

NRC FORM 313

(10-2015)

10 CFR 30, 32, 33, 34
35, 36, 37, 39, and 40

U.S. NUCLEAR REGULATORY COMMISSION

APPROVED BY OMB: NO. 3150-0120

EXPIRES: 12/31/2015

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.

APPLICATION FOR DISTRIBUTION OF EXEMPT PRODUCTS FILE APPLICATIONS WITH:

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

ALL OTHER PERSONS FILE APPLICATIONS AS FOLLOWS:

IF YOU ARE LOCATED IN:

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,

SEND APPLICATIONS TO:

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

IF YOU ARE LOCATED IN:

ILLINOIS, INDIANA, IOWA, MICHIGAN, MINNESOTA, MISSOURI, OHIO, OR WISCONSIN,
SEND APPLICATIONS TO:

MATERIALS LICENSING BRANCH
U.S. NUCLEAR REGULATORY COMMISSION, REGION III
2443 WARRENVILLE ROAD, SUITE 210
LISLE, IL 60532-4352

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,

SEND APPLICATIONS TO:

NUCLEAR MATERIALS LICENSING BRANCH
U.S. NUCLEAR REGULATORY COMMISSION, REGION IV
1600 E. LAMAR BOULEVARD
ARLINGTON, TX 76011-4511

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.

1. THIS IS AN APPLICATION FOR (Check appropriate item)

☐ A. NEW LICENSE☒ B. AMENDMENT TO LICENSE NUMBER 24-32827-01MD☐ C. RENEWAL OF LICENSE NUMBER

2. NAME AND MAILING ADDRESS OF APPLICANT (Include ZIP code)

Zevacor Molecular
14395 Bergen Blvd.
Noblesville, IN 46060

3. ADDRESS WHERE LICENSED MATERIAL WILL BE USED OR POSSESSED

2220 West Sunset St. 14395 Bergen Blvd.
Springfield, MO 65807 Noblesville, IN 46060

1968 Innerbelt Business Center Dr.
Overland, MO 63114

4. NAME OF PERSON TO BE CONTACTED ABOUT THIS APPLICATION

John Zehner

BUSINESS TELEPHONE NUMBER

(317) 578-1251

BUSINESS CELLULAR TELEPHONE NUMBER

(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.

5. RADIOACTIVE MATERIAL

a. Element and mass number; b. chemical and/or physical form; and c. maximum amount which will be possessed at any one time.

6. PURPOSE(S) FOR WHICH LICENSED MATERIAL WILL BE USED.

7. INDIVIDUAL(S) RESPONSIBLE FOR RADIATION SAFETY PROGRAM AND THEIR TRAINING EXPERIENCE.

8. TRAINING FOR INDIVIDUALS WORKING IN OR FREQUENTING RESTRICTED AREAS.

9. FACILITIES AND EQUIPMENT.

10. RADIATION SAFETY PROGRAM.

11. WASTE MANAGEMENT.

12. LICENSE FEES (Fees required only for new applications, with few exceptions*)
(See 10 CFR 170 and Section 170.31)

FEE CATEGORY

N/A

AMOUNT
ENCLOSED \$

0.00

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.

CERTIFYING OFFICER - TYPED/PRINTED NAME AND TITLE

John A. Zehner, Executive VP and COO

SIGNATURE

DATE

12/16/15

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

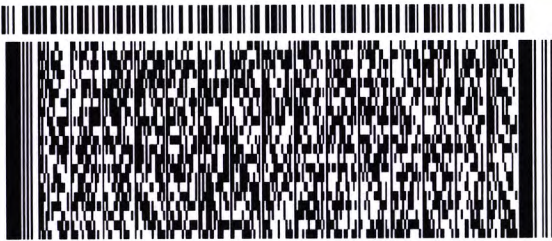
TO MATERIALS LICENSING BRANCH
 NUCLEAR REGULATORY COMMISSION
 2443 WARRENVILLE ROAD
 SUITE 210
 Lisle IL 60532

5539J17130831D0

(317) 578-1251
 INV
 PO

REF:

DEPT:



FedEx
 Express



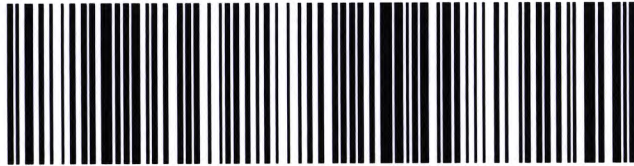
J1532915481061ur

THU - 17 DEC 3:00P
 STANDARD OVERNIGHT

TRK# 7752 2704 6700
 0201

NA ENLA

60532
 IL-US ORD



RECEIVED DEC 17 2015

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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.

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