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. 73-2714 Filed 2-9-73; 8:45 am]

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[DESI 5504; Docket No. FDC-D-587; NDAs 5-674; 5-757]

METHAMPHETAMINE HYDROCHLORIDE (PARENTERAL)

OPPORTUNITY FOR HEARING ON PROPOSAL TO WITHDRAW APPROVAL OF NEW DRUG APPLICATIONS

The Food and Drug Administration published a notice (DESI 5504) in the Federal Register of February 23, 1971 (36 FR 3387), regarding the efficacy of the following drugs containing methamphetamine hydrochloride for parenteral use and classifying them as effective, probably effective, or lacking substantial evidence of effectiveness for certain indications.

NDA 5-674 (incorrectly listed as 5-504); Methedrine Injection; formerly marketed by Burroughs Wellcome & Co., Inc., 3030 Cornwallis Road, Research Triangle Park, NC 27709.

NDA 5-757; Drinalfa Injection: E. R. Squibb & Sons, Georges Road, New Brunswick, N.J. 08903.

Subsequent to that notice, a publication in the Federal Register of August 8, 1972 (37 FR 15946), further ruled on those indications that had initially been classified as probably effective.

The Food and Drug Administration has recently reviewed the entire class of drugs offered for use as anorectic agents and the available evidence pertaining to their safe and effective use, including their potential misuse and abuse. On the basis of this recent survey, the Commissioner of Food and Drugs concludes that the well-documented history of abuse of parenteral methamphetamine, together with the severe risk of dependence and the presence of effective alternative drugs, creates an unfavorable balance of risk to benefit.

Therefore, notice is hereby given to the holders of the new drug applications listed above and to any interested person who may be adversely affected, that the Commissioner of Food and Drugs proposes to issue an order under section 505(e) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 355(e)) withdrawing approval of the above new drug applications and all amendments and supplements thereto. It is proposed to withdraw approval of these applications on the grounds that new evidence, not contained in the new drug applications or not available to the Commissioner until after the applications were approved, evaluated together with the evidence available to him when the applications were approved, show that methamphetamine hydrochloride for parenteral administration is not shown to be safe for use under the conditions of use upon the basis of which the application was approved.

All identical, related, or similar products, not the subject of an approved new drug applications, are covered by the new drug applications reviewed. See 21 CFR 130.40 (37 FR 23185, October 31, 1972). Any manufacturer or distributor of such an identical, related or similar product is an interested person who may in response to this notice submit data and information, request that the new drug applications not be withdrawn, request a hearing, and participate as a party in any hearing. 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.

In accordance with the provisions of section 505 of the Act (21 U.S.C. 355) and the regulations promulgated thereunder (21 CFR Part 130), the Commissioner hereby gives the applicant(s) and any other interested person an opportunity for a hearing to show why approval of the new drug application(s) should not be withdrawn.

The applicant(s) and any other interested person is required to file with the Hearing Clerk, Department of Health, Education, and Welfare, Room 6-88, 5600 Fishers Lane, Rockville, MD 20852, on or before March 14, 1973, a written appearance electing whether or not to avail himself of the opportunity for a hearing. Failure of an applicant or any other interested person to file a written appear-