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PETITION RULE PRM-35-1 (44FR26817)

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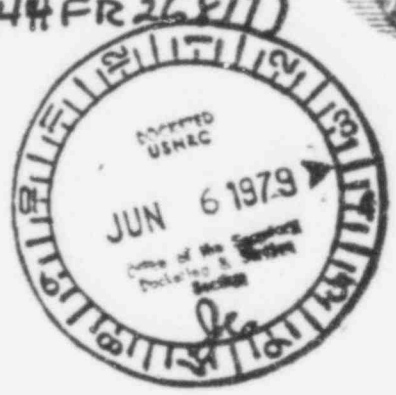

June 1, 1979

Secretary of the Commission
United States Nuclear Regulatory Commission
Washington, D.C. 20555

Attention: Docketing and Service Branch

This letter is to comment upon a petition filed by Dr. George V. Taplin, Division of Nuclear Medicine, University of California, Los Angeles, California for rule making requesting the Nuclear Regulatory Commission to amend its regulation, "Human Uses of Byproduct Material," 10 CFR Part 35. I support Dr. Taplin's request to permit physicians greater latitude when working with certain low-risk diagnostic radiopharmaceuticals, that they no longer be required to use an approved drug (radiopharmaceutical test agent) strictly in accordance with the manufacturer's package insert. I view this new limitation as being more restrictive than the current FDA regulation, which leaves the route of administration to the judgement of the physician in charge. This new NRC regulation would preclude the use of certain radioactive drugs which might potentially be of benefit to patients when used by an appropriately trained physician. In addition, greater flexibility of dosage range than presented in the package insert is also advisable. I strongly support Dr. Taplin's claim that, "This change is in direct opposition to the current objectives of both the NRC and FDA which permit physicians to use approved drugs according to their best knowledge and judgement and in the interest of the patient. In my opinion this new regulation will hinder the development of new safe applications of approved drugs..."

Sincerely yours,

H. J. Dworkin, M.D.

Howard J. Dworkin, M.D.
Chief, Department of Nuclear Medicine

Acknowledged by card 6/11

HJD:cg

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