DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

21 CFR Part 184

[Docket No. 78N-0023]

GRAS Status of Ammonium Bicarbonate, Ammonium Carbonate, Ammonium Chloride, Ammonium Hydroxide, and Mono- and Dibasic Ammonium Phosphate

Correction

In FR Doc. 82-28348 beginning on page 46113 of the issue for Friday, October 15, 1982, on page 46115, the third column, in § 184.1137, paragraph (a), the first line should read "(a) Ammonium carbonate ($(NH_4)_2CO_3$,".

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21 CFR Parts 333, 347, and 348

[Docket Nos. 75N-0183, 78N-0021, 78N-0301, and 80N-0476]

Topical Antifungal, Topical Antimicrobial, External Analgesic, and Skin Protectant Drug Products for Over-the-Counter Human Use; Advance Notices of Proposed Rulemaking; Extension of Time for Comments and Reply Comments

AGENCY: Food and Drug Administration.

ACTION: Advance notices of proposed rulemaking; extension of comment periods.

SUMMARY: The Food and Drug Administration (FDA) is extending the comment periods to February 4, 1983, and the reply comment periods to March 7, 1983, for the advance notices of proposed rulemaking to establish conditions for the safety, effectiveness, and labeling of over-the-counter (OTC) topical antifungal, topical antimicrobial, external analgesic, and skin protectant drug products as the relate to OTC diaper rash drug products. FDA is taking this action in response to a request to allow more time for interested persons to address adequately issues related to diaper rash drug products as a product category and to consult experts so that more informed comments may be submitted to FDA.

DATES: Written comments by February 4, 1983, and reply comments by March 7, 1983.

ADDRESS: 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, National Center for Drugs and Biologics (HFN-510), Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857, 301-443-4960.

SUPPLEMENTARY INFORMATION: In the Federal Register of September 7, 1982 (47 FR 39406, 39412, 39436, and 39464), FDA issued four advance notices of proposed rulemaking to establish conditions under which OTC topical antifungal, topical antimicrobial, external analgesic, and skin protectant drug products used (1) For the treatment of diaper rash; (2) for the prevention of poison ivy, oak, and sumac; (3) for the treatment of fever blisters; (4) as male genital desensitizers; (5) as astrigents; and (6) as insect bite neutralizers are generally recognized as safe and effective and not misbranded. These notices reopened the administrative records for OTC topical antifungal, topical antimicrobial, external analgesic, and skin protectant drug products to allow for consideration of recommendations on drug products for the six drug categories listed above that were received from the Advisory Review Panel on OTC Miscellaneous External Drug Products. These notices relate to the development of monographs for topical antifungal, topical antimicrobial, external analgesic, and skin protectant drug products in general, as part of the ongoing review of OTC drug products conducted by FDA. Interested persons were given until December 6, 1982 to comment on each advance notice of proposed rulemaking and until January 5, 1983 for reply comments. FDA advised that comments and reply comments were limited to those that relate to drug products for the six drug categories listed above.

In response to the advance notices of proposed rulemaking, The Proprietary Association requested a 60-day extension of the comment periods in order to allow adequate time for the association to address what it considered a number of unique and unexpected problems concerning OTC drug products for the treatment of diaper rash. The Proprietary Association stated that, because categorization of data and a proposed monograph were not included in the Panel's statement on diaper rash drug products, and because of the complexity of the subject of diaper rash and diaper rash drug products, more time was needed by member company experts and outside consultants to study adequately and consider the best options for handling these products in the OTC drug review process.

FDA has carefully considered the request. The agency believes that information described in the request may be of assistance in adequately establishing the safety and effectiveness of OTC topical antifungal, topical antimicrobial, external analgesic, and skin protectant drug products used for the treatment of diaper rash and is in the public interest. The agency considers a general extension of the comment periods for 60 days to be appropriate. This extension applies only to comments on diaper rash drug products. Accordingly, the comment periods for submissions by any interested person are extended to February 4, 1983 and the reply comment periods are extended to March 7, 1983. Interested persons may submit to the Dockets Management Branch (address above) written comments regarding these advance notices of proposed rulemaking as they relate to OTC diaper rash drug products. Three copies of any comments are to be submitted, except that individuals may submit one copy. Comments may be seen in the Dockets Management Branch betwen 9 a.m. and 4 p.m., Monday through Friday.

Dated: December 22, 1982.

William F. Randolph,

Acting Associate Commissioner for Regulatory Affairs.

[FR Doc. 82-35205 Filed 12-23-82; 11:48 am]

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21 CFR Part 356

[Docket No. 81N-0033]

Oral Health Care Drug Products for Over-the-Counter Human Use; Advance Notice of Proposed Rulemaking; Extension of Time for Reply Comments

AGENCY: Food and Drug Administration.

ACTION: Advance notice of proposed rulemaking; extension of reply comment period.

SUMMARY: The Food and Drug Administration (FDA) is extending to January 21, 1983, the reply comment period for the advance notice of proposed rulemaking to establish conditions for the safety, effectiveness, and labeling of over-the-counter (OTC) oral health care drug products. FDA is taking this action in response to a request to allow more time for interested persons to address adequately several important issues raised during the comment period.

DATE: Written reply comments by January 21, 1983.

ADDRESS: Written reply 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, National Center for Drugs and Biologics (HFN–510), Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857, 301–443–4960.

SUPPLEMENTARY INFORMATION: In the **Federal Register** of July 30, 1982 (47 FR 32953), FDA issued an extension of comment periods for an advance notice of proposed rulemaking to establish conditions for the safety, effectiveness, and labeling of oral health care drug products for OTC human use. This advance notice of proposed rulemaking, which was based on the recommendations of the Advisory Review Panel on OTC Oral Cavity Drug Products, is part of the ongoing review of OTC drug products conducted by FDA. Interested persons were given until November 22, 1982, to comment on the advance notice of proposed rulemaking and until December 22, 1982, for reply comments.

The Proprietary Association has requested a 60-day extension of the reply comment period in order to allow adequate time for the association to analyze and evaluate comments submitted in response to the advance notice of proposed rulemaking and to prepare reply comments. The association stated that as of December 2, 1982 all comments were not yet available at the Dockets Management Branch, and that the number and length of the comments available on December 2, 1982 were extensive. The association pointed out that the reply comment period runs through the holiday season when many member company employees are not available to analyze and evaluate the comments fully.

FDA has carefully considered the request. The agency believes that an extension of the reply comment period may be of assistance in establishing the safety and effectiveness of OTC oral health care drug products and is in the public interest. Because the comment and reply comment periods have already been extended once and because the submitted comments are now available at the Dockets Management Branch, the agency considers an additional extension of 20 days for the reply comment period to be appropriate. Accordingly, the reply comment period for submissions by any interested person is extended to January 21, 1983. Interested persons may submit to the Dockets Management Branch (address above) written reply comments to comments submitted in response to the advance notice of proposed rulemking. Three copies of any reply comments are to be submitted, except that individuals may submit one copy. Comments and reply comments may be seen in the Dockets Management Branch between 9 a.m. and 4 p.m., Monday through Friday.

Dated: December 21, 1982.

William F. Randolph,

Acting Associate Commissioner for Regulatory Affairs.

[FR Doc. 82–35070 Filed 12–22–82; 11:39 am]

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DEPARTMENT OF LABOR

Occupational Safety and Health Administration

29 CFR Part 1910

[Docket No. S–010]

Servicing of Multi-Piece and Single Piece Rim Wheels; Extension of Comment Period

AGENCY: Occupational Safety and Health Administration (OSHA), Labor.

ACTION: Extension of time for submission of written comments.

SUMMARY: This notice extends the comment period for written responses to the questions OSHA presented in the notice of proposed rulemaking: "Servicing of Multi-Piece and Single Piece Rim Wheels" (47 FR 51159, November 12, 1982).

DATES: Written responses to the November 12, 1982 notice must submitted on or before January 26, 1983.

ADDRESS: Comments and hearing requests should be sent to: Docket Officer, Docket No. S–101, Room S–6212, U.S. Department of Labor, Washington, D.C. 20210 (202) 523–7894.

FOR FURTHER INFORMATION CONTACT: Mr. Richard Sauger, U.S. Department of Labor—OSHA, Office of Mechanical Engineering Safety Standards, Room N–3506, Washington, D.C. 20210 (202) 523–7213.

SUPPLEMENTARY INFORMATION: On November 12, 1982, OSHA published in the **Federal Register** (47 FR 51159) a proposed rule, "Servicing of Multi-Piece and Single Piece Rim Wheels." In the proposed rule, OSHA included requirements for the training of all tire servicing employees, establishing a safe practice procedure for servicing single piece rim wheels, using restraining devices or other means of securing the rim wheel during inflation and using only matching rim wheel components (tires and rims). The proposal also contains several minor amendments to the provisions currently applicable to multi-piece rim wheel servicing operations.

In the notice, OSHA requested written responses to many general and special issues pertaining to multi-piece and single piece rim wheels. The written responses were to have been received December 27, 1982.

OSHA has been asked to extend the comment period to ensure that interested parties have sufficient time to compile data and prepare responses to the issues raised in the notice. OSHA believes that the information gathering process will be improved if all interested parties are granted additional time for submission of comments. Thus, OSHA has decided to extend the written comments period to January 26, 1983.

(Sec. 6, 84 Stat. 1593 (29 U.S.C. 655), 29 CFR Part 1911; Secretary of Labor's Order No. 8–76 (41 FR 25059))

Signed at Washington, D.C., this 22nd day of December 1982.

Thorne G. Auchter,

Assistant Secretary of Labor.

[FR Doc. 82–35144 Filed 12–27–82; 8:45 am]

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DEPARTMENT OF THE INTERIOR

Office of Surface Mining Reclamation and Enforcement

30 CFR Part 913

Public Comment Procedures and Opportunity for Public Hearing on Modified Portions of Illinois Permanent Regulatory Program

AGENCY: Office of Surface Mining Reclamation and Enforcement (OSM), Interior.

ACTION: Proposed Rule.

SUMMARY: OSM is announcing procedures for the public comment period and for requesting a public hearing on the substantive adequacy of certain program amendments submitted by the State of Illinois to satisfy conditions imposed by the Secretary of the Interior on the approval of the Illinois permenent regulatory program (hereinafter referred to as the Illinois program) under the Surface Mining Control and Reclamation Act of 1977 (SMCRA).

This notice sets forth the times and locations that the Illinois program and the proposed amendments are available