FORM FD-1572 (8/64)

DEPARTMENT OF
HEALTH, EDUCATION, AND WELFARE
FOOD AND DRUG ADMINISTRATION

STATEMENT OF INVESTIGATOR
(Clinical Pharmacology)

TO SUPPLIER OF THE DRUG *(Name and Address)*	NAME OF INVESTIGATOR *(Print or Type)*
	DATE
	NAME OF DRUG

Dear Sir:

The undersigned, _____, submits this statement as required by section 505(i) of the Federal Food, Drug, and Cosmetic Act and §130.3 of Title 21 of the Code of Federal Regulations as a condition for receiving and conducting clinical pharmacology with a new drug limited by Federal (or United States) law to investigational use.

1. A STATEMENT OF THE EDUCATION AND TRAINING THAT QUALIFIES ME FOR CLINICAL PHARMACOLOGY.

2. THE NAME AND ADDRESS OF THE MEDICAL SCHOOL, HOSPITAL, OR OTHER RESEARCH FACILITY WHERE THE CLINICAL PHARMACOLOGY WILL BE CONDUCTED.

3. THE EXPERT COMMITTEES OR PANELS RESPONSIBLE FOR APPROVING THE EXPERIMENTAL PROJECT.

4. THE ESTIMATED DURATION OF THE PROJECT, AND THE MAXIMUM NUMBER OF SUBJECTS THAT WILL BE INVOLVED.

5. A GENERAL OUTLINE OF THE PROJECT TO BE UNDERTAKEN. *(Modification is permitted on the basis of experience gained without advance submission of amendments to the general outline.)*

(Continued on reverse)