The Research Committee directed that the problem of obesity control be brought to the Bureau Director for serious consideration and direction as to the steps which should be taken by the Bureau of Drugs.

5. Arterial damage from protein derived parenteral drugs, Martin, FDA

Dr. Martin of the FDA presented Dr. Minick's proposal from Cornell. By a vote of 5 to 4 this proposal was disapproved, but the suggestion was made that with certain changes in the protocol it might receive Committee approval. Dr. Martin promised to canvass the Committee for suggestions and have the proposal resubmitted.

6. Screening of protein derived drugs for antigenicity, Martin, FDA

This was approved unanimously for funding with a priority of 288.

7. The effects of long-term exposure of people who are not iron-deficient to a diet containing several times the usual amount of iron, Dr. Crosby, Tufts University

This is exactly the same proposal as submitted and considered in the early part of this year. Again it was turned down by the Research Committee by unanimous vote.

November 5th and December 10th were the dates set for the next meeting of the Research Committee. It was suggested by one or more members of a committee that when an individual has a proposal before the Research Committee that he absent himself when the vote is taken. This was agreed to by the Committee.

The Committee adjourned at 11:55 a.m.

C. H. MAXWELL, *M.D., Secretary.*

DEPARTMENT OF HEALTH, EDUCATION AND WELFARE,
FOOD AND DRUG ADMINISTRATION,
Rockville, Md., Aug. 31, 1971.

Re: NDA 16-618

GENTLEMEN: Enclosed in triplicate is a revised and updated New Drug Application for Pondimin (fenfluramine hydrochloride) tablets, 20 mg.

The original New Drug Application for this article was submitted on March 3, 1967. The questions in your communication dated August 31, 1967 concerning the chemistry and control portions of the application were answered in our communication dated December 15, 1967. In June 1968 the application was declared inadequate due to questions concerning the clinical data, and the file was closed. Subsequently, in November 1968 fourteen additional volumes of summaries, data and other information were submitted in support of the effectiveness of this article.

On June 17, 1969 we requested that the New Drug Application for this article be withdrawn without prejudice and resubmitted as of that date. Accompanying our submission were a summary evaluation and patient data from clinical study number 1426.

On November 25, 1969 we submitted clinical data and an analysis of data from a well controlled study by eight different investigators (Protocol #25) all of whom evaluated the appetite suppressant effect of fenfluramine hydrochloride according to the same study plan. Included also were other newly available study reports, copies of published papers, manuscripts and translations.

The present submission, comprising 66 volumes, is an overall summarization of all available data on fenfluramine hydrochloride. This includes a resubmission of all data and information contained in previous submissions and all new data available to us since the submission dated November 25, 1969 through an April 1, 1971, "cutoff" date. The new clinical data consists principally of Protocol #30, a well controlled multiclinic study in 307 patients in which fenfluramine hydrochloride was compared with placebo on a double blind basis (Volume 4.15 page 6). In addition, the data from a previously-submitted, well controlled multiclinic trial (Protocol #25) have been re-audited to reduce extraneous variables and re-analyzed to eliminate the objections raised by your agency in your letter dated September 11, 1970, and in the subsequent conference concerning this communication on September 30, 1970.