



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

December 28, 1989

The Honorable Alan Cranston
United States Senate
Washington, DC 20510

Dear Senator Cranston:

Thank you for your letter of November 27, 1989, regarding the comments by Dr. Malcolm R. Powell of the University of California at San Francisco on a petition for rulemaking.

As noted in the correspondence enclosed with your letter, 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 governing the use of radiopharmaceuticals in nuclear medicine to allow the use of therapeutic radiopharmaceuticals for medical indications not listed in the package insert and permit deviations from the manufacturer's instructions for eluting generators or preparing reagent kits. Dr. Powell expressed strong support for the petition.

The NRC published a Federal Register notice (54 FR 38239, September 15, 1989) announcing the receipt of the petition and providing a 90-day public comment period. We have received more than 400 public comment letters, including Dr. Powell's letter which was enclosed with your letter.

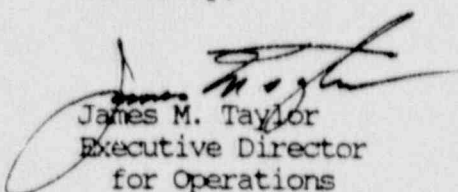
In light of the information submitted by the petitioners and the commenters, the NRC is currently reexamining its regulations governing the use of radiopharmaceuticals in nuclear medicine. The issues raised in the petition and in Dr. Powell's letter will be addressed in a rulemaking proceeding specifically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

I want to assure you that Dr. Powell's comments will be considered with the others in reexamining our regulations. However, it would be premature for the NRC to predict the outcome of the reexamination before the completion of the rulemaking proceeding.

I trust that the above information is responsive to your request.

Sincerely,

9001160225 891228
PDR PRM
35-9 PDC


James M. Taylor
Executive Director
for Operations

Enclosure:
10/17/89 ltr, Powell to NRC

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December 28, 1989

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Original Signed By
James M. Taylor
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Executive Director
for Operations

Enclosure:
10/17/89 ltr, Powell to NRC

*See previous concurrences.

	NMSS	OGC	GPA	CA	ESD
	JGlenn*	STreby*	VMiller*	DRathbun	JTaylor
	12/19/89	12/19/89	12/19/89	12/18/89	12/21/89
OFF:	RDB/DRA	RDB/DRA	DRA/RES	DRA/RES	RES
NAME:	ATse/JTelford*	SBahadur*	ZRosztoczy*	BMorris*	TSpeis
DATE:	12/19/89	12/19/89	12/20/89	12/20/89	12/21/89
				RES	EBeckjord