

October 2, 2019

US Nuclear Regulatory Commission, Region III
Division of Nuclear Materials Safety
Attn: Medical and Licensing Assistance Branch
2443 Warrenville Road, Suite 210
Lisle, Illinois 60532

Subject: Request for additional information on Control Numbers 614055 and 614059

Dear Sir or Madam,

Please see the attached return agreement between Eckert and Ziegler and PharmaLogic for their Ge68/Ga68 generator. This is being sent to be incorporated into the license amendment information for mail control numbers 614055 and 614059.

Should you need any further information regarding this amendment request, please contact me at 703.851.3025

Best regards,

Reid Gadziala, PharmD., BCNP
Director of Operations
PharmaLogic Holdings Corp
rgadziala@radiopharmacy.com

RETURN AGREEMENT FOR GalliaPharm™ $^{68}\text{Ge}/^{68}\text{Ga}$ 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 $^{68}\text{Ge}/^{68}\text{Ga}$ 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 $^{68}\text{Ge}/^{68}\text{Ga}$ contained in GalliaPharm™ (Licensee).

The GalliaPharm™ $^{68}\text{Ge}/^{68}\text{Ga}$ 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): Radiopharmacy Inc. Evansville

GalliaPharm™ Serial# or Batch#: _____

Address of Licensee pharmacy where 1409 East Virginia Street

GalliaPharm™ is to be/has been delivered by E&Z: Evansville, IN 47711

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-life 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

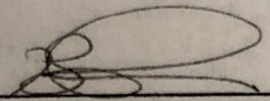
will not influence the return of GalliaPharm™ already delivered by E&Z to the Licensee prior to any such changes in applicable laws and regulations.

Signature for accepting the above:

Licensee:

Name: Glen Palmer

Title: COO Radiopharmacy Inc.
Evansville

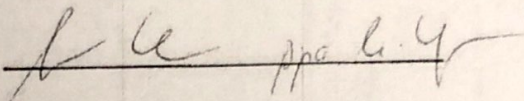
Signature: 

Date: 2-27-17

Eckert & Ziegler Radiopharma GmbH:

Name: Dr. André Heß Martina Leplow

Title: General Manager Authorized Signatory

Signature: 

Date: 23 February 2017

Song, Taehoon

From: Reid Gadziala <rgadziala@radiopharmacy.com>
Sent: Wednesday, October 02, 2019 12:51 PM
To: Parker, Bryan
Subject: [External_Sender] Re: E&Z return agreement
Attachments: E and Z return agreement.pdf

Good afternoon Bryan,

Please see the attached return agreement with a signed cover letter referencing the two mail control numbers.

Please let me know if you need anything additional!

Thanks,

Reid Gadziala, PharmD., BCNP
Director of Operations
Pharmalogic Holdings Corp
703.851.3025

From: Parker, Bryan <Bryan.Parker@nrc.gov>
Sent: Wednesday, October 2, 2019 11:39 AM
To: Reid Gadziala <rgadziala@radiopharmacy.com>
Subject: RE: E&Z return agreement

Hey Reid,

I just realized – I need you to re-submit this to me with a signed cover letter as additional info for CNs 614055 and 614059 (those are the Control Nos. for each of the actions).

So please email me the same thing again, but with an attached SIGNED cover letter indicated it is Additional Information for those CNs.

Thanks.
Bryan

From: Reid Gadziala <rgadziala@radiopharmacy.com>
Sent: Monday, September 30, 2019 4:42 PM
To: Parker, Bryan <Bryan.Parker@nrc.gov>
Subject: [External_Sender] E&Z return agreement

Good afternoon Bryan,

As a follow-up to our conversation on Friday, please see the attached return agreement between Pharmalogic and Eckert and Ziegler.

Hopefully this is the last piece of information you need to issue the amendments for Mid America Isotopes and Radiopharmacy of Indiana. Please let me know if you have any additional questions or concerns.

Thank you,

Reid Gadziala, PharmD., BCNP.
Pharmalogic Holdings Corp.
Director of Operations
703.851.3025