

**From:** [Gallagher, Robert](#)  
**To:** [LRozear@centralpetvet.com](mailto:LRozear@centralpetvet.com)  
**Subject:** Request for Additional Information - Mail Control Number 602280  
**Date:** Monday, March 19, 2018 11:40:00 AM  
**Attachments:** [image001.png](#)  
[image002.png](#)

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PLEASE CONFIRM RECEIPT OF THIS REQUEST FOR ADDITIONAL INFORMATION BY RETURN EMAIL

License No. 06-35047-01  
Docket No. 03038622  
Control No. 602280

Dr. Rozear;

This is in reference to your application dated January 19, 2018 requesting an amendment to License Number 06-35047-01 to authorize possession and use of Tin-117m to treat arthritic canine elbows. In order to continue our review, we need the following additional information:

1. Please submit detailed release calculations you will use to meet the 100 mrem annual limit pursuant to 10 CFR 20.1301;
2. Describe the criteria that will be used to approve release of the animals to their owners and provide the detailed instructions to be provided to each pet owner specific to your operations. Additionally, please include emergency contact information on your release instructions.
3. Please describe the planned dosing for each animal (e.g. 1 joint and a limit of xx mCi; or multiple joints with a maximum total injection of xx mCi).

We will continue our review upon receipt of the above requested information. Please provide the requested information as soon as possible.

Regards,

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