DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

21 CFR Part 310

[Docket No. 93N-0181]

Adverse Experience Reporting Requirements for Human Drug; Correction

AGENCY: Food and Drug Administration, HHS.

ACTION: Proposed rule; correction.

SUMMARY: The Food and Drug Administration (FDA) is correcting a proposed rule that appeared in the **Federal Register** of October 27, 1994 (59 FR 54046). The document proposed to amend its current adverse experience reporting regulations for human drug products and for licensed biological products. The document was published with an error in the codified section. This document corrects that error. **FOR FURTHER INFORMATION CONTACT:**

FOR FURTHER INFORMATION CONTACT: Howard P. Muller, Center for Drug Evaluation and Research (HFD–362), Food and Drug Administration, 7500 Standish Pl., Rockville, MD 20855, 301– 594–1049.

In FR Doc. 94–26483, appearing on page 54046 in the **Federal Register** of October 27, 1994, the following correction is made:

§ 310.305 [Corrected]

On page 54056, in the second column, in § 310.305, paragraph (b)(2) is corrected to read as follows:

§ 310.305 Records and reports concerning adverse drug experiences on marketed prescription drugs for human use without approved new drug applications.

(b) * * *

(2) Adverse drug experience means any adverse event associated with the use of a drug in humans, whether or not considered drug related, including the following: An adverse event occurring in the course of the use of a drug product in professional practice; an adverse event occurring from drug overdose, whether accidental or intentional; an adverse event occurring from drug abuse; an adverse event occurring from drug withdrawal; and any failure of expected pharmacological action.

Dated: January 5, 1995.

William K. Hubbard,

Interim Deputy Commissioner for Policy. [FR Doc. 95–1436 Filed 1–19–95; 8:45 am] BILLING CODE 4160–01–F

DEPARTMENT OF LABOR

Occupational Safety and Health Administration

29 CFR Parts 1910, 1915, and 1926 [Docket No. H-049]

RIN 1218-0099

Respiratory Protection; Proposed Rule

AGENCY: Occupational Safety and Health Administration (OSHA), Labor. **ACTION:** Extension of Comment Period and Rescheduling of Public Hearing.

SUMMARY: By this document the Occupational Safety and Health Administration (OSHA) is extending the comment period and dates for submitting notices of intention to appear, as well as hearing testimony and evidence, and is postponing the public hearing on the proposed rule on respiratory protection which was published on November 15, 1994 (59 FR 58884). The comment period was to end on February 13, 1995; public hearings were scheduled to begin on March 7, 1995. Following publication of the proposal, four written requests to extend the comment period were received. In response to these requests, OSHA is extending the comment period to April 14, 1995. Public hearings will begin on June 6, 1995.

DATES: Comments must be postmarked on or before April 14, 1995. Notices of intention to appear at the public hearing must be postmarked on or before March 31, 1995. Testimony and evidence to be submitted at the hearings must be postmarked by April 14, 1995. The hearing will begin at 9:30 a.m., Tuesday, June 6, 1995 in Washington, DC.

ADDRESSES: Written comments should be submitted in quadruplicate or 1 original (hardcopy) and 1 disk (5 1/4 or 3 1/2) in WordPerfect 5.0, 5.1, 6.0 or ASCII to: Docket Office, Docket H–049, U.S. Department of Labor, Occupational Safety and Health Administration, Room N2625, 200 Constitution Avenue, N.W. Washington, D.C. 20210; (202) 219–7894. Any information not contained on disk, e.g., studies, articles, etc., must be submitted in quadruplicate.

Notices of intention to appear at the informal rulemaking hearing, testimony, and documentary evidence are to be submitted in quadruplicate to: Mr. Thomas Hall, OSHA Division of Consumer Affairs, Occupational Safety and Health Administration, 200 Constitution Avenue, N.W., Room N3649, Washington, D.C. 20210; (202) 219–8615. Written comments received,

notices of intention to appear, and all other material in the public record will be available for inspection and copying in the Docket Office, Room N2439, at the above address.

The hearing will be held in the auditorium of the U.S. Department of Labor, 200 Constitution Avenue, NW., Washington, DC.

FOR FURTHER INFORMATION CONTACT:

Proposal: Ms. Anne Cyr, Office of Information and Consumer Affairs, Occupational Safety and Health Administration, 200 Constitution Avenue, N.W., Room N3647, Washington, D.C. 20210; (202) 219–8151.

Hearings: Mr. Thomas Hall, Division of Consumer Affairs, Occupational Safety and Health Administration, 200 Constitution Avenue, N.W., Room N3649, Washington, D.C. 20210; (202) 219–8615.

SUPPLEMENTARY INFORMATION:

Background

On November 15, 1994, OSHA published a notice of proposed rulemaking on it's respiratory protection standard (59 FR 58884 et seq.). The proposal is intended to update the current respirator standard to reflect changes in methodology, technology, and approach related to respiratory protection that have occurred since the existing respiratory protection standard was adopted in 1971.

Extension of the Comment Period and Re-scheduling of the Public Hearings

OSHA has received four written requests to extend the comment period for an additional 60 days from: Organization Resources Counselors, Inc. (Ex. 54–13); the American Petroleum Institute (Ex. 54-4); the Dow Chemical Company (Ex. 54–12); and TSI Incorporated (Ex. 54-15). The requesters state that because of the holidays and the press of other year-end business, the opportunity for interested persons to submit extensive comments, and for trade associations to coordinate among their members requires an extension of the time for comment. Based on these requests, the Agency has agreed to extend the comment period. It also has re-scheduled the public hearings.

OSHA's procedures for participating in its rulemaking were printed in the proposal notice (59 FR 58935). All persons interested in participating are requested to review these procedures in their entirety. For convenience these procedures are summarized below.