From: Gallaghar, Robert
To: ksciole@nemours.org
Subject: Request for Additional Information - Mail Control Number 600553
Date: Tuesday, August 29, 2017 1:37:00 PM
Attachments: image002.png

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

License No. 07-16199-02
Docket No. 03019939
Control No. 600553

Ms. Sciole;

I am in the process of reviewing your request to amend License No. 07-16199-02 to add authorization to possess and use Yttrium 90 in the form of microspheres (TheraSphere®) and to add Allison Aguado, M.D. as an authorized user. In order to complete my review of your request, the following additional information will be necessary:

1. Please confirm that you will follow the manufacturer's procedures for calculating and documenting the dose or activity to the treatment site; preparing the dose for administration; determining shunting to non-treatment sites; and performing pre- and post-vial dose measurements; or submit alternative methods.
2. Please confirm that administration of Y-90 microspheres will be performed in accordance with the written directive. In addition please confirm that you will record the dose or activity delivered to the treatment site. The record should be prepared within 24 hours after the completion or termination of the administration and must include the name of the individual who determined the administered dose or activity and the date.
3. In your letter you state that you understand that prescribed activity may be used in lieu of prescribed dose for the purposes of written directives and medical event reporting. Please confirm that, if prescribed activity is used in lieu of prescribed dose, the prescribed activity will be used for all documentation and evaluations.
4. Please confirm that, in the event the administration was terminated because of stasis, then the total dose or activity to the treatment site is the value of the total dose or activity administered when stasis occurred and the administration was terminated. The record should be prepared within 24 hours after the completion or termination of the administration and must include the name of the individual who determined the administered dose or activity, the date, and the signature of the authorized user for Y-90 microspheres.
5. Please confirm that, in the event a procedure must be modified due to emergent patient conditions that prevent administration in accordance with the written directive (e.g., artery spasm or sudden change in blood pressure), the authorized user will document such changes in the written directive within 24 hours after the completion or termination of the administration. The modification to the written directive should include the reason for not administering the intended dose or activity, the date, and the signature of the authorized user for Y-90 microspheres.
6. Please confirm that you will develop procedures that describe measures taken to ensure that radiation emissions, which may include bremsstrahlung, from each patient or human research subject permits his or her release in accordance with 10 CFR 35.75.
7. Please describe the procedure and equipment to be used to evaluate the presence of long-lived radioactive contaminant. Please confirm that you will: a) hold the remaining microspheres longer in decay-in-storage in accordance with 10 CFR 35.92; or b) return the microspheres to the manufacturer, if the manufacturer is authorized to receive Y-90 microspheres; or c) transfer the microspheres to an authorized recipient.

We will continue our review upon receipt of the requested information. If you have any questions please contact Robert Gallaghar by telephone at (610) 337-5182, or by email at Robert.gallaghar@nrc.gov.

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