

MEMORANDUM

DEPARTMENT OF HEALTH, EDUCATION, AND WELFARE
PUBLIC HEALTH SERVICE
FOOD AND DRUG ADMINISTRATION

TO : Henry E. Simmons, M.D., M.P.H.
Director
Bureau of Drugs

DATE: April 10, 1972

FROM : Chief Chemist
Bureau of Drugs

SUBJECT: Asbestos Problem: Progress Report

1. A Special Survey Program has been prepared by the Office of Compliance which involves the inspection of 14 firms producing large and small volume parenterals.

The program calls for the inspectors to obtain information on the filtering procedures and also obtain samples of drug products from each firm for examination in our laboratories.

Arrangements are being made with Mr. H. Eiduson/EDRO to have these samples received at our N.Y. District Laboratories and analyzed there by an expert microscopist with a polarizing optical microscope. This procedure was decided upon because, at present, although there is a polarizing microscope available in our laboratories in OPRT, there is no expert microscopist to operate it. The Bureau of Foods does have the requisite expertise and equipment but it cannot accommodate us fully in this regard because of its priority programs.

Methodology to be followed in our laboratories is being prepared. Hopefully, this preliminary program should be completed in 4-6 weeks from the time it is initiated.

2. A conference was held with Dr. Selikoff and his staff at Mt. Sinai School of Medicine, New York, on March 23, 1972. The FDA members participating were Drs. Kraybill, Gowdy, and Weissler from the Bureau of Foods and Drs. Casola and Lamar from the Bureau of Drugs. Attached is a copy of the memorandum of the conference proceedings.

Dr. Selikoff reiterated his concern for medical hazards due to asbestos. With regard to parenterals, he stated that 17 samples of drugs have been studied for the presence of asbestos by means of electron microscopy. The attached memorandum contains details of his methodology. The results of his study are to be published in several months in an issue of J.A.M.A. He promised to provide the FDA with a pre-publication copy. Dr. Selikoff did submit to us two tables of results as they will appear in the article. These results indicate 3 products that have shown the greatest amount of asbestos present. The respective firms have been included in the program in an attempt to corroborate these findings.

Page 2 - Henry E. Simmons, M.D., M.P.H.

3. The Bureau of Foods has contracted with Professor S. Lewin of New York University to analyze 100 samples of products containing talc by X-ray diffraction and optical microscopy. The Bureau of Foods agreed to submit to Professor Lewin 5 drug samples known to contain talc obtained from the Bureau of Drugs Sample Room in an initial study to determine whether asbestos particles are present. Attached is a list of those drugs submitted for the study. When the data has been received, a complete report will be submitted.

A printout has been received that lists all approved NDAs whose subject drug formulations contain talc.

A handwritten signature in cursive script that reads "Armand R. Casola".

Armand R. Casola, Ph.D.

Attachments