



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

NOV 15 1979

Ref: SA/ECA

Mr. T. K. DeBoer, Director
Technical Development Programs
New York State Energy Office
Agency Building 2
2 Rockefeller Plaza
Albany, New York 12223

Dear Mr. DeBoer:

Identified below is a licensee in New York who was confirmed to have received Xe-133 shipments from Oak Ridge National Laboratory (ORNL) during fiscal year 1978. ORNL is, among others, a non-FDA-approved Xe-133 supplier; i.e., it does not hold an FDA-issued IND or NDA for supplying Xe-133. This State licensee was mentioned by Nuclear Pharmacy, Inc's. (NPI) response to an NRC Notice of Violation.

Sloan-Kettering Institute
New York, New York

It was noted during NRC's investigation of the NPI violation case, that apparently some ambiguity exists in the NPI License Condition No. 15 (Standard License Condition No. 55) which reads as follows:

Radioactive gases as free gas or in solution, to be administered to humans, shall be procured from a supplier who distributes the product indicated for human use in accordance with the Food, Drug and Cosmetic Act.

Further clarification or even replacement of this License Condition for involved licensees is expected soon.

This is a request for you to review the identified license to determine if the above License Condition in the same wording, or similar wording, is used, and notify us of the results of your findings.

Based on your review of the license you may want to initiate enforcement action against the licensee.

Sincerely,

A handwritten signature in cursive script, appearing to read "G. Wayne Kerr".

G. Wayne Kerr, Assistant Director
for State Agreements Program
Office of State Programs

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