VCM
Vinyl Chloride

proposed rules

DEPARTMENT OF LABOR

Occupational Safety and Health Administration

[29 CFR Part 1910]

[Docket No. OSH-36]

VINYL CHLORIDE

Availability of Economic Impact Study

On May 10, 1974, pursuant to sections 6(b), 6(c), and 8(c) of the Williams-Steiger Occupational Safety and Health Act of 1970 (84 Stat. 1593, 1596, 1599; 29 U.S.C. 655, 657), Secretary of Labor's Order No. 12-71 (36 FR 8754), and 29 CFR Part 1911, a proposed standard concerning occupational exposure to vinyl chloride was published in the FEDERAL REGISTER (39 FR 16896). On June 25-28 and July 8-11, 1974, an informal rulemaking hearing was held on the proposal pursuant to section 6(b)(3) of the Act.

At the close of the hearing, the presiding Administrative Law Judge, Gordon J. Myatt, ruled, in accordance with the authority granted him under 29 CFR 1911.16(g), that the record would remain open until August 23, 1974 for the receipt of general comments and an additional period after that date solely for the submission of written comments on the economic impact study being conducted for OSHA by an independent consultant. The study, which examines the economic and technological feasibility of compliance with the proposed standard in the monomer, polymer and copolymer producing industries, is now available for examination and copying in Room 230, 1726 M Street, NW., Occupational Safety and Health Administration, Washington, D.C. 20210. All comments regarding the economic impact study should be mailed to the Docket Officer, Docket OSH-36, at the above address, and must be postmarked no later than September 6, 1974.

Signed at Washington, D.C. this 22nd day of August, 1974.

JOHN STENDER,
Assistant Secretary of Labor.

[FR Doc.74-19767 Filed 8-23-74;8:46 am]

DEPARTMENT OF HEALTH, EDUCATION, AND WELFARE

Food and Drug Administration

[21 CFR Parts 1 and 314]

REQUIREMENTS FOR DISPENSING CONTAINERS FOR PRESCRIPTION DRUGS

Notice of Proposed Rulemaking

Recent trends towards the use of dispensing containers made of materials other than glass and the increased use of films, laminates, papers, and foils present new problems to the pharmacist in dispensing a drug product because of the different properties of these materials. Many drug products are subject to decomposition or deterioration if not properly protected from heat, light, and exposure to air or moisture; therefore it is necessary that the container used by the pharmacist in dispensing the drug product to the patient be adequate to maintain the product's original identity, strength, quality, and purity.

The monographs for many of the drug products recognized in the official compendia include requirements for the use of specific types of dispensing containers, e.g., light-resistant container, tight container, well-closed container. These requirements for the use of specified containers apply to products when dispensed by the pharmacist unless otherwise indicated in the monograph. In the absence of official tests and specifications, the pharmacist often has little or no information available to assist him in selecting a suitable container.

The Food and Drug Administration has met with representatives of the National Formulary (N.F.) and the United States Pharmacopeia (U.S.P.) to develop official standards and test procedures for determining that dispensing containers for prescription drugs meet the requirements for specified types of containers as defined in the official compendia. The N.F. on January 2, 1974, proposed the first such official standard for tightness of drug containers. The proposal includes a test procedure as well as suggested limits for "tight containers" and "well-closed containers" as defined by the compendia. The proposed requirements are applicable to multiple-unit containers, i.e., a vial or other drug container permitting withdrawal of successive doses or portions of the contents. It is anticipated that implementation of the standards will be made simultaneously by the N.F. and the U.S.P.

The Commissioner of Food and Drugs has determined that the pharmacist must have information readily available to him as to the type of dispensing container which must be used to maintain a drug product's original identity, strength, quality, and purity. Chemically identical drugs, because of formulation differences, may have different requirements for packaging and storage that may not be apparent without extensive testing. It is not reasonable to expect the pharmacist to test each and every drug product to determine the type of container that must be used to maintain the identity, strength, quality, and purity of the product after it has been dispensed to the patient. The Commissioner is of the opinion that the manufacturer of the drug product is the person most able to supply the necessary information as to what constitutes a suitable container for dispensing his drug product.

Therefore, the Commissioner proposes to require that the manufacturer include, as part of the prescription drug product label, information, directed to the pharmacist, as to the type of container to be used in dispensing the drug product to the patient. This information may be in terms of specific materials, containers, or in terms included in the official compendia to define suitable containers, e.g., "Preserve in a tight container". In the case of containers too small or otherwise unable to accommodate a label with sufficient space to bear this information, but which are packaged within an outer container from which they are removed for dispensing or use, this information may be contained in other labeling on or within the package from which it is to be dispensed.

The Commissioner proposes that the requirements of this proposal be implemented so as to be concurrent with simultaneous implementation of container standards by the N.F. and the U.S.P.

Therefore, pursuant to provisions of the Federal Food, Drug, and Cosmetic Act (secs. 502, 503, 505, 507, 701, 52 Stat. 1050-53, 1055-56, as amended, 59 Stat. 463, as amended; 21 U.S.C. 352, 353, 355, 357, 371) and the Public Health Service Act (sec. 351, 58 Stat. 702; 42 U.S.C. 262), and under authority delegated to him (21 CFR 2.120), the Commissioner of Food and Drugs proposes to amend Parts 1 and 314 as follows:

PART 1—REGULATIONS FOR THE ENFORCEMENT OF THE FEDERAL FOOD, DRUG, AND COSMETIC ACT AND THE FAIR PACKAGING AND LABELING ACT

1. In § 1.106 by revising paragraph (b)(2)(vi), adding a new paragraph (b)(2)(vii) and by revising the undesignated material at the end of paragraph (b)(2) to read as follows:

§ 1.106 Drugs and devices; directions for use.

* * * * * * *

(b) * * *

(2) * * *

(vi) An identifying lot or control number from which it is possible to determine the complete manufacturing history of the package of the drug; and

(vii) A statement directed to the pharmacist specifying the type of container to be used in dispensing the drug prod-

OLI 1140