

Forster, Sara

From: Forster, Sara
Sent: Thursday, July 11, 2019 11:00 AM
To: Reid Gadziala
Subject: RE: Additional Information Request concerning Hot Shots Nuclear Medicine etc., Lic. Nos. 21-32812-01MD and 21-26597-01MD, CN611553 and CN611554

Dear Mr. Gadziala:

We are finishing up our review of the March 7, 2019 Transfer of Control (TOC) consent request for the referenced NRC Radioactive Materials licenses. The letter indicated that the TOC was anticipated to occur on or about June 3, 2019.

Could you please provide an update as to whether the transaction has already occurred? If so, could you please provide confirmation of the transaction, as requested previously? If not, could you please provide a new anticipated date on which you expect the TOC to occur?

You may attach a pdf file version of the scanned-in letter to an email message, and e-mail it directly to me. Upon receipt of the confirmation, we will continue our review. Do not hesitate to call or email me with any additional questions you might have.

Thank you very much!

Sara A. Forster, Health Physicist Licensing Reviewer

U.S. Nuclear Regulatory Commission - Region III

Division of Nuclear Materials Safety

2443 Warrenville Rd. - Ste. 210

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sara.forster@nrc.gov

Direct: (630) 829-9892

Facsimile: (630) 515-1078



From: Forster, Sara
Sent: Friday, May 10, 2019 12:03 PM
To: Reid Gadziala <rgadziala@pharmalogic.info>
Subject: RE: Transfer of Control application status - CN611553 and CN611554

Dear Mr. Gadziala:

This message is a follow-up to our conversation yesterday.

The Change of Ownership for Hot Shots Nuclear Medicine and CPI Pharmacy Services was removed from the public website on Wednesday, May 8th. The NRC received no notice of comments, and our office will be proceeding with completing the action – confirming NRC consent to the Transfer of Control. We will let you know – by email or by phone – whether anything else is needed to complete our review, in order to issue our formal written consent to the transaction.

Please note that, because the transferee (Pharmalogic) is an existing NRC licensee, with authorizations for the use of byproduct material that are similar to those that CPI and Hot Shots are authorized for, we do not anticipate any showstopping issues that would interfere with the action going through.

If the transaction is finalized prior to the NRC's issuance of our formal consent letter, please notify our office promptly, in writing, within 30 days of the transaction. Please include a signed copy of the acquisition agreement, confirming completion of the transaction, with your letter. With this confirmation, we may issue an administrative amendment to your NRC license to reflect the transaction, if necessary.

Please do not hesitate to contact me with any questions you may have.

Sincerely yours,

Sara A. Forster, Health Physicist Licensing Reviewer
U.S. Nuclear Regulatory Commission - Region III
Division of Nuclear Materials Safety
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From: Reid Gadziala [<mailto:rgadziala@pharmalogic.info>]
Sent: Thursday, May 09, 2019 1:43 PM
To: Forster, Sara <Sara.Forster@nrc.gov>
Subject: [External_Sender] Re: Re: Re: Transfer of Control application

Sara,

Thank you very much for letting me know. We can set up the call for Monday, but if you do get word before then, could you please let me know. You can call me any time.

I really appreciate it, as we are looking forward to completing the transfer and this is our last piece we are waiting on.

What time would be best for you on Monday?

Thank you,

Reid Gadziala

On Thu, May 9, 2019 at 2:01 PM Forster, Sara <Sara.Forster@nrc.gov> wrote:

Hi Mr. Gadziala:

I have noted that your notification has been removed from our website. However, I am waiting on final confirmation that there were no comments. I am expecting to receive that today, but it may not be till Monday. Would it be possible to plan a call for Monday 5/13?

Thank you,

Sara Forster

U.S. NRC

From: Reid Gadziala [mailto:rgadziala@pharmalogic.info]
Sent: Thursday, May 09, 2019 6:14 AM
To: Forster, Sara <Sara.Forster@nrc.gov>
Subject: [External_Sender] Re: Re: Transfer of Control application

Good morning Sara,

Are you available for a call today to discuss this transfer of control? What time would be best for you? The comment period has expired, so I wanted to confirm with you that we have not received any comments and have your approval to move forward.

Thank you very much,

Reid Gadziala, PharmD., BCNP, MBA

Pharmalogic Holdings Corp.

Director, Quality and Regulatory Affairs

(703) 851.3025

On Wed, Mar 27, 2019 at 8:22 AM Forster, Sara <Sara.Forster@nrc.gov> wrote:

I apologize... This hasn't been posted yet but we will get it posted before the end of this week.

Thank you,

Sara

From: Reid Gadziala [mailto:rgadziala@pharmalogic.info]
Sent: Wednesday, March 27, 2019 6:42 AM
To: Forster, Sara <Sara.Forster@nrc.gov>
Subject: [External_Sender] Re: Transfer of Control application

Good morning Sara,

I am checking in to see how the initial review of this application is going, as I have not been able to find it on the ADAMS posts yet. If I may have missed it, could you please send a link so I can keep track of it? Or, if it hasn't yet been posted, any idea when we can expect it to drop?

Just would like to keep everyone updated.

Thank you very much,

Reid Gadziala, PharmD., BCNP, MBA

Pharmalogic Holdings Corp.

Director of Operations

(703) 851.3025

On Thu, Mar 21, 2019 at 12:52 PM Forster, Sara <Sara.Forster@nrc.gov> wrote:

Dear Mr. Gadziala:

I am writing to confirm that we have reviewed the package submitted in support of requesting consent for NRC consent to Transfer of Control. At this time, it does not appear that we will need any additional information to complete our review. However, because the request must be posted to the NRC public website for at least 30 days, prior to us issuing our consent, we may not be able to issue our formal written consent and evaluation prior to the anticipated closing on 4/30/2019. If no comments are received prior to the close of the 30-day comment period, there should be no problem with your proceeding as planned, even if the formal consent is not issued. We will let you know if that happens. However, it is very unusual for our office to receive public comments on such a high-level indirect transfer of control; we are not expecting any such comments.

If you could resubmit your letter with your inquiry, and information concerning your points of contact, that is appreciated. You may submit the letter signed and dated as a pdf file, attached to an email.

We will let you know if anything else is needed to complete our review. Please don't hesitate to contact me should you have any questions concerning this message.

Sincerely,

Sara Forster

U.S. NRC

(630) 829-9892

From: Reid Gadziala [mailto:rgadziala@pharmalogic.info]
Sent: Thursday, March 21, 2019 10:24 AM
To: Forster, Sara <Sara.Forster@nrc.gov>
Subject: [External_Sender] Re: Re: Re: Transfer of Control application

Good morning Sara,

Please see the attached letter we discussed on our call yesterday regarding Pharmalogic closing on Hot Shots on April 30th. If you could please confirm receipt, and that you are OK with this proceeding on schedule. Paul Sale from Hot Shots will be following up with an email to you that all correspondence to Hot Shots should flow through him. Thank you so much for your assistance. If you have any questions or comments, please don't hesitate to reach out.

Reid Gadziala, PharmD., BCNP, MBA

Pharmalogic Holdings Corp.

Director of Operations

(703) 851.3025

On Wed, Mar 20, 2019 at 12:19 PM Forster, Sara <Sara.Forster@nrc.gov> wrote:

Ok. I will call you at 12:30 eastern (11:30 am central).

From: Reid Gadziala [mailto:rgadziala@pharmalogic.info]
Sent: Wednesday, March 20, 2019 11:16 AM
To: Forster, Sara <Sara.Forster@nrc.gov>
Subject: [External_Sender] Re: Re: Transfer of Control application

Good afternoon Sara,

No hurry, but I am now available for the rest of the afternoon, so whenever you'd like to give me a call would be great!

Reid Gadziala, PharmD., BCNP, MBA

Pharmalogic Holdings Corp.

Director of Operations

(703) 851.3025

On Wed, Mar 20, 2019 at 7:52 AM Forster, Sara <Sara.Forster@nrc.gov> wrote:

Great! I will call you at 2 pm eastern (1 pm central).

Sara Forster

U.S. NRC

From: Reid Gadziala [mailto:rgadziala@pharmalogic.info]

Sent: Tuesday, March 19, 2019 2:30 PM

To: Forster, Sara <Sara.Forster@nrc.gov>

Subject: [External_Sender] Re: Transfer of Control application

Thank you for getting back with me. I am free tomorrow after 2pm EST if that works for you. Please let me know.

Thanks again,

Reid Gadziala, PharmD., BCNP, MBA

Pharmalogic Holdings Corp.

Director of Operations

(703) 851.3025

On Tue, Mar 19, 2019 at 12:45 PM Forster, Sara <Sara.Forster@nrc.gov> wrote:

Dear Mr. Gadziala:

Thank you for the inquiry. Yes, I have been assigned the transfers for Pharmalogic. I am in meetings today. Are you available tomorrow (3/20) for a call? I will put you on my calendar and call you then.

Sara A. Forster, Health Physicist Licensing Reviewer

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From: Reid Gadziala [mailto:rgadziala@pharmalogic.info]
Sent: Tuesday, March 19, 2019 12:30 PM
To: Forster, Sara <Sara.Forster@nrc.gov>
Subject: [External_Sender] Transfer of Control application

Good afternoon Sara,

I left you a message yesterday regarding a transfer of control application I submitted last week. I was told that you were assigned these transfers. If you could, could you please give me a call to discuss these transfers. Just wanted to touch base with you over the phone. My cell phone number is 703.851.3025.

Thank you very much,

Reid Gadziala, PharmD., BCNP, MBA

Pharmalogic Holdings Corp.

Director, Quality and Regulatory Affairs

(703) 851.3025

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Reid Gadziala, PharmD., BCNP, MBA
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