syncor

January 24, 1989

JLC 90124 A
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William J. Adam, Ph.D.
Materials Licensing Section
U.S.N.R.C., Region III
799 Roosevelt Road
Glen Ellyn, IL 60137

RE: Control Numbers 86147 through 86162

Dear Dr. Adam:

In reference to the above control numbers, we are submitting further information regarding the initial request for license amendment and answering the questions raised in your October 14, 1988 letter. The item numbers below refer to those in your October 14, 1988 letter.

1. Please find enclosed a revised cover page for the QC procedures stating the procedures will be completed and evaluated before leaving the control of Syncor for distribution to customers.

2. A revised version of Section 12.4.1(d) is enclosed which reads as requested.

3. Section 13 (revised) is enclosed which clearly states that radiopharmaceuticals not meeting these acceptance criteria shall be withheld from distribution.

4. Section 14 of the manual has been changed. Particle size for particulate radiopharmaceuticals is ensured by the manufacturer in their NDA as part of their manufacturing process. The test performed on this type radiopharmaceutical is for particle clumping rather than for particle size. The new Section 14 for particle clumping is enclosed. Please note the instructions to shake the vial before withdrawing a sample so a representative sample is assured.

5. Radiopharmaceuticals dispensed and the reagents used to compound these radiopharmaceuticals shall be pyrogen-free. The sterility as well as the apyrogenicity of the reagents and radiopharmaceuticals is certified by the manufacturers of these products. Aseptic technique is used in preparation to assure the sterility of dispensed products.

6. Results of the QA/QC tests in the amendment request shall be filed and maintained for a period of one year from the date of the test.

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7. We confirm that any changes pertaining to radionuclidic or radiochemical purity limits, or acceptance levels for tagging efficiencies submitted in our September 26, 1988 letter or described in our response letter will not be instituted unless and until we have submitted those changes as an amendment request to the affected license(s) and have received authorization in the form of an amendment to our license(s). We do, however, reserve the right to make procedural changes not affecting the noted areas. We confirm these changes will be equivalent or superior to those submitted.

8. Copies of the relevant sections of the U.S. Pharmacopeia XXI are enclosed which list the basis for the acceptance criteria given in our procedures.

9. The request to use commercially available kits is withdrawn. Only the procedures described in our manual will be used.

10. Revised versions of Section 13 and 14 are enclosed which verify the requirement of recording the final results and not simply "raw data".

Thank you for your attention to this matter. Please contact us if you have any questions regarding this letter.

Sincerely,

Jack L. Coffey

Jack L. Coffey
Corporate Radiation Safety Officer

enclosures

cc: Frank Comer
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Affected Syncor facilities