

Forster, Sara

From: Forster, Sara
Sent: Tuesday, February 05, 2019 1:47 PM
To: Barth, Jessica P.
Cc: griffin.foster@FaegreBD.com; Xu, Le-Cun
Subject: RE: Change of ownership, Materials License No. 13-32212-01, Mail Control Number 610645

Dear Ms. Barth:

In addition to an update, could you please provide any insight you have into other radioactive materials licenses that are held by either Novartis AG, either directly or by one or more of its subsidiaries. Please include any radioactive materials licenses held not only by the U.S. NRC but also by any Agreement States (e.g. New Jersey, etc.) When responding, please provide the licensee name, the license number, the issuing jurisdiction, and the last inspection date (if known). If you could respond via a signed and dated letter, scanned in as a pdf file and attached to an email reply, that would be the most expedient.

Thank you,

Sara Forster
U.S. NRC

From: Forster, Sara
Sent: Tuesday, February 05, 2019 11:20 AM
To: 'Barth, Jessica P.' <Jessica.Barth@FaegreBD.com>
Subject: RE: Change of ownership, Materials License No. 13-32212-01, Mail Control Number 610645

Dear Ms. Barth:

Could you please provide an update to your response?

Thank you,

Sara Forster
U.S. NRC

From: Forster, Sara
Sent: Friday, January 04, 2019 9:27 AM
To: 'Barth, Jessica P.' <Jessica.Barth@FaegreBD.com>
Subject: RE: Change of ownership, Materials License No. 13-32212-01, Mail Control Number 610645

Dear Ms. Barth:

I agree that the description of our conversation, below, is accurate. I apologize for not replying prior to the planned closing of the transaction.

Could you please let me know whether the transaction has already occurred? If so, if you could send a signed and data letter including a signed copy of the merger agreement, confirming completion of the transaction. Just a letter from Endocyte is needed to transmit this information. You may submit that as a pdf file attached to an email. You may also send it via hardcopy mail or as a facsimile.

Please do not hesitate to call should you have any additional questions.

Sincerely,

Sara A. Forster, Health Physicist Licensing Reviewer

U.S. Nuclear Regulatory Commission - Region III

Division of Nuclear Materials Safety

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Lisle, IL 60532-4352

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Facsimile: (630) 515-1078



From: Barth, Jessica P. [<mailto:Jessica.Barth@FaegreBD.com>]

Sent: Tuesday, December 18, 2018 10:58 AM

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

Subject: [External_Sender] RE: Change of ownership, Materials License No. 13-32212-01, Mail Control Number 610645

Good morning Ms. Forster,

I just wanted to write to see if you would not mind confirming that the below description of our conversation reflected your understanding as well.

Also, would it be acceptable for the post-closing letter to come from Endocyte, or does Novartis need to sign in addition?

Thanks so much –
Jessica

Jessica P. Barth

Counsel

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Faegre Baker Daniels LLP

600 E. 96th Street | Suite 600 | Indianapolis, IN 46240, USA

From: Barth, Jessica P.

Sent: Thursday, December 13, 2018 1:30 PM

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

Cc: Foster, Griffin D. <griffin.foster@FaegreBD.com>

Subject: Change of ownership, Materials License No. 13-32212-01, Mail Control Number 610645

Dear Ms. Forster,

Thanks again for talking with Griffin and me today about the timing of Endocyte's indirect change of ownership. I am providing a summary of our conversation for your review; if the summary differs from your understanding, please let me know.

We discussed that the merger transaction described in the letter to NRC, dated November 28, 2018, is expected to close on December 21, 2018, during the required 30-day public comment period. You indicated that it was common for transactions to close prior to NRC issuing its final written consent, and that in cases where there are no or minor changes to the licensed program, so long as no safety concerns are present and the licensee is pursuing the proper process, NRC leaves it to the licensee's judgment whether to continue the licensed activities during the period between the consummation of the merger and the issuance of consent. NRC does not have an expectation that the licensed activities will cease during this period.

Once the merger transaction closes, you requested a letter confirming that fact along with an indication of any changes needed to the license and a certificate or other basic documentation of the merger. One follow-up question I have for you is whether the letter can come from just the licensee (Endocyte) or if both Endocyte's and Novartis's signatures are needed (as on the letter requesting approval).

Thanks again for all your help,
Jessica Barth

Jessica P. Barth

Counsel

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