person who intends to assert or rely on such a sanction shall submit proof of its existence in response to this proposal. The regulation proposed above will constitute a determination that excluded uses would result in adulteration of the food in violation of section 402 of the act, and the failure of any person to come forward with proof of such an applicable prior sanction in response to this proposal constitutes a waiver of the right to assert or rely on such sanction at any later time. This notice also constitutes a proposal to establish a regulation under Part 181 (21 CFR 181), incorporating the same provisions, in the event that such a regulation is determined to be appropriate as a result of submission of proof of such an applicable prior sanction in response to this proposal.

Interested persons may, on or before April 4, 1978, submit to the Hearing Clerk (HFC-20), Food and Drug Administration, Room 4-65, 5600 Fishers Lane, Rockville, Md. 20857, written comments regarding this proposal. Four copies of all comments shall be submitted, except that individuals may submit single copies of comments, and shall be identified with the Hearing Clerk docket number found in brackets in the heading of this document. Received comments may be seen in the above office between the hours of 9 a.m. and 4 p.m., Monday through Friday.

The Food and Drug Administration has determined that this document does not contain a major proposal requiring preparation of an economic impact statement under Executive Order 11821 (as amended by Executive Order 11949) and OMB Circular A-107. A copy of the economic impact assessment is on file with the Hearing Clerk, Food and Drug Administration.

Dated: January 25, 1978.

JOSEPH P. HILE,
Associate Commissioner for Compliance.

[FR Doc. 78-2723 Filed 2-2-78; 8:45 am]

[4110-03]

[21 CFR Part 333]

[Docket No. 75N-0183]

OTC TOPICAL ANTIMICROBIAL PRODUCTS

Extension of Time for Objections and Requests for Hearing

AGENCY: Food and Drug Administration.

ACTION: Thirty-day extension of time for objections and/or requests for hearing before the Commissioner.

SUMMARY: The Food and Drug Administration is extending until March 6, 1978, the time for filing written objections and requests for hearing before the Commissioner on a proposal to establish conditions under which over-the-counter (OTC) topical antimicrobial drugs are generally recognized as safe and effective and not misbranded. The extension is granted in response to requests for additional time to study the proposal.

DATE: Written objections and/or requests for oral hearing before the Commissioner by March 6, 1978.

ADDRESS: Written objections and/or requests for hearing to the Hearing Clerk (HFC-20), Food and Drug Administration, Room 4-65, 5600 Fishers Lane, Rockville, Md. 20857.

FOR FURTHER INFORMATION CONTACT:

William E. Gilbertson, Bureau of Drugs (HFD-510), Department of Health, Education, and Welfare, Food and Drug Administration, 5600 Fishers Lane, Rockville, Md. 20857, 301-443-4960.

SUPPLEMENTARY INFORMATION: In the FEDERAL REGISTER of January 6, 1978 (43 FR 1210), the Commissioner of Food and Drugs issued a tentative final regulation containing a tentative final monograph which would establish conditions for the safety, effectiveness, and labeling of over-the-counter (OTC) products such as antibacterial soaps, surgical scrubs, skin cleaners and first-aid preparations. The tentative final monograph is based on the recommendations and findings of the OTC Antimicrobial I Panel and a proposal by the Commissioner of Food and Drugs, published in the FEDERAL REGISTER of September 13, 1974 (39 FR 33103), in accordance with the OTC drug review procedures in § 330.10(a)(7) (21 CFR 330.10(a)(7)). Interested persons were given until February 6, 1978 to file written objections and request an oral hearing before the Commissioner.

The agency has received requests from the Proprietary Association, The Soap and Detergent Association, Ferro Corp., Acme United Corp., Procter and Gamble Co., and Scientific and Regulatory Services to extend the time for objections and/or requests for hearing before the Commissioner. The requests have argued that the tentative final monograph is substantially changed from the Panel's recommended monographed and that nearly 3½ years have elapsed since the original proposal. The requests also note that major revisions have been proposed in labeling and that the required testing guidelines have been extensively modified. The requests for extension are on file in the office of the Hearing Clerk, Food and Drug Administration.

The Commissioner is persuaded that granting additional time for objections and/or requests for a hearing before the Commissioner is appropriate.

Accordingly, interested persons may file written objections and/or request an oral hearing before the Commissioner on this tentative order on or before March 6, 1978. Requests for an oral hearing must specify points to be covered and time requested. All objections and requests shall be submitted (in quintuplicate and identified with the Hearing Clerk docket number found in brackets in the heading of this document) to the Hearing Clerk (HFC-20), Food and Drug Administration, Room 4-65, 5600 Fishers Lane, Rockville, Md. 20857, and may be accompanied by a memorandum or brief in support thereof. Objections and requests may be seen in the above-named office between 9 a.m. and 5 p.m., Monday through Friday. Any schedule oral hearing will be announced in the FEDERAL REGISTER.

This action is taken under the Federal Food, Drug, and Cosmetic Act (secs. 502, 505, 701(a), 52 Stat. 1050-1053 as amended, 1055 (21 U.S.C. 352, 355, 371(a)) and under authority delegated to the Commissioner (21 CFR 5.1)).

Dated: January 31, 1978.

WILLIAM F. RANDOLPH,
Acting Associate Commissioner for Compliance.

[FR Doc. 78-3102 Filed 2-1-78; 11:14 am]

[4110-03]

[21 CFR Part 500]

[Docket No. 76N-0286]

NEW ANIMAL DRUGS: BOVINE TEAT DIPS

Extension of Time For Filing Comments on Proposed Rulemaking

AGENCY: Food and Drug Administration.

ACTION: Proposed rule; extension of comment period.

SUMMARY: This document further extends the comment period on a proposed rule concerning uses of bovine teat dips for an additional 90 days, as requested by the National Mastitis Council.

DATES: Comments by March 10, 1978.

ADDRESSES: Written comments to the Hearing Clerk (HFC-20), Room 4-65, Food and Drug Administration, 5600 Fishers Lane, Rockville, Md. 20857.

FOR FURTHER INFORMATION CONTACT:

Howard Meyers, Bureau of Veterinary Medicine (HFV-214), Food and