Such person may request an opinion of the applicability of this notice to a specific drug product by writing to the Division of Drug Labeling Compliance (address given above).

A. *Effectiveness classification.* The Food and Drug Administration has reviewed all available evidence and concludes that the drug is effective for the indication in the labeling conditions below.

B. *Conditions for approval and marketing.* The Food and Drug Administration is prepared to approve abbreviated new drug applications and abbreviated supplements to previously approved new drug applications under condition described herein.

1. *Form of drug.* Tolbutamide is in tablet form suitable for oral administration.

2. *Labeling conditions.* a. The label bears the statement, "Caution: Federal law prohibits dispensing without prescription."

b. The drug is labeled to comply with all requirements of the act and regulations, and the labeling bears adequate information for safe and effective use of the drug. The Indication is as follows:

For use in uncomplicated diabetes mellitus of the stable, mild or moderately severe, nonketotic, maturity-onset type that cannot be completely controlled by diet alone.

3. *Marketing status.* a. Marketing of such a drug product that is now the subject of an approved or effective new drug application may be continued provided that, on or before January 29, 1978, the holder of the application has submitted (i) a supplement for revised labeling as needed to be in accord with the labeling conditions described in this notice, and complete container labeling if current container labeling has not been submitted, and (ii) a supplement to provide updating information with respect to items 6 (components), 7 (composition), and 8 (methods, facilities, and controls) of new drug application form FD-356H (21 CFR 314.1(c)) to the extent required in abbreviated new drug applications (21 CFR 314.1(f)).

b. Approval of an abbreviated new drug application (21 CFR 314.1(f)) must be obtained prior to marketing such products. Bioavailability regulations (21 CFR 320.21) published in the FEDERAL REGISTER of January 7, 1977 (42 FRf 1638), require any person submitting an abbreviated new drug application after July 7, 1977, to include either evidence demonstrating the in vivo bioavailability of the drug or information to permit waiver of the requirement. No waiver will be granted for tolbutamide as it is included in the list of effective drugs (21 CFR 320.22(c)) having a known or potential bioequivalence problem published in the FEDERAL REGISTER of January 7, 1977. Marketing prior to approval of a new drug application will subject such products, and those persons who caused the products to be marketed, to regulatory action.

This notice is issued under the Federal Food, Drug, and Cosmetic Act (secs. 502, 505, 52 Stat. 1050-1053, as amended (21 U.S.C. 352, 355)) and under the authority delegated to the Director of the Bureau of Drugs (21 CFR 5.70).

Dated: November 17, 1978.

J. RICHARD CROUT,
Director, Bureau of Drugs.

[FR Doc. 78-33091 Filed 11-27-78; 8:45 am]

[4110-03-M]

Food and Drug Administration

[Docket No. 78D-0322]

OTC COMBINATION DRUG PRODUCTS

Availability of Guideline

AGENCY: Food and Drug Administration.

ACTION: Notice.

SUMMARY: This document announces the availability of a guideline that states in detail the agency policy for combining two or more safe and effective over-the-counter (OTC) active drug ingredients. The agency will use this guideline, in addition to the existing regulatory requirements for OTC combination drugs, in evaluating the safety and effectiveness of all OTC combination drug products.

ADDRESS: Written comments to the Hearing Clerk (HFA-305), 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: The regulatory requirements for OTC combination drug products, set forth in § 330.10(a)(4)(iv) (21 CFR 300.10(a)(4)(iv)), are sufficiently general that they allow various interpretations. The OTC drug advisory review panels have been encouraged to exercise their own scientific judgment in developing all aspects of their reports, and different panels have, in fact, variously interpreted the OTC combination regulations. The Commissioner of Food and Drugs is therefore making available a guideline entitled "General Guidelines for OTC Drug Combination Products September 1978" that specifically sets forth acceptable criteria for combining Category I active ingredients in certain situations that are not covered by the broad regulation. For example, the guidelines explain the Food and Drug Administration's position regarding combinations of ingredients from: different therapeutic categories and which are intended to treat different symptoms; the same therapeutic category but with different mechanisms of action; and the same therapeutic category and with the same mechanism of action. The agency will apply the criteria in the guideline, in addition to the regulatory requirements in § 330.10(a)(4)(iv) in determining the safety and effectiveness of all OTC combination drug products.

The Division of OTC Drug Evaluation (HFD-510), Bureau of Drugs is responsible for maintaining the guideline.

A copy of the guideline is available for public examination between 9 a.m. and 4 p.m., Monday through Friday, in the office of the Hearing Clerk. Requests for single copies of the guideline may be submitted to the office of the Hearing Clerk, identifying the guideline with the Hearing Clerk docket number found in brackets in the heading of this document.

Interested persons may submit written comments on the guideline to the Hearing Clerk (HFA-305), Food and Drug Administration, Rm. 4-65, 5600 Fishers Lane, Rockville, MD 20857 (preferably in four copies, identified with the Hearing Clerk docket number). Such comments will be considered in determining whether amendments or revisions to the guideline are warranted. Received comments will be incorporated into the public file on the guideline and may be seen in the above office between 9 a.m. and 4 p.m., Monday through Friday, except holidays.

Dated: November 21, 1978.

WILLIAM F. RANDOLPH,
Acting Associate Commissioner for Regulatory Affairs.

[FR Doc. 78-33215 Filed 11-27-78; 8:45 am]

[4110-84-M]

Health Services Administration

FEDERAL ADVISORY COMMITTEES

Filing of Annual Reports

Notice is hereby given that pursuant to section 13 of Pub. L. 92-463, the Annual Report for the following Health Services Administration Federal Advisory Committee has been filed with the Library of Congress: