

RECORD OF EMAIL CONVERSATION

Submission Information

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| Application Type | BLA |
| STN | 125428/0.0 |
| Review Office | OVRR |
| Applicant | Dynavax Technologies Corporation / Lic. # 1883 |
| Product | Hepatitis B Vaccine (Recombinant), Adjuvanted |
| Trans-BLA Group: | No |

Telecon Details

| | |
|---------------------------------|--|
| Telecon Date/Time | 16-JUN-2016 11:36 AM |
| Author | CHOUDHARY, ANIL |
| EDR | Yes |
| Post to Web | No |
| Outside Phone Number | No |
| FDA Originated? | Yes |
| Communication Categories | IR - Information Request |
| Related STNs | None |
| Related PMCs | None |
| Telecon Summary | IR related to May 24th request; documents not in English, missing documents, missing expiry dates for reagents |
| FDA Participants | Katherine Berkousen |
| Applicant Participants | Elaine Alambra |

Telecon Body:

From: Berkousen, Katherine
Sent: Thursday, June 16, 2016 11:36 AM
To: 'Elaine Alambra'

RECORD OF EMAIL CONVERSATION

Cc: Daemer, Richard J.; Major, Marian

Subject: RE: HEPLISAV: Biologics License Application: STN 125428 / IR 5 24May2016

Dear Elaine,

We received your response to our May 24, 2016 information request for reagents, standards and controls associated with different analytical methods. Your email to Dr. Anil Choudhary (below) had 17 requalification certificates attached but the appendices of DUS-SOP-QC-0089-09 including the validated worksheet for the calculation of potency **were not found attached** to this email. Additionally, all the 17 documents are in German.

We request the following be provided to us:

- 1) all documents translated into English.
- 2) the appendices of DUS-SOP-QC-0089-09 including the validated worksheet for the calculation of potency
- 3) the expiry dates for all the reagents as none of the reagents have any assigned expiry date to them

Kind regards,
Katherine Berkhausen

From: Elaine Alambra [<mailto:EAlambra@dynavax.com>]

Sent: Thursday, June 16, 2016 10:11 AM

To: Berkhausen, Katherine

Cc: Daemer, Richard J.; Campbell, Karen M

Subject: HEPLISAV: Biologics License Application: STN 125428 / IR 5 24May2016

Dear Katherine,

This is a courtesy copy of part of the shipment of samples/reagents/standards and documents as requested in the *Information Request* dated 24 May 2016.

Please let me know if you have any questions.

Kind regards,

Elaine

Elaine Alambra • Regulatory Affairs • Dynavax Technologies Corporation ☎ Tel: 510-665-0474 ✉ email: ealambra@dynavax.com

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From: Melanie Billens [<mailto:MBillens@dynavax.com>]

Sent: Thursday, June 16, 2016 7:46 AM

To: Choudhary, Anil

Cc: Regina Schroetel; Campbell, Karen M; Elaine Alambra; Annette Hillebrand

Subject: Biologics License Application: STN 125428 / IR 5 24May2016

Biologics License Application: STN 125428

Product Name: HEPLISAV

BLA Sponsor: Dynavax Technologies Corporation

License #: 1883

Dear Mr. Choudhary,

In response to your request to Dynavax Technologies Corporation regarding reagents, standards and controls associated with different analytical methods, in a first shipment we are providing you with the materials listed below. The materials were picked up yesterday by (b) (4), the tracking # is **490293215**. Estimated arrival time is Monday afternoon, 20.Jun.2016.

(b) (4)

RECORD OF EMAIL CONVERSATION

Further, hard copies of the following documents are provided:

- Requalification report for (b) (4)
- Requalification report for (b) (4)
- Requalification report for (b) (4)
- Requalification report for (b) (4)
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- Requalification report for (b) (4)
- Requalification report for (b) (4)
- Qualification report for (b) (4)
- Qualification/Requalification reports for (b) (4)
- Preparation protocol DUS-PP-0384-02 (Vaccine Diluent)
- Preparation protocol PP228-03 (b) (4) (Formulation buffer for (b) (4))
- DUS-SOP-QC-0204-01 (b) (4)
- DUS-SOP-QC-0089-09 In vivo Potency Assay Part III: Measurement of titers

Please note that the requalification for quality control sample (b) (4) is due on 10.Jul.2016, we will send you an electronic copy of the requalification report once it has been approved.

Electronic copies of the abovementioned documents plus the appendices of DUS-SOP-QC-0089-09 including the validated worksheet for the calculation of potency are attached to this email.

A second shipment including the (b) (4) test kits will be sent next week, we will update you on the shipment details.

If you have any questions regarding this shipment, please do not hesitate to contact me.

Sincerely,



RECORD OF EMAIL CONVERSATION

Melanie Billens
QA Manager

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