

Phasmaceutical Division

4842 MANCHESTER ROAD

ST. LOUIS 19, MISSOURI July 15, 1960

Phone WOodland 2-2162

Lester R. Rogers, Chief Radiation Safety Branch Division of Licensing & Regulation U. S. A. F. C. Washington 25, D.C.

Dear Les:

I received your form letter of June 17, 1960 and the enclosed radiation warning signs and labels. Thanks. This, however brings to mind something I've been meaning to check with you on for some time.

This is the problem of proper labels for our radiopharmaceuticals. As you know, our labels must be approved by the F.D.A. and NIH in addition to complying with Section 20.203 of the regulations. The last time we redesigned labels we got all the necessary approvals including the AEC (I believe Mason made the comments at that time). In order to end up with a less expensive one color job, we settled for a less attractive label which would still conform to the regulations. We used a yellow stock and printed in a magenta purple. In checking some of our (all of our!) competitors, we find they have more attractive (one color) labels but based on my interpretation of the regulations do not conform. Who's right? We package our material in various type and sizes of glass vials. These vials all have labels affixed which carry the radiation symbol and the words "Caution, Radioactive Materials" in purple on yellow. These are in some instances placed in lead shields on which we sometimes place the same label, sometimes none, and finally this is placed into a tin and fiber can. Another label giving all the pertinent information (not necessarily the radiation symbol, at least not necessarily in the proper colors) is then affixed to this can. This can is placed into the center of an  $3\frac{1}{2} \times 3\frac{1}{2} \times 3\frac{1}{2}$  inch cardboard box. The proper labels are placed on this shipping box. It is my understanding that the inside glass vial is the container and should conform to the regulations. The small inside shipping safe and the can do not have to but again the outside shipping box does. Could you please give me an official interpretation of this regulation as it applies to our problem? Either I'm coing to a lot of unnecessary trouble and expense or my competition is not complying as I have been instructed to do. Whichever is the case is fine with me, however I obviously don't want to be placed at a disadvantage.

I should very much appreciate your comments on this problem at your earliest convenience since we are about to redesign and reprint our "outside can" labels. Thanks.

Best personal regards.

NUCLEAR CONSULTANTS CORPORATION

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V. R. Konneker, Ph.D. President

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