DEPARTMENT OF HEALTH, EDUCATION, AND WELFARE,
PUBLIC HEALTH SERVICE,
FOOD AND DRUG ADMINISTRATION,
Rockville, Md., 20852 June 3 1970.

HON. GAYLORD A. NELSON,
Chairman, Subcommittee on Monopoly, Select Committee on Small Business, U.S. Senate, Washington, D.C.

DEAR MR. CHAIRMAN: During the hearings on the Pharmaceutical Industry conducted on March 4, 1970 by the Subcommittee on Monopoly of the Select Committee on Small Business, several requests were made for additional information.

During the testimony, Senator McIntyre asked if the budget request for Fiscal Year 1971 included any increase for additional research involving oral contraceptives. The Food and Drug Administration's budget for Fiscal Year 1971 does not include an increase over that budgeted for Fiscal Year 1970 ($700,000) for research projects concerning oral contraceptives.

In addition the following are enclosed:

1. Copy of "Report on ENOVID" (August 4, 1963)
2. Copy of "Final Report on ENOVID" (September 12, 1963)
3. Copies of correspondence regarding the change from the first version (8/4/63) of the Wright Committee report to the final version (9/12/63) of the report.

The remaining information requested for the record will follow as soon as it is available.

Sincerely yours,

ROBERT C. WETHERELL
For M. J. Ryan, Acting Director,
Office of Legislative Services.

3 Enclosures ["Report on Enovid," August 4, 1963, and "Final Report on Enovid," September 12, 1963, appears in Oral Contraceptives—Volume Three—Appendixes.]

CONFIDENTIAL

New York, N.Y., August 30, 1963.

DR. LEONARD SCHUMAN,
School of Public Health,
University of Minnesota,
Minneapolis 14, Minnesota

DEAR DR. SCHUMAN: A careful rechecking of the statistical data prepared for the Ad Hoc Committee on Enovid of the Federal Drug Administration by Drs. Leonard Schuman and Peter James has resulted in the discovery of an arithmetical error in the computation. This has been explained to me in some detail by Dr. Schuman. The result of correction of this error is that the apparent risk associated with the use of Enovid in women from 35 years to 45 years has been found to be non-existent. In other words, the conclusion of the statistical study is that no increased risk of deaths from thromboembolism in Enovid users has been established. This correction was verified by the Federal Drug Administration and it was decided to try to have the corrected version published in the JAMA. The original version was in the course of going to press. I had a lengthy telephone conversation with John Talbot and I was confronted with the immediate choice of either allowing the original version to be printed or to make an editorial deletion over the phone which resulted in the removal of reference to increased risk in the older age groups. The latter choice seemed obviously best since publishing the erroneous report in the JAMA would have established a situation whereby we would be correcting it for years to come. It is unfortunate that any reports were released prior to this but the position can be taken that these were preliminary and that the final summary report is the one which will appear in the September 7th issue of the JAMA.

I hope that you understand the position in which I found myself and will approve of the action which I took. Dr. Schuman will forward the details of