**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 ($(NH_4)_2CO_3$,".

BILLING CODE 1505-01-M

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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.*

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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.