

Date: June 26, 2029

To: Mr. Duane White, Acting 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. White,

On June 17, 2020, the Nuclear Regulatory Commission (NRC) sent Exubrion a second Request for Additional Information (RAI) for the review of a hypothetical license amendment for treatment of dogs with Synovetin OA® containing Sn-117m. This letter transmits our responses.

Attached to this document is our proposed procedure for use of Synovetin OA®, the technical basis for our proposed release criteria, and our responses to the individual RAI comments. The remainder of our package remains unchanged.

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

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Chief Executive Officer, Exubrion Therapeutics, Inc.

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



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