NRC Form 313 Supplement

1. **Application**

   This is a request for an amendment of License No [*Licensee insert licensee*]

2. **Address**

   [*Licensee insert address*]

3. **Use Location**

   [*Licensee insert use location*]

4. **Contact Information**

   [*Licensee insert contact information*]

5. **Radioactive Material**

   a. Radionuclide: Tin-117m
   b. Chemical/Physical Form: Colloidal suspension
   c. Maximum Amount: 100 mCi [*Licensee modify maximum activity to suit projected workload*]

6. **Purposes for which radioactive material will be used**

   Treatment of osteoarthritis in canine elbows with Synovetin OA™. A maximum of 3 mCi per elbow (6 mCi per dog) will be used. No more than one treatment per household may be performed in a one year period.

7. **Individuals Responsible for Radiation Safety Program and their training and experience**

   [*Licensee insert name of RSO and user(s) authorized for therapeutic use on current license.*]

8. **Training**

   [*Licensee describe additions/modifications to training program unique to Sn-117m]*

   An outline of the Synovetin OA-specific training to be provided is contained in Attachment A.

9. **Facilities and Equipment**

   [*Licensee describe facilities and equipment changes due to addition of Sn-117m].*

10. Radiation Safety Program

- [*Licensee describe radiation safety program changes due to addition of Sn-117m].*

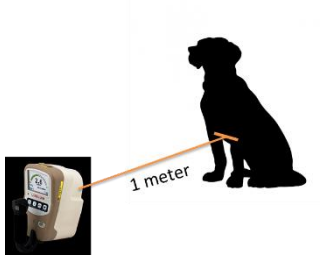
- Patient excreta monitoring is not applicable. Synovetin OA stays in the injected joint at a published rate of greater than 99.1%.[1]

- Routine bioassay of personnel is not necessary as Synovetin OA is in an aqueous, non-volatile, colloidal solution.

a. Public Radiation Safety

- Robust screening will be conducted to determine if the patient owner behavior pattern is suitable for the therapy. Release instructions will be provided to the owner during the screening interview to ensure the instructions can be met. Patient specific release instructions are again provided the day of the treatment and signed by the dog owner to ensure that radiation doses do not exceed federally established public dose limits.

- Dogs will be surveyed prior to release. Surveys will be taken at a distance of 1 meter from the closest treated elbow in the anterior and lateral directions at the height of the dog's elbow. A maximum exposure rate in excess of 0.45 mR/h at a distance of 1 m from the injection site will preclude the immediate release of the patient. Exposure rates will be measured with either a calibrated pressurized ionization chamber or calibrated Geiger-Mueller (GM) counter with energy flattening filter. In the case where the measured exposure rate is less than 0.45 mR/h, the animal will be released to the owner after instructions have been provided.



- The procedure for performing Synovetin OA injections is contained in Attachment B.

- Release of the animals on an outpatient basis will meet local and federal public dose limitations according to NUREG 1556 Volume 7 Appendix K and the appropriate State regulations. Extensive studies have been completed demonstrating compliance with the public dose restrictions with additional layers of conservatism. The technical basis for the release criteria is contained in Attachment C.

11. Waste Management

[*Licensee describe waste management changes due to addition of Sn-117m].*

12. Fees

Not applicable to license amendment.

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[1] Lattimer J, et al, *Intrarticular injection of Tin-117m radisynoviorthesis agent in normal canine elbows causes no adverse effects*, Vet Radiol Ultrasound 2019; 60:567-574.

Attachment A
Synovetin OA Training Outline

Example Synovetin OA Training Outline:

- Synovetin OA Practical Use and Radiation Safety
    - Radioactive Materials License
    - Authorized Users
    - Radiation Safety Officer
- Synovetin OA technical aspects
- Owner Interview and Basic Owner Precautions / Release Instructions
- Ordering, Shipping, and Receiving
- Dose Measurement
- Syringe shield use
- Leaded carrier use
- Option to measure residual from tubing/syringe
- Decay in Storage
- Owner Precautions / Release Instructions
- Release Measurement
- Organic Waste
- Compliance Surveys

Attachment B
Procedure for use of Synovetin OA

Attachment C
Technical Basis for Release Criteria