



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

April 27, 2020

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

SUBJECT: REQUESTS FOR ADDITIONAL INFORMATION FOR THE REVIEW OF THE
HYPOTHETICAL LICENSE AMENDMENT APPLICATION 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), Exubriion Therapeutics, Inc. (Exubriion) submitted a request to the U.S. Nuclear Regulatory Commission (NRC) to review its generic procedures for the release of a dog following treatment with Synovetion OA™ containing Sn-177m in a hypothetical license amendment. The NRC has reviewed the information contained in the request and has identified areas where additional information is needed to complete its review. The enclosure lists the requests for additional information (RAIs). As part of the RAIs, staff included some licensing-specific questions unrelated to animal release procedures since that information was included as part of Exubriion's application. These questions are included in the enclosure to provide Exubriion with a general idea of the types of information that an NRC license reviewer would need to review as part of a specific license amendment request. If Exubriion's intent is that specific licensees provide additional information for these questions, the application should be updated to direct specific licensees to ensure they address it for their specific application.

As discussed during the pre-submittal meeting, your response to the RAIs should be provided to the NRC within 30 days from the date of this letter to stay on the schedule discussed. However, please contact me if more time is needed to ensure appropriate responses.

If you have any questions regarding this request, please contact me at 301-415-5422, or via e-mail at Christian.Einberg@nrc.gov.

Sincerely,

Christian 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

Enclosure: Requests for Additional Information

Cc w/encl: Distribution List

SUBJECT: REQUEST FOR ADDITIONAL INFORMATION CONCERNING HYPOTHETICAL
LICENSE AMENDMENT APPLICATION FOR TREATMENT OF DOGS WITH
SYNOVETIN OA™ CONTAINING SN-117M

DATE: APRIL 27, 2020

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ADAMS Accession No.: ML20091M172 – Package

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