

(10-2015)
10 CFR 30, 32, 33, 34
35, 36, 37, 39, and 40



**APPLICATION FOR MATERIALS
LICENSE**

Estimated burden per response to comply with this mandatory collection request: 4.3 hours. Submittal of the application is necessary to determine that the applicant is qualified and that adequate procedures exist to protect the public health and safety. Send comments regarding burden estimate to the FOIA, Privacy, and Information Collections Branch (T-5 F53), U.S. Nuclear Regulatory Commission, Washington, DC 20555-0001, or by internet e-mail to Infocollections.Resource@nrc.gov, and to the Desk Officer, Office of Information and Regulatory Affairs, NEOB-10202, (3150-0120), Office of Management and Budget, Washington, DC 20503. If a means used to impose an information collection does not display a currently valid OMB control number, the NRC may not conduct or sponsor, and a person is not required to respond to, the information collection.

INSTRUCTIONS: SEE THE APPROPRIATE LICENSE APPLICATION GUIDE FOR DETAILED INSTRUCTIONS FOR COMPLETING APPLICATION. SEND TWO COPIES OF THE ENTIRE COMPLETED APPLICATION TO THE NRC OFFICE SPECIFIED BELOW. *AMENDMENTS/RENEWALS THAT INCREASE THE SCOPE OF THE EXISTING LICENSE TO A NEW OR HIGHER FEE CATEGORY WILL REQUIRE A FEE.

<p>APPLICATION FOR DISTRIBUTION OF EXEMPT PRODUCTS FILE APPLICATIONS WITH:</p> <p>MATERIALS SAFETY LICENSING BRANCH DIVISION OF MATERIAL SAFETY, STATE, TRIBAL AND RULEMAKING PROGRAMS OFFICE OF NUCLEAR MATERIALS SAFETY AND SAFEGUARDS U.S. NUCLEAR REGULATORY COMMISSION WASHINGTON, DC 20555-0001</p> <p>ALL OTHER PERSONS FILE APPLICATIONS AS FOLLOWS:</p> <p>IF YOU ARE LOCATED IN:</p> <p>ALABAMA, CONNECTICUT, DELAWARE, DISTRICT OF COLUMBIA, FLORIDA, GEORGIA, KENTUCKY, MAINE, MARYLAND, MASSACHUSETTS, NEW HAMPSHIRE, NEW JERSEY, NEW YORK, NORTH CAROLINA, PENNSYLVANIA, PUERTO RICO, RHODE ISLAND, SOUTH CAROLINA, TENNESSEE, VERMONT, VIRGINIA, VIRGIN ISLANDS, OR WEST VIRGINIA,</p> <p>SEND APPLICATIONS TO:</p> <p>LICENSING ASSISTANCE TEAM DIVISION OF NUCLEAR MATERIALS SAFETY U.S. NUCLEAR REGULATORY COMMISSION, REGION I 2100 RENAISSANCE BOULEVARD, SUITE 100 KING OF PRUSSIA, PA 19406-2713</p>	<p>IF YOU ARE LOCATED IN:</p> <p>ILLINOIS, INDIANA, IOWA, MICHIGAN, MINNESOTA, MISSOURI, OHIO, OR WISCONSIN, SEND APPLICATIONS TO:</p> <p>MATERIALS LICENSING BRANCH U.S. NUCLEAR REGULATORY COMMISSION, REGION III 2443 WARRENVILLE ROAD, SUITE 210 LISLE, IL 60532-4352</p> <p>ALASKA, ARIZONA, ARKANSAS, CALIFORNIA, COLORADO, HAWAII, IDAHO, KANSAS, LOUISIANA, MISSISSIPPI, MONTANA, NEBRASKA, NEVADA, NEW MEXICO, NORTH DAKOTA, OKLAHOMA, OREGON, PACIFIC TRUST TERRITORIES, SOUTH DAKOTA, TEXAS, UTAH, WASHINGTON, OR WYOMING,</p> <p>SEND APPLICATIONS TO:</p> <p>NUCLEAR MATERIALS LICENSING BRANCH U.S. NUCLEAR REGULATORY COMMISSION, REGION IV 1600 E. LAMAR BOULEVARD ARLINGTON, TX 76011-4511</p>
--	--

PERSONS LOCATED IN AGREEMENT STATES SEND APPLICATIONS TO THE U.S. NUCLEAR REGULATORY COMMISSION ONLY IF THEY WISH TO POSSESS AND USE LICENSED MATERIAL IN STATES SUBJECT TO U.S. NUCLEAR REGULATORY COMMISSION JURISDICTIONS.

<p>1. THIS IS AN APPLICATION FOR <i>(Check appropriate item)</i></p> <p><input type="checkbox"/> A. NEW LICENSE</p> <p><input checked="" type="checkbox"/> B. AMENDMENT TO LICENSE NUMBER <u>24-32827-01MD</u></p> <p><input type="checkbox"/> C. RENEWAL OF LICENSE NUMBER _____</p>	<p>2. NAME AND MAILING ADDRESS OF APPLICANT <i>(Include ZIP code)</i></p> <p>Zevacor Molecular 14395 Bergen Blvd. Noblesville, IN 46060</p>								
<p>3. ADDRESS WHERE LICENSED MATERIAL WILL BE USED OR POSSESSED</p> <p>2220 West Sunset St. 14395 Bergen Blvd. Springfield, MO 65807 Noblesville, IN 46060</p> <p>1968 Innerbelt Business Center Dr. Overland, MO 63114</p>	<p>4. NAME OF PERSON TO BE CONTACTED ABOUT THIS APPLICATION</p> <p>John Zehner</p> <table border="1"> <tr> <td>BUSINESS TELEPHONE NUMBER</td> <td>BUSINESS CELLULAR TELEPHONE NUMBER</td> </tr> <tr> <td>(317) 578-1251</td> <td>(317) 459-8315</td> </tr> <tr> <td colspan="2">BUSINESS EMAIL ADDRESS</td> </tr> <tr> <td colspan="2">jzehner@zevacor.com</td> </tr> </table>	BUSINESS TELEPHONE NUMBER	BUSINESS CELLULAR TELEPHONE NUMBER	(317) 578-1251	(317) 459-8315	BUSINESS EMAIL ADDRESS		jzehner@zevacor.com	
BUSINESS TELEPHONE NUMBER	BUSINESS CELLULAR TELEPHONE NUMBER								
(317) 578-1251	(317) 459-8315								
BUSINESS EMAIL ADDRESS									
jzehner@zevacor.com									

SUBMIT ITEMS 5 THROUGH 11 ON 8-1/2 X 11" PAPER. THE TYPE AND SCOPE OF INFORMATION TO BE PROVIDED IS DESCRIBED IN THE LICENSE APPLICATION GUIDE.

<p>5. RADIOACTIVE MATERIAL</p> <p>a. Element and mass number; b. chemical and/or physical form; and c. maximum amount which will be possessed at any one time.</p>	<p>6. PURPOSE(S) FOR WHICH LICENSED MATERIAL WILL BE USED.</p>
<p>8. TRAINING FOR INDIVIDUALS WORKING IN OR FREQUENTING RESTRICTED AREAS.</p>	<p>7. INDIVIDUAL(S) RESPONSIBLE FOR RADIATION SAFETY PROGRAM AND THEIR TRAINING EXPERIENCE.</p>
<p>10. RADIATION SAFETY PROGRAM.</p>	<p>9. FACILITIES AND EQUIPMENT.</p> <p>11. WASTE MANAGEMENT.</p>

<p>12. LICENSE FEES <i>(Fees required only for new applications, with few exceptions*)</i> <i>(See 10 CFR 170 and Section 170.31)</i></p>	<p>FEE CATEGORY <u>N/A</u> AMOUNT ENCLOSED \$ <u>0.00</u></p>
---	---

13. CERTIFICATION. *(Must be completed by applicant)* THE APPLICANT UNDERSTANDS THAT ALL STATEMENTS AND REPRESENTATIONS MADE IN THIS APPLICATION ARE BINDING UPON THE APPLICANT.

THE APPLICANT AND ANY OFFICIAL EXECUTING THIS CERTIFICATION ON BEHALF OF THE APPLICANT, NAMED IN ITEM 2, CERTIFY THAT THIS APPLICATION IS PREPARED IN CONFORMITY WITH TITLE 10, CODE OF FEDERAL REGULATIONS, PARTS 30, 32, 33, 34, 35, 36, 37, 39, AND 40, AND THAT ALL INFORMATION CONTAINED HEREIN IS TRUE AND CORRECT TO THE BEST OF THEIR KNOWLEDGE AND BELIEF.

WARNING: 18 U.S.C. SECTION 1001 ACT OF JUNE 25, 1948 62 STAT. 749 MAKES IT A CRIMINAL OFFENSE TO MAKE A WILLFULLY FALSE STATEMENT OR REPRESENTATION TO ANY DEPARTMENT OR AGENCY OF THE UNITED STATES AS TO ANY MATTER WITHIN ITS JURISDICTION.

<p>CERTIFYING OFFICER -- TYPED/PRINTED NAME AND TITLE</p> <p>John A. Zehner, Executive VP and COO</p>	<p>SIGNATURE</p>	<p>DATE</p> <p>12/16/15</p>
---	------------------	-----------------------------

FOR NRC USE ONLY					
TYPE OF FEE	FEE LOG	FEE CATEGORY	AMOUNT RECEIVED	CHECK NUMBER	COMMENTS
			\$		
APPROVED BY				DATE	

RECEIVED DEC 17 2015

December 10, 2015

Materials Licensing Branch
U.S. Nuclear Regulatory Commission, Region III
2443 Warrenville Road, Suite 210
Lisle, IL 60532-4352

Dear Sir or Madam,

Re: Amendment Request for Radioactive Materials License Number 24-32827-01MD.

Global Isotopes, LLC d/b/a Zevacor Molecular requests to amend the radioactive materials license referenced above to allow the receipt, storage, and the use of germanium-68/gallium-68 generators to prepare radioactive drugs for distribution to authorized recipients. The requested possession limit are as follows:

Item 5.

a. Byproduct, source, and/or special nuclear material	b. Chemical and/or physical form	c. Maximum amount that licensee may possess at any one time under this license
Germanium - 68	Generator	300mCi
Gallium - 68	Generator; Liquid	200mCi

Zevacor Molecular intends to receive germanium-68/gallium-68 generators for use in the preparation of radioactive pharmaceuticals. The Ge-68/Ga-68 generator would be eluted, yielding gallium-68 solution. The gallium-68 would then be labeled to a chemical compound. The gallium-68 labeled chemical compound would be distributed to authorized recipients for use in diagnostic imaging.

The generators are self-contained systems, similar to Tc99 generators, which are received in from the manufacturer and then upon depletion are returned to the manufacturer. The generators will be received at the facility in the same location that other radioactive materials are received. They will be checked in and transferred to the appropriate location within the restricted area of the radiopharmacy where pharmacy compounding currently take place. It is anticipated that the generators will be sourced from a variety of approved suppliers.

We are prepared to discuss in more detail or provide additional information to support your review. If additional information is required, please contact me at (317) 459-8315. Thank you for your assistance in this process.

Sincerely,



John Zehner
Chief Operating Officer and Executive Vice President
Zevacor Molecular
jzehner@zevacor.com

Attachments: NRC Form 313

ORIGIN ID: MZZA (317) 578-1251
ZEVACOR MOLECULAR

14395 BERGEN BOULEVARD

FISHERS, IN 46060
UNITED STATES US

SHIP DATE: 16DEC15
ACTWGT: 1.00 LB
CAD: 105219914/INET3670

BILL SENDER

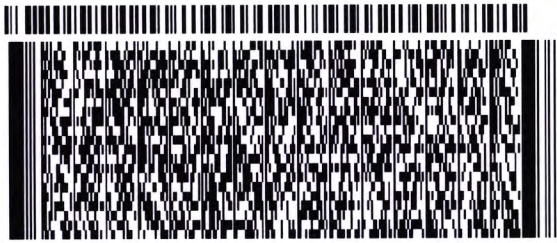
TO MATERIALS LICENSING BRANCH
NUCLEAR REGULATORY COMMISSION
2443 WARRENVILLE ROAD
SUITE 210
LISLE IL 60532

539J17130631D0

(317) 578-1251
INV
PO

REF:

DEPT:



FedEx
Express



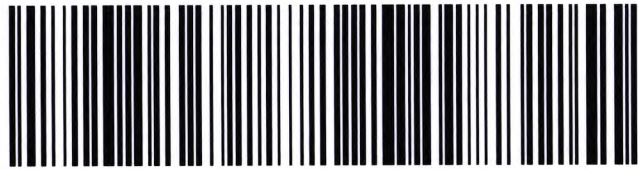
J153216811001ur

THU - 17 DEC 3:00P
STANDARD OVERNIGHT

TRK# 7752 2704 6700
0201

NA ENLA

60532
IL-US ORD



RECEIVED DEC 17 2015

After printing this label:

1. Use the 'Print' button on this page to print your label to your laser or inkjet printer.
2. Fold the printed page along the horizontal line.
3. Place label in shipping pouch and affix it to your shipment so that the barcode portion of the label can be read and scanned.

Warning: Use only the printed original label for shipping. Using a photocopy of this label for shipping purposes is fraudulent and could result in additional billing charges, along with the cancellation of your FedEx account number.

Use of this system constitutes your agreement to the service conditions in the current FedEx Service Guide, available on fedex.com. FedEx will not be responsible for any claim in excess of \$100 per package, whether the result of loss, damage, delay, non-delivery, misdelivery, or misinformation, unless you declare a higher value, pay an additional charge, document your actual loss and file a timely claim. Limitations found in the current FedEx Service Guide apply. Your right to recover from FedEx for any loss, including intrinsic value of the package, loss of sales, income interest, profit, attorney's fees, costs, and other forms of damage whether direct, incidental, consequential, or special is limited to the greater of \$100 or the authorized declared value. Recovery cannot exceed actual documented loss. Maximum for items of extraordinary value is \$1,000, e.g. jewelry, precious metals, negotiable instruments and other items listed in our ServiceGuide. Written claims must be filed within strict time limits, see current FedEx Service Guide.