

## Edens, Karimah

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**From:** Gallagher, Robert  
**Sent:** Monday, June 14, 2021 10:04 AM  
**To:** Lance Rozear  
**Cc:** Chad Smith  
**Subject:** Request for Additional Information - Control No. 625415

License No. 06-35047-01  
Docket No. 03038622  
Control No. 615415

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

Dr. Rozear;

This request for additional information concerns your letter dated March 15, 2021 requesting authorization to add Tin-117m for use in treating canine osteoarthritis. In order for us to continue our review we need the following additional information:

1. Please confirm you wish to add Cara Blake, DVM as an Authorized User for use of Tin-117m for the treatment of canine osteoarthritis.
2. The original letter contained a facility diagram that did not show the proposed location of use (the diagram is cut off on the right edge). Please submit a detailed facility diagram showing where licensed materials will be used and stored. Also clearly mark areas adjacent, above and below and indicated if these areas are controlled or unrestricted areas.
3. The original letter should have been signed by a management representative rather than Dr. Rozear. Please submit a letter signed by a management representative indicating that management has reviewed the application and concurs in the statements and representations contained therein. Note also that a management representative should sign all future correspondence that requests a change in your license.
4. Please provide information about the source of the Synoventin OA (manufacturer, distributor, License No.).

We will continue our review upon receipt of the above requested information. Please contact Robert Gallagher with any questions.

Regards,

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