Senator NELSON. Are these requests which are for information which is necessary for the Food and Drug Administration to carry out its assigned responsibilities under the law?

Mr. CROWTHER. Yes, sir, they are and the legal constraints that the Food and Drug Administration operates under in carrying out its regulatory authority as between various product lines is quite different. Under the law, the Food and Drug Administration is provided with greater authority for access to information on prescription drugs than it is for information on over-the-counter drugs. In cases where a firm manufactures both products, they could be side by side. The Food and Drug Administration may have complete access to formulation data on the prescription drug line but does not have the same access authority on over-the-counter type drugs. Consequently, FDA inspectors are unable to determine whether or not all the ingredients are put in properly or whether the formula has been followed.

Also, since FDA's authority goes to those items shipped in interstate commerce, it is necessary for FDA to have access to records showing whether or not an item is shipped in interstate commerce. But quite often, the burden of proof is placed upon the Food and Drug Administration, rather than to be freely allowed access, to even shipping records.

Senator NELSON. Were there actually 10,000 refusals in 3 years? How can there be 10,000 in 3 years? That runs about 10 a day.

Mr. STAATS. These would not be that many companies——

Senator NELSON. Are all these 10,000 refusals in areas where the FDA needs the information but does not in fact have legal authority to get it?

Mr. CROWTHER. I would say most of the cases here are in that category. Again, we have not completed our work, so I cannot give you a breakdown on how many are and how many are not in that category, but probably most of them fall in that category.

Senator NELSON. Most of them fall in the category where the FDA does not have the legal authority to demand and require production of the information?

Mr. CROWTHER. That is correct, and this information is needed in order for FDA to perform its job, but FDA does not have legal authority to get access to the data.

Senator NELSON. You say most of it. Do you have any notion how much? Were they refused on a large number of cases, a fourth or fifth, in which they do in fact have legal authority?

Mr. CROWTHER. I just do not have that information.

Senator NELSON. You have not made any evaluation of that?

Mr. CROWTHER. Not yet.

Senator NELSON. We will take that up with the Food and Drug Administration.

Did you, in checking on procurement, check the question of the total amount of drug contracts, negotiated or otherwise, received by small businesses as so classified under the law?

Mr. CROWTHER. Yes, sir; I think these were included in a separate letter to you on February 3, 1972. Some of that information, if you would like, we could repeat for the record.

At that time, we provided information on small business purchasers from the Defense Supply Agency and the Veterans' Administration for fiscal years 1969, 1970, and 1971.