

From: Kumar, Vasantha
To: [Denloye, Aderonke O \(Ade.Denloye@shire.com\)](mailto:Denloye.Aderonke.O@shire.com)
Cc: [Maruna, Thomas \(Thomas.Maruna@fda.hhs.gov\)](mailto:Maruna.Thomas@fda.hhs.gov)
Subject: FW: STN BL 125596/0 - Question regarding Lot Release- FDA response
Date: Wednesday, July 06, 2016 9:15:00 AM
Attachments: [Lot Release Letter Bundle 2014-OCT \(2\).pdf](#)

Dear Ms. Denloye,

I am writing on behalf of Thomas Maruna.

We have reviewed your questions in your email of June 24 and our responses to your questions are embedded in your email below in red.

Please let us know if you have any further questions.

Thanks
Vasantha

Vasantha Kumar, Ph.D.
U.S. Food & Drug Administration
CBER/OBRR
10903 New Hampshire Ave.
White Oak Building 71, Rm 4206
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From: Valencia, Iliana
Sent: Friday, June 24, 2016 4:16 PM
To: Denloye, Aderonke O
Cc: Cagungun, Nannette; Campbell, Karen M
Subject: RE: STN BL 125596/0 - Question regarding Lot Release

Dear Ms. Denloye,

Thank you. We will review your questions and get back to you as soon as we can.

Sincerely,

Iliana

240.402.8444

Iliana.valencia@fda.hhs.gov

From: Denloye, Aderonke O [<mailto:Ade.Denloye@shire.com>]
Sent: Friday, June 24, 2016 10:26 AM
To: Valencia, Iliana; Maruna, Thomas
Cc: Cagungun, Nannette; Campbell, Karen M
Subject: STN BL 125596/0 - Question regarding Lot Release

Dear Ms. Valencia & Thomas:

Hope this finds you doing very well. In SEQ 0026 Amendment submitted on 20 June 2016, Baxalta believes that the Lot Release Protocol (LRP) submitted represents the final LRP. As a result, we would like to clarify the following regarding lot release samples in anticipation for approval in September 2016:

§ Does FDA agree that we can now submit the LRP for IGSC, 20% Lots (b) (4) samples submitted in February 2016?

Yes, the LRP template submitted in amendment 125596/0.25, on 20-Jun-2016 is acceptable for use.

§ For future lot release, how many vials per lot are required?

Two vials per lot will be required.

§ For future lot release for the vials that will be submitted, should we follow the same process for labeling, packing and addressee requirements as was done for the samples submitted in February to Ms. Erin Kelly?

Please label samples at a minimum with the company name; name of product; lot number; and licensing number. If possible, it is helpful if the volume of product is listed as well. I have attached a Lot Release Letter Bundle which describes the information that needs to be submitted to the sample custodian for lot release.

The address for submitting samples is:

Food and Drug Administration

Center for Biologics Evaluation and Research

Sample Custodian

10903 New Hampshire Avenue

WO75-G707

Silver Spring, MD 20993-0002

§ What is the expected release timeframe once the samples are submitted?

Typically, within 45 days, from the date that the LRP for the lot is received.

§ Baxalta will be submitting some IGSC, 20% samples for lot release, our experience from previous lots in support of BLA/Supplements has been that the lots are released simultaneously with BLA/Supplement approval, does FDA concur with that?
Yes, providing samples and lot release protocols are submitted with enough time for testing and review of the protocol.

Thanks so much for your clarification and help in addressing these questions.

Best regards,

Aderonke Denloye, MPH

Associate Director, Global Regulatory Affairs

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Baxalta, now part of Shire

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