UNITED STATES
NUCLEAR REGULATORY COMMISSION
REGION III
2443 WARRENVILLE RD. SUITE 210
LISLE, IL 60532-4352

JUL 2 8 2015

John Zehner, R.Ph.
Executive Vice President, COO
Global Isotopes, LLC
d/b/a Zevacor Molecular
14395 Bergen Boulevard
Noblesville, IN 46060

Dear Mr. Zehner:

This refers to your letters to us dated May 1, 2015, July 17, 2015, July 23, 2015, and the application dated July 7, 2015, requesting another pharmacy address of use in Noblesville, Indiana.

We find that we will need additional information to complete our review.

Please respond to the items below within 6 calendar days from the date of this letter (August 3, 2015). If an alternative timeframe for response is needed, please contact me promptly to arrange that. Address your response, which must be currently dated and signed, to my attention as 'additional information to control number 586735."

As this is the third time we are seeking additional information for this amendment, it is possible that it will become necessary to void your request if an appropriate response is not provided to us permitting issuance of the amendment. Much of the information we are asking for at this time is repetitive from our previous requests to you, especially from our letter dated July 14, 2015.

If we void your request, it would mean that we would take it out of our active pending casework database temporarily until we receive an appropriate response from you. We would then resume our review.

My direct telephone number is (630) 829-9841 and my fax number is (630) 515-1078. My email address is colleen.casey@nrc.gov.

!. Given that you are adding a new pharmacy address of use, located in another state from the pharmacies currently listed on the license in Missouri, it appears that the structure of your license and the structure of your licensed radiation safety program are unclear.

Your letter dated July 17, 2015, stated that the current RSO, Ms. Zeigler, will spend 10 hours per month serving as RSO for the Springfield and Overland, Missouri locations. However, your letter did not specify if she will spend 10 hours per month total for RSO duties including both locations or if she would spend 10 hours per month at each of the two locations. Please clarify this important distinction.

Our understanding is that this license will have two RSO's: Ms. Zeigler for the two Missouri locations and you for the Noblesville, Indiana location.

Please describe and illustrate the reporting chain in your corporate structure to reflect these two positions? Who reports to whom, for purposes of the licensed programs? Who constitutes senior management, and pharmacy managers, site RSO's, and how do you, as a site RSO fit into this structure, especially considering that you have identified yourself in correspondence to us as "Corporate RSO," which has not been defined in this license or recognized.

Please explain clearly and concisely the issues above.

2. There are still some issues with the newly proposed facility in Noblesville, Indiana.

   a. A key issue with your responses to our requests for information for the Noblesville, Indiana facility concerned airborne materials, ventilation rates, air sampling, bioassays, volatile materials, and so on. Your response stated that "all volatile radioactive material will not be repackaged. The volatile radioactive material will only be handled in prepackaged containers."

      What we understand this to mean is that your current authorization for volatile and/or airborne materials that may be in unsealed form should be deleted from your license under Subitem Nos. 6-9 H for iodine-131, J for iodine-123 and L for xenon-133. Please note that this deletion would first need to be supported by additional information and a historical review of your uses of these materials, as well as explicit written direction from you to delete them. Also, the removal of these authorizations will extend to both of the Missouri locations also.

      As we really are not certain what your intentions are here, it would be best to discuss this issue with me via telephone contact to ensure a mutual understanding and enable you to make the best informed decision. Please contact me to arrange this.

   b. Please explain how the radioactive materials packages are transferred from the after-hours receipt area to the pharmacy. Please explain how the doses prepared for outbound shipment are transported and loaded into your delivery vehicles and where the delivery vehicles are parked for this purpose.

   c. The diagram on page "A9.1 Noblesville Facility Layout Page 1" contained font too tiny to read. Therefore, we still could not identify most of the other areas in the building. Please resubmit this diagram with a font large enough to be legible. If enlarging the diagram into 2 pages, each containing half of the facility, would help, that might be sufficient.

   d. Please describe what the afterhours receipt area consists of, structurally. Is this a climate-controlled enclosed structure? Is it constructed of transparent material or opaque, non-translucent materials, such that radioactive packages contained within it will not constitute an "attractive nuisance?"

   e. On "page 2 of 2" of your letter dated July 17, 2015, at the top is a paragraph about "Area 2." Please restate and clarify, in simple terms, what you are trying to say here because the language used is ambiguous and confusing. It appears to be describing some things that are already obvious while not describing

information that would be useful in understanding specifically what operations will be carried out in "Area 2."

f. Also on this same page, under "HVAC and Ventilation Systems," you state that "Zevacor Molcular certifies....." Please explain what "certifies" means in the context of this license and the commitments for the radiation safety program that we are seeking. It appears that it may be more appropriate to remove this term.

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

Sincerely,

Colleen Carol Casey

Colleen Carol Casey
Materials Licensing Branch

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Docket No. 030-38460/030-37831
Control No. 586735