use accompanied the request. His comments concerning safety of the drug and espousing a principle that allows continued availability notwithstanding the known potential for misuse and abuse are testimonial at best and do not comprise adequate proof of safety. Thus, based on the information before him and a review of the statements made by Dr. Diment to support his contention that approval of the new drug applications should not be withdrawn, the Commissioner finds that there has been a failure to present adequate evidence of safety for parenteral methamphetamine hydrochloride and the request for a hearing is denied.

Comments were received from two physicians, Dr. William K. Hamilton, Professor and Chairman, Department of Anesthesia, School of Medicine, University of California, San Francisco, and Dr. Jack Moyers, Chief of Anesthesia, Professor and Head of Department of Anesthesia, University of Iowa, both objecting to the removal of a useful drug from the market because of its use and abuse for nontherapeutic purposes. No data accompanied the responses.

In response to the notices of opportunity for hearing published in the Federal Register of February 12, 1973 (33 FR 4279 and 4282), none of the holders of the following new drug applications named in those notices have filed a written appearance of election as provided by said notice. The failure to file such an appearance constitutes an election by such persons not to avail themselves of the opportunity for a hearing:

NDA No.	Drug	NDA holder
6-946	Du-Oria tablets containing methamphetamine hydrochloride and reserpine.	Formerly marketed by B. F. Asher & Co., Inc., Post Office Box 827, Kansas City, Mo. 64130.
10-207	Dexserpine "5" tablets containing dextroamphetamine sulfate and reserpine.	Formerly marketed by Nysco Laboratories, Inc., 34-24 Vernon Blvd., Long Island City, N.Y. 11106.
11-280	Bamadex tablets, containing dextrose amphetamine sulfate and meprobamate.	Lederle Laboratories Division, American Cynamamid Co., Post Office Box 500, Pearl River, N.Y. 10965.
11-538	Biphetamine-T "12½" capsules and Biphetamine-T "20" capsules, containing dextroamphetamine, amphetamine, and methaqualone, all as cation exchange resin complexes of sulfonated polystyrene.	Strasenburgh Pharmaceutical, Division Pennwalt Corp., 755 Jefferson Rd., Rochester, N.Y. 14623.
12-127	Appetrol tablets, cottaining dextroamphetamine sulfate and meprobamate.	Wallace Pharmaceuticals, Division of Carter-Wallace, Inc., Half Acre Rd., Cranbury, N.J. 08512.
12-371	Prelu-Vite capsules, containing phenmetrazine hydrochloride, Vitamine A, Vitamin D, thiamine mononitrate, riboflavin, niscinamide, calcium pantothenate, pyridoxine hydrochloride, cobalamin concentrate, ascorbic acid, iron, calcium, phosphorus, iodine, and copper.	Formerly marketed by Geigy Pharmaceuticals, Division of Ciba Geigy Co., Saw Mill River Rd., Ardsley, N.Y. 10502.
12-415	Delfeta-sed Stedytabs (sustained release tablets), containing di-methamphetamine hydrochloride and amobarbital.	Eastern Research Laboratories Inc., 302 South Central Ave., Baltimore, Md. 21202.
12-624	Appetrol-S.R. (sustained release capsules), containing dextroamphetamine sulfate and meprobamate.	Wallace Pharmaceuticals.
5-674	Methedrine Injection, containing methamphetamine hydrochloride.	Formerly marketed by Burroughs Wellcome & Co., Inc., 3030 Cornwallis Rd., Research Triangle Park, N.C. 27709.
5-757	Drinalfa, Injection, containing methamphetamine hydrochloride.	E. R. Squibb & Sons, Georges Rd., New Brunswick, N.J. 08903.

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, Oct. 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.

The Commissioner of Food and Drugs, pursuant to the provisions of the Federal Food, Drug, and Cosmetic Act (sec. 505, 52 Stat. 1053, as amended; 21 U.S.C. 355), and the Administrative Procedure Act (5 U.S.C. 554), and under authority delegated to him (21 CFR 2.120) finds on the basis of new information before him, evaluated together with the evidence available to him at time of approval of the applications that, with respect to the above-listed combination preparations for which no hearing was requested: (1) there is a lack of substantial evidence that the drugs will have all the effects they purport or are represented to have; and (2) the drugs are not shown to be safe for use under the conditions of use prescribed, recommended, or suggested in their labeling; and with respect to the parenteral drug products containing methamphetamine hydrochloride, such products are not shown to be safe for use under the conditions of use prescribed, recommended, or suggested in their labeling.