base support for appropriations here in Congress to give the FDA more personnel to supervise that critically important aspect of the IND.

Dr. LEY. We will be pleased to provide this data for your committee, sir.

(The subsequent information was received and follows:)

DEPARTMENT OF HEALTH, EDUCATION, AND WELFARE,
PUBLIC HEALTH SERVICE,
*Washington, D.C., October 20, 1699.*

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

DEAR SENATOR NELSON: During our appearance before your Subcommittee on August 12, 1969, you requested that certain information be submitted for the record. The submissions are as follows:

1. How many "Notices of Claimed Investigational Exemptions for a New Drug" (IND's) have been received for the past couple of years?

| Fiscal year: | |
|---|---|
| 1968 | 859 |
| 1969 | 956 |

2. How many investigators, associated with these IND's were inspected at their places of business?

| Fiscal year: | |
|---|---|
| 1968 | 11 |
| 1969 | 11 |

3. How many man-years are expended by FDA in direct oversight of clinical investigators?

| Fiscal year 1968: | |
|---|---|
| Bureau of medicine | 3.2 |
| Field | .6 |
| **Fiscal year 1969:** | |
| Bureau of medicine | 6.2 |
| Field | 1.6 |

4. Estimate the manpower and money necessary to provide adequate supervision over clinical investigators.

FDA is currently developing an integrated surveillance program of all the investigatonal phases of drug development and evaluation. It will include on-site visits to clinical investigators, inspection of clinical facilites and of laboratories used for preclinical testing, and surveillance over the monitoring activities of the sponsor of the investigational drug. The program will involve the Office of New Drugs in conducting the visits and inspections as well as continuing the efforts of the Division of Scientific Investigations in their oversight of suspect clinical investigators.

At present, the regulations place the responsibility for monitoring clinical investigators on the drug sponsors. The Office of New Drugs is currently undertaking a program to survey the adequacy of these monitoring efforts. Thus far, they have inspected one such sponsor and are evaluating the findings. We are planning a few more inspections of this nature to determine the feasibility of this new approach to oversigbt of investigational drug activities.

We anticipate that this new program will be available shortly. At that time, we will be in a better position to provide you with the estimated manpower and resources necessary for implementation of this program.

5. Is there anything in the Alabama Medical Association report on "The Use of Prisoners for Drug Trials in Alabama" (Southern Food and Drug Research, Inc., Dr. A. R. Stough, President) that is incorrect?

In general, the "Alabama Report" is thoughtful and factual. There are, however, some errors involving FDA's field of activity as follows:

(*a*) On page 10, the second paragraph contains the statement "In the present instance there is no reason to believe that the pharmaceutical firms failed to act in good faith or failed to discharge their responsibilities to the general public to develop safe, effective therapeutic agents. They contracted with approved clinical investigators to carry out approved research projects."