termination. It has now been decided that such disclosure should be reflected in regulations and should be continued, but at a time after publication of the tentative determination, not before; or before a final affirmative determination pursuant to § 153.36 of the Customs Regulations (19 CFR 153.36). This disclosure is independent of the opportunity provided to present oral views before the Treasury Department, which interested persons may request in connection with a tentative Treasury action, or as appropriate, prior to a final Treasury action where final action is taken pursuant to § 153.36 of the Customs Regulations (19 CFR 153.36).

Accordingly, it is proposed that § 153.31 of the Customs Regulations (19 CFR 153.31) be amended by inserting a new paragraph 153.31(d) to read as follows:

§ 153.31 Full-scale investigation.

* * * * *

(d) *Disclosure Conference.* After the publication in the FEDERAL REGISTER of a "Withholding of Appraisement Notice," or any other notice of tentative disposition of an antidumping investigation, the Commissioner of Customs shall conduct, at the request of any interested person, a disclosure conference during which the Customs Service will disclose to such interested person the bases for the tentative disposition of an antidumping investigation. Where it appears to the Secretary that an affirmative determination pursuant to § 153.36 is required, and no request has been made for a withholding of appraisement under § 153.35 (b), persons known to be interested in the proceeding will be so informed in sufficient time so they may request a disclosure prior to the hearing which may be requested pursuant to § 153.40. Confidential information will be treated consistently with the procedures set forth in § 153.22. Nothing in this subsection will affect access to information which is otherwise available pursuant to § 153.21."

The Customs Service invites comments from all interested persons on the proposed amendments to the Customs Regulations. Comments submitted will be available for public inspection in accordance with § 103.8(b) of the Customs Regulations (19 CFR 103.8(b)) during regular business hours at the Regulations and Legal Publications Division, Headquarters, U.S. Customs Service, 1301 Constitution Avenue NW., Washington, D.C. 20229.

R. E. CHASEN,
Commissioner of Customs.

Approved: December 30, 1977.

HENRY C. STOCKWELL, JR.,
Acting General Counsel of the Treasury.

[FR Doc.78-267 Filed 1-5-78;8:45 am]

[4110-03]

DEPARTMENT OF HEALTH, EDUCATION, AND WELFARE

Food and Drug Administration

[21 CFR Part 343]

[Docket No. 77N-0094]

OVER-THE-COUNTER DRUGS

Establishment of a Monograph for OTC Internal Analgesic, Antipyretic and Antirheumatic Products; Extension of Time

AGENCY: Food and Drug Administration.

ACTION: Extension of time for reply comments.

SUMMARY: The Food and Drug Administration is extending by 30 days the time for filing reply comments on a proposal to establish conditions under which over-the-counter (OTC) internal analgesic, antipyretic and antirheumatic drugs are generally recognized as safe and effective and not misbranded. The extension is in response to requests for such extensions.

DATE: Reply comments by February 6, 1978.

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

FOR FURTHER INFORMATION CONTACT:

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

SUPPLEMENTARY INFORMATION: In the FEDERAL REGISTER of July 8, 1977 (42 FR 35345), the Commissioner of Food and Drugs issued a proposed regulation containing the monograph recommended by the Advisory Review Panel on OTC Internal Analgesic and Antirheumatic Products establishing: (1) conditions under which OTC internal analgesic, antipyretic and antirheumatic drugs are generally recognized as safe and effective and not misbranded; (2) a statement of the conditions excluded from the monograph on the basis of a determination by the Panel that they would result in the drugs' not being generally recognized as safe and effective or would result in misbranding; (3) a statement of the conditions excluded from the monograph on the basis of a determination by the Panel that the available data are insufficient to classify such conditions under either (1) or (2) above; and (4) the conclusions and recommendations of the Panel to the Commissioner. Interested persons were given until October 6, 1977 to submit comments on the proposal and until November 7, 1977 to reply to any comments so filed.

In response to several requests, an extension of time of 60 days was granted both for comments and reply comments until December 5, 1977 and January 6, 1978, respectively. This extension was published in the FEDERAL REGISTER of October 4, 1977 (42 FR 53980).

The agency has received subsequent requests from the Proprietory Association, McNeil Laboratories, and Sterling Drug, Inc. to extend the time for reply comments, arguing that 30 days after the comment period, as granted in the proposal, is insufficient time to respond, in view of the delay encountered in receiving requested copies of comments on file in the office of the Hearing Clerk. 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 reply comments is appropriate. Accordingly, interested persons are invited to submit reply comments (preferably four copies and identified with the Hearing Clerk docket number found in brackets in the heading of this document) regarding the comments on the July 8, 1977 proposal on file with the Hearing Clerk. Such reply comments should be addressed to the office of the Hearing Clerk (HFC-20), Food and Drug Administration, Rm. 4-65, 5600 Fishers Lane, Rockville, Md. 20857 and submitted on or before February 6, 1978. Received comments may be seen in the above-named office between 9 a.m. and 4 p.m., Monday through Friday.

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: December 30, 1977.

WILLIAM F. RANDOLPH,
Acting Associate Commissioner for Compliance.

[FR Doc.78-188 Filed 1-3-78;12:14 pm.]

[4110-03]

[21 CFR Part 511]

[Docket No. 77N-0336]

EXPORT OF NEW ANIMAL DRUGS FOR INVESTIGATIONAL USE

Proposed Rule Making

AGENCY: Food and Drug Administration.

ACTION: Proposed rule.

SUMMARY: This is a proposal to amend the new animal drug regulations to set