mitted data or information on these products to the Panel will be notified by letter of the transfer.

Dated: February 27, 1979.

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

[FR Doc. 79-6586 Filed 3-5-79; 8:45 am]

[4110-03-M]

TRANSFER OF RESPONSIBILITY FOR REVIEW OF OVER-THE-COUNTER DRUG PRODUCTS FOR THE TREATMENT OR PROHPHYLAXIS OF DANDRUFF OR SEBORRHEA

Implementation

AGENCY: Food and Drug Administration.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) has transferred responsibility for the review of over-the-counter (OTC) drug products for the treatment or prophylaxis of dandruff or seborrhea from the Advisory Review Panel on OTC Antimicrobial (II) Drug Products to the Advisory Review Panel on OTC Miscellaneous External Drug Products. Data and information developed by, and all submissions to, the Advisory Review Panel on OTC Antimicrobial (II) Drug Products regarding drug products or active ingredients recommended for this use have been transferred to the Advisory Review Panel on OTC Miscellaneous External Drug Products.

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 a notice published in the FEDERAL REGISTER of December 16, 1972 (37 FR 26842), FDA requested the submission of data and information on antimicrobial active ingredients for the treatment or prophylaxis (prevention) of specific disorders including dandruff and seborrhea. The data and information revceived in response to the notice were submitted to the FDA Advisory Review Panel on OTC Antimicrobial (II) Drug Products for review under the procedures in § 330.10 (21 CFR 330.10) for classifying OTC drugs as generally recognized as safe and effective and not misbranded, and for establishing monographs.

In notices published in the FEDERAL REGISTER of November 16, 1973 (38 FR 31697), and August 27, 1975 (40 FR 38179), FDA requested the submission of data and information on miscellaneous external drug products including those used for hair growers, psoriasis, and sebum hair loss. The August 27, 1975 notice was published because the response to the November 16, 1973 notice was inadequate. The data and information received in response to these two notices were submitted to the FDA Advisory Review Panel on OTC Miscellaneous External Drug Products for review under the procedures in § 330.10 (21 CFR 330.10). Because there is a considerable amount of overlapping of ingredients and data between the two panels in their review and consideration of agents for the treatment or prophylaxis of dandruff, seborrhea, and psoriasis, a review of all ingredients by one panel would save much time and effort.

Therefore, FDA has concluded that it would greatly facilitate the review of these drug products if active ingredients for the treatment or prophylaxis of dandruff, seborrhea, and psoriasis were reviewed by the same advisory review panel. After carefully considering the schedules, workloads, and available expertise of both panels, the agency has determined that this review should be the responsibility of the Advisory Review Panel on OTC Miscellaneous External Drug Products. Members of the Advisory Review Panel on OTC Antimicrobial (II) Drug Products may be invited to serve as consultants to the Advisory Review Panel on OTC Miscellaneous External Drug Products if their assistance is needed for those overlapping ingredients that have an antimicrobial action.

This notice therefore announces that FDA has transferred the review responsibility for drug active ingredients for the treatment or prophylaxis of dandruff and seborrhea from the Advisory Review Panel on OTC Antimicrobial (II) Drug Products to the Advisory Review Panel on OTC Miscellaneous External Drug Products. All data and information on drug active ingredients for the treatment or prophylaxis of dandruff and seborrhea submitted in response to the December 16, 1972 notice that were submitted to the Advisory Review Panel on OTC Antimicrobial (II) Drug Products are being transferred and need not be resubmitted.

Persons who submitted data and information on these products and ingredients will be notified by letter of the transfer to the Advisory Review Panel on OTC Miscellaneous External Drug Products.

Dated: February 23, 1979.

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

[FR Doc. 79-6585 Filed 3-5-79; 8:45 am]

[4110-35-M]

Health Care Financing Administration

PHARMACEUTICAL REIMBURSEMENT BOARD

Maximum Allowable Cost Limits For Certain Drugs; Closing of the Record

AGENCY: Health Care Financing Administration (HCFA), HEW.

ACTION: Notice.

SUMMARY: The comment periods for the following drugs will close on (15 days from date of publication): (1) amoxicillin 250 and 500 mg capsules and amoxicillin oral solution 125 and 250 mg/5cc; (2) hydrochlorothiazide 25 and 50 mg tablets; and (3) erythromycin (base) 250 tablets.

DATE: End of comment period: March 21, 1979.

FOR FURTHER INFORMATION CONTACT:

Peter Rodler Executive Secretary, Pharmaceutical Reimbursement Board, 3076 Switzer Building, 330 C Street S.W., Washington, D.C. 20201 202-472-3820.

SUPPLEMENTARY INFORMATION: 1. On August 21, 1978 the Pharmaceutical Reimbursement Board (Board) announced proposed MAC limits and a public hearing on October 18 and 19, for amoxicillin 250 and 500 mg capsules and amoxicillin oral solution 125 and 250 mg/5cc. (See 43 FR 40547-8). We later extended the comment period in order to review claims of patent infringement with regard to amoxicillin (See 43 FR 56102-3). We now find it necessary to reopen the record and extend the comment period until [15 days from date of publication] in order to include in the record the FDA response to a drug quality issue raised during the comment period. The purpose of this notice is to inform interested persons that the FDA analysis has been received and is now available for inspection in the Office of Pharmaceutical Reimbursement, Room 3076 Switzer Building, 330 C Street SW., Washington, D.C. 20201. Those who wish to have their comments on the FDA analysis included in the record must submit them by March 21, 1979.

2. In reference to hydrochlorothiazide and erythromycin, the Board announced proposed MAC limits and a public hearing (See 43 FR 40547-8 and 43 FR 38941). On October 27, 1978 FDA informed us that, "in light of the data we have recently received through the Board from Upjohn and directly from Merck regarding the quality of marketed hydrochlorothiazide and erythromycin products, we