UNITED STATES
NUCLEAR REGULATORY COMMISSION
REGION I
2100 RENAISSANCE BLVD.
KING OF PRUSSIA, PA 19406-2713

February 22, 2017

Todd M. Hockemeyer
Vice President of Quality and Regulatory Affairs
Zevacor Pharma, Inc.
21000 Atlantic Boulevard, Suite 730
Dulles, VA 20166

SUBJECT: VOIDANCE OF YOUR REQUEST FOR AMENDED LICENSE, MAIL CONTROL NO. 592465

Dear Mr. Hockemeyer:

This concerns your request for an amended license dated November 21, 2016. Because you informed us that you are not currently able to provide the additional information required to complete the requested action, we have voided your request. This action is taken without prejudice to the resubmission of your request. If you wish to resubmit your request to add the Eckert and Ziegler GalliaPharm Germanium-68/Gallium-68 pharmacy grade generator, you may resubmit your application in whole or reference Mail Control No. 592465 and provide the following additional information, which was originally requested by email on February 6, 2017:

1. Please confirm that the Eckert and Ziegler GalliaPharm™ Germanium-68/Gallium-68 Pharmacy Grade Generator will be used at both the Morgantown, West Virginia and Kansas City, Missouri locations. Also, please confirm the maximum number of Eckert and Ziegler GalliaPharm generators that will be possessed at one time, per location.

2. Please confirm that the authorized use will be "for use of the Eckert and Ziegler GalliaPharm™ generator to prepare Ga-68 radiopharmaceuticals for imaging and localization studies." In addition, please confirm that Zevacor will not be distributing the Eckert and Ziegler GalliaPharm™ generator, but only unit dosages of Ga-68 radiopharmaceuticals for imaging and localization studies.

3. The U.S. Nuclear Regulatory Commission (NRC) licensing guidance document, "Eckert and Ziegler GalliaPharm™ Germanium-68/Gallium-68 Pharmacy Grade Generator," dated October 17, 2016 (ML16287A403), outlines expectations for materials and use authorizations, specific to commercial nuclear pharmacy. The above-referenced letter did not include a facility diagram.

   Accordingly, please submit a facility diagram and description of the location(s) where the generator will be received, used, and stored. The diagram should be drawn to scale and indicate a brief description (i.e. cafeteria, offices, restrooms, inaccessible roof, etc.) of uses above, below, and adjacent to the Ge-68/Ga-68 use area. If applicable, provide a description of imaging rooms and patient waiting rooms and include shielding information and calculations appropriate for the PET facility. American Association of Physicists in Medicine Task Group 108, "PET and PET/CT Shielding Requirements," provides guidance

on how to design a PET facility and perform associated shielding calculations. Additional information can also be found in NUREG-1556, Volume 9, Revision 2.

4. Please provide a list of the individuals that you wish to be authorized for the Eckert and Ziegler GalliaPharm generator.

5. In the above-referenced letter, Mr. Hockemeyer stated that the licensee would develop procedures to determine breakthrough of 5 microcuries Ge-68 per 50 millicuries of Ga-68. However, the above-referenced NRC licensing guidance document includes an update to the breakthrough limit due to a conversion error made in the September 28, 2016 version of that document.

   Accordingly, please confirm that the licensee will develop and implement written procedures for the determination of breakthrough that will detect whether the eluate exceeds the manufacturer's 0.001 percent breakthrough limit, i.e., the presence of Ge-68 in excess of a ratio of 0.01 µCi Ge-68 per mCi Ga-68.

6. Please commit to the following:

   (i) We will notify by telephone the NRC Operations Center (301-816-5100) and the manufacturer/distributor of the generator within 7 calendar days after discovery of an eluate (excluding eluates from flushing the generator in accordance with manufacturer's procedures) that exceeded the manufacturer's stated breakthrough limits of Ge-68. Include in the report to the NRC Operations Center the manufacturer, model number, and serial number (or lot number) of the generator; the results of the measurement; the date of the measurement; whether dosages were administered to patients or human research subjects; when the manufacturer/distributor was notified; and the action taken.

   (ii) We will send a written report to the appropriate NRC Regional Office within 30 days after discovery of an eluate, excluding eluates from flushing the generator in accordance with manufacturer procedures that exceeded the manufacturer's stated breakthrough limits of Ge-68. Include in the written report the action taken by the licensee; the patient dose assessment; the methodology used to make this dose assessment if the eluate was administered to the patients of human research subjects; probable cause and assessment of failure in the licensee's equipment, procedures or training that contributed to the excessive readings if an error occurred in the licensee's breakthrough determination, and the information in the telephone report made as described above.

7. Under 10 CFR 30.35(a)(1), an applicant for a license to use and possess Ge-68/Ga-68 generators must submit a Decommissioning Funding Plan (DFP) together with financial assurance determined from the DFP.

   Via memo dated July 29, 2016 (ML16082A415), NRC's Office of Nuclear Material Safety and Safeguards (NMSS) authorized the NRC Region I Office to grant specific exemptions from the 10 CFR 30.35(a)(1) DFP requirement noted above. As noted in the memo, our office may grant such an exemption provided that the application provides documentation:

   (i) Explicitly requesting an exemption from the 10 CFR 30.35 DFP requirement;

(ii) Demonstrating that a legally binding agreement is in place for the licensee to return the generators to the manufacturer or distributor when the generators expire and are no longer used to prepare Ga-68 radiopharmaceuticals for patients, or if the licensee ceases its preparation of Ga-68 radiopharmaceuticals; that legally binding agreement between the licensee and generator manufacturer or distributor must highlight licensee commitments to return expired generators back to the manufacturer or distributor and also must include a manufacturer or distributor commitment to take expired generators back; and

(iii) Including Financial Assurance (FA) certification based on possession limit –

a. For up to two generators and up to 100 millicuries total, FA amount is $225,000; or

b. For three to twenty generators and up to 1 curie total, FA amount is $1,125,000.

Our review of the above-referenced letter indicated the following:

(i) Although it contained a copy of an agreement between Zevacor Pharma, Inc. and AAA, it is our understanding that AAA is not currently authorized to distribute or receive the Eckert and Ziegler GalliaPharm™ Germanium-68/Gallium-68 Pharmacy Grade Generator.

Accordingly, please submit a legally binding agreement that ensures the Eckert and Ziegler GalliaPharm™ Germanium-68/Gallium-68 Pharmacy Grade Generator will be returned to the manufacturer or distributor at the end of use. At a minimum, in addition to information already contained in the submitted agreement, the document should:

a. Include the licensee's name and license number;

b. Be signed and dated by either you or other duly authorized representative of Zevacor Pharma, Inc., including a description explaining that individual's authority to sign on behalf of the licensee;

c. Be co-signed and dated by a duly-authorized E&Z representative, including a legibly printed or typed name and title;

d. Include a manufacturer or distributor commitment to accept expired generators from the licensee, regardless of the licensee's financial status or shipping specifications, etc. (any "return guidelines" that are required as part of the agreement should be included with the agreement for NRC review); and

e. Include any additional requirements specified in NRC's July 29, 2016 exemption memo and enclosure.

(ii) To date, no FA has been submitted on behalf of Zevacor Pharma, Inc. on behalf of the licensee's request to receive, use, and possess Ge-68/Ga-68 generators. The NRC Region I office cannot issue a Ge-68/Ga-68 generators authorization prior to receipt and review of FA documents, as required by 10 CFR 30.35.

Accordingly, please submit FA documents as required by 10 CFR 30.35. The amount of FA to be submitted would be based on the number of generators possessed. For instance, licensees possessing more than 2 and up to 20 Ge-68 generators (with an estimated activity of >100 to 1000 mCi) would be subject to the requirement in § 30.35(d) for a minimum $1,125,000 in financial assurance for the decommissioning of site(s). Licensees possessing one or two Ge-68 generators (50 to 100 mCi) would be subject to a $225,000 FA minimum. For additional guidance, please refer to Appendix A, "Standard Format and Content of Financial Assurance Mechanisms for Decommissioning" of NUREG-1757, Volume 3, revision 1, "Financial Assurance, Recordkeeping, and Timeliness." FA must be in place and complete prior to amending the NRC license for possession of this material.

If the legally binding agreement mentioned above is not received, please submit a Decommissioning Funding Plan (DFP) in accordance with 10 CFR 30.35(a)(1) together with financial assurance determined from the DFP.

8. Please confirm if you wish to be authorized to make minor revisions to your Eckert and Ziegler GalliaPharm generator program, and that you will follow the conditions below. An applicant initially applying for authorization for the use of the Eckert and Ziegler GalliaPharm generator for preparation of Ga-68 radiopharmaceuticals for imaging and localization studies for may request to incorporate into its license a change process similar to 10 CFR 35.26. Such a change process can allow some future changes to radiation safety programs provided that the change process requires the following conditions to be met for revisions to the radiation safety program:

    1) The revision does not require a license amendment under 10 CFR 35.13; and

    2) the revision is based upon NRC's current guidance for use of the Eckert and Ziegler GalliaPharm generator to prepare Ga-68 radiopharmaceuticals for imaging and localization studies under 10 CFR 35.1000 posted on the NRC Medical Uses Licensee Toolkit;

    3) the revision has been reviewed and approved by the licensee's Radiation Safety Officer and management; and

    4) the affected individuals are instructed on the revised program before the change is implemented; and

    5) the licensee will retain a record of each change for five years; and

    6) the record will include a copy of the current guidance for use of the Eckert and Ziegler GalliaPharm generator to prepare Ga-68 radiopharmaceuticals for imaging and localization studies under 10 CFR 35.1000, the old procedure, the new procedure, the effective date of the change, and the signature of the licensee management that reviewed and approved the change.

If approved, these conditions for use of updated guidance will be incorporated as license conditions in the licensee's license.

In accordance with 10 CFR 2.390 of the NRC's "Agency Rules of Practice and Procedure," a copy of this letter will be available electronically for public inspection in the NRC Public Document Room or from the Publicly Available Records component of NRC's Agencywide Documents Access and Management System (ADAMS). ADAMS is accessible from the NRC Web Site at http://www.nrc.gov/reading-rm/adams.html.

Thank you for your cooperation.

Sincerely,

/RA/

Janice Nguyen, Senior Health Physicist
Medical Branch
Division of Nuclear Materials Safety
Region I

License No. 45-25221-01MD
Docket No. 030-32974
Mail Control No. 592465

cc: Michael A. Levy, R.Ph.,
Radiation Safety Officer

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Thank you for your cooperation.

Sincerely,

/RA/

Janice Nguyen, Senior Health Physicist
Medical Branch
Division of Nuclear Materials Safety
Region I

License No. 45-25221-01MD
Docket No. 030-32974
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cc: Michael A. Levy, R.Ph.,
Radiation Safety Officer

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SUNSI Review Complete: JNguyen
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