In response to the proposal, The Proprietary Association requested a 60-day extension of the comment period in order to allow adequate time for the association to address several important issues raised by the Panel, including the Panel's combination drug policy and its definition of toothache. The Association stated that it plans to contact experts on these issues in the course of its preparation of comments on the proposal. The Association pointed out the difficulty of contacting such experts during the summer months.

FDA has carefully considered the request. The agency believes that information described in the request may be of assistance in establishing the safety and effectiveness of OTC drug products for the relief of oral discomfort and is in the public interest. The agency considers a general extension of the comment period for 60 days to be appropriate. Accordingly, the comment period for submissions by any interested person is extended to October 22, 1982, and the reply comment period is extended to November 22, 1982. Comments may be seen in the Dockets Management Branch, Food and Drug Administration, at the address noted above, between 9 a.m. and 4 p.m., Monday through Friday.

Dated: July 22, 1982.

William F. Randolph,

Acting Associate Commissioner for Regulatory Affairs.

[FR Doc. 82-20475 Filed 7-29-82; 8:45 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 Comments and Reply Comments

AGENCY: Food and Drug Administration.

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

SUMMARY: The Food and Drug Administration (FDA) is extending to November 22, 1982, the comment period and to December 22, 1982 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. This action is being taken in response to two requests to allow more time for interested persons to address adequately several important issues raised by the Panel and to consult experts so that more informed comments may be submitted to FDA.

DATES: Written comments by November 22, 1982, and reply comments by December 22, 1982.

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 (HFD-510), Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857, 301-443-4960.

SUPPLEMENTARY INFORMATION: In the **Federal Register** of May 25, 1982 (47 FR 22760), FDA issued an advance notice of proposed rulemaking to establish conditions for the safety, effectiveness, and labeling of oral health care 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 the agency. Interested persons were given until August 23, 1982, to comment on the advance notice of proposed rulemaking and until September 22, 1982, for reply comments.

In response to the proposal, The Proprietary Association requested a 60-day extension of the comment period in order to allow adequate time for the association to address important issues raised by the Panel concerning antimicrobial agents and OTC mouthwash products. The Association stated that it plans to solicit the views of dental researchers and scientists who did not participate in the Panel's deliberations so that FDA may have the widest possible views regarding the Panel's recommendations. Warner-Lambert Co. requested a 90-day extension to permit careful and thorough evaluation of the Panel's report and to consult other oral health care experts in order to respond with meaningful comments. The company pointed out the difficulty of contacting such experts during the summer months.

FDA has carefully considered the requests. The agency believes that information described in the requests may be of assistance in establishing the safety and effectiveness of OTC oral health care drug products and is in the public interest. Because of the length of the Panel's report, the agency considers a general extension of the comment period for 90 days to be appropriate. Accordingly, the comment period for submissions by any interested person is extended to November 22, 1982, and the reply comment period is extend to December 22, 1982. Comments may be seen in the Dockets Management Branch, Food and Drug Administration, at the address noted above, between 9 a.m. and 4 p.m., Monday through Friday.

Dated: July 22, 1982.

William F. Randolph,

Acting Associate Commissioner for Regulatory Affairs.

[FR Doc. 82-20476 Filed 7-29-82; 8:45 am]

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21 CFR Part 600

[Docket No. 82N-0138]

Biological Products; Inspection Frequency of All Licensed Biological Establishments and Their Additional Location(s)

AGENCY: Food and Drug Administration.

ACTION: Proposed rule.

SUMMARY: The Food and Drug Administration (FDA) is proposing to amend the biologics regulations by changing the required minimum frequency of inspections for all licensed biological establishments and their additional location(s) from at least once every year to at least once every 2 years. This action is being proposed (1) to provide flexibility for the agency to reduce the inspection burden on a specific portion of the regulated drug and device industry; (2) to provide the agency with greater flexibility in management of its resources; and (3) to provide a uniform requirement for frequency of inspection for all drugs and devices consistent with requirements in the Federal Food, Drug, and Cosmetic Act.

DATE: Comments by September 28, 1982.

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: Rada Proehl, National Center for Drugs and Biologics (HFB-620), Food and Drug Administration, 8800 Rockville Pike, Bethesda, MD 20205, 301-443-1306.

SUPPLEMENTARY INFORMATION: Since Congressional approval of the Biologics Control Act in 1902, biological products entering into interstate commerce have been required to be licensed under Federal law. In 1903, the Secretary of the Treasury approved the first regulations for the enforcement of the Biologics Control Act. The regulations, promulgated by a board consisting of the Surgeon General of the Public