We request your reply within 15 days after receipt of this letter stating your intentions with respect to your products, if any, which are not in compliance with the announcement, and the immediate removal of all outstanding stocks from trade channels down to the retail level.

The FDA district office will contact you shortly to work out the details of the recall. We are enclosing for your convenience, a model recall letter which you may put into immediate use to facilitate your recall efforts, and a representative of BNDD will contact you to inform you of required accounting and disposition procedures for your inventory and returned goods.

In the event you have already discontinued marketing, FDA would appreciate particulars on the following for each product:

(1) the date discontinued;
(2) an estimate of size and frequency of previous shipments for the past year;
(3) to whom shipped; and
(4) an estimate of outstanding stocks on the market and in your possession.

This program is being carried out with the full cooperation of BNDD. Because of the required record keeping under the regulations administered by BNDD (21 CFR 307.21), any destruction of your inventories must be BNDD authorized. Completion of BND–41, (Voluntary Destruction) is required as well as a witness to the destruction. A list of BNDD offices is attached to assist you in notifying BNDD once you are ready to destroy drugs returned to your firm.

For purpose of this recall only, BNDD has waived the need to use order form (BND–222C) until June 30, 1973. In lieu of order forms a complete and accurate record must be retained by *both* your firm and your customer, identifying both parties, date of transaction, and the kind and quantity of each drug that is returned. Any Schedule II controlled substance returned after that date will require the use of order forms.

All responses or inquiries to this letter should be directed to the Food and Drug Administration, Bureau of Drugs, Office of Compliance (BD–317), 5600 Fishers Lane, Rockville, Maryland 20852.

Sincerely yours,

SHERWIN GARDNER,
Acting Commissioner, Food and Drug Administration.
JOHN E. INGERSOLL,
Director, Bureau of Narcotics and Dangerous Drugs.

FOOD AND DRUG ADMINISTRATION,
Rockville, Md., September 28, 1974.

Dr. ALEXANDER M. SCHMIDT,
Commissioner of the Food and Drug Administration,
Parklawn Building, Rockville, Md.

DEAR DR. SCHMIDT: We are in receipt of your September 18th letter, and wish to comply with the need of an investigating committee for accurate, complete, and specific information concerning our testimony of August 15, 1974. We cannot fulfill this request immediately, because of the time and care we deem necessary for response and because we feel that final response to you at this time would jeopardize attempts to obtain a reliable account of the agency's work.

We continue to be deeply concerned about your plan to issue a separate report on the issues at hand. We feel that one independent group should do the investigating, and that we should not be subjected to multiple information demands and judgments. Should you issue a report in the near future, the Secretary's committee might find it difficult to override you. If you desire to make an investigation and report, we ask you to do so on the basis of documents and testimony of the Secretary's committee, and issue the report only after that committee has completed and released its work.

We want to publicly present the facts underlying our testimony, so that the American people will be informed.

Any investigation must be open. The potential for serious abuses is inherent in the promise that material will be held confidential. The term "trade secrets" has not be defined. Therefore, we request that any investigating committee refrain from keeping any information confidential, and provide a straightforward, unambiguous definition of "trade secrets."