Parker, Bryan

From: Sent: To: Subject: Attachments: Parker, Bryan Wednesday, January 29, 2014 11:11 AM 'thockemeyer@zevacor.com' NRC Request for Add'l Info Zevacor RAI.docx

Hey Todd,

Per our discussion by phone this morning, here is the Request for Additional Information to continue the review of Zevacor's amendment request.

Please review and respond as appropriate. If I could get a response back by early next week, that'd be perfect.

As discussed, when you respond, please attach the response to an email back to me as a scanned PDF document with a signed cover letter.

If you have any questions, please contact me by phone or email.

Thanks. Bryan Bryan A. Parker Health Physicist U. S. Nuclear Regulatory Commission - Region III 2443 Warrenville Road, Suite 210 Lisle, IL 60532-4352

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Request for Additional Information

Pioneer Pharmacy (dba Zevacor Molecular) - CN582419

 Since the requested amendments to compound iodine-131 and other radioisotopes appear to be for the Springfield location only, we will need to put these materials as separate line items on your license since they will differ in chemical form from that already authorized. Also, in order to keep your total possession limit of I-131 within the quantities listed in 30.72 Schedule C regarding emergency plans (10 curies), you will need to lower the amount requested (9.9 curies) to account for the 950 millicuries already authorized.

Please confirm that these are for the Springfield location only and provide an updated proposed possession limit for I-131 (total and/or _____ + 950 mCi).

- You requested some PET isotopes to be added to the license (N-13, C-11 and O-15); however, you have not yet obtained authorization for a cyclotron to produce these isotopes. Therefore, please confirm that these isotopes will not be listed at this time. (They may be added while the cyclotron application is under review.)
- 3. Please provide additional description of facilities and equipment in Item 9 of your request. Specifically, please indicate typical exhaust rates for glove boxes. Also, please indicate minimum face velocities to be maintained for fume hoods (typically, 100-150 feet per minute). Please assure that hood faces will be free from obstructions and the velocity will exceed exhaust velocity of the room to assure no backflow into worker breathing zones. Lastly, you described the monitoring of charcoal filters. Please describe any other means utilized to monitor the use of volatile isotopes.
- 4. Regarding your procedures attached to your request (RSM-SOP-014 and RSM-SOP-016), please note that throughout each procedure, the word "should" is used in places where a "will," "shall," or "must" would be more appropriate. Please either provide revised procedures or break out those statements concerning bioassay, use of glove boxes and fume hoods, and airflow checks as separate commitments.