3. Publish a *Statement of Policy and Interpretation* on amphetamines.
Approved ———— Disapproved ————.
4. Publish follow-up efficacy notices on DESI drugs for which data have been submitted in response to a previous Notice.
Approved ———— Disapproved ————.

FOOD AND DRUG ADMINISTRATION,
Rockville, Md., March 26, 1973.

DELCO CHEMICAL CO., INC.
7 MacQuesten Parkway North
Mt. Vernon, New York

GENTLEMEN: This letter is being issued under the combined sposorship of the Food and Drug Administration (FDA) and the Bureau of Narcotics and Dangerous Drugs (BNDD) and is in reference to the product(s) you manufacture, distribute, or repack, containing amphetamine, dextroamphetamine or levamfetamine drugs alone or in combination with other drugs.

On February 12, 1973, Regulation 21 CFR 130.46, "Amphetamines (amphetamines, dextroamphetamine and their salts and levamfetamines and its salts) for Human Use", copy enclosed, was published in the Federal Register (38 FR 4249) setting forth the Food and Drug Administration's position regarding:

1. Combination drugs containing amphetamine or dextroamphetamine and their salts in combination with other drugs (for example—sedatives, tranquilizers, rauwolfia derivatives, vitamins, etc.);
2. Parenteral amphetamines;
3. Levamfetamine and its salts; and
4. Specifies certain conditions for marketing of single entity oral dosage forms of amphetamine or dextroamphetamine. (For purposes of the regulation, a mixture of dextroamphetamine and amphetamine is ordinarily regarded as a single drug entity).

The Food and Drug Administration has concluded, in part, that:

1. Combinations of anorectic and other drugs were not found to differ either in efficacy or in the incidence of adverse side effects from the anorectic drugs alone (please see the enclosed Federal Register announcement of October 15, 1971, "Fixed Combination Drugs for Humans");
2. That the benefit-to-risk ratio is unfavorable for parenteral injections of amphetamines, therefore, amphetamines may be marketed in the future only for oral use; and
3. FDA has not received substantial evidence of effectiveness nor is there a general recognition among qualified experts that levamfetamine preparations currently on the market are safe and effective for the treatment of obesity.

If any drug contains an amphetamine or dextroamphetamine or their salts in combination with other drugs such as sedatives, tranquilizers, rauwolfin derivatives, vitamins, etc., or is a parenteral amphetamine preparation, or is or contains levamfetamine, it is subject to the February 12, 1973 announcement, and is therefore a new drug for which an approved new drug application is not in effect and is misbranded under the appropriate provisions of the Federal Food, Drug and Cosmetic Act.

The purpose of this letter is to advise you that Regulation 130.46, which became effective March 14, 1973, makes illegal the continued marketing in interstate commerce of products which fall under the scope of that portion of the announcement which deals with combinations, injectables, or levamfetamine and its salts without an approved new drug application. The continued marketing of such drugs is in violation of the new drug and misbranding provisions of the Act and outstanding stocks of the articles in trade channels are subject to regulatory proceedings under the appropriate provisions of the Act. Consequently, the marketing of such drugs must cease immediately upon receipt of this letter.

The Bureau of Narcotics and Dangerous Drugs will no longer allow procurement quotas for drugs deemed violative under this regulation.

With respect to that portion of the announcement which deals with amphetamines and/or dextroamphetamines and their salts, the announcement also specifies certain conditions for the marketing of single entity oral dosage forms. Any marketing of such drugs must be under an approved new drug application and appropriate labeling as indicated in the regulation. Failure to comply with these provisions will result in regulatory proceedings.