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

October 30, 2020

ALL AGREEMENT STATES

NOTIFICATION OF ISSUANCE OF TECHNICAL EVALUATION REPORT FOR THE EXUBRION THERAPEUTICS PROPOSED LICENSE APPLICATION TEMPLATE FOR THE RELEASE OF DOGS FOLLOWING TREATMENT WITH A TIN-117M COLLOID (STC-20-074)

Purpose: To inform the Agreement States that the U.S. Nuclear Regulatory Commission (NRC) issued the technical evaluation report (TER) finding the proposed license application by Exubrion Therapeutics acceptable for the release of dogs following treatment with tin-117m (Sn-117m) colloid.

Background: By letter dated December 4, 2019 (Agencywide Documents Access and Management System (ADAMS) Accession No. ML19343C192 (package)), Exubrion Therapeutics (Exubrion) submitted a proposed license application template to support the submission of license amendments by veterinary licensees. This application template included the procedure for using Synovetin OA®, a radioactive tin (Sn-117m) colloid, to treat osteoarthritis (OA) in a dog's elbow joints. Exubrion is the manufacturer of Synovetin OA®. Exubrion's procedure included a prescreening questionnaire and release instruction template; its technical basis for release of animals following treatment; and a generic release procedure for dogs and owners following treatment. This procedure would allow veterinary licensees to release dogs following treatment of Synovetin OA®. The most recent version of Exubrion's procedure and technical basis was provided to the NRC on September 13, 2020 (ADAMS Accession No. ML20282A513).

On June 25, 2020, the NRC staff hosted a government-to-government meeting with the Agreement States to discuss the staff's review of Exubrion's proposed license application template. Feedback provided during the meeting resulted in changes and are reflected in the final TER. In addition, Agreement States provided comments on a draft version of this TER (ADAMS Accession No. ML20192A003). The NRC appreciates the thoroughness of the Agreement States' review of Exubrion's application and the draft TER. The NRC staff made significant changes in the final TER based on the comments received. On October 26, 2020, the Organization of Agreement States (OAS) provided additional comments to the NRC for consideration (ADAMS Accession No. ML20301A416). Enclosure 1 provides the NRC staff's responses to these comments.

On June 18, 2020, the NRC staff met with the Standing Committee on Compatibility to determine the level of compatibility for the use of Exubrion's procedure. The Committee's review was conducted in accordance with the "Agreement State Program Policy Statement" (82 FR 48535); October 18, 2017, and the categorization process for NRC program elements in NRC Management Directive 5.9, "Adequacy and Compatibility of Program Elements for Agreement State Programs." The Committee determined that because the staff's evaluation and guidance is only instructing NRC staff and licensees on how to meet applicable requirements, it is not a program element that is a matter of compatibility with the Agreement States, and therefore should be designated as Compatibility Category D. An Agreement State

has the flexibility to choose whether or not to adopt and implement this program element within its jurisdiction.

Discussion: Enclosure 2 provides the NRC staff's TER documenting staff's review of Exubrion's proposed procedure to release dogs following treatment with Synovetin OA®. The staff's evaluation was specific to Exubrion's request of a maximum administered dose of up to 222 MBq (6 mCi) of Sn-117m to the dog's elbows. The NRC recommends acceptance of Exubrion's release procedure contained in their application dated June 1, 2020 (ADAMs Accession Number ML20282A513) as part of an individual license amendment to treat dogs with up to 222 MBq (6 mCi) of Sn-117m as part of Synovetin OA® treatment. The NRC recommends license reviewers closely evaluate any specific licensee deviations from Exubrion's proposed release procedure analyzed in the TER before approval of the deviation. In addition to the release procedure, the license reviewer should evaluate all other pertinent information as described in the most recent revision of NUREG-1556, Volume 7. Particular attention should be given to the guidance in NUREG-1556, Volume 7, Appendix D, "Guidance for Laboratory Animal and Veterinary Medicine Uses" (ADAMS Accession No. ML18065A006).

As documented in the TER, the NRC staff found Exubrion's release procedure provides adequate measures to ensure public dose limits will not be exceeded when owners provide complete and accurate information. As there is the potential to exceed public dose limits if prescreening and release instructions are not followed, staff recommends license reviewers obtain the commitments contained in enclosure 3 from individual licensees prior to approving the use of this procedure to ensure licensees take necessary precautions to keep exposures below the public dose limits. However, as documented in the TER, the NRC staff notes that public dose limits could be exceeded to members of the household if an owner provides incomplete or inadequate information during prescreening or instructions are not followed.

If you have any questions regarding this correspondence, please contact me at 301-415-3340 or the individual named below:

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Enclosures:
1. Response to Organization of Agreement State comments on the draft Technical Evaluation Report
2. U.S. Nuclear Regulatory Commission Technical Evaluation Report for the Exubrion Therapeutics Proposed License Application Template for the Release of Dogs Following Treatment with a Tin-117m Colloid
3. Notes to License Reviewers Evaluating License Applications to Treat Dogs with Synovetin OA®

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DATED: OCTOBER 30, 2020

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