July 9, 1970: Sponsor's letter to Dr. Edwards includes a comment re the "obvious bias" on the part of Dr. Knox.

August 6, 1970: Dr. Freeman's Memo to Dr. Dobbs concludes that the results of the 6 studies reviewed are inadequate individually and collectively to establish anorexigenic efficacy for fenfluramine.

September 11, 1970: Dr. Simmons/Finkel letter—inadequate (b) (1)—incorporates Dr. Freeman's conclusions.

August 31, 1971: 66 more volumes of data submitted by sponsor.

November 8, 1971: Dr. Knox received phone call from Dr. Leong who told him he was being detailed to Div. of Oncology & Radiopharmaceuticals as of 11–9–71.

August 21, 1972: Dr. Knox receives Notice of Personnel Action, dated 3–31–72, notifying him of his transfer to BD–150.

June 14, 1973: NDA 16–618 approved.

MEMORANDUM OF TELEPHONE CONVERSATION

A. H. ROBINS CO., INC.
Richmond, Va., June 7, 1968.

Between: R. William Dent, Jr., M.D., A. H. Robins Co., Inc., and Robert M. Hodges, M.D., Office of New Drugs.
Subject: Ponderex.

Dr. Dent was called and told that we had discussed this application with Dr. Ley who agreed with our evaluation and recommendation. Because of a more critical approach to the evaluation of anorexigenic agents we had again reviewed the clinical data available to support the efficacy of this product. They had been subjected to statistical review and it was our conclusion that only one study, that of Dr. Colmore, supported the efficacy of this drug compared with a placebo. It was, therefore, felt that we could not recommend approval of this application. We would be pleased to discuss with the sponsor the protocol for studies which we felt would demonstrate the efficacy of the product. Dr. Dent said that he would make an appointment with Dr. Gibson for this purpose, and I said that I felt it would be appropriate for their statistician to meet with Mr. Peter James for the same purpose.

ROBERT M. HODGES, M.D.

FOOD AND DRUG ADMINISTRATION,
Washington, D.C., June 20, 1968.

Attention: R. William Dent, Jr.
A. H. ROBINS CO., INC.
Richmond, Va.

NDA 16–618—AF 16–375

Gentlemen: Reference is made to your new drug application dated March 3, 1967 submitted pursuant to section 505(b) of the Federal Food, Drug, and Cosmetic Act for Ponderex (Fenfluramine Hydrochloride) Tablets and Capsules 20 mg.

We also acknowledge receipt of your additional communication dated December 15, 1967.

We have completed our review and find that the application is not approvable. The information presented is regarded as inadequate under section 505(b) (1) of the Act as follows:

As I stated in a June 7, 1968 telephone conversation with R. William Dent, Jr., M.D. of your company and also in a June 11 conference between members of Office of New Drugs, Bureau of Medicine, and representatives of your firm, four of the control clinical studies with Ponderex subjected to statistical analysis revealed deficiencies in the study designs that placed in question the efficacy of Ponderex as an anorexigenic agent.

This file is now closed. If you wish to reopen it, the submission should be in the form of an amendment to this application, adequately organized, which represents the information necessary to remove all deficiencies we have outlined.