anorectic drugs. This notice was based on evaluation of data submitted pursuant to the Federal Register notice of August 8, 1970 (35 FR 12678). This data was found, after review, not to provide substantial evidence that the drugs named in the Federal Register notice of February 12, 1973, were effective as fixed combination for their claimed anorectic uses. Based on this lack of substantial evidence of effectiveness of the drugs as fixed combinations, the recognized potential for abuse of these combination drugs, and the availability of alternative therapeutic measures which are safe and effective, the named drugs were also found to be lacking in proof of safety. The Commissioner further found that the data submitted in response to the Federal Register notice of August 8, 1970, did not support a contention that the combination products decrease the incidence or severity of side effects associated with the abuse potential of the single entity anorectic drug. Notice was therefore given to holders of the named new drug applications and all other interested persons, including those marketing similar, identical or related drugs (§ 130.40 (21 CFR 130.40) that the Commissioner proposed to withdraw approval of these new drug applications based on a lack of substantial evidence of effectiveness and a lack of proof of safety. All holders of the NDA's and persons marketing similar, identical or related drugs, and other interested persons were invited to request a hearing on the proposed withdrawals and to submit with such request a well organized and full-factual analysis of the clinical and other investigational data they were prepared to prove in support of their opposition to the withdrawal of the named NDA's and any such similar, identical or related drugs. The notice stated that if substantial evidence of effectiveness and evidence if safety was received for any of the named drugs, or for similar, identical and related drugs, the notice would be rescinded as to such drugs.

In response to the notice in the Federal Register of February 12, 1973, requests for a hearing were received from four persons for five drugs. The persons and the drugs were named in the Federal Register notice of March 30, 1973 (38 FR 8290). The subject final order concerns only two of those persons requesting hearings.

Rexar Pharmacal Co., 396 Rockaway Ave., Valley Stream, NY 11582, requested a hearing for the drugs Obetrol-10 and Obetrol-20 Tablets (NDA 11-522). These drugs are the subject of an NDA which was made conditionally effective on July 24, 1959, and fully effective on February 23, 1960. The Obetrol drugs had been reviewed by the NAS-NRC and found to be possibly effective as an adjunct in the management of some forms of obesity in which an appetite depressant is indicated. The NAS-NRC finding was incorporated into the August 8, 1970 Federal Register notice discussed above (35 FR 12678).

Delco Chemical Co., 7 McQuesten Parkway North, Mount Vernon NY 10550, requested a hearing for the drugs Delcobese Sustainted Release Tablets and Capsules and Delcobese Tablets and Capsules. Pursuant to the August 8, 1970 Federal Register order, the Commissioner received from Barrows Pharmacal Inc., 300 Prospect St., Inwood, NY 11696, four new drug applications on the following dates for the following drugs: March 15, 1971, NDA 17-162, Delcobese Tablets, 5 mg., 10 mg., 15 mg., and 20 mg.; March 15, 1971, NDA 17-161, Delcobese Capsules, 5 mg., 10 mg., 15 mg., and 20 mg.; March 26, 1971, NDA 17-160, Delcobese Sustained Release Capsules, 5 mg., 10 mg., 15 mg., and 20 mg., and June 24, 1971, NDA 17-159, Delcobese Sustained Release Double-Layer Tablets, 5 mg., 10 mg., 15 mg., and 20 mg. All four of the drugs consist of a combination of amphetamines and methamphetamines. No data was submitted in support of the efficacy of these combination drugs; the sponsor merely paraphrased the conclusions stated in the August 8, 1970 Federal Register notice in support of the stafety and efficacy of the drugs for use as anorectics and in treating narcolepsy and minimal brain dysfunction in children.

Due to the large number of new drug applications received pursuant to the August 8, 1970 Federal Register order, a review and evaluation of the new drug applications submitted by Barrows was delayed. Barrows was notified of this delay by a letter from the Food and Drug Administration on February 25, 1972. On January 15, 1973, a letter was sent to Barrows from J. Richard Crout, M.D., Acting Director, Office of Scientific Evaluation, Bureau of Drugs, stating the conclusion of the Food and Drug Administration that the four new drug applications submitted by Barrows could not be approved because the submissions

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