cal experience to the contrary since that time. This argument is irrelevant in the absence of evidence showing that the drug is effective as a fixed combination. As has been shown, Lederle has totally failed to provide such evidence. No drug can be considered safe if it is not effective. Moreover, it is now clear that the marketing history of a product, standing alone, cannot meet the standards of substantial evidence. *Upjohn* v. *Finch*, 422 F. 2d 944, 954 (C.A. 6, 1970).

Lederle's last argument is that by combining meprobamate, a Schedule IV controlled substance (under the Drug Abuse Prevention and Control Act, 21 U.S.C. 801 et seq.), with dextroamphetamine, a Schedule II controlled substance under the same act, the abuse potential of the latter drug is reduced, and therefore, the safety of the principal ingredient is enhanced within the meaning of 21 CFR 3.86(a)(2). It is significant to note that the Attorney General placed Bamadex drug products under Schedule II, the same as for dextroamphetamine, rather than in the less restrictive Schedule IV in which meprobamate is placed. A claim of decreased abuse potential, like other claims, must be supported by evidence, not speculation. No such evidence is offered by Lederle. Lederle does not support its contention that the abuse potential of a drug is lowered by combining it with another drug with an intrinsic abuse potential of its own.

VI. Findings

On the basis of the foregoing review of Lederle's evidence and legal arguments, the Commissioner finds that: (1) There is a lack of substantial evidence that this drug has the effects it is represented to have under the conditions of use recommended, suggested, or prescribed in its labeling and (2) new evidence of clinical experience, not contained in the application and not available to the Commissioner until after the application was approved, evaluated together with the evidence available to the Commissioner when the application was approved, shows that Bamadex Sequels have not been shown to be safe for use under the conditions of use upon the basis of which the application was approved. The evidence fails to show either that each component of the combination contributes to the total effects claimed or that meprobamate enhances the safety or minimizes the abuse potential of the principal active ingredient, dextroamphetamine. Therefore, Bamadex fails to meet the requirements of 21 CFR 3.86. Furthermore, Lederle has not submitted any evidence to show that there exists a significant patient population requiring the concurrent therapy for exogenous obesity together with anxiety and tension or that Bamadex is effective for that indication as required by 21 CFR 3.86.

Lederle has failed to offer a substantial legal argument or to set forth facts showing there is a genuine and substantial issue of fact requiring a hearing.

Therefore, pursuant to provisions of the Federal Food, Drug and Cosmetic Act (sec. 505(e), 52 Stat. 1052, as amended (21 U.S.C. 355(e))) and under authority delegated to the Commissioner (21 CFR 2.120), the request for a hearing is denied, and the approval of the new drug application (NDA 12-570) for Bamadex Sequels, including all amendments and supplements thereto, is withdrawn, effective June 2, 1975.

Dated: May 15, 1975.

A. M. Schmidt,
Commissioner of Food and Drugs.

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Memorandum

February 20, 1973.

To: Deputy Director, Division of Neuropharmacological Drug Products.
From: Acting Director, Office of Scientific Evaluation.
(Through: Director, Division of Neuropharmacological Drug Products.)
Subject: Sustained Release Formulations of Anorectic Drugs—Action Memorandum.

ISSUE

Decisions are required on claims for sustained-release formulations of anorectic drugs for *Federal Register* follow-up publications. These decisions will also be applicable to amphetamine products being handled on a case-by-case basis.