We are pleased that full access to all agency records has been offered, as we requested in our September 13th letter to you. I have requested through Divisional channels all volumes of NDA 16–618; to date, only six volumes have been delivered.

We appreciate your assurance that we will have an "adequate opportunity to prepare and present . . . views and supporting materials." I shall supply an accurate, complete, and specific report as soon as possible. The following are examples of matters I am reviewing and intend to report upon:

The evaluation and handling of NDA 16–618 and NDA 16–880.

Attached is a condensed summary concerning NDA 16–618.

Sincerely yours,

ROBERT O. KNOX, M.D.

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MEMORANDUM

JULY 9, 1976.

To: Ed Melton, OLS.
From: Bill Crabbs, HFD–120.
Subject. Ionamin, Biphetamine, your memo of June 23, 1976.

Steve Kennedy has spoken to Mr. Gordon on the phone and referred him to DEA for drug abuse information on the drugs. I understand that Mr. Gordon is primarily interested in Ionamin, therefore I've concentrated on this drug in gathering the attachments. The attached material about the Task Force review of anorectics applies to both Ionamin and Biphetamine.

The original NDA for Ionamine includes studies by Burton M. Cohen, M.D. and S. Charles Freed, M.D.; the NDA was allowed to become "effective" on May 14, 1959. The Cass study of Ionamin, Biphetamine and Biphetamine-T was included with the firm's annual report on Ionamin submitted on June 24, 1966 and was, as far as I can tell, not requested by FDA. Apparently no medical review of the study was done and the study had no impact on the status of the drug which had previously been allowed to be marketed on the basis of other data.

Ionamin and Biphetamine were originally published as "possibly effective" on August 8, 1970. Two clinical efficacy studies on Ionamin were done as a follow-up to the DESI notice and were reviewed as a part of the Anorectic Task Force. These were done by Eugene Jolly, M.D. and Robin Shearer, M.D. and showed statistically significant efficacy.

Similarly, 3 studies were done on Biphetamine, two by Albert Cohen, M.D. and one by Eugene Jolly, M.D.

As a result of the Task Force review and evaluation, both Ionamin and Biphetamine were upgraded to "effective" (see July 19, 1974 FR statement).

The NDA for Biphetamine-T was withdrawn on March 30, 1973 since the data submitted did not show efficacy of the drug as a fixed combination.

I've attached pertinent reviews, including the Task Force review and a copy of the Cass study.

I don't know if there is any problem with respect to releasing any of the information since some is confidential, but I'll leave that up to you.

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MEMORANDUM

To: Director, Bureau of Drugs through the Deputy Director.
From: J. Richard Crout, M.D., Acting Director, Office of Scientific Evaluation.
Subject: Amphetamines and Other Anorectic Drugs—Action Memorandum.

OBJECTIVE

This memorandum is aimed at providing discussion of issues, data, and alternative actions necessary for a comprehensive policy with respect to drugs used as anorectics in the treatment of obesity. Policy and implementing actions will be discussed with respect to both the therapeutic usefulness and the abuse potential of the drugs.

ISSUES

In simplest terms, the major issues are as follows:

1. Some or all drugs used therapeutically as anorectics have marked potential for abuse.