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

October 30, 2020

MEMORANDUM TO:

Donna M. Janda, Chief
Medical and Licensing Assistance Branch
Division of Nuclear Materials Safety
Region I

Robert J. Orlikowski, Chief
Materials Licensing Branch
Division of Nuclear Materials Safety
Region III

Heather J.Gepford, Chief
Licensing and Decommissioning Branch
Division of Nuclear Materials Safety
Region IV

FROM:

Christian E. Einberg, Chief
Medical Safety and Events Assessment Branch
Division of Materials Safety, Security, State and Tribal Programs
Office of Nuclear Materials Safety and Safeguards

Christian Einberg
Digitally signed by Christian Einberg
Date: 2020.10.30 09:42:38 -04'00'

SUBJECT: 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

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. These license amendments would allow veterinary licensees to release dogs following treatment of Synovetin OA®, a radioactive tin (Sn-117m) colloid, to treat osteoarthritis (OA) in a dog's elbows. Exubrion is the manufacturer of Synovetin OA®. Exubrion's application template was revised several times, with the most recent version provided to the NRC on September 13, 2020 (ADAMS Accession No. ML20282A513). This application template included the procedure for using Synovetin OA®, which includes a prescreening questionnaire and release instruction template; its technical basis for release of animals following treatment; and a generic release procedure for dogs following treatment.

CONTACT: Katherine Tapp
301-415-0236

Enclosure 1 provides the Nuclear Regulatory Commission (NRC) staff's technical evaluation report (TER) which documents staff's review of Exubrion's proposed procedure to release dogs following Synovetin OA® treatment. 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. NMSS recommends license reviewers accept 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. License reviewers should 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 assurance that public dose limits will not be exceeded when licensees perform adequate prescreening and post-treatment release instructions are followed. However, as there is potential to exceed public dose limits if prescreening and release instructions are not followed, staff recommends license reviewers obtain the commitments contained in enclosure 2 from individual licensees prior to approving use of this procedure.

Enclosures
1. 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
2. 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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VHolahan, NMSS
BUllrich, RI

ADAMS Accession No.: ML20269A274 (Package) ***via email**

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DATE	10/14/2020*	10/30/2020	

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