NUCLEAR REGULATORY COMMISSION
WASHINGTON, D. C. 20555

January 31, 1980

MEMORANDUM FOR: Lawrence J. Strickler, Investigative Manager
Office of Inspector and Auditor

FROM: David H. Gamble, Investigator
Office of Inspector and Auditor

SUBJECT: MEETING BETWEEN NUCLEAR PHARMACY, INC. AND NRC ON JANUARY 21, 1980

As requested by a representative of the U. S. Department of Justice, I interviewed James H. Sniezek, Director, Division of Fuel Facility and Materials Safety Inspection, Office of Inspection and Enforcement (IE) on January 29, 1980, to obtain his recollection of the January 21 meeting between representatives of Nuclear Pharmacy, Inc. (NPI) and NRC.

Sniezek said the meeting had been called before Christmas and was finally held on January 21, 1980. He understood the meeting resulted from telephone calls among NPI Attorney Vakerics, Victor Stello (Director, IE), and James Murray (Rulemaking and Enforcement Division Director and Chief Counsel, Office of the Executive Legal Director (ELD)). Sniezek said that the meeting was the first time he had ever met Vakerics, NPI President Sanchez, or the other NPI representative present.

In response to a question as to what was covered in the meeting, Sniezek said that NPI merely reiterated everything they had written to IE in response to the notice of violation. When asked to be more specific, Sniezek said that NPI wanted to convince IE not to go forward with the notice of violation. Sniezek said that, while not routine, IE often receives (and entertains) requests for such meetings with alleged violators: he said to refuse to so meet would be unfair. Sniezek did not feel that NPI was using the meeting to determine what information NRC had about them.

Sniezek recalled that Vakerics claimed the charges against NPI were not valid. He recalled Sanchez' main argument as being that NPI does not need a New Drug Application (NDA) to handle the Xenon-133 in question and, furthermore, he (Sanchez) had never heard of a requirement for NPI to obtain material from a manufacturer possessing an NDA. Sniezek said that he countered Sanchez' claim of lack of knowledge by giving him a copy of a letter from Gyarfas (FDA) to Sanchez dated May 9, 1975 (attached), which outlined the requirement for an NDA.

ENCLOSURE 2
18.

I asked Sniezek whether NPI questioned whether IE felt NPI had done anything to endanger the public health or safety. Sniezek indicated NPI did ask this and he responded that IE has never said this action is harmful to health: IE is saying that, by NPI's not complying with the FDA requirement to have an NDA, NRC did not have the affirmative assurance that NPI's operation was not a health hazard.

I asked Sniezek what was NPI's comment on any recent amendments to their license. He said NPI tried to make the argument that an amendment NRC made to their license subsequent to IE's notice of violation demonstrated the shortcomings of the license condition which NPI was being cited for violating. Sniezek said he informed NPI that the Office of Nuclear Materials Safety and Safeguards made this same amendment to similar licenses based upon a problem identified at another licensee. Sniezek said the timing of the amendment was unfortunate, but it was clear from the FDA letter that NPI was aware of the FDA requirement for an NDA.

I asked Sniezek what NPI's allegation was concerning the VA hospitals. Sniezek only recalled that it was a general allegation that he felt encompassed drugs other than Xenon-133 (i.e., both radioactive and nonradioactive drugs). Sniezek told me that (1) NRC has no interest in nonradioactive drugs and (2) the VA may also be procuring radioactive drugs for, e.g., animal experimentation, as opposed to NPI's human use of Xenon-133. Sniezek said he may have also informed NPI of this - but he was not certain.

In response to my question, Sniezek said NPI alleged that, since NRC granted an exemption from license condition 15 (i.e., the condition requiring compliance with FDA requirements which NPI allegedly violated) to Letterman Army Hospital, it is not necessary for NPI to comply with this condition. Sniezek recalled advising NPI that this conclusion did not follow because Letterman had a broad license and that prior to the exemption Letterman was required to submit their procedures to NRC for approval. He said that this information was supplied to IE by NMSS. Sniezek noted to me that NRC's exemption does not necesarily relieve Letterman of their responsibilities to the FDA.

I asked Sniezek what NPI's argument was concerning labelling of the product. Sniezek said he did not fully understand NPI's point, but they said the package of Xenon-133 they received from Union Carbide was labelled for medical use. Sniezek showed me a photocopy of some labels provided by NPI. Sniezek recalled that NPI said they added their labels to the products before distributing them - but they claimed they did not remove any Union Carbide labels. Sniezek said Stello then asked him (Sniezek) whether IE's checking determined that the Union Carbide labels were on or off the products. Sniezek responded that he did not know.

When I asked Sniezek if he recalled NPI's allegation that an NRC inspector had informally approved of NPI's procuring Xenon-133 from Union Carbide, Sniezek replied that the allegation is untrue. Sniezek said that IE has located the inspector involved (in Region V) and the inspector's recollection was that the NPI manager said they get their Xenon from Union

Carbide like everyone else in the industry. Sniezek said the inspector did not say anything which could be construed as an approval - he just did not pick up on the fact that Union Carbide did not have an NDA and was therefore an improper source. Sniezek said that this inspector was not alone: apparently no one in IE picked up on this problem until the State of Texas brought it to NRC's attention.

In response to my question, Sniezek recalled NPI's asserting that Xenon-133 was approved by the FDA by virtue of its being listed on FDA's Drug Master File. Sniezek said he immediately countered NPI's claim by informing them that the Drug Master File is only a registry and listing thereon does not constitute FDA approval.

I asked Sniezek what NPI's contention was regarding General Electric's (GE) purchases of Xenon-133. He replied that NPI said GE purchases Xenon-133 from Union Carbide and does not do anything more to it before distributing it further; therefore, NPI is entitled to do the same thing. Sniezek said he informed NPI that GE has a contract with the Federal Government (NDA) to process the Xenon-133 in a manner that the FDA has found to assure it is safe for human use.

I asked Sniezek whether Stello agreed to reconsider the notice of violation, whether in fact the notice was being rewritten, and what understanding was reached whereby NRC agreed to let NPI review and discuss the language of the final notice of violation. Sniezek said Stello agreed to look into whether IE discovered the Union Carbide labels to be on or off the products after NPI had distributed them: Stello did not in any way agree to change the notice. Sniezek said that he later (i.e., after the meeting) determined that IE found products at hospitals without the Union Carbide labels. He said the notice is not being rewritten based on information from the meeting. Sniezek said item one of the notice involves a $16,000 fine for getting Xenon from an unauthorized manufacturer; he said this item will probably appear in the final order unchanged from how it went out in the notice. Sniezek said, however, that a second item (with a proposed fine of $8,000) was dropped. Sniezek said the decision to drop this item was made before the January 21 meeting; he said this item was dropped based upon review of the licensees written response, because it was an invalid citation from the legal standpoint. Sniezek said Vakerics asked if it would be okay if NPI saw in advance the wording in the letter and order imposing the civil penalty. Sniezek said Murray agreed to describe the contents of the letter and order to Vakerics on the telephone just before it was mailed to NPI. Sniezek said this is common practice for NRC and is designed to prevent the licensee from hearing about the penalty from, e.g., the newspapers since violation information is released to the public a few days after mailing. Sniezek said that NRC did not agree to let NPI have any input into the exact language of the final letter or order.

Sniezek recalled that Stello left the meeting first, then Lawrence Strickler (OIA) left at about 3:00 and they continued until about 4:15 with only

Murray and himself representing NRC. Sniezek said that during this period they rehashed the same points; NPI continued to make general claims that they try to follow regulations.

Attachment:
As stated.