

(System Info - 233745 BERKHOUSEN KATHERINE 04/18/2013 16:34:11
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RECORD OF EMAIL CONVERSATION

Submission Type: BLA Submission ID: 125428/0 Office: OVRR

Product: Hepatitis B Vaccine (Recombinant), Adjuvanted

Applicant: Dynavax Technologies Corporation

Email Date/Time: 17-Apr-2013 2:26 PM Initiated by FDA? Yes

Telephone Number:

Communication Category(ies): Other - CR Letter clarification of CMC comments

Author: KATHERINE BERKHOUSEN

Telecon Summary:

CBER response to sponsor questions regarding several CMC comments found in the February 22, 2013 CR letter.

FDA Participants: Katherine Berkousen, Dick Daemer, Marian Major

Non-FDA Participants: William Turner, Elaine Alambra

Trans-BLA Group: No

Related STNs: None

Related PMCs: None

Telecon Body:

Dynavax emailed us on April 9, 2013 to 1) state that they plan to submit a new meeting request in response to CBER's Type A meeting denial, 2) as a follow up to the CMC questions asked in the initial Type A Meeting Request dated March 11, 2013, and 3) to ask for clarification of CMC comments in the CR Letter (CRL) which Dynavax believes they previously responded to as part of an information request in amendment #18, dated Nov 12, 2012.

CBER responded to item 2 above in a telecon dated April 11, 2013. CBER provides a response to item 3 above regarding Dynavax's request for additional CRL item clarification:

Regarding CRL Item No. 11: The reagents and samples requested by CBER in the October 15, 2012 teleconference were received. The lots sent could not be released because your facility/process issues were not resolved by the action due date. We anticipate that we will need new samples of conformance lots if you intend to distribute

at some future date and we may possibly require new or additional reagents. With most of the products that use reagents made or qualified by a manufacturer, we need to request new reagents or requalification documents every 1 to 2 years, depending on expiry dates. We anticipate that it will take some time to get to the point of final testing. When you are in a position to submit new samples of conformance lots please contact CBER so that we can ensure we have the appropriate reagents and samples in house for all necessary testing.

Regarding CRL items 12a, 15b and d, 17 d, e, and g, 18 e, f, and k, 19, 20 a, b, and c, 21 b, c, and d, 22 i, ii, , 23a and b, and 24 a, c, and d: In your complete response you may cross reference to amendment 125428/0.18 submitted on November 12, 2012 regarding these items.

From: Turner, William [<mailto:wturner@dynavax.com>]
Sent: Tuesday, April 09, 2013 12:22 PM
To: Daemer, Richard J.; Berkhausen, Katherine
Cc: Major, Marian; Alambra, Elaine
Subject: Dynavax - CRL follow-up

Dear Dick and Katherine,

In follow up to our 14 March telecom, I wanted to send you a note that we plan to re-submit the meeting request/briefing document tomorrow. In that telecom, CBER stated that the CMC questions in the 11 March 2013 Meeting Request had been distributed for review and that Dynavax would receive a written response. Can you update us on the status of the review of those two questions?

In addition, there are several CMC questions that were previously asked and responded to as a part of the Information Request cycle. Several of these responses were prior to the 29 December 2012, 15 January 2013, 01 February 2013, and the 17 February 2013 amendments that CBER acknowledged in the CRL would need to be referenced. Dynavax needs guidance as to whether these questions were asked again because our original responses were inadequate. Please note, some of the questions were re-asked with slight modifications, however, some of the questions were re-asked verbatim. If helpful, Dynavax can provide a table of those CRL items in question.

Thank you,
Bill

*William Turner
Vice President
Regulatory Affairs*