**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**


**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 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 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”.


Linwood A. Watson, Jr.,

Acting Secretary.

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BILLING CODE 6717–01–M
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.