Only if we are completely satisfied, pursuant to advice from medical experts here in the United States, that the end use is, in fact, something that will achieve a beneficial result without adverse side effects and that there is a complete understanding of any dangers that may be connected with the finished product, only in those instances will we authorize the financing of these bulk pharmaceuticals and combination drugs.

Senator NELSON. What followup do you have to insure that the drug is promoted for the limited purposes that the FDA authorizes and that the finished product is provided with the same package insert as it has here, describing the indications for use, side effects, and contraindications?

Mr. SALANT. Part of our agreement with the importing government is that they will monitor and follow through on our recommendations.

Senator NELSON. What recommendations do you actually give? Suppose that you finance purchases of tetracycline or one of its numerous brand named duplicates. Do you supply the foreign government with the FDA's package insert that must go to every pharmacist who buys it, and do you also advise the foreign government as to the limited purposes for which that drug may be used in this country?

Mr. SALANT. Yes, that information is provided. Agreement is reached with the individual governments as to the types of information that will affect the proposed finished product and also the uses to which the final dosage will be employed.

Senator NELSON. I would appreciate having in the record the instructions that you send, to whom you send them, the Government as well as the foreign subsidiary.[1]

Mr. SALANT. The information is submitted by our agency to our missions in the country concerned. Our mission transmits that information to the health department of the cooperating country and to the importer of the drug product.

Senator NELSON. What information, specifically, do you submit? All of the FDA requirements?

Mr. SALANT. The basic FDA requirements, not necessarily all of the requirements; but we follow closely the FDA requirements as published in the Federal Register.

Senator NELSON. The package insert which lists all of the indications and contraindications, does that go with it?

Mr. SALANT. The package insert would be inserted if required by the government of the importing country. We finance, of course, the bulk material; we provide the information with respect to it. If the country wishes to have that information inserted, it will so stipulate.

I might indicate in this connection that in financing these raw drugs, the ingredients for further processing, we are helping to establish industries in these countries, thus providing to them the ability to gain the technical skills in the field of pharmaceuticals. We are likewise offering them a possibility to conserve foreign exchange to the extent there may be savings between cost of ingredients

[1] See p. 7392.