23. D-O-E- Tablets containing 5 milligrams methamphetamine hydrochloride per tablet; Tilden-Yates Laboratories, Inc., 295 Lafayette Street, New York, N.Y. 10012 (NDA 5-603).

A. *Effectiveness classification.* 1. The Food and Drug Administration has considered the reports of the Academy, as well as other evidence, and concludes that there is a lack of substantial evidence of effectiveness of the methamphetamine-containing preparations for: use as an adjunct in some cases in which nervousness, tension, and irritability are combined with feelings of depression, anxiety, and lassitude; use in the management of alcoholism (acute and chronic); enuresis; nausea and vomiting of pregnancy; use as a mild analeptic in barbiturate overdosage; restoration of optimism and mental alertness in the case of depressive state of mind; and temporary or emergency use as a cerebral stimulant to decrease fatigue and increase the urge to work.

2. All the above-listed drugs are regarded as possibly effective for their claimed anorectic effects; for their claims for prolonged, continuous, or sustained release; and for all other labeled indications not listed in paragraph A1.

B. *Marketing status.* 1.a. Within 60 days from the date of publication of this announcement in the Federal Register, the labeling of methamphetamine-containing drugs should be revised as needed to delete those indications described in paragraph A1 for which substantial evidence of effectiveness is lacking.

b. The holder of any previously approved new-drug application for such drug is requested to submit a supplement within 60 days after publication hereof to provide for such revised labeling. The supplement should be submitted under the provisions of § 130.9 (d) and (e) of the new-drug regulations (21 CFR 130.9 (d) and (e)), which permit certain changes to be put into effect at the earliest possible time. Failure to put such labeling into use may result in a proposal to withdraw approval of the new-drug application.

2.a. Holders of previously approved new-drug applications for the drugs listed above and persons marketing any of these drugs without approval will be allowed 6 months from the date of publication of this announcement in the Federal Register to obtain and to submit in a supplemental or original new-drug application data to provide substantial evidence of effectiveness for those indications for which these drugs have been classified as possibly effective.

b. For preparations claiming sustained-action, timed-release, or other delayed or prolonged effect, such data should be adequate to assure the biologic availability of the drug in the formulation which is marketed and should show that the drug is available at a rate of release which will be safe and effective and that it has the prolonged effect claimed.

3. At the end of the 6-month period, any such data will be evaluated to determine whether there is substantial evidence of the effectiveness for such uses. After the evaluation, the conclusions concerning the drug will be published in the Federal Register. If no studies have been undertaken or if the studies do not provide substantial evidence of effectiveness, procedures will be initiated to withdraw approval of the new-drug applications for these drugs, pursuant to the provisions of section 505(e) of the Federal Food, Drug, and Cosmetic Act. Withdrawal of approval of the applications will cause any such drugs on the market to be new drugs for which an approval is not in effect.

The above-named holders of the new-drug applications for these drugs have been mailed a copy of the NAS-NRC reports. Any interested person may obtain a copy of a report by writing to the office named below.

Communications forwarded in response to this announcement should refer to DESI 5378 which identifies this announcement and should be directed to the attention of the following appropriate office and addressed, unless otherwise specified, to the Food and Drug Administration, 5600 Fishers Lane, Rockville, Md. 20852:

Supplements (identify with new-drug application number): Office of Marketed Drugs (BD-200), Bureau of Drugs.

Original new-drug applications: Office of New Drugs (BD-100), Bureau of Drugs.

Comments on this announcement: Special Assistant for Drug Efficacy Study Implementation (BD-201), Bureau of Drugs.

Requests for NAS-NRC reports: Press Relations Staff (CE-200), Food and Drug Administration, 200 C Street SW., Washington, D.C. 20204.