

From: [Gerard Strugala](#)
To: [Nguyen, Janice](#); [Plourde, Laura K](#)
Cc: [Buttiglieri, Amy](#)
Subject: [External_Sender] Re: [EXTERNAL] RE: Re: [EXTERNAL] FW: LMI Puerto Rico - NRC Transfer of Ownership Confirmation
Date: Thursday, February 18, 2021 3:58:09 PM
Attachments: [Outlook-p2zqqjka.png](#)
[Joint Letter to NRC confirming consummation of transaction2.8.2021 - signed.pdf](#)
[Response to NRC Request Additional Information Jan 2021 Signed JB signed GP.pdf](#)
[image001.png](#)

Janice,

This email provides licensee name change information for the following NRC License #s:

52-25361-02 (Docket #: 030-38114)

52-25361-01 MD (Docket #: 030-34187)

Since the Securities Purchase Agreement transaction has been completed, the licensee name change, as described in correspondence dated, 10 December 2020 and 13 January 2021, should be reflected on both RAM Licenses. The correct name for both licenses should be **"Lantheus MI Radiopharmaceuticals Inc."**

Please contact if further clarification is required.

Thank you
Gerard

Gerard A. Strugala, RPh, BCNP
Vice President, Quality & Regulatory
PharmaLogic Inc
gstrugala@radiopharmacy.com

From: Nguyen, Janice <Janice.Nguyen@nrc.gov>
Sent: Wednesday, February 17, 2021 4:36 PM
To: Gerard Strugala <gstrugala@radiopharmacy.com>; Plourde, Laura K <Laura.Plourde@lantheus.com>
Cc: Buttiglieri, Amy <Amy.Buttiglieri@lantheus.com>
Subject: [EXTERNAL] RE: Re: [EXTERNAL] FW: LMI Puerto Rico - NRC Transfer of Ownership Confirmation

CAUTION: This email originated from outside of the organization. Do not click links or open attachments unless you recognize the sender and know the content is safe.

Thank you. The name on the other license is Lantheus Medical Imaging. Will that name stay the

same for the time being?

Jan

Janice Nguyen
Senior Health Physicist
Division of Nuclear Materials Safety
U.S. Nuclear Regulatory Commission Region I
2100 Renaissance Boulevard, Suite 100
King of Prussia, PA 19406
Office (610) 337-5006
FAX (610) 337-5269

From: Gerard Strugala <gstrugala@radiopharmacy.com>
Sent: Wednesday, February 17, 2021 4:09 PM
To: Nguyen, Janice <Janice.Nguyen@nrc.gov>; Plourde, Laura K <Laura.Plourde@lantheus.com>
Cc: Buttiglieri, Amy <Amy.Buttiglieri@lantheus.com>
Subject: [External_Sender] Re: [EXTERNAL] FW: LMI Puerto Rico - NRC Transfer of Ownership Confirmation

Janice,

Thank you for the receipt confirmation of our email message regarding completion of the ownership transfer.

At this time the business entity name will remain the same (Lantheus MI Radiopharmaceuticals Inc). I will be submitting separate correspondence regarding the proposed name change in the near term.

Thank you
Gerard

Gerard A. Strugala, RPh, BCNP
Vice President, Quality & Regulatory
PharmaLogic Inc
gstrugala@radiopharmacy.com



From: Nguyen, Janice <Janice.Nguyen@nrc.gov>
Sent: Wednesday, February 17, 2021 3:55 PM
To: Plourde, Laura K <Laura.Plourde@lantheus.com>

Cc: Gerard Strugala <gstrugala@radiopharmacy.com>

Subject: [EXTERNAL] FW: LMI Puerto Rico - NRC Transfer of Ownership Confirmation

CAUTION: This email originated from outside of the organization. Do not click links or open attachments unless you recognize the sender and know the content is safe.

Thank you for the confirmation of sale. I do have one question. Is the name on either license changing at this time?

Thank you in advance for your help!

Jan

Janice Nguyen
Senior Health Physicist
Division of Nuclear Materials Safety
U.S. Nuclear Regulatory Commission Region I
2100 Renaissance Boulevard, Suite 100
King of Prussia, PA 19406
Office (610) 337-5006
FAX (610) 337-5269

From: Gerard Strugala <gstrugala@radiopharmacy.com>

Sent: Tuesday, February 16, 2021 12:09 PM

To: Nguyen, Janice <Janice.Nguyen@nrc.gov>

Subject: [External_Sender] LMI Puerto Rico - NRC Transfer of Ownership Confirmation

Janice,

I have attached a Confirmation Letter that the Securities Purchase Agreement of LMI Puerto Rico has been completed. The attached letter has been reviewed, agreed to and signed by both the Buyer and Seller.

Upon review, please contact if further information is required.

Thank you

Gerard

Gerard A. Strugala, RPh, BCNP
Vice President, Quality & Regulatory
PharmaLogic Inc
gstrugala@radiopharmacy.com

January 13, 2021

Division of Nuclear Material Safety
U.S. Nuclear Regulatory Commission Region I
2100 Renaissance Blvd Suite 100
King of Prussia, PA 19406

Subject: Request for Additional Information (Mail Control Numbers 624028 and 624029)
Application for Approval of Change of Control
NRC License Number: 52-25361-02 (Docket No.: 030-38114)
NRC License Number: 52-25361-01-MD (Docket No.: 030-34187)

Expedited Review Requested

Dear Administrator:

This letter is to follow up on the Application for Approval of Change of Control (the "**Application**") filed on December 10, 2020, by which Lantheus Medical Imaging, Inc., and Lantheus MI Radiopharmaceuticals, Inc. sought to transfer to PharmaLogic Holdings Corp. two NRC licenses, namely NRC License Number 52-25361-02 (held by Lantheus Medical Imaging, Inc.) and NRC License Number 52-25361-01-MD (held by Lantheus MI Radiopharmaceuticals, Inc.) These licenses both relate to operations at the premises located at 150 Federico Costa St. Suite 1, San Juan, PR 00918-1303 (the "**Premises**"). As a result of our conversation on January 12, 2021, we are writing to clarify certain matters in the Application.

As we discussed, Lantheus Medical Imaging, Inc. currently owns Lantheus MI Radiopharmaceuticals, Inc. (referred to as "Lantheus MI" in the Application). Pursuant to a Securities Purchase Agreement dated November 30, 2020, Lantheus Medical Imaging, Inc. will sell all of the outstanding stock of Lantheus MI Radiopharmaceuticals, Inc. to PharmaLogic Holdings Corp. (the "**Sale**"). As part of the Sale, both NRC License Number 52-25361-02 and NRC License Number 52-25361-01-MD will be transferred to PharmaLogic Holdings Corp. (to be held in PharmaLogics' newly -owned subsidiary, which will continue to operate under the name Lantheus MI Radiopharmaceuticals, Inc. for a time following the Sale). As we discussed, some confusion may have arisen in the Application, because references to "Lantheus MI" in the Application refer in some cases to the pre-closing entity owned by Lantheus Medical Imaging, Inc., and in other cases to the post-closing entity owned by PharmaLogic Holding Corp.

Further, by executing this letter, PharmaLogic Holdings Corp. confirms that it is aware that Lantheus Medical Imaging, Inc. received two Severity Level III violations and was subject to a civil penalty of \$7,500 for an inspection conducted by the U.S. Nuclear Regulatory Commission (NRC) on February 14, 2018, March 7, 2018, and April 10, 2018, with continued in-office review through November 13, 2019, at the Lantheus Medical Imaging, Inc. (LMI) facilities in Billerica, Massachusetts and San Juan, Puerto Rico and an associated NRC investigation completed on June 6, 2019. The violations were issued in Enforcement Action (EA-19-068) dated April 23, 2020, and the civil penalty was paid in May 2020.


If you have any questions or comments or require additional information pertaining to this transaction, please contact Lantheus' counsel for nuclear regulatory matters, Laura Plourde at Laura.Plourde@Lantheus.com or 617-935-1543.

As we discussed during our conversation on January 12, we request expedited review in order to allow the transaction to close at the end of January.

[Remainder of Page Left Blank/ Signature Pages Follows]

I declare under penalty of perjury under the laws of the United States of America that to the best of my knowledge the information contained in the license transfer Application and this Letter pertaining to Lantheus Holdings, Inc. and its affiliated companies is true and correct.

Executed on January 13, 2021

A handwritten signature in dark ink, appearing to read "John Bolla", is written over a horizontal line.

John Bolla, Chief Operating Officer

Lantheus Holdings, Inc.; Lantheus Medical Imaging, Inc. and Lantheus MI Radiopharmaceuticals, Inc.

Address for Lantheus Holdings, Inc. and Lantheus Medical Imaging, Inc.:

331 Treble Cove Rd

Billerica, Ma 01862

I declare under penalty of perjury under the laws of the United States of America that to the best of my knowledge the information contained in the license transfer Application and this Letter pertaining to PharmaLogic Holdings Corp. and its companies is true and correct.

Executed on January 13, 2021

A handwritten signature in blue ink, appearing to be "Glen Palmer", is written over a horizontal line.

Glen Palmer, Chief Operations Officer
PharmaLogic Holdings Corp.

February 5, 2021

Via Electronic Submission

Division of Nuclear Material Safety
U.S. Nuclear Regulatory Commission Region I
2100 Renaissance Blvd Suite 100
King of Prussia, PA 19406

Subject: Confirmation of Closing of Transaction between Lantheus and PharmaLogic Holdings Corp. (Mail Control Numbers 624028 and 624029)
NRC License Number: 52-25361-02 (Docket No.: 030-38114)
NRC License Number: 52-25361-01-MD (Docket No.: 030-34187)

Dear Administrator:

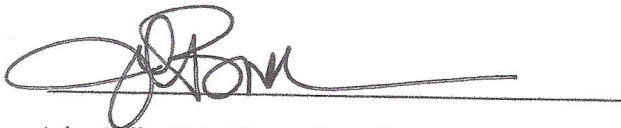
In follow up to the NRC's Acceptance of Notification of Indirect License Transfers dated January 26, 2021, the undersigned hereby confirm that the Securities Purchase Agreement transaction set forth in the filings and letters to the NRC dated December 10, 2020 and January 13, 2021 (the "Letters") has closed on the terms disclosed in such Letters. Following the closing of the transaction, Lantheus MI Radiopharmaceuticals, Inc. is the holder of both licenses referenced above (namely NRC License Number 52-25361-02 (formerly held by Lantheus Medical Imaging, Inc.) and NRC License Number 52-25361-01-MD (held by Lantheus MI Radiopharmaceuticals, Inc.) and is also a wholly-owned subsidiary of PharmaLogic Holdings Corp.

If you have any questions or comments or require additional information pertaining to this transaction, please contact Lantheus' counsel for nuclear regulatory matters, Laura Plourde at Laura.Plourde@Lantheus.com or 617-935-1543.

[Remainder of Page Left Blank/ Signature Pages Follows]

I declare under penalty of perjury under the laws of the United States of America that to the best of my knowledge the information contained in this Letter pertaining to Lantheus Holdings, Inc. and its affiliated companies is true and correct.

Executed on February 5, 2021

A handwritten signature in black ink, appearing to read 'JBolla', is written over a horizontal line.

John Bolla, Chief Operating Officer

Lantheus Holdings, Inc. and Lantheus Medical Imaging, Inc.

Address for Lantheus Holdings, Inc. and Lantheus Medical Imaging, Inc.:

331 Treble Cove Rd

Billerica, Ma 01862

I declare under penalty of perjury under the laws of the United States of America that to the best of my knowledge the information contained in this Letter pertaining to PharmaLogic Holdings Corp. and its companies (including Lantheus MI Radiopharmaceuticals, Inc.) is true and correct.

Executed on February 8, 2021

A handwritten signature in black ink, appearing to read 'Glen Palmer', is written over a horizontal line.

Glen Palmer, Chief Operations Officer
PharmaLogic Holdings Corp. and Lantheus MI Radiopharmaceuticals, Inc.