

members of the public to receive up to 5 mSv from patients. The petitioner also proposes to delete § 20.1301(d) because EPA's radionuclide NESHAPS will become a national standard, and its more restrictive nature would take the place of the airborne effluent limit in the amended part 20.

Conclusion

The petitioner states if this petition is granted, there will be zero-additional cost. The petitioner has included detailed economic impact calculations to support the technical basis for the petition.

Dated at Rockville, Maryland this 6th day of June, 1991.

Samuel J. Chilk,

Secretary of the Commission.

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

21 CFR Parts 201 and 331

[Docket No. 90N-0309]

Drug Labeling; Sodium Labeling for Over-the-Counter Drugs; Proposed Amendment; Extension of Comment Period

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice; extension of comment period.

SUMMARY: The Food and Drug Administration (FDA) is extending to July 24, 1991, the period for submission of comments on the notice of proposed rulemaking for sodium labeling for over-the-counter (OTC) drug products. FDA is taking this action in response to a request to extend the comment period for an additional 30 days to allow more time to comment on this proposal.

DATES: Written comments by July 24, 1991.

ADDRESSES: Written comments to the Dockets Management Branch (HFA-305), Food and Drug Administration, Rm. 4-62, 5600 Fishers Lane, Rockville, MD 20857.

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

SUPPLEMENTARY INFORMATION: In the Federal Register of April 25, 1991 (56 FR 19222), FDA issued a notice of proposed

rulemaking to amend the general labeling provisions for OTC drug products to: (1) Require that the sodium content of all orally administered OTC drug products be included in labeling when the product contains 5 milligrams (mg) or more sodium per a single recommended dose; (2) require that orally administered OTC drug products containing more than 140 mg sodium in the maximum recommended daily dose be labeled with a general warning that persons who are on a sodium-restricted diet should not take the product unless directed by a doctor; and (3) provide for the voluntary use of certain descriptive terms relating to the product's sodium content. FDA issued the notice of proposed rulemaking in order to provide uniform sodium content labeling for all orally administered OTC drug products, and to provide for the voluntary use in OTC drug labeling of the same terms used to describe sodium content in food labeling. Interested persons were given until June 24, 1991, to submit comments on the proposal.

On May 24, 1991, the Nonprescription Drug Manufacturers Association (NDMA), a trade association, requested a 30-day extension to July 24, 1991, in which to file written comments. NDMA contended that the proposal is sweeping in nature, covering virtually all therapeutic classes of OTC drugs that are administered orally. NDMA added that the proposal also raises significant questions of science and policy that merit careful review. NDMA mentioned that it has established a committee to analyze the proposal, particularly the proposed new warning requirements. NDMA noted that antacids are already required to bear sodium labeling, including a warning; that there is no public health and safety urgency to close the comment period; and that a 30-day extension of time for comment would not delay completion of the agency's OTC drug review because the proposal would apply to all orally administered OTC drugs and would be included in the general labeling requirements of 21 CFR part 201, rather than in OTC drug review monographs.

FDA has carefully considered the request and believes that additional time for comment is in the public interest. The agency notes that NDMA intends to file comments to assist the agency. The agency believes that additional time will allow for more useful comments to be developed. Thus, the agency considers a limited extension of the comment period to be appropriate.

Interested persons may, on or before July 24, 1991, submit to the Dockets Management Branch (address above)

written comments regarding sodium labeling of orally administered OTC drug products. Three copies of any comments are to be submitted that individuals may submit. Comments are to be identified with the docket number found in the brackets in the heading of this document. Comments received may be seen in the office above between 9 a.m. and 4 p.m., Monday through Friday.

Dated: June 7, 1991.

Gary Dykstra,

Acting Associate Commissioner for Regulatory Affairs.

[FR Doc. 91-13985 Filed 6-11-91; 8:45 am]

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DEPARTMENT OF DEFENSE

Office of the Secretary

32 CFR Part 199

[DoD 6010.8-R]

Civilian Health and Medical Program of the Uniformed Services (CHAMPUS); Supplemental Insurance Plans

AGENCY: Office of the Secretary, DoD.

ACTION: Proposed amendment of rule.

SUMMARY: This rule proposes to amend DoD 6010.8-R (32 CFR part 199) to implement the Civilian Health and Medical Program of the Uniformed Services (CHAMPUS). The rule defines and limits the types of plans recognized as supplemental insurance coverage under CHAMPUS. The rule will also help provide guidance in identifying plans that would come under the CHAMPUS double coverage regulations.

DATES: Written public comments must be received on or before July 12, 1991.

ADDRESSES: Office of the Civilian Health and Medical Program of the Uniformed Services (OCHAMPUS), Aurora, Colorado 80045-6900.

FOR FURTHER INFORMATION CONTACT: Stan Regensberg, Office of Program Development, OCHAMPUS, Aurora, Colorado 80045-6900, telephone (303)-361-3572.

SUPPLEMENTARY INFORMATION: In FR Doc. 77-7834, appearing in the Federal Register on April 4, 1977 (42 FR 17972), the Office of the Secretary of Defense published its regulation, DoD 6010.8-R, "Implementation of the Civilian Health and Medical Program of the Uniformed Services (CHAMPUS)," as part 199 of this title. DoD 6010.8-R was revised and published in the Federal Register on July 1, 1986 (51 FR 24008).