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Dr. Charles L. Dunham, Deputy Director,
Division of Biology and Medicine

August 11, 1954

James F. Haggerty, Medical Branch,
Division of Biology and Medicine

TUNGOLIN COMPANY

SYMBOL: BMM:JFH

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You will recall that shortly after the March 1 shot, Dr. Bugher was contacted by phone by a Dr. Murdock M. Snelling of Gulfport, Mississippi. The purpose of the call was to recommend that a tung oil and ointment, prepared by the Tungolin Company, be administered to patients suffering from radiation burns. Dr. Snelling followed up his phone call with a letter to Dr. Bugher dated March 25, 1954, wherein he stated the conditions under which the oil and ointment should be applied. Accompanying the letter were three one-pint jars of a preparation labelled, "60% Especially Processed Tung Oil in a Petroleum Jelly Base" and three 16 ounce jars of a sterile tung oil, both the above products manufactured by the Tungolin Company, Inc., of Long Beach, Mississippi.

On May 12, 1954, a Mr. Lamont Rowlands of Picayune, Mississippi wrote Chairman Strauss a personal letter wherein he referred to the subject tung oil. Mr. Rowlands states in part, "the uses that they have been finding for this oil in connection with skin diseases, such as athlete's foot, skin cancer, eczema, etc." He also makes reference to the material sent to Dr. Bugher by Dr. Snelling, and indicated his desire for a report on the results of this material in connection with burns. Mr. Rowlands also enclosed a letter from Mr. John Watts, President of the Tungolin Company, a copy of which is attached. Also included in this letter was a reprint entitled, "The Multiple Uses of Processed Tung Oil in Industrial Surgery" by Dr. Snelling. This article appeared in the Mississippi Doctor in May, 1953, pages 397-402 inclusive. Enclosed also was a two-page writeup from a Dr. S. H. Dart, a veterinarian, enumerating observations made by him wherein he used tung oil. Mr. Rowlands' letter was forwarded to us by the Chairman's office, and a reply was prepared for the Chairman's signature and dated July 22, 1954, a copy of which I enclose.

Shortly after seeing the letter from Mr. Watts to Mr. Rowlands, this office became concerned about the reference to Dr. Sprunt of the Department of Pathology at the University of Tennessee. A photostat of Mr. Watts' letter was forwarded to Dr. Sprunt under cover of my letter of June 22, in which I asked for his comments. Dr. Sprunt's reply of August 4 is self-explanatory. His letter is attached.

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On August 3 Mr. Rowlands again wrote Chairman Strauss a short personal note, wherein he then referred to the tung oil. Mr. Rowlands also enclosed a letter from Mr. John Watts to Mr. Rowlands. This letter was dated July 30, 1954. In the second paragraph of Mr. Watts' letter he makes reference to the Food and Drug Administration, and I quote in part, "as you know, exploding the belief that tung oil caused dermatitis was one of our first accomplishments.....we did a pretty good job of proving to the Food and Drug authorities in Washington that our refined processed, pure American tung oil was non-toxic externally as well as internally." This reference to the FDA prompted me to contact Mr. Rankin, who briefed me concerning their contact with the Tungolin Company.

In January of 1952 the FDA received a request from the Tungolin Oil Company of Long Beach, Mississippi, concerning the possibility of marketing a derivative of pure tung oil. At that time there was some question as to whether or not this may be a new drug within the meaning of the Federal Food, Drug, and Cosmetic Act. In April of 1952 an administrator and a representative of the medical staff of FDA talked with Mr. John Watts, who visited their Washington office. At this meeting he indicated that the company was interested in marketing two preparations. One of these he referred to as tungolin, which he described as a heat processed tung oil which did not solidify on exposure to light. The other preparation he referred to as a tungolin cream. This contained 20-25 per cent of a tungolin oil in a cold cream base. At this meeting the FDA officials indicated to Mr. Watts that, in their opinion, the preparation in question was not a new drug under the meaning of the Act, and that it was not necessary for Food and Drug to pass judgment on the labelling. After his return to Mississippi, Mr. Watts during the same month, April, 1952, submitted sample labels to the FDA. On May 8, 1952, FDA in a letter to Mr. Watts confirmed their statements during the April 7 interview and reiterated that his product was not a new drug. They did indicate to him that there was not adequate information in the scientific literature to estimate the value of tung oil for the treatment as he had indicated, namely, for acne, burns, and other skin disorders. They also stated that, as a general rule, oily materials are not suitable for the treatment of acne, and they felt that his broad reference to other skin diseases was not justified.

Nothing was heard from the company until October 4 of 1952, when Mrs. John Watts arrived at the administrative office of FDA seeking an interview with one of the officials. She talked to an administrative official and also a physician. The prime purpose of her visit this time was to discuss the labels for their products. She indicated a fairly large demand for their tung oil products in the state of Mississippi. She also mentioned a third product that they were interested in marketing, namely, a rectal ointment. The representatives of FDA

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informed Mrs. Watts just as they had her husband on an earlier visit that there was not sufficient information in the literature to support their claims. No further contact has been made to FDA since that day. Mr. Rankin informed me that at no time did any member of FDA state or imply that the tung oil produced by this company would not cause dermatitis. He did say that the tung oil produced by this company appeared to be the same oil used in certain paints. There has been no complaint of any skin disorders from the use of these paints. As far as Mr. Watts' reference to "proving to the Food and Drug authorities that the refined processed tung oil is non-toxic externally as well as internally" is meaningless. The only ruling the FDA made was that the preparation, in their opinion, was not considered a new drug.

I have discussed the tung oil preparation with Dr. Keith Cannon, Director, Medical Sciences Division, National Research Council, and shall supply him with background information by letter. The Committee on Cancer Diagnosis and Therapy of the National Research Council will consider the efficacy of the tungolin oil preparation at its fall meeting, scheduled for sometime in October. I shall hold the sample material in this office awaiting further disposition.

Enclosures:
Letter from Mr. John Watts
Copy of reply to Mr. Rowlands' letter
Copy of Mr. Sprunt's letter dated August 4

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