



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

January 11, 1990

The Honorable Lloyd Bentsen
United States Senator
961 Federal Building
Austin, Texas 78701

Dear Senator Bentsen:

This is to acknowledge receipt of your letter dated December 15, 1989, transmitting correspondence from your constituents, Messrs. Bao Nguyen and Richard Sheriff, in support of a petition for rulemaking to revise 10 CFR 35 Regulations.

The petition for rulemaking was submitted to the Nuclear Regulatory Commission (NRC) by the American College of Nuclear Physicians and the Society of Nuclear Medicine. The petitioners requested that the NRC modify current regulations to allow: (a) the use of radiopharmaceuticals for therapeutic indications not listed in the package insert (diagnostic indications are not restricted by current regulations), (b) deviations from the manufacturer's instructions in preparing radiopharmaceuticals, and (c) compounding radiopharmaceuticals from reagent chemicals.

The NRC published a Federal Register notice (54 FR 38239, September 15, 1989), announcing receipt of the petition and providing a 90-day public comment period. We have received more than 400 comment letters.

In light of the information submitted by the petitioners and the commenters, the NRC is currently reexamining its regulations governing the use of radiopharmaceuticals in nuclear medicine. The issues raised will be addressed in a rulemaking proceeding specifically designed to resolve the petition. During this rulemaking process, the NRC will consult with the Food and Drug Administration, which approves the package inserts and the manufacturer's instructions, and the State Boards of Pharmacy and invite their views regarding the resolution of this petition.

I want to assure you that the comments of your constituents will be considered along with the others in reexamining our regulations. However, it would be premature to predict the outcome of the reexamination before completion of the rulemaking proceeding.

I trust this information is responsive to your request.

Sincerely,

A handwritten signature in cursive script that reads "Dennis K. Rathbun".

Dennis K. Rathbun, Director
Congressional Affairs
Office of Governmental and
Public Affairs

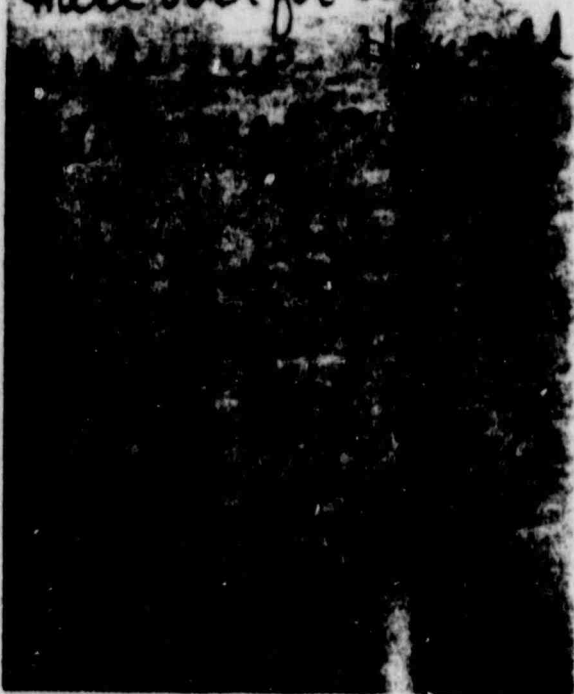
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Mr. Blaha

Dennis Rathbun brought
these over for OEDD's



Letter also verbally approved by Jim Blaha and Mike Weber
(per Dennis Rathbun/Betsy Keeling) *on 1-11-90.*