UNITED STATES
NUCLEAR REGULATORY COMMISSION
WASHINGTON, D. C. 20555

DEC 15 1979

MEMORANDUM FOR: Roger Fortuna, Assistant Director for Investigations, OIA

FROM: George C. Gower, Acting Executive Officer for Operations Support, IE

SUBJECT: ALLEGATIONS OF IMPROPER ACTIVITIES BY NUCLEAR PHARMACY, INC. (NPI)

Enclosed for your information and use, as appropriate, is a copy of a letter received from a Mr. , East Cleveland, Ohio.

Mr. letter indicates an awareness of the pending enforcement action against NPI and includes a number of issues which appear to warrant further investigation. In view of the nature of the allegations and their impact upon the current NPI case, if true, we would like to meet with you and discuss our planned followup on this matter.

We understand that you have made a preliminary contact with Mr. to acknowledge the Agencies' receipt of his letter and that further contacts with him are planned.

George C. Gower
Acting Executive Officer
for Operations Support, IE

Enclosure:
Letter to Sniezek
dtd 12/1/79

cc w/enclosure:
D. Thompson, IE
P. Baci, IE
J. Murray, ELD
B. Davis, RIII

cc w/o enclosure:
J. Sniezek

15.

I, , a registered pharmacist, presently employed by Pharmatopes, Inc., a radiopharmacy located in Oak Park, Michigan, having been sworn, do solemnly swear that I have been advised of the nature of this inquiry and provide the following information freely, voluntarily and with no threats or promises.

I presently reside at , East Cleveland, Ohio, 44112 (216). I am a graduate of the University of Wisconsin, School of Pharmacy, Madison, Wisconsin (1967). Prior to my employment with Pharmatopes, Inc., I was employed by Pharmaco Nuclear, Inc., in Cleveland, Ohio, from September-December 1979. Previous to that I was employed by Pharmaco Nuclear, Inc., in Chicago, Illinois, from approximately October 1977 to September 1979 and in Cleveland from January 1976 to October 1977.

I am the author of the attached letter directed to a Mr. James Sniezek of NRC and dated December 1, 1979. I drafted this letter because of my knowledge of these issues and my professional concern as a registered pharmacist.

I first heard of Nuclear Pharmacy, Inc. (NPI) and this issue in approximately late 1976 while working in Cleveland with Pharmaco Nuclear, Inc. (during my first employment with them) from . Mr. who resides on in Cleveland Heights, Ohio (216 was then (1976) a former employee of NPI's El Paso, Texas, pharmacy. He is presently employed by Pharmaco Nuclear, Inc., Cleveland, Ohio. at that time told me that while working for NPI at El Paso that NPI was receiving non-NDA Union Carbide Xenon-133 in bulk and that he was repacking it into unit doses for sale to hospitals. The hospitals used this material for patients for diagnostic inhalation studies. also advised that when repacking the bulk Xenon-133, it was repacked into spent (used) New England Nuclear (NEN) unit dose vials. The significance of this practice was that the hospitals then assumed they were giving patients NDA approved unit doses of Xenon-133 for inhalation studies. This was the last I heard of this matter until early 1979 and more specifically in the summer of 1979 when I saw a copy of an NRC Region III letter transmitting an NRC circular regarding NPI and Xenon-133.

I then called an associate, , St. Luke's Hospital, , Milwaukee, Wisconsin (414-). Ms. is a chief technician in the Nuclear Medicine Department. Her supervisor is a Dr. of Nuclear Medicine. (phonetic) was the pharmacist for the Nuclear Medicine Department. Ms. advised me the hospital was buying Xenon-133 in bulk from NPI labeled not for human use and had an NPI prescription on it. Since it had a prescription she felt that it was suitable for humans. I had called Ms. about the NRC circular. The hospital (St. Luke's) had bought in bulk from NPI up through about April 1979 or later. Ms. continued and told me that she had talked with a pharmacist at NPI Milwaukee who told her that he was breaking the bulk Xenon-133 down and repacking it

into unit dose vials, some of which were spent NEN vials. The NEN gas originally in the vials had an NDA approval. She had asked if the bulk was all right. The NPI pharmacist assured her it was since he was breaking it down into unit doses.

I am not sure who Ms. was referring to as the NPI pharmacist but I believe it was either or

A few months ago I spoke to Mr. again regarding this matter and he again told me that when he worked at NPI in El Paso he had been ordered by Robert Sanchez, President of NPI, in 1976-77 to refill spent NEN until (sic) dose vials. I would think that , Regional Director for NPI would be the person who told the Milwaukee NPI pharmacist(s) to repackage bulk Zenon-133 (sic) in spent NEN unit dose vials.

Shortly thereafter I spoke with , a pharmacist at NPI in Chicago. I believe that presently resides in , Illinois (312- . told me in that conversation and others during roughly the same time frame that he was to tell his accounts per Zimmer's orders that bulk Zenon (sic) "not for human use" from Union Carbide was only shipped to industrial accounts not hospitals.

I spoke with again later in the summer (1979) and she advised that she had a phone call with NPI Milwaukee and was told that the bulk Zenon-133 (sic) only went to industrial accounts not hospitals. knew that was not true since she had seen her hospital receive bulk shipments of Union Carbide Xenon-133 from NPI.

I spoke with Ms. again in September of this year. She said her boss Dr. had called the President of NPI, Sanchez. A little later an attorney from the Washington, D. C., area representing NPI called. Ms. said that the attorney advised that she and the hospital could be in trouble for talking about this matter since it was all a mistake.

I have read the foregoing statement of 12 pages and it is true and correct.

/s/

Sworn and subscribed to me at Oak Park, Michigan, this 28th day of December 1979.

/s/ Roger A. Fortuna
Roger A. Fortuna

/s/ Edward M. Podolak, Jr.
Edward M. Podolak, Jr.