuse as class I devices exempt from the premarket notification requirements. These comments asserted that deregulation of home drug test collection systems outlined in the proposed rule made drug testing more affordable and more accessible. These comments indicated support for the testing laboratory to provide a health care professional to communicate the proper interpretation of test results from the laboratory to the lay user.

B. Consumer Versus Workplace Test Kits

2. One comment stated that the rule fails to distinguish between test systems marketed directly to consumers and those intended for use in the workplace because the rule fails to take into account the additional safeguards that are present when drug testing is performed in the workplace. This comment went on to suggest that even if FDA concludes that it has jurisdiction to regulate all test systems, it should nevertheless exercise enforcement discretion with respect to drugs of abuse tests for the workplace because the workplace setting offers sufficient protections to ''ensure sample integrity and test accuracy.''

FDA disagrees with this comment. As explained in the proposed rule, FDA concluded that there should be consistency in its regulation of drugs of abuse test sample collection systems used in the home, workplace, insurance, and sports settings. Issues related to consumer use and quality are similar in all these settings, including concerns about sample integrity and test accuracy. FDA believes the need to provide assurance of test accuracy and reliability applies equally in all these areas.

However, FDA will continue to exercise its enforcement discretion with respect to the use of these products in the law enforcement setting because there are protections to ensure sample integrity and test accuracy that are not generally available in the home, workplace, insurance and sports settings. The additional protections include the use of rules of evidence in judicial proceedings and the representation of the accused (i.e., the person being tested) through the judicial process.