



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

NOV 15 1979

Ref: SA/ECA

Mr. Albert J. Hazle, Director
Radiation & Hazardous Waste Control
Division
Office of Health Protection
Department of Public Health
4210 East 11th Avenue
Denver, Colorado 80220

Dear Mr. Hazle:

Identified below are licensees in Colorado who were 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. These State licensees were mentioned by Nuclear Pharmacy, Inc's. (NPI) response to an NRC Notice of Violation.

Memorial Hospital
Colorado Spring, Colorado

Mini-Dose Labs, Inc.
Denver, Colorado

Penrose Hospital
Colorado Springs, Colorado

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.

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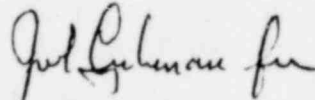
Mr. Albert J. Hazle

- 2 -

This is a request for you to review the identified licenses 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 licenses you may want to initiate enforcement action against the licensees.

Sincerely,



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

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