



February 8, 2017

Nuclear Regulatory Commission
11555 Rockville Pike
Rockville, MD 20852

Please be advised that on August 31, 2016, all of the outstanding shares of Radiopharmacy, Inc. were acquired by PharmaLogic Holdings Corp. ("PHC") and as a result of the acquisition, Radiopharmacy, Inc. became a wholly owned subsidiary of PHC. In connection with the acquisition, Steven Chilinski, Frank Edwards and Glen Palmer were named as and continue to be the officers of Radiopharmacy, Inc. with full authority to enter into legal agreements on behalf of PHC and Radiopharmacy, Inc.

If you require further information, please contact the undersigned.

Sincerely,

A handwritten signature in black ink, appearing to read "Steve C", is written over a horizontal line.

Steven Chilinski

President and CEO
Pharmalogic Holdings Corp.
Radiopharmacy, Inc.



RETURN AGREEMENT FOR GalliaPharm™ ⁶⁸Ge/Ga⁶⁸ 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/Ga⁶⁸ 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/Ga⁶⁸ contained in GalliaPharm™ (Licensee).

The GalliaPharm™ ⁶⁸Ge/Ga⁶⁸ 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:

<u>Manufacturer of GalliaPharm™:</u>	Eckert & Ziegler Radiopharma GmbH (E&Z)
<u>Name of Licensee or applicant (10 CFR Part 32.72):</u>	Pharmalogic
<u>GalliaPharm™ Serial# or Batch#:</u>	
<u>Address of Licensee pharmacy where</u>	All Pharmalogic Radiopharmacies
<u>GalliaPharm™ is to be/has been delivered by E&Z:</u>	licensed to possess E&Z's GalliaPharm (⁶⁸ Ge/Ga ⁶⁸ 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-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 Pharmalogic

Signature: 

Eckert & Ziegler Radiopharma GmbH:

Name: DR. ANDRÉ HER MARTINA LEPOW

Title: General Manager Authorized Signatory

Signature:  

