



Date: September 20, 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: Notice of intent to submit a hypothetical license amendment for treatment of dogs with Synovetin OA™ containing Sn-117m and request for pre-submittal meeting

Dear Mr. Einberg,

Pursuant to the conversations and options presented in the September 12, 2019 public conference call between the NRC and Exubrion Therapeutics, we wish to inform you of our intent to submit a hypothetical license amendment for treatment of dogs with Synovetin OA™ containing Sn-117m. The hypothetical license amendment will be structured assuming the hypothetical licensee is already licensed to perform I-131 therapy on cats.

We request a pre-submittal meeting at the earliest opportunity to engage NRC staff in a dialogue related to the hypothetical license amendment so that we may fully understand your concerns regarding this matter and exact structure and sequence of this new process going forward. We request your staff review our previous letters on this matter prior to the pre-submittal meeting in order to be prepared to discuss their concerns and the necessary content of the hypothetical license amendment with us. We would like to maintain a dialogue with your staff during their review to provide any necessary information in a timely manner to facilitate their review.

You or your staff can reach me by phone or email (details below) to coordinate a meeting or to raise any other general matters.

Peter Selover  
678-733-0420  
[pselover@exubrion.com](mailto:pselover@exubrion.com)

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



If you have any technical questions in advance of a meeting, I invite you to contact Dr. Matthew Arno at Foxfire Scientific.

Dr. Matthew Arno  
817-995-6762  
[arno@foxfirescientific.com](mailto:arno@foxfirescientific.com)

I look forward to hearing from you.

Sincerely,

A handwritten signature in black ink, appearing to read "Pete Selover", is positioned above a thin blue horizontal line.

Pete Selover (Sep 20, 2019)

Peter Selover  
Chief Executive Officer, Exubrion Therapeutics, Inc.

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