



Date: May 15, 2029

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: Response to NRC April 27, 2020 Request for Additional Information for the review of a hypothetical license amendment for treatment of dogs with Synovetin OA™ containing Sn-117m

Dear Mr. Einberg,

On April 27, 2020, the Nuclear Regulatory Commission (NRC) sent Exubrion a Request for Additional Information (RAI) for the review of a hypothetical license amendment for treatment of dogs with Synovetin OA™ containing Sn-117m. We subsequently provided draft responses on May 4, 2020, in preparation for a video conference call held with the NRC on May 7, 2020 in which the draft responses were discussed. This letter transmits our formal responses. The enclosed package replaces in its entirety our previous submittal on December 4, 2019.

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, a procedure for use of Synovetin OA, the technical basis for our proposed release criteria, and our responses to the individual RAI comments.

When you offered process options last fall, we chose this particular process primarily because it would allow for more direct communication between the review team and Exubrion. We value the clarity that comes from direct dialogue and I encourage you and your staff to contact us if there are any questions or concerns with this package. Please do not feel obligated to hold any questions until the review is complete. We are happy to take questions as they arise. In fact, we prefer it.

You or your staff can reach me by phone or email (details below).

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

5203 Bristol Industrial Way
Buford, GA 30518
770-831-5243



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,

A handwritten signature in black ink that reads "Peter Selover".

Peter Selover
Chief Executive Officer, Exubrion Therapeutics, Inc.

cc: Michael Layton
Kevin Williams
Katie Tapp
Irene Wu
Matt Arno