[Memorandum]

DEPARTMENT OF HEALTH, EDUCATION, AND WELFARE,
PUBLIC HEALTH SERVICE,
Washington, D.C., December 11, 1970.

Subject: Drug Products Declared as "Ineffective" and "Possibly Effective" by the Food and Drug Administration.
To: All Department Agencies.

1. The National Academy of Sciences/National Research Council, after a review of the clinical data of drug products approved by the FDA between 1938 and 1962, has classified some drug products "ineffective" and some, "possibly effective". Notices concerning these drugs are published in the Federal Register by the FDA after a review and concurrence with the NAS/NRC findings.

The criteria for classifying the drug products and the definitions of the four categories of effectiveness are in paragraph three below.

2. It is the policy of the Department that Federal funds will not be expended for purchasing drug products classified "ineffective", or "possibly effective" by the Food and Drug Administration for use in its direct care programs, its contract care programs under the direct care programs, its Federal grant programs and the Medicare and Medicaid programs for inpatients and outpatients with the following two exceptions:

a. Federal funds may be expended to purchase "ineffective" and "possibly effective" drug products for use in the pursuit of approved clinical research projects.

b. Federal funds may be expended to purchase a "possibly effective" drug product when no alternate means of therapy with drug products in the "probably effective" or "effective" classification is available.

3. In arriving at its decision in determining the effectiveness of a drug product the judgements of the NAS/NRC Panel were based on the following criteria:

a. Factual information that is freely available in the scientific literature.

b. Factual information that is available from the FDA, from the manufacturer or other sources, or

c. On the experience and informed judgement of the members of the Panels.

Definitions of the four categories of effectiveness are as follows:

a. Category A—*Effective.* For the presented indication, the drug is effective on the basis of the criteria stated above.

b. Category B—*Probably Effective.* For the indication presented, effectiveness of the drug is probable on the basis of the criteria stated above, but additional evidence is required before it can be assigned to Category A. The recommendation to the FDA could be for further research or for modification of claims or both.