All other communications regarding this announcement: Drug Efficacy Study Implementation Project Office (BD-60), Bureau of Drugs.

All identical, related, or similar products, not the subject of an approved new drug application, are covered by the new drug applications reviewed and are subject to this notice. See 21 CFR 130.40 (37 FR 23185, October 31, 1972). Any person who wishes to determine whether a specific product is covered by this notice should write to the Food and Drug Administration, Bureau of Drugs, Office of Compliance (BD-300), 5600 Fishers Lane, Rockville, MD 20852.

This notice is issued pursuant to the Federal Food, Drug, and Cosmetic Act (secs. 502, 505, 52 Stat. 1050-53, as amended; 21 U.S.C. 352, 355) and the Administrative Procedure Act (5 U.S.C. 554), and under the authority delegated to the Commissioner of Food and Drugs (21 CFR 2.120).

Dated: February 7, 1973.

WILLIAM F. RANDOLPH,
Acting Associate Commissioner
for Compliance.

[FR Doc. 73-2718 Filed 2-9-73; 8:45 am]

[DESI 12101]

COMBINATION DRUG CONTAINING SYROSINGOPINE AND HYDROCHLOROTHIAZIDE

DRUGS FOR HUMAN USE; DRUG EFFICACY STUDY IMPLEMENTATION

The Food and Drug Administration has evaluated reports received from the National Academy of Sciences-National Research Council, Drug Efficacy Study Group on the following drug:

Singoserp-Esidrix Tablets (2 strengths) containing syrosingopine and hydrochlorothiazide; Ciba Pharmaceutical Company, Division of Ciga-Geigy Corp., 556 Morris Avenue, Summit, NJ 07901 (NDA 12-101).

Such drugs are regarded as new drugs (21 U.S.C. 321 (p)). The effectiveness classification is described below.

A. *Effectiveness classification.*—The Food and Drug Administration has considered the Academy's reports, as well as other available evidence, and concludes that the drug is less than effective (possibly effective) for its labeled indications.

B. *Submission of data.*—Any data submitted in response to this notice to support indications for which the drug is classified as less than effective must be previously unsubmitted and include data from adequate and well-controlled clinical investigations (identified for ready review) as described in § 130.12(a)(5) of the regulations published in the Federal Register of May 8, 1970 (35 FR 7250). Carefully conducted and documented clinical studies obtained under uncontrolled or partially controlled situations are not acceptable as a sole basis for approval of claims of effectiveness, but such studies may be considered on their merits for corroborative support of efficacy and evidence of safety.

A copy of the Academy's report has been furnished to the firm referred to above. Communications forwarded in response to this announcement should be identified with the reference number DESI 12101, directed to the attention of that appropriate office listed below, and addressed to the Food and Drug Administration, 5600 Fishers Lane Rockville, MD 20852.

Supplements (identify with NDA number): Office of Scientific Evaluation (BD-100), Bureau of Drugs.

Requests for the Academy's report: Drug Efficacy Study Information Control (BD-66), Bureau of Drugs.

All other communications regarding this announcement: Drug Efficacy Study Implementation Project Office (BD-60), Bureau of Drugs.

All identical, related, or similar products, not the subject of an approved new drug application, are covered by the new drug application(s) reviewed and are subject to this notice. See 21 CFR 130.40 (37 FR 23185, October 31, 1972). Any person who wishes to determine whether a specific product is covered by this notice should write to the Food and Drug Administration, Bureau of Drugs, Office of Compliance (BD-300), 5600 Fishers Lane, Rockville, MD 20852.

This notice is issued pursuant to provisions of the Federal Food, Drug, and Cosmetic Act (secs. 502, 505, 52 Stat. 1050-53, as amended: 21 U.S.C. 352, 355) and