



UNITED STATES  
NUCLEAR REGULATORY COMMISSION  
WASHINGTON, D.C. 20555-0001

June 17, 2020

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

SUBJECT: SECOND REQUEST FOR ADDITIONAL INFORMATION FOR THE REVIEW OF  
THE HYPOTHETICAL LICENSE AMENDMENT APPLICATION FOR  
TREATMENT OF DOGS WITH SYNOVETIN OA™

Dear Mr. Selover:

By letter dated May 15, 2020 (Agencywide Documents Access and Management System Accession No. ML20142A291), Exubrion Therapeutics, Inc. (Exubrion) submitted a revised hypothetical license amendment application to the U.S. Nuclear Regulatory Commission (NRC) for review containing its generic procedures for release of a dog following treatment with Synovetion OA™. The NRC has reviewed the revised application and has identified certain areas where additional information is needed to complete its review. Enclosed are the NRC staff's second round of requests for additional information (RAIs). Staff is willing to meet with Exubrion representatives to discuss and/or clarify staff's expectations for these RAIs; otherwise, please either respond to these RAIs or provide a schedule for submitting your responses within 30 days of receipt of this letter.

If you have any questions regarding this request, please contact me at 301-287-3627, or via e-mail at [Duane.White@nrc.gov](mailto:Duane.White@nrc.gov).

Sincerely,

*Duane E. White*

Duane White, Acting Chief  
Medical Safety and Events Assessment Branch  
Division of Materials Safety, Security, State,  
and Tribal Programs  
Office of Nuclear Material Safety  
and Safeguards

Enclosure:  
Requests for Additional Information

cc w/encl: Vince Holahan, NMSS  
EUIIrich, RI

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DATE: JUNE 17, 2020

**DISTRIBUTION:**

VHolahan, NMSS  
EUllrich, RI

**ADAMS Accession Package Number ML20169A412**

**\*via e-mail**

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