

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: 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.

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Dated: January 5, 1995.

William K. Hubbard,
Interim Deputy Commissioner for Policy.

[FR Doc. 95-1436 Filed 1-19-95; 8:45 am]

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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, N.W., 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 its 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.

Notice of Intention to Appear at the Informal Hearing

Pursuant to section 6(b)(3) of the OSH Act, an opportunity to submit oral testimony concerning all issues raised by the proposed standard will be provided at an informal public hearing to be held in Washington, DC from June 6, 1995 and continuing until Friday, June 23.

The hearing will commence at 9:30 a.m. on June 6, 1995, in the auditorium of the Frances Perkins Building, U.S. Department of Labor, 3rd Street and Constitution Avenue N.W., Washington, DC 20210.

All persons desiring to participate at the hearing must file in quadruplicate a notice of intention to appear, postmarked on or before March 31, 1995. The notice of intention to appear, which will be available for inspection and copying at the OSHA Technical Data Center Docket Office (Room N2625), telephone (202) 219-7894, must contain the following information:

1. The name, address, and telephone number of each person to appear;
2. The capacity in which the person will appear;
3. The approximate amount of time required for the presentation;
4. The issues that will be addressed;
5. A brief statement of the position that will be taken with respect to each issue; and
6. Whether the party intends to submit documentary evidence and, if so, a brief summary of it.

The notice of intention to appear shall be mailed to Mr. Thomas Hall, OSHA Division of Consumer Affairs, Docket H-049, Room N3649, U.S. Department of Labor, 200 Constitution Avenue N.W., Washington, DC 20210; telephone (202) 219-8617.

A notice of intention to appear also may be transmitted by facsimile to (202) 219-5986, by the same date, provided the original and 3 copies are sent to the same address and postmarked no more than 3 days later.

Any party who has not filed a notice of intention to appear may be allowed to testify for no more than 10 minutes as time permits, at the discretion of the Administrative Law Judge, but will not be allowed to question witnesses.

Filing of Testimony and Evidence Before the Hearing

In addition to a notice of intention to appear, any party requesting more than ten (10) minutes for a presentation, or who will submit documentary evidence, must provide in quadruplicate the complete text of the testimony, including any documentary evidence to

be presented. One copy shall not be stapled or bound and be suitable for copying. These materials must be provided to Mr. Thomas Hall, OSHA Division of Consumer Affairs at the address above and be postmarked no later than April 14, 1995.

Each such submission will be reviewed in light of the amount of time requested. In those instances where the information submitted does not justify the amount of time requested, a more appropriate amount of time will be allocated and the participant will be notified of that fact prior to the hearing.

Any party who has not substantially complied with this requirement may be limited to a ten-minute presentation, and may be requested to return for questioning at a later time during the hearing.

Notices of intention to appear, testimony and evidence will be available for inspection and copying at the Docket Office at the address above.

Conduct and Nature of Hearing

The hearing will commence at 9:30 a.m. on the first day. At that time, any procedural matters relating to the proceeding will be resolved.

The nature of an informal rulemaking hearing is established in the legislative history of section 6 of the OSH Act and is reflected by OSHA's rules of procedure for hearings (29 CFR 1911.15(a)). Although the presiding officer is an Administrative Law Judge and limited questioning by persons who have filed notices of intention to appear is allowed on crucial issues, the proceeding is informal and legislative in type. The Agency's intent, in essence, is to provide interested persons with an opportunity to make effective oral presentations which can proceed expeditiously.

Since the hearing is primarily for information gathering and clarification, it is an informal administrative proceeding rather than an adjudicative one. The technical rules of evidence, for example, do not apply. The regulations that govern hearings and the pre-hearing guidelines to be issued for this hearing will ensure fairness and due process and also facilitate the development of a clear, accurate and complete record. Those rules and guidelines will be interpreted in a manner that furthers that development.

The hearing will be conducted in accordance with 29 CFR Part 1911. It should be noted that § 1911.4 specifies the Assistant Secretary may upon reasonable notice issue alternative procedures to expedite proceedings or for other good cause.

The hearing will be presided over by an Administrative Law Judge who makes no decision or recommendation on the merits of OSHA's proposal. The responsibility of the Administrative Law Judge is to ensure that the hearing proceeds at a reasonable pace and in an orderly manner. The Administrative Law Judge, therefore, will have all the powers necessary and appropriate to conduct a full and fair informal hearing as provided in 29 CFR Part 1911 including the powers:

1. To regulate the course of the proceedings;
2. To dispose of procedural requests, objections and comparable matters;
3. To confine the presentations to the matters pertinent to the issues raised;
4. To regulate the conduct of those present at the hearing by appropriate means;
5. In the Judge's discretion, to question and permit the questioning of any witness and to limit the time for questioning; and

6. In the Judge's discretion, to keep the record open for a reasonable, stated time (known as the post-hearing comment period) to receive written information and additional data, views and arguments from any person who has participated in the oral proceedings.

OSHA recognizes that there may be interested persons or organizations who, through their knowledge of the subject matter or their experience in the field, would wish to endorse or support the whole proposal or certain provisions of the proposal. OSHA welcomes such supportive comments, including any pertinent data and cost information which may be available, in order that the record of this rulemaking will present a balanced picture of the public response on the issues involved.

Authority and Signature

This document was prepared under the direction of Joseph A. Dear, Assistant Secretary of Labor for Occupational Safety and Health, U.S. Department of Labor, 200 Constitution Avenue, NW., Washington, DC 20210. It is issued pursuant to section 6(b) of the Occupational Safety and Health Act of 1970 (84 Stat. 1593, 29 U.S.C. 655).

Signed at Washington, DC., this 17th day of January, 1995.

Joseph A. Dear,

Assistant Secretary of Labor.

[FR Doc. 95-1518 Filed 1-19-95; 8:45 am]

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