



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

December 20, 2019

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

SUBJECT: ACCEPTANCE REVIEW OF REQUEST FOR HYPOTHETICAL LICENSE  
AMENDMENT FOR TREATMENT OF DOGS WITH SYNOVETIN OA™  
CONTAINING SN-117M

Dear Mr. Selover:

By letter dated December 4, 2019 [Agencywide Documents Access and Management System (ADAMS) Accession No. ML19343C192], Exubrion Therapeutics, Inc. (Exubrion) submitted a request to the U.S. Nuclear Regulatory Commission to review its generic procedures for release of a dog following treatment with Synovetin OA™ containing Sn-117m in a hypothetical license amendment.

The staff has conducted an acceptance review of the application and determined that it contains sufficient technical information to begin a detailed technical review. We have established a review schedule based on current workload and priorities. The schedule would allow the staff to complete and issue its requests for additional information (RAIs) in early February 2020, and a draft technical evaluation report in early May 2020, based on Exubrion satisfactorily responding to the RAIs in early March 2020.

If you have any questions, please contact me at 301-415-5422.

Sincerely,

/RA/

Chris Einberg, Branch Chief  
Medical Safety and Events  
Assessment Branch  
Division of Materials Safety,  
Security, State, and Tribal  
Programs  
Office of Nuclear Material Safety  
and Safeguards

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DATED: DECEMBER 20, 2019

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**ADAMS Accession No.: ML19353C760**

\*concur via email

<b>OFFICE:</b>	MSST	MSST	MSST
<b>NAME:</b>	IWu	LDimmick	CEinberg
<b>DATE:</b>	12/19/2019	12/19/2019	12/20/2019

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