When published in the Federal Register on August 8, 1970 (35 FR 12652), § 130.46 permitted continued marketing of these amphetamines based upon receipt of a new drug application. In response to that regulation, 106 new drug applications were received and continued marketing of those products was permitted pending their detailed review in conjunction with a review of all anorectic drugs and consideration of any issues they presented.

Also published in the Federal Register on February 12, 1973 were notices of opportunity for a hearing to withdraw approval of all previously approved new drug applications providing for anorectic drugs in combination with other ingredients such as sedatives, tranquilizers, rauwolfia derivatives, or vitamins (38 FR 4279) and for parenteral methamphetamine hydrochloride (38 FR 4282). Thirty days were allowed for holders of the new drug applications or any interested person who manufactures or distributes a drug similar, related, or identical to a drug provided for in the approved new drug applications to file a written appearance requesting a hearing and giving the reasons why new drug application approval should not be withdrawn, together with a well-organized and full-factual analysis of the clinical and other investigational data they were prepared to prove in support of their opposition.

In accordance with the decision announced with the revision of § 130.46 published in the Federal Register of February 12, 1973 (38 FR 4249), each of the the new drug applications providing for a combination anorectic drug for oral administration or for parenteral methamphetamine hydrochloride, whether submitted pursuant to § 130.46 or the subject of a previous approval, has been the subject of a notice of opportunity for hearing, either in a letter mailed to the firm or through notice in the Federal Register, or both.

Pursuant to those notices, requests for hearings have been received with respect to the following combination drugs:

NDA No.	Drug	NDA holder
1-522	Obetrol-10 and Obetrol-20 tablets, containing methamphetamine saccharate, methamphetamine hydrochloride, amphetamine sulfate, and dextroamphetamine sulfate.	Obetrol Pharmaceuticals, Division of Rexar Pharmacal Corp., 382 Schenek Ave., Brooklyn, N.Y. 11207.
2-042	Eskatrol Spansules (sustained release capsules), containing dextroamphetamine sulfate and prochlorperazine (as the maleate).	Smith Kline & French Laboratories, 1500 Spring Garden St., Philadelphia, Pa. 19101.
12-570	Bamadex Sequels (sustained release capsules), containing dextroamphetamine sulfate and meprobamate.	Lederle Laboratories Division, American Cyanamid, Post Office Box 500, Pearl River, N.Y. 10965.
	Dexamyl Tablets, Dexamyl Elixir, Dexamyl Spansules (No. 1) (sustained release capsules), and Dexamyl Spansules (No. 2) (sustained release capsules), containing amobarbital and dextroamphetamine sulfate.	Smith Kline & French Laboratories.
	Delcobese Tablets, Delcobese Sustained Release Tablets, Delcobese Capsules, and Delcobese Sustained Release Capsules, containing dextroamphetamine sulfate, methamphetamine hydrochloride, methamphetamine adipate, and amphetamine sulfate.	Delco Chemical Co., Inc., 7 MacQuesten Parkway North, Mount Vernon, N.Y. 10550.

The products specifically named above may continue to be marketed pending a ruling on the requests for hearing.

Also, pursuant to the notice of opportunity for hearing for parenteral methamphetamine hydrochloride proposing to withdraw approval on the grounds that the drug is not shown to be safe, a request for hearing was received from Merle Diment, M.D. pertaining to all such products. Included in the request were the writer's opinion concerning the effectiveness of parenteral amphetamines in improving the mental status and well being of patients in their toleration of, and recovery from, anesthetic procedures, and his statements taking exception to the Commissioner's conclusion that the well-documented history of abuse of this dosage form, the severe risk on dependence, and the availability of effective, alternative drugs constitute lack of proof of safety. The contentions of Dr. Diment have been considered and the Commissioner of Food and Drugs concludes that there is no genuine and substantial issue of fact requiring a hearing. No charge was made in the notice of opportunity for hearing that parenteral methamphetamine hydrochloride lacks substantial evidence of effectiveness; rather, the notice stated that such products were considered effective. However, the use for which Dr. Diment recommends continued availability of the drugs has not been approved in the new drug applications, and no substantial evidence to support such