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February 8, 1971

Hearing Clerk
 Department of Health,
 Education and Welfare
 Room 6-82
 5600 Fishers Lane
 Rockville, Maryland 20852

REPOSITORY Records Holding Area Bldg. 494
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 FOLDER Medical Dept Policy
and PROCEDURES 1963-1974

Dear Sir:

The recent proposal of the Food and Drug Administration which has been listed in the Federal Register, Volume 36, No. 18, Wednesday, January 27, 1971, has been brought to my attention. This proposal is on Pages 1274 and 1275 and, as usual with official statements, is difficult for one not trained in the legal profession to understand the exact meaning and implications of this proposal. I would, therefore, like further clarification.

Among the radionuclides and pharmaceuticals listed in Paragraph C of this proposal are several forms of technetium-99m for various purposes. We possess IND numbers for technetium-99m pertechnetate and technetium-99m sulfur colloid among others. We are not engaged in inter-state commerce and the materials are used both for investigational purposes as well as for medical services in our laboratory. Is it required that we file for New Drug Applications? This question is of considerable interest, not only to us, but to the many hundreds of other physicians throughout the country who are processing radionuclides for radiopharmaceutical manufacture to be used only at the site of manufacture and are not to be shipped outside the institution.

If the answer to this question is that, indeed, we must file NDA's, I wish to ask for an extension of the 30-day limit as noted in the last paragraph of this proposal.

I should also like to add that I am surprised at the listing of technetium-99m pertechnetate as accepted procedure for placenta localization and blood pool scans. Although the studies certainly can be done with pertechnetate, I think that most people would agree that they are better performed with technetium-labeled human serum albumin. Almost all the publications covering this procedure indicate that the labeled serum albumin is the pharmaceutical of choice.

Sincerely,

Harold L. Atkins, M. D.

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