



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

December 12, 1990

CHAIRMAN

David A. Kessler, M.D., Commissioner
U.S. Food and Drug Administration
5600 Fishers Lane
Rockville, Maryland 20857

Dear Dr. Kessler:

I am writing to request your assistance in the Nuclear Regulatory Commission's (NRC's) efforts to expand the membership and enhance the effectiveness of our Advisory Committee on the Medical Uses of Isotopes (ACMUI). Because both NRC and FDA exercise regulatory responsibilities governing the medical use of byproduct material, we believe that a member of the Food and Drug Administration staff could make substantial contributions to our ACMUI as it develops recommendations on NRC regulatory policy and guidance. Therefore, we invite you to designate an FDA employee with experience in biologics, drugs, and medical devices to serve as a member of the Advisory Committee.

The ACMUI advises the NRC on policy and technical issues that arise in regulating the medical use of byproduct material for diagnosis and therapy. Responsibilities include providing guidance and comments on changes in NRC rules, regulations, and guides concerning medical use; evaluating certain non-routine uses of byproduct material for medical use; and providing technical assistance in licensing, inspection, and enforcement cases. The ACMUI will meet approximately twice a year in the Washington metropolitan area.

We recognize that the FDA employee you may select might only present his or her individual views based on personal knowledge and experience and not necessarily the views of the FDA. NRC will continue to work directly with the FDA to obtain the FDA's official position on issues common to both agencies.

We also recognize that FDA has three distinct Centers that handle biologics, drugs, and medical devices, and that it may not be practical to have only one FDA representative. Therefore, you may want to designate a single representative from one of the centers, and alternates from the other two centers. The FDA designated representative should be the primary point of contact with NRC with respect to ACMUI activities and would be a voting member of the ACMUI. Any alternate that you select could vote in place of the designated representative. Because members of NRC

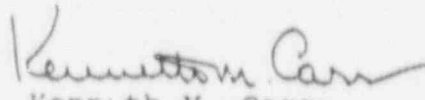
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advisory committees are subject to pre-appointment conflict of interest reviews, the designate and alternates you select will be considered members of ACMUI for this purpose.

I hope you will be able to assist us by designating an FDA employee to serve on this important advisory committee. If you have any questions, please contact me or Richard E. Cunningham, Director of the Division of Industrial and Medical Nuclear Safety. Mr. Cunningham can be reached by telephone at (301) 492-3426.

Sincerely,


Kenneth M. Carr