21 CFR Part 358

Docket No. 82N-0214]

Dandruff, Seborrheic Dermatitis, and Psoriasis Drug Products for Over-the-Counter Human Use; Tentative Final Monograph; Extension of Comment Period

AGENCY: Food and Drug Administration.

ACTION: Notice of proposed rulemaking; extension of comment period.

SUMMARY: The Food and Drug Administration (FDA) is extending to October 29, 1986, the comment period for the notice of proposed rulemaking to establish conditions under which over-the-counter (OTC) dandruff, seborrheic dermatitis, and psoriasis drug products are generally recognized as safe and effective and not misbranded. This action responds to a request to extend the comment period for an additional 30 days to allow more time for interested persons to address important issues proposed by the agency and to allow greater participation by those affected by this rulemaking.

DATE: Written comments by October 29, 1986.

ADDRESS: Written comments to the Dockets Management Branch (HFA-305), Food and Drug Administration, Rm. 4-62, 5600 Fishers Lane, Rockville, MD 0857.

FOR FURTHER INFORMATION CONTACT: William E. Gilbertson, Center for Drugs and Biologics (HFN-210), Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857, 301-295-8000.

SUPPLEMENTARY INFORMATION: In the Federal Register of July 30, 1986 (51 FR 27346), FDA issued a notice of proposed rulemaking to establish conditions under which OTC dandruff, seborrheic dermatitis, and psoriasis drug products are generally recognized as safe and effective and not misbranded. This notice of proposed rulemaking, which was based on the agency's evaluation of the recommendations of the Advisory Review Panel on OTC Miscellaneous External Drug Products and public comments on those recommendations, is part of the ongoing review of OTC drug products conducted by the agency. Interested persons were given until September 29, 1986, to comment on the notice of proposed rulemaking.

In response to the proposal, The Proprietary Association requested a 30-day extension of the comment period in order to allow adequate time for the association to address important issues proposed by the agency concerning OTC dandruff, seborrheic dermatitis, and psoriasis drug products. The Proprietary Association stated that the rulemaking is of significant interest to the OTC drug industry and that extending the comment period will allow greater participation by all those who will be affected by the proposal.

FDA has carefully considered the request. The agency believes that greater participation by those affected by the proposal is in the public interest, and may be of assistance in establishing the conditions under which OTC dandruff, seborrheic dermatitis, and psoriasis drug products are generally recognized as safe and effective and not misbranded. Thus, the agency considers a general extension of the comment period for 30 days to be appropriate.

Interested persons may, on or before October 29, 1986, submit to the Dockets Management Branch (address above) written comments concerning the notice of proposed rulemaking. Three copies of any comments are to be submitted, except that individuals may submit one copy. Comments are to be identified with the docket number found in brackets in the heading of this document. Received comments may be seen in the office above between 9 a.m. and 4 p.m., Monday through Friday.

Dated: September 25, 1986.

John M. Taylor,

Acting Associated Commissioner for Regulatory Affairs.

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DEPARTMENT OF LABOR

Occupational Safety and Health Administration

29 CFR Part 1910

[Docket No. H-041]

Occupational Exposure to 1, 3-Butadiene

AGENCY: Occupational Safety and Health Administration [OSHA], Labor.

ACTION: Advance notice of proposed rulemaking (ANPR).

SUMMARY: This notice announces the initiation of action by OSHA with respect to reducing worker exposures to 1, 3-butadiene (BD) under section 6(b) of the Occupational Safety and Health Act of 1970 (29 U.S.C. 655(b)). This regulatory action follows: (a) The release of scientific studies indicating that BD caused cancer through inhalation in two animal species, and (b) OSHA's acceptance of the Environmental Protection Agency's (EPA's) referral of the chemical under the authority of section 9(a) of the Toxic Substances Control Act (TSCA) (50 FR 41393).

This notice summarizes information currently available to OSHA concerning production and use of BD, health effects, estimates of employees exposure and risk assessments. This notice invites interested parties to submit data, views, and comments regarding all issues involved in OSHA's development of a revised standard for BD, including the appropriate scope of coverage.

DATE: Comments in response to this Advance Notice should be submitted by December 30, 1986.

ADDRESS: Comments should be submitted in quadruplicate to the Docket Officer, Occupational Safety and Health Administration, Docket No. H-041, Room N-3670, U.S. Department of Labor, 200 Constitution Avenue, NW., Washington, DC 20210.

FOR FURTHER INFORMATION CONTACT: James F. Foster, Occupational Safety and Health Administration, U.S. Department of Labor, Office of Information, Room N-3641, Washington, DC 20210, Telephone (202) 523-8151.

SUPPLEMENTARY INFORMATION:

I. Background

1. Chemical and Physical Characteristics

The chemical 1, 3-Butadiene (Chemical Abstracts Service Registry Number 106-99-0) is a colorless, noncorrosive, flammable gas at standard ambient temperature and pressure with a mild aromatic odor. It has a molecular weight of 54.1, boiling point of −4.7 °C at 760 mm Hq, a Lower Explosive Limit of 2%, and an Upper Explosive Limit of 11.5%. It is highly reactive, dimerizes to 4-vinylcychlohexane, and polymerizes easily. Because of its low odor threshold, high flammability and explosiveness, BD has been handled with extreme care in industry.

BD is a major commodity product of the petrochemical industry. Total U.S. production of BD in 1985 was 2.5 billion pounds. About 70% is used in production of styrene-butadiene rubber and polybutadiene rubber for the tire industry. Other uses include copolymer latexes for carpet backing and paper coating, as well as resins and polymers for pipes and automobile and appliance parts. It is also used as an intermediate in the production of such chemicals as fungicides. In "1, 3-Butadiene Use and Substitutes Analysis" (Ex. 17-15), EPA identified 140 major, minor and potential uses of butadiene in the chemical industry.