

(System Info - 214359 DAEMER RICHARD 09/27/2012 11:37:17 DAEMER)

RECORD OF TELEPHONE CONVERSATION

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

Product:
Hepatitis B Vaccine (Recombinant)

Applicant:
Dynavax Technologies Corporation

Telecon Date/Time: 26-Sep-2012 10:00 AM Initiated by FDA? Yes

Telephone Number:

Communication Categorie(s):
1. Information Request

Author: RICHARD DAEMER

Telecon Summary:
Information Request concerning Dynavax request to remove certain tests

FDA Participants: Richard DaemerNone

Non-FDA Participants: Elaine Alambra, William TurnerNone

Trans-BLA Group: No

Related STNs: None

Related PMCs: None

Telecon Body:
We are sending the following Information Request:

1. CBER agrees with your proposal to remove the following tests as release tests for 1018 ISS:

(b) (4)

2. CBER agrees with your proposal to remove the following tests from the stability plan for 1018 ISS:

(b) (4)

3. CBER agrees with your proposal to remove the following tests from the stability plan for the HBsAg Drug Substance:

(b) (4)

4. CBER agrees with your proposal to remove the following tests from the stability plan for the HEPLISAV Drug Product:

(b) (4)

5. CBER does not agree with your proposal to remove (b) (4) to calculate the amount of 1018ISS relative to reference as a release test for 1018 ISS. Please provide the method validation protocol and report for the analytical method used for this test. As previously noted in Information Request # 6 sent to you on August 16, the validation report for this test, which was submitted in the BLA was not acceptable and CBER does not consider that this test was adequately validated.
6. CBER does not agree with your proposal to remove the General Safety test as a release parameter for HEPLISAV Drug Product. Please provide the method validation protocol and report for this method. If the test has been modified, please provide details on the test procedure, justification for the use of a reduced dose in guinea pigs, details on the titration studies used to determine the acceptable dose in these animals and the number of lots used for the studies. Please provide the results from all lots tested.
7. CBER does not agree with your proposal to remove the following tests from the stability plan for 1018 ISS:

(b) (4)

Please submit a revised stability plan for the adjuvant that includes these tests.

8. CBER does not agree with your proposal to remove the following tests from the stability plan for the HBsAg Drug Substance:

(b) (4)

Please submit a revised stability plan for the Drug Substance that includes these tests.

9. CBER does not agree with your proposal to remove the following tests from the stability plan for the HEPLISAV Drug Product:

pH

Particle size
1018 ISS adjuvant content
HBsAg concentration
HBsAg (b) (4)

Please submit a revised stability plan for the Drug Product that includes these tests.

10. Please include into the HBsAg Drug Substance Commercial Release Specification the following tests:

(b) (4)

A large rectangular area of the document is redacted with a grey box. The redaction covers several lines of text, likely detailing the tests mentioned in the previous paragraph.

Please submit the test procedures, method validation protocols, validation reports and SOPs to the BLA for review. Method validation may not be required if compendial method is used for the measurement of (b) (4)

11. Please include into the HEPLISAV Drug Product Commercial Release Specification the following test:

(b) (4)

Please submit the test procedure, method validation protocol, validation report and SOP to the BLA for review.

[Enter details of telecon here]