UNITED STATES GENERAL ACCOUNTING OFFICE
WASHINGTON, D.C. 20548

MANPOWER AND WELFARE
DIVISION

B-164031(2) FEB 15 1974

The Honorable
The Secretary of Health,
Education, and Welfare

Dear Mr. Secretary:

During our survey of the administration of the Medicaid drug program, we found that the three States included in the survey (California, Ohio, and Texas) were expending significant amounts of funds (portions of which are reimbursed by the Federal Government) for prescription drugs that have been declared ineffective or possibly effective by the Food and Drug Administration (FDA). The Department of Health, Education, and Welfare (HEW) has not issued regulations prohibiting the use of Federal funds for the purchase of ineffective and possibly effective drugs under the Medicaid program. We believe that HEW should expedite the issuance of such regulations.

BACKGROUND

The 1962 Amendments (P.L. 87-781) to the Federal Food, Drug and Cosmetic Act required that drugs be effective before they can be approved for marketing. Under these amendments, FDA began evaluating the effectiveness of all drugs that it had approved for marketing under a safety criteria in force before the amendments. After analysis by the National Academy of Sciences/National Research Council of the available data relating to the effectiveness of a drug, FDA publishes in the Federal Register a notice of its initial classification of the drug as being effective, probably effective, possibly effective, or ineffective.

If a drug is not classified as effective, a notice of an opportunity for a hearing is also published. If interested parties justify, on the basis of new evidence, the need for a hearing, one is held. After the hearings FDA publishes its final determination of the effectiveness of the drug and declares it to be either effective or ineffective.