If you do not agree with our conclusions, the law provides you an opportunity to obtain a hearing, if requested within 30 days from the date of issuance of this letter, on the question of whether the application, as you have presented it, is approvable. This may be obtained by a written request for filing over protest, as authorized by section 130.5(d) of the regulations. Notice of opportunity for a hearing will be published in the Federal Register.

Sincerely yours,

ROBERT M. HODGES, M.D.,
Director, Office of New Drugs,
Bureau of Medicine.

MEMORANDUM

AUGUST 9, 1968.

To: Acting Director, DND/OND/MED.
From: Division of Statistics, Office of Medical Support/MED.

Meeting with Mr. Lester W. Preston, Jr., Statistician for A. H. Robins Company and an Evaluation of Data Submitted at this meeting.

On June 27, 1968 I met with Mr. Preston for about four hours of intensive discussion. The possibility and desirability of this meeting was indicated at an earlier meeting (June 11, 1968) with a number of A. H. Robins representatives. It was my understanding at that time that the purpose of Mr. Preston's visit was to discuss and review new protocols and designs for future studies. These were to incorporate some of our suggestions and criteria for valid clinical and statistical work.

When I met with Mr. Preston it was immediately apparent that his visit had two purposes. First, to present to me (or the Bureau) additional tabulations of older studies and data and to discuss these with me. Second, to present and discuss protocols for new studies. The protocol was introduced after we had spent some time is discussing the older data.

The material and data which he submitted to us at this meeting are listed below (for our in-house consideration and evaluation):

1. Tabular summaries give some "baseline" and weight change information on all "controlled" clinical studies involving the testing of Fenfluramine (AHR-3002) under NDA 16-618.

2. Backed-up computer tables listing certain data for individuals used in these studies.

3. A folder of information which I reviewed with Mr. Preston. This folder, containing a new protocol and my views on its contents, were to be submitted to you after you had an opportunity to evaluate the firm's new tabulations of old data and discuss these with me. The material in this folder was subsequently modified and supplemented by Mr. Preston. Following our meeting, he mailed me a new protocol which incorporated changes influenced by my additional suggestions and criticisms.

4. Some additional material was delivered to me by messenger on July 16, 1968. It showed modifications of the tabular material included under items 1 and 2 above. It purports to be a copy of data submitted to the Canadian Directorate of Food and Drug. This was identified as such and placed on your desk the same day.

On July 30 I turned over to you and Dr. Robert Knox all of the material listed above. I also informed you that, according to Mr. Preston, the firm believes that these new tabulations, based on previous studies, demonstrate conclusively that their product is effective. Further, that these tabulations also constitute a response and rebuttal to the "incomplete" letter issued recently. Mr. Preston asked that I convey these points to you as well as his analyses and discussion points made during the course of my meeting with him.

The balance of my memorandum is a detailed analysis and discussion of the material submitted by Mr. Preston. A few of my findings and doubts about these data were made orally at the July 30 meeting with you and Dr. Knox.

As background I should point out that my participation in the second meeting represented a back-up for Mrs. Lucille Pogue who was attending the University of Pittsburgh at the time. Since her return I have briefed her on developments and my findings in the material submitted by Mr. Preston. She is now in position to resume full responsibility for this NDA and any additional evaluations or discussions which may ensue.