

(System Info - 206565 DAEMER RICHARD 07/19/2012 15:06:30 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: 12-Jul-2012 10:36 AM Initiated by FDA? Yes

Telephone Number:

Communication Categorie(s):
1. Information Request

Author: RICHARD DAEMER

Telecon Summary:
Request for validation reports, sterility results, and release testing clarification

FDA Participants: None

Non-FDA Participants: None

Trans-BLA Group: No

Related STNs: None

Related PMCs: None

Telecon Body:
INFORMATION REQUEST

1. HEPLISAV Bioburden Validation Report, DYN-QCMic QBA061HEPLISAV_MVR_v1.0, for (b) (4) is missing. Please provide.
2. According to document 3.2.P.3.3, Description of Manufacturing Process and Process Controls and Figure 3.2.P.3.3.8, Comparison of (b) (4) Process, during (b) (4) production process, bioburden test will be performed (b) (4) followed by release sterility on final containers. However in HEPLISAV drug product (b) (4) process validation report, bulk sterility results (b) (4) are missing and only release testing (final container sterility) under section 8, Release, are provided. Please provide bulk

sterility results, unless there is consideration of the new sterility testing rule for not providing the results.

3. Under section 2.4, Observations and Deviations, of HEPLISAV Sterility Validation Report, DYN-QCMic QBA041 HEPLISAV_MVR_v1.0, please clarify the statement "...recommended (b) (4) vials for release testing have to be tested in a (b) (4)-fold determination" and explain how this will be performed.