Date: December 04, 2019

To: Mr. Chris Einberg, Director
Medical Safety and Events Assessment Branch
Division of Materials Safety, Security, State, and Tribal Programs (MSST)
Office of Nuclear Material Safety and Safeguards
U.S. Nuclear Regulatory Commission
Washington, DC 20555-0001

From: Peter Selover, Chief Executive Officer
Exubrion Therapeutics, Inc.
5203 Bristol Industrial Way
Buford, GA 30518

Re: Request for review of a hypothetical license amendment for treatment of dogs with Synovetin OA™ containing Sn-117m

Dear Mr. Einberg,

Pursuant to discussions in the September 12, 2019 public conference call and the November 6, 2019 public meeting between the NRC and Exubrion Therapeutics, we wish to submit a hypothetical license amendment for treatment of dogs with Synovetin OA™ containing Sn-117m. The hypothetical license amendment is structured assuming the hypothetical licensee is already licensed to perform I-131 therapy on cats.

Attached to this document is a supplement to NRC Form 313 covering the salient sections of that form. Attached to the supplement is an outline of the proposed training, the Synovetin OA package insert and SDS, a procedure for use of Synovetin OA, and the technical basis for our proposed release criteria. The table below provides a crosswalk between the subject matters to be covered by the hypothetical license amendment package as presented by your staff in the November 6, 2019 meeting and where they are contained in our hypothetical license amendment package.

Subject Matter	Location Addressed
Introduction	
Scope	Form 313 supplement
Information applicants will need to provide	Noted in bracketed italics in Form 313 supplement.
Administration limitation	Form 313 supplement
Training specific to Sn-117m use	Outline in Form 313 supplement Appendix A
Proposed Generic Procedures for Release	
Assumptions and limitations	Technical evaluation
Release dose rate or method to calculate dog specific criteria	Range of allowed dose rates provided in Synovetin OA use procedure
Screening criteria	Synovetin OA use procedure
Instructions	Synovetin OA use procedure
Surveys	Synovetin OA use procedure and Form 313 supplement
Documentation	Synovetin OA use procedure
Boarding	Synovetin OA use procedure
Proposed screening criteria	
Define licensee responsibilities under 10 CFR 20	Synovetin OA use procedure
Describe screening criteria	Synovetin OA use procedure
Provide procedural steps that give high confidence public dose limits are met.	Synovetin OA use procedure
Describe how licensees will allow owners to modify behavior	Synovetin OA use procedure
Proposed Generic Instructions	
Distances	Release instructions
Timelines	Release instructions
What to do in emergency or death	Release instructions
Owner signature	Release instructions
Describe dose if instructions not followed	Technical evaluation
Technical Basis Demonstrating Compliance	
Defend assumptions	Contained in applicable section of technical evaluation
Provide attenuation data	Torso attenuation report
Dose rate data for different size animals	Technical evaluation
Figures demonstrating distances and geometry	Technical evaluation
Justification for expected animal behavior	Technical evaluation and cited references
Retention studies	Study referenced in technical evaluation
Maximum dose with instruction and screening compliance	Technical evaluation
Maximum dose with no instruction and screening compliance	Technical evaluation

You or your staff can reach me by phone or email (details below) with any questions you may have or to raise any other general matters.

Peter Selover
678-733-0420
pselover@exubrion.com

If you have any technical questions, I invite you to contact Dr. Matthew Arno at Foxfire Scientific.

Dr. Matthew Arno
817-995-6762
arno@foxfirescientific.com

I look forward to hearing from you.

Sincerely,

Peter Selover
Chief Executive Officer, Exubrion Therapeutics, Inc.