DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

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PROPOSED RULE PR-35
(47 FR 15798)

Secretary of the Commission
U.S. Nuclear Regulatory Commission
Attention: Docketing and Service Branch
Washington, D.C.

Dear Sir:

With reference to the Federal Register Notice (Vol. 47, No. 71, Tuesday April 13, 1982, page 15798 thru 15801) we request you consider the following comment.

The FDA thru the Radiopharmaceutical Advisory Committee and other interested parties is often requested to review appropriate material and approve a new indication for an already approved drug product (NDA). If approval takes place, the time period of notification of the NDA holders (and requesting them to submit a supplement for this new indication) to the approval of this can take many months. This is a burden on the medical community since they must still file an IND for this indication because of Nuclear Regulatory Commission requirements. We propose that the NRC develop a method to allow holders of the appropriate licenses to use the approved drug in the new approvable indication while the package insert is being supplemented by the holders of the NDA's to permit issuance of the final approval.

For example, 35.14(b)(9) "Any radiopharmaceutical which has an approved NDA may be used for any new indication that has been found approvable by the FDA while the package insert is being supplemented to conform with this." The NRC will transmit the new indication to all users by mail.

We request you to consider this in regard to your proposed rule.

Sincerely yours,

William J. Gyarfas

William J. Gyarfas, M.D.
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Acknowledged by card. 9/22/82 emp