

We are presently engaged in establishing more formal procedures which will better insure that FDA is notified of such rejections by DSA when diversion to consumer channels is a possibility.

We have met with DSA representatives, and as a result of these meetings DSA has developed proposed revised instructions to its field personnel involved in subsistence rejection procedures. These instructions clearly require reporting to DSA "regional" centers, I am told. The proposed instructions were submitted to FDA for review and comment. We have commented favorably on these and have suggested that the next logical step is to establish direct contact channels between their regional centers and the appropriate FDA District Offices.

In the discussions between DSA and FDA we have recognized the need for the development of guidelines which will inform DSA personnel of FDA's responsibilities. We have offered to participate in local level conferences and to reinstate participation by FDA in DSA personnel training programs at Chicago. The details of these arrangements are currently under negotiation.

May I say at this point, in the slightly over 2 years that I have been Commissioner of the Food and Drug Administration I have found the DSA to be a most cooperative group. They have been very helpful to us in working on the problems related to generic drugs, which are familiar to this committee and to others in Congress as well. We value the working relationships that we have established with them. And I do not, by my statement, mean to deprecate in any fashion the very fine work that they have carried out in their center in Philadelphia. We have benefited by this.

I am simply trying to indicate that we are taking additional steps to strengthen our ties. Thus, we can more substantially protect the American consumer from episodes that have unfortunately occurred in the past, and see that they do not reoccur in the future.

With respect to drugs, we have asked DSA to explore the possibility of informing FDA of all drug rejections, including in-plant rejections by their own inspectors.

Your investigation, Mr. Chairman, has shown a need for improved communication between FDA and other Federal agencies that purchase food and drugs. I would like to assure the committee that we will do everything within our capabilities to establish a truly effective system of coordination which will protect the consumer from any adulterated or misbranded foods or drugs rejected by the Government.

This goes to our relationships with the VA, Public Health Service, and the many other Federal agencies that are involved.

I thank you for the opportunity to appear today.

My colleagues and I will be happy to attempt to answer any questions you have.

Mr. ROSENTHAL. Your full statement will be printed at this point in the record.

(The statement referred to follows:)

PREPARED STATEMENT OF JAMES L. GODDARD, M.D., COMMISSIONER OF FOOD AND DRUGS, U.S. DEPARTMENT OF HEALTH, EDUCATION, AND WELFARE

Mr. Chairman, I appreciate the opportunity of appearing before you this morning to discuss the Food and Drug Administration's policies relative to the sale in commercial channels of foods and drugs rejected for Federal use because of a failure to meet Government specifications.