The Secretary of the Commission
U.S. Nuclear Regulatory Commission
Washington, DC 20555

May 23, 1985

Re: Notice of Proposed Rule-Making to amend 10 CFR 35.14(b)(7) which appeared at 50 FR 15752 (Monday, 22 April 1985)

Dear Sir:

First I would like to make it clear that these comments are my own and do not represent the official viewpoint of the Food and Drug Administration. However as a member of that organization with the title of Reviewing Pharmacist and with the responsiblility of reviewing clinical aspects of many INDs and NDAs and supplements to NDAs, being Executive Secretary of the FDA's Radiopharmaceutical Drugs Advisory Committee, interacting with the Nuclear Medicine Community on a daily if not hourly basis, plus being the Chairman-Elect of the SIG for Nuclear Pharmacy for the American Society of Hospital Pharmacists, I feel my comments are important for inclusion regarding this decision process. Further, I am the individual responsible for the letter that the NRC received from the FDA which it then published the changes in 35.100 as stated in the Federal Register dated February 25, 1985.

Therefore I respectively ask that you include my remarks even though the time limit has passed for comments. It is very inappropriate for the NRC to evaluate routes of administration and give the appearance of approving new indications for FDA approved products. The NRC is not privy or appears knowledgeable to all the ramifications that their decisions may involke regarding these petitions.

For example, the NRC approved the Taplin petition which allowed for the use of Technetium Tc 99m DTPA to be administered by an aerosol. Has the NRC even wonder why the FDA has not approved that route? Have they even researched or contacted the FDA and ascertained if any of the various devices advertised or used for this route have been approved? I believe and know the answer is no. I am not saying that route is unsafe but that unless proper procedures are followed, use with an device that does meets certain standards to produce an aersolized solution of a certain size, range of size and that the dose is of a proper amount, the patient and personnel administering the drug are placed in an unsafe circumstance. This I believe has happened with the approval of the Taplin petition. There is no approved device for that procedure to my knowledge. The FDA has not approved a dosage for that nor has the FDA approved a supplement or petition which would allow that indication to be placed in the package insert of an approved NDA. For the NRC to approve that petition has caused nothing but possible harm for the community. So far I beleive that we have been lucky thanks to the clinical competence of the community.

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add: Norman McElroy, 39655

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The petitions in question are in some cases for routes and indications that the FDA has already approved. I have nothing but praise for the NRC to go ahead and publish in the FR notices to the community to allow them to utilized approved products in approved routes of administration in order to provide the community a method of utilizing those drugs during the time period that it takes the manufactures to place those indications in the package inserts. I was one of the innovators of this method.

I reviewed the petition for the use of Tc 99m MAA, HAM, and Sulfur Colloid presented by the FDA's Radiopharmaceutical Drugs Advisory Committee for the FDA and found that it is not only safe but effective in detecting the patency of LeVeen shunts. Hopefully the other layers of review at the FDA will also approve the petition and this indication will be placed in the package insert in the near furture. At that time I would then again draft a letter to the NRC and forward it for signature. It would be similar to the one that the NRC mentions in the February 25, 1985 FR notice. However for the NRC to approve that petition based on their own evaluation is totally wrong.

The other petitions for the use of products which involve the possible introduction of material into the cerebrospinal fluid is ludicrous on its face. Those approved products which are petioniened for that route of administration have not been manufactured to meet certain requirements regarding pyrogen limits. The introduction of pyrogens into the cerebrospinal fluid can cause serious reactions and even death. Will the NRC take the responsibility for this? I employ you not to do this. For the NRC to approve a route of administration (and again infer clinical indications by doing this) based just on the criteria of "no unjustified dose to the patient and demonstration of adequace of occupational radiation protection measures" are not enough.

Let the FDA work with the Radiopharmaceutical Drugs Advisory Committee and approve these indications (if possible) in a safe and correct manner. I further request that you set up a better communication mechanism between the NRC and myself or someone else in the FDA to assure that new routes of administration that the NRC evaluates will allow users to administer products that are indeed safe and not possibly cause harm to the public.

Sincerely yours

Neil M. Abel

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