UNITED STATES
NUCLEAR REGULATORY COMMISSION
WASHINGTON, D.C. 20555-0001

October 10, 1996

The Honorable Charles S. Robb
United States Senate
Washington, DC 20510-4603

Dear Senator Robb:

In response to your letter dated August 19, 1996, regarding a petition for rulemaking from Tri-Med Specialties, Inc., the Nuclear Regulatory Commission (NRC) staff is working to resolve this petition as soon as possible. The NRC has been communicating with the Food and Drug Administration (FDA) and expects to resolve the petition and make the rule effective in a time frame consistent with FDA approval. However, I would like to point out that existing NRC and Agreement State regulations already permit the use of Tri-Med's product by physicians, to the extent permitted by the FDA, provided they are working under an NRC or Agreement State license for medical use of radioactive materials.

The NRC has completed the safety analysis and other necessary evaluations that form the technical bases for resolving the petition. The staff's preliminary determination is to grant the petition and to promulgate a direct final rule providing for the use of Tri-Med's product. Because a rule change granting Tri-Med's petition would affect the Agreement States, a draft document, called a "rulemaking plan," which articulates the nature of the rulemaking and conveys the safety analyses and other evaluations that support the rulemaking, has been forwarded to the Agreement States for their comments. After the NRC staff receives the Agreement State responses and addresses any comments provided by the Agreement States and assuming there is no objection from the Agreement States, the staff intends to seek Commission approval for rulemaking.

I assure you that the NRC will continue working toward resolving the petition and expects to publish a rule in the Federal Register early in 1997. Responses to the letter you received from Tri-Med dated July 24, 1996, are enclosed.

Sincerely,

James M. Taylor
Executive Director
for Operations

Enclosure:
As stated

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RESPONSES TO TRI-MED'S CONCERNS

Tri-Med's letter stated "(T)he committee [refers to the NRC's Advisory Committee on the Medical Uses of Isotopes (ACMUI)] recommended the exemption route versus a rule change because it would be the most expeditious and the easiest means of resolving this issue."

The ACMUI indicated, in the official minutes of its October 1995 meeting, that "it endorsed the wide availability of this diagnostic test and that the radioactive drug could be used under a general license or an exemption, whichever the NRC thought to be procedurally easier." Under the current regulations, only physicians who are "authorized users" (i.e., physicians who meet specific training and experience requirements and are authorized by the NRC or an Agreement State to administer radioactive material) can administer radioactive drugs containing byproduct material to humans. Either option recommended by the ACMUI would require NRC to make a "rule change" and the staff concluded that promulgation of the rule as a direct final rule is the most expeditious way to complete action on the petition.

Tri-Med also stated "Looking at the steps listed above it is obvious that a ruling will not be made by the end of 1996. It has already been 2 years since the submission of our application and a final ruling is nowhere is sight."

In regard to the status of this petition, a draft "rulemaking plan," which articulates the nature of the rulemaking and conveys the safety analyses and other evaluations that support the rulemaking, has been forwarded to the Agreement States for their comments. The comment period for Agreement States to submit comments, normally 45 days, has been shortened to 30 days because this rulemaking is not complicated. After the NRC staff considers the comments from the Agreement States, a direct final rule is expected to be published in early 1997, pending Commission approval, for a 75-day public comment period. The NRC has considered whether the public comment period can be shortened. It has concluded that the 75-day period cannot be decreased for this rulemaking because Executive Order 12662 of December 31, 1988, implementing the United States - Canada Free Trade Implementation Act, requires "--- not less than 75 days before the comment due date, except where, in urgent circumstances, delay would frustrate the achievement of a legitimate domestic objective." Although the Order provides for exceptions, this rulemaking would not qualify as "urgent circumstances" since NRC regulations do not currently prohibit the use of this drug by authorized users. If no significant adverse comments are received, the rule will become effective at the end of the comment period. If significant adverse comments are received, the NRC will withdraw the direct final rule, address the public comments under a proposed rule, and publish a final rule. Under this situation, the rulemaking process would be lengthened approximately 3 months.

Enclosure