Executive Order 11821 (as amended by Executive Order 11949) and OMB Circular A-107.

Dated: September 27, 1977.

HOWARD R. ROBERTS,
Acting Director, Bureau of Foods.

[FR Doc.77-28997 Filed 9-29-77;8:45 am]

[4110-03]

[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 comments and reply comments.

SUMMARY: The Food and Drug Administration is extending by 60 days the times for filing comments and 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.

DATES: Comments by December 5, 1977 and reply comments by January 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.

The agency has received requests from the Proprietary Association, the National Association of Pharmaceutical Manufacturers, the American Home Products Corp., and the Bristol-Myers Co. to extend the time for comments, arguing that 90 days as granted in the proposal is insufficient time to respond properly to the Commissioner's expressed hope that publication of the Panel's findings would "stimulate discussion, evaluation, and comment on the full sweep of the Panel's deliberations" and to obtain his goal of receiving "full public comment before any decision is made on the recommendations of the Panel." The requests noted that the findings cover nearly 450 columns of small FEDERAL REGISTER print and also information contained in more than 150 volumes of submitted data and additional references. They also pointed out that extensive redrafting of the findings was completed by the Panel and that this information was not in previous drafts supplied to the public. 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 comment is appropriate. Accordingly, interested persons are invited to submit written comments (preferably four copies and identified with the Hearing Clerk docket number found in brackets in the heading of this document) regarding the proposal on or before December 5, 1977. Such 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 may be accompanied by a memorandum or brief in support thereof. Additional comments replying to any comments so filed may also be submitted on or before January 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: September 29, 1977.

WILLIAM F. RANDOLPH,
Acting Associate Commissioner for Compliance.

[FR Doc.77-29204 Filed 10-3-77; 8:45 am]

[1410-03]

LIBRARY OF CONGRESS

Copyright Office

[37 CFR Part 201]

[Docket RM 77-10]

NONDRAMATIC LITERARY WORKS

Voluntary License To Permit Reproduction Solely for Use of the Blind and Physically Handicapped

AGENCY: Library of Congress, Copyright Office.

ACTION: Proposed rule.

SUMMARY: This notice of proposed rulemaking is issued to inform the public that the Copyright Office of the Library of Congress is considering adoption of a new regulation designed to implement section 710 of the Act for General Revision of the Copyright Law. This section directs the Register of Copyrights to establish procedures by which the owner of copyright in nondramatic literary works may, at the time of copyright registration, grant the Library of Congress a license to reproduce and distribute the work for the use of the blind and physically handicapped. The effect of the proposed regulation is to establish the terms and conditions of these licenses.

DATES: Initial comments should be received on or before October 21, 1977. Reply comments on or before November 4, 1977.

ADDRESSES: Interested persons should submit five copies of their written comments, if by mail, to: Office of the General Counsel, Copyright Office, Library of Congress, Caller No. 2999, Arlington, Va. 22202, or, if by hand, to: Office of the General Counsel, Copyright Office, Library of Congress, Room 519, Crystal Mall Building No. 2, 1921 Jefferson Davis Highway, Arlington, Va.

FOR FURTHER INFORMATION CONTACT:

Jon Baumgarten, General Counsel, Copyright Office, Library of Congress, Washington, D.C. 20559 (703-557-8731).

SUPPLEMENTARY INFORMATION: One of the major programs of the Library of Congress is to provide Braille editions and special sound recordings of readings of works for the exclusive use of the blind and physically handicapped. In an effort to simplify and speed up the copyright procedures that are a necessary part of this program, section 710 of the first section of Pub. L. 94-553 (90 Stat. 2541) provides for the establishment of a voluntary licensing system to be tied in with copyright registration. Section 710 directs the Register of Copyrights, after consultation with the Division for the Blind and Physically Handicapped of the Library of Congress, to establish forms and procedures by which the copyright owner of a nondramatic literary work may, at the time of copyright registration, grant a license to the Library of Congress. This license would permit the Library "to reproduce the work by means of Braille or similar tactile symbols, or by fixation of a reading of the work in a phonorecord, or both, and to distribute the resulting copies and phonorecords solely for use of the blind and physically handicapped." We propose to give copyright owners the opportunity to grant licenses under section 710 by including, on the application form for registration of nondramatic literary works (Form TX), a statement with "check off" boxes. The statement would make clear that, by checking on