

Mid-America Isotopes, Inc.
706 E. Liberty Lane
Ashland, MO 65010
573.657.1776

06/17/21

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

**Subject: Request of additional information for renewal of license.
License No. 24-26241-01MD
Control No. 624224**

Dear Sir or Madam,

Per your request I have enclosed the additional information related to the legally binding agreement for the return of the Germanium-68/Gallium-68 Pharmaceutical Grade Generators agreement in accordance with the Germanium-68/Gallium-68 Pharmaceutical Grade Generators Licensing Guidance dated July 2019 as requested by the email from Frank Tran dated June 10, 2021.

Please refer to enclosed attached material.

If you need additional information, please write to the address above or please call me at 573.657.1776

Respectively,



Jon W. Woodward, R.Ph., RSO
Nuclear Pharmacist and Radiation Safety Officer

Enclosures

Return Agreement for Germanium-68/Gallium-68 Generators

This Return Agreement for IRE ELIT, S.A. (IRE) Germanium-68/Gallium-68 Generators (Return Agreement) is entered into by and between Pharmalogic Holdings Corp (Pharmalogic) and Cardinal Health 414, LLC (Cardinal Health), effective September 10, 2018 (Effective Date).

Background

1. Pharmalogic is purchasing Gallium-68/Germanium-68 generators (Generators) from Cardinal Health. The Generator is a radioactive substance, the possession and use of which are subject to several regulatory requirements.
2. Cardinal Health is the sole distributor for the Generators in the United States. The Generators are filed with the US FDA under Type II Drug Master File (DMF) number 031715. Pursuant to its distribution agreement with IRE, the manufacturer of the Generators, Cardinal Health entered into a return agreement dated October 1, 2017 with IRE whereby Cardinal Health commits to return and IRE commits to accept all expired or unused Generators distributed in the United States under the parties' distribution agreement.
3. The July 29, 2016, U.S. NRC Memorandum entitled Authorization for Granting Specific Exemption from Decommissioning Funding Plan Requirement for Germanium-68/Gallium-68 Generators (NRC Memorandum) authorizes NRC regions to issue decommissioning exemptions to licensees when requested if a licensee has a binding agreement in place to return the generators to the manufacturer, including a commitment from the manufacturer to take generators back when the generators are expired or are no longer used to prepare gallium-68 radiopharmaceuticals for patients, or the licensee ceases its preparation of gallium-68 radiopharmaceuticals.
4. This Return Agreement documents a commitment between the parties to a standard return procedure for the Generator as referenced in the NRC Memorandum.

NOW THEREFORE, the parties agree as follows:

Agreement

1. Return Commitment: For each Pharmalogic radiopharmacy that possesses a Generator, Pharmalogic commits to return each Generator and Cardinal Health commits to accept the return of each Generator by Pharmalogic, subject to the terms and conditions of this Return Agreement and in compliance with all applicable laws. Such commitment by each party above applies upon expiration of the Generator or in the event Pharmalogic no longer uses the Generator to prepare gallium-68 radiopharmaceuticals for patients, or Pharmalogic ceases its preparation of gallium-68 radiopharmaceuticals.
2. Return Process:
 - 2.1 Pharmalogic will contact Cardinal Health to obtain a returned materials authorization (RMA).
 - 2.2 Any Generator returns shall be accomplished in accordance with Cardinal Health's reasonable instructions as mutually agreed upon by Pharmalogic. In the case of the Generator's shelf-life expiry, return must take place at the latest sixty (60) days following the expiry date; provided that Cardinal Health will accept the return of the Generator at any earlier date as may be requested by Pharmalogic.
3. Term. This Return Agreement commences on the Effective Date and will continue until Pharmalogic returns the final Generator and Pharmalogic confirms to Cardinal Health in writing that it no longer intends to possess any Generator.

4. Miscellaneous: The terms herein represent the entire agreement between the parties regarding the subject matter herein. This Return Agreement supersedes all previous communications, representations or agreements, whether oral or written, between the parties regarding the subject matter herein. This Return Agreement will not be amended except by mutual written agreement between the parties. Notices required herein will be provided by each party to the other via overnight courier, hand delivery or certified mail/return receipt, directed to the address under the signature lines below. Without limitation to the foregoing, this Return Agreement is in addition to any terms which may be agreed upon by the parties regarding Pharmalogic's purchase of the Generators.

Signature for accepting the above:

Pharmalogic Holdings Corp:

Name: Steven Chilinski
Title: President

Signature: Steven Chilinski
Digitally signed by Steven Chilinski
Date: 2018.10.01
13:23:16 -0400

Address: 1 South Ocean Blvd
Boca Raton FL 33432

Cardinal Health 414, LLC

Name: David W. Pellicciarini
Title: Vice President, Pharmacy Safety,
Practice and Tech. Ops.

Signature: David W. Pellicciarini

Address: 7200 Cardinal Place
Dublin, OH 43017

7/24/2019 DP



RETURN AGREEMENT FOR GalliaPharm™ ⁶⁸Ge/⁶⁸Ga GENERATORS

Background

As regular users of radioactive substances and radiopharmaceuticals, we assume that you are aware that possession and use of both are subject to several regulatory requirements to ensure public health and safety.

These considerations include the final return of these materials and products.

Hence, purchases and deliveries of GalliaPharm™, Eckert & Ziegler's ⁶⁸Ge/⁶⁸Ga generator, have to undergo a standard return procedure.

This AGREEMENT applies to deliveries of GalliaPharm™ from E&Z to site(s) that are authorized by the United States Nuclear Regulatory Commission or Agreement states to possess the required maximum radioactive quantity of ⁶⁸Ge/⁶⁸Ga contained in GalliaPharm™ (Licensee).

The GalliaPharm™ ⁶⁸Ge/⁶⁸Ga generator has been approved by the FDA (DMF #28741) for use in the radiolabeling of NETSpot® and certain restrictions on its use apply – see GalliaPharm™ Instructions for Use.

1. Contract Parties:

Manufacturer of GalliaPharm™: Eckert & Ziegler Radiopharma GmbH (E&Z)

Name of Licensee or applicant (10 CFR Part 32.72): PHARMALOGIC

GalliaPharm™ Serial# or Batch#: _____

Address of Licensee pharmacy where All Pharmalogic Radiopharmacies licensed

GalliaPharm™ is to be/has been delivered by E&Z: to possess E&Z's GalliaPharm™ ⁶⁸Ge/⁶⁸Ga Generator.

2. General Handling, Safety and Return:

2.1 The Licensee is obligated to return each GalliaPharm™ and E&Z (directly or through its subsidiaries, affiliates and/or distributors) is obligated to accept the return of these GalliaPharm™ by the Licensee to the terms and condition of this Agreement.

2.2 The Licensee will contact E&Z to obtain a returned materials authorization (RMA).

2.3 Any returns shall be accomplished in accordance with E&Z's instructions. In the case of GalliaPharm's™ shelf-live expiry, return has to take place at the latest sixty (60) days following the expiry date. The Licensee shall contact E&Z in due time for return guidance and instructions (phone: +1 508-497-0060 or GalliaPharm@ezag.com).

2.4 If the Licensee fails to facilitate due return of GalliaPharm™, does not inform E&Z in due time and/or deviates from any guidance and instructions given by E&Z, the Licensee will indemnify E&Z against loss, damage and expense incurred by E&Z in relation to the inadequate or delayed

return including cost of return freight and all labor and third party associated costs, fees or penalties.

2.5 If prior to the expiry date of the GalliaPharm™, the RAM license expires, is terminated or withdrawn for whatever reason or in case of the Licensee's insolvency, receivership or bankruptcy or its dissolution or ceasing to do business, E&Z is entitled to directly or indirectly through qualified representatives package and effect return of the GalliaPharm™ according to its return guidelines.

3. Documentation:

3.1 The Licensee may not permit any person reasonably within the Licensee's control to

- (i) open, breach or modify the GalliaPharm™ and/or
- (ii) copy, clone, reverse engineer any hardware GalliaPharm™ components or
- (iii) copy, modify or decompile any documents accompanying the GalliaPharm™ without E&Z's prior written consent.

3.2 Non-compliance with the above, in particular if a return GalliaPharm™ has not been prepared according to the E&Z return guidance and/or applicable legislation including residual activity estimation of GalliaPharm™, exposure rate and Transport Index measurements on the package, correct packaging assembly, labeling and documentation, can result in rejection of the respective return consignment until the irregularities are corrected and the GalliaPharm™ is resubmitted for return.

4. No Resale or Transfer:

The Licensee acknowledges that due to its FDA approved status, any delivered, unpacked and commissioned GalliaPharm™ generator may not be sold, leased or otherwise locally transferred to or utilized by any third parties, end-users at any other location other than the original delivery location holding the respective license. If the Licensee violates this section, the GalliaPharm™ warranty will be violated and E&Z will not be responsible for any loss, damage and expense incurred by such unauthorized use.

5. Miscellaneous:

This Agreement may be amended or terminated by either Party if the current return policies and guidelines regarding GalliaPharm™ generators are amended, modified or explicitly codified. This

will not influence the return of GalliaPharm™ already delivered by E&Z to the Licensee prior to any such changes in applicable laws and regulations.

Signature for accepting the above:

Licensee:

Name: Glen Palmer

Title: COO Pharmalogic

Signature: 

Date: 2-27-17

Eckert & Ziegler Radiopharma GmbH:

Name: Dr. André Heß Martina Leplow

Title: General Manager Authorized Signatory

Signature: 

Date: 23 February 2017

Pavon, Sandy

From: Tran, Frank
Sent: Thursday, June 17, 2021 7:58 PM
To: Pavon, Sandy; Song, Taehoon
Cc: Tomczak, Tammy
Subject: FW: RE: RE: RE: Request additional information for NRC License No. 24-26241-01MD
Attachments: MAI response to Frank Trank to email 061021.pdf; NRC 665_Additional information dated June 17 2021.pdf

Dear IM Center,

Please add the attachment as additional information. A 665 Form is also attached.

Please let me know if you have any questions.

Thank you,
Frank

From: Jon Woodward <jwoodward@midamericaisotopes.com>
Sent: Thursday, June 17, 2021 5:25 AM
To: Tran, Frank <Frank.Tran@nrc.gov>
Subject: [External_Sender] RE: RE: RE: Request additional information for NRC License No. 24-26241-01MD

Frank,

Enclosed is the requested material as requested.

Sincerely,

Jon

Jon Woodward, RSO
Mid-America Isotopes
573.657.1776

From: Tran, Frank <Frank.Tran@nrc.gov>
Sent: Thursday, June 10, 2021 4:08 PM
To: Jon Woodward <jwoodward@midamericaisotopes.com>
Subject: RE: RE: RE: Request additional information for NRC License No. 24-26241-01MD

Dear Mr. Woodward:

Your application requests to continue be authorized for IRE Galli-Eo® Ge-68/Ga-68 generators. We reviewed the application and the response dated June 3, 2021; however, we could not locate the legally binding agreement for the licensee to return the IRE Galli-Eo® Ge-68/Ga-68 generators to the manufacturer or distributor (such as Cardinal Health 414, LLC) when the generators are no longer used. Please provide the agreement in accordance with the Germanium-68/Gallium-68 Pharmaceutical Grade Generators Licensing Guidance dated July 2019.

We appreciate if you could provide the additional information above (with a dated and signed cover letter) by June 18, 2021.

If you have questions, require additional time to respond, or require clarification on any of the information stated above, please contact me at 630-829-9623 or reply to this email.

Sincerely,

Frank Tran