

RECORD OF TELEPHONE CONVERSATION

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

Product:
Hepatitis B Vaccine (Recombinant), Adjuvanted

Applicant:
Dynavax Technologies Corporation

Telecon Date/Time: 15-Oct-2012 11:00 AM Initiated by FDA? no

Telephone Number:

Communication Categorie(s):
1. Advice

Author: KAREN CAMPBELL

Telecon Summary:
To discuss the sample and reagent request for STN 125428.

FDA Participants:

Karen Campbell, Marian Major, Destry Sullivan, Katherine Berkousen, Muhammad Shahabuddin, Lokesh Bhattacharyya, Alfred Del Grosso, Anil Choudhary, William McCormick, Richard Daemer, Catherine Poole

Non-FDA Participants: William Turner, Stephen Tuck, Martin Gohlke, Marina Chan, Jeanne Bonelle, Elaine Alambra

Trans-BLA Group: No

Related STNs: None

Related PMCs: None

Telecon Body:

Agenda

1. Clarify the number of samples
2. Discuss testing plans
3. Confirm reagent requests
4. Discuss potential additional requests (columns etc...)

Meeting Discussion

I. Samples Requested

200 FC vials of 3 conformance launch lots were requested for CBER in-support testing. Dynavax can provide the requested samples from three conformance lots and is prepared to do so.

Dynavax asked if 200 FC vials would be requested for commercial release lots and, if so, they would like to negotiate that number. Their batch size is (b) (4) and they require only (b) (4) vials for testing. CBER informed them that they would discuss the issue internally and would let them know how many would be needed at a later time. Dynavax is prepared to send 200 for the in-support testing.

Samples will be sent to the Sample Custodian with a concurrent testing letter. DBSQC reminded Dynavax to check the For Licensing box and to provide the STN number on the concurrent testing form. The concurrent testing form should be sent with the samples. Dynavax asked about sending the lot release protocol with the lots. DBSQC told them to send the lot release protocol template when it would be ready and not to send it for these lots until they got comments back from us on it.

Dynavax plans to send the samples from the three conformance lots the week of 22Oct12.

Dynavax is anticipating (b) (4) batches for release / year but can provide more accurate numbers as review process moves forward.

II. Reagents Requested

Dynavax may not be able to provide the aliquot size or dilution requested but can provide sufficient reagents for the specified number of assays (with exceptions noted below). Dynavax asked if this would be acceptable. CBER agreed that it was acceptable.

Dynavax is qualifying new lots for standards/reagents that were depleted during their testing. Some of the reagents/standards sent will not be the same lot that was used during their testing. CBER agreed that this was OK.

1. Determination of HBsAg Identity and (b) (4) for HEPLISAV Drug Product
 - a. Qualified Anti-HBsAg (b) (4) – Dynavax has no problems providing requested amount.
 - b. Qualified Anti-HBsAg (b) (4) – Dynavax can only provide sufficient reagent for (b) (4) assays. DBSQC agreed that this was OK.
 - c. Qualified HBsAg Standard – Dynavax has no problems providing the requested amount.
 - d. Qualified HBsAg Quality Control Sample – Dynavax has no problem providing the requested amount.
2. Potency Assay – *in-vivo*

- a. Qualified Immunoassay Test Kit for detection of anti-HBsAg antibodies – (b) (4). Dynavax uses the kit sold in Europe and can provide CBER with the kits sold in Europe. Dynavax recommended using the European kit. Dynavax does not qualify these kits. The expiry date of the kits is 1 year. There are currently 5 kits available from their European site. Dynavax asked if CBER would like them to send the 5 kits and DBSQC replied that Dynavax could supply the 5 kits.
 - b. Qualified Potency HBsAg Standard – Dynavax can provide sufficient reagent for (b) (4) assays. DBSQC agreed that this was OK.
 - c. Qualified (b) (4) – Dynavax can provide sufficient reagent for (b) (4) assays. DBSQC agreed that this was OK.
3. Determination of (b) (4) of HBsAg in HEPLISAV Drug Product by (b) (4)
 - a. HBsAg Reference Standard – Dynavax has no problem providing the requested amount.
 4. HBsAg Concentration by (b) (4) Assay
 - a. HEPLISAV system suitability/ assay control – Dynavax has no problem providing the requested amount.
 - b. (b) (4) to be used as a blank sample – Dynavax has no problem providing the requested amount.
 5. 1018 ISS Adjuvant Identity by (b) (4)
 - a. Reference material containing 1018 ISS from lyophilized material – Dynavax has no problem providing the requested amount.
 - b. System suitability sample – Dynavax has no problem providing the requested amount.

Reagents will be sent to Karen Campbell. The shipment is scheduled for the week of 29Oct12.

Marian Major informed Dynavax that CBER would be requesting new conformance lots to be made once the cleaning validation had been approved by Destry Sullivan. Dynavax was not aware of this and would like to discuss further with Marian and Destry. DBSQC requested to be kept updated as this impacts testing.

Dynavax asked CBER how they determined if the assay transfer would be successful. DBSQC responded that there would be three criteria 1) no issues with the performance of the assay – if there were issues, Dynavax would be contacted to resolve 2) system suitability criteria for all 3 lots would meet and 3) results for all 3 lots would be within specifications.

Dynavax asked CBER if there were any other supplies or equipment that they would like to have provided. DBSQC responded that none are needed at this time, but if anything would come up CBER would discuss it with them.

DBSQC signed off the conference all to allow Dynavax, Marian and Destry to further discuss the conformance lots. DBSQC requested to be updated regarding the outcome of the discussion.