of the proposed rule should be corrected to read "§ 270.208."

Kenneth F. Plumb,

Secretary.

[FR Doc. 80-15973 Filed 5-23-80; 8:45 am]

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

21 CFR Part 331

[Docket No. 79N-0433]

Antacid Drug Products for Over-The-Counter Human Use; Proposed Amendment of a Monograph

AGENCY: Food and Drug Administration.

ACTION: Proposed Rule.

SUMMARY: The Food and Drug Administration (FDA) proposes to amend the administrative procedures by which persons might request and be granted a modification of the in vitro test for over-the-counter (OTC) antacid drug products. This action is taken to make these procedures conform to the agency's current administrative regulations and to clarify the procedure for submitting such a request.

DATES: Comments by July 28, 1980.

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

FOR FURTHER INFORMATION CONTACT: William E. Gilbertson, Bureau of Drugs (HFD—510), Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857, 301-443-4960.

SUPPLEMENTARY INFORMATION: In the **Federal Register** of June 4, 1974 (39 FR 19862), FDA issued the final order for OTC antacid drug products generally recognized as safe and effective and not misbranded (21 CFR Part 331). This order was issued under § 330.10 of the OTC drug review procedures (21 CFR 330.10) promulgated in the **Federal Register** of May 11, 1972 (37 FR 9464) and was based on the conclusions and recommendations of the Advisory Review Panel on OTC Antacid Drug Products.

Section 331.29 (21 CFR 331.29) of the antacid monograph contains provisions for seeking a modification of the in vitro testing procedures set forth in Subpart C of Part 331 (21 CFR Part 331). The regulation currently requires that any proposed modifications and the data to support them be submitted to the Assistant Director for Implementation, OTC Drug Products Evaluation Staff, Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857, for approval before use. Because of a reorganization within the Bureau of Drugs since this final order was published, there is no such position at the present time. Also, the current regulation does not explain how requests for test modifications will be processed by the agency.

It is the purpose of this proposed amendment to indicate that the request for, and data in support of, proposed modifications of the in vitro testing procedures should be submitted to the office of the Hearing Clerk in the form of a citizen petition under the procedures established in the agency's general administrative regulations § 10.30 (21 CFR 10.30). Consistent with the procedures under § 10.30, the agency will notify the petitioner in writing whether the petition is granted or denied. It is the intention of FDA that the authority to grant or deny petitions seeking modification of the vitro testing procedures in 21 CFR Part 331 be redelegated from the Commissioner of Food and Drugs to the Director or Deputy Director of the Division of Over-The-Counter Drug Evaluation. Therefore, final regulations issued under this proposal will include a redelegation of authority under Subpart B of Part 5 (21 CFR Part 5).

The proposed procedure in which any request for a test modification is to be submitted as a petition to the office of the Hearing Clerk is in keeping with the public nature of the OTC drug review. Similarly, any decisions regarding such a petition will be placed on public display.

The Food and Drug Administration has determined that under 21 CFR 25.24(b)(12) (proposed in the **Federal Register** of December 11, 1979; 44 FR 71742) this proposed action is of a type that does not have a significant effect on the human environment. Therefore, neither an environmental assessment nor an environmental impact statement is required.

Therefore, under the Federal Food, Drug, and Cosmetic Act (secs. 201, 502, 505, 701, 52 Stat. 1040-1042 as amended, 1050-1053 as amended, 1055-1056 as amended by 70 Stat. 919 and 72 Stat. 948 (21 U.S.C. 321, 352, 355, 371) and the Administrative Procedure Act (secs. 4, 5, 10, 60 Stat. 238 and 243 as amended (5 U.S.C. 553, 554, 702, 703, 704)) and under authority delegated to the Commissioner of Food and Drugs (21 CFR 5.1)), it is proposed that Part 331 be amended by revising § 331.29, to read as follows:

§ 331.29 Test modifications.

The formulation or mode of administration of certain products may require modification of this in vitro test. Any proposed modification and the data to support it shall be submitted as a petition under the rules established in § 10.30 of this chapter. All information submitted will be subject to the disclosure rules in Part 20 of this chapter.

Interested persons may, on or before July 28, 1980, submit to the Hearing Clerk (HFA-305), Food and Drug Administration, Rm. 4-62, 5600 Fishers Lane, Rockville, MD 20857, written comments regarding this proposal. Four copies of any comments are to be submitted, except that individuals may submit one copy. Comments are to 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 9 a.m. and 4 p.m., Monday through Friday.

In accordance with Executive Order 12044, the economic effects of this proposal have been carefully analyzed, and it has been determined that the proposed rulemaking does not involve major economic consequences as defined by that order. A copy of the regulatory analysis assessment supporting this determination is on file with the Hearing Clerk, Food and Drug Administration.

Dated: May 20, 1980.

William F. Randolph,

Acting Associate Commissioner for Regulatory Affairs.

[FR Doc. 80-15979 Filed 5-23-80; 8:45 am]

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DEPARTMENT OF TRANSPORTATION

Coast Guard

33 CFR Part 117

[CGD 80-059]

Drawbridge Operation Regulations; Barnegat Bay, N.J.

AGENCY: Coast Guard, DOT.

ACTION: Proposed rule.

SUMMARY: At the request of the New Jersey Department of Transportation, the Coast Guard will consider changing the regulations governing the operation of the Route 37 drawbridge across Barnegat Bay, mile 14.1 of the Intracoastal Waterway of New Jersey, at Island Heights, New Jersey to allow the draw to remain closed to marine traffic from 11 p.m. to 7 a.m. during the months of December, January, February