

Our STN: BL125737/0

**LATE-CYCLE  
MEETING MEMORANDUM**

VBI Vaccines (Delaware) Inc.  
Attention: Norman W. Baylor, Ph.D.  
Biologics Consulting Group, Inc. (Authorized U.S. Agent)  
1555 King Street, Suite 300  
Alexandria, VA 22314

Dear Dr. Baylor:

Attached is a copy of the memorandum summarizing your September 2, 2021 Late-Cycle Meeting teleconference with CBER. This memorandum constitutes the official record of the meeting teleconference. If your understanding of the meeting teleconference outcomes differs from those expressed in this summary, it is your responsibility to communicate with CBER in writing as soon as possible.

Please include a reference to the appropriate Submission Tracking Number (STN) in future submissions related to the subject product.

If you have any questions, please contact Paul Keller (email: [Paul.Keller@fda.hhs.gov](mailto:Paul.Keller@fda.hhs.gov)) or Katherine Berkhausen (email: [Katherine.Berkhausen@fda.hhs.gov](mailto:Katherine.Berkhausen@fda.hhs.gov)).

Sincerely,

Doran Fink, MD, PhD  
Deputy Director - Clinical  
Division of Viral Products and Related Product  
Applications  
Office of Vaccines Research and Review  
Center for Biologics Evaluation and Research

### Late-Cycle Meeting Summary

**Meeting Date:** September 2, 2021

**Meeting Location:** Teleconference

**Application Number:** 125737/0

**Product Name:** Hepatitis B Vaccine (Recombinant)

**Proposed Indications:** Prevention of infection caused by all known subtypes of the hepatitis B virus in adults 18 years and older

**Applicant Name:** VBI Vaccines (Delaware), Inc.

**Meeting Chair:** Paul Keller, PhD

**Meeting Recorders:** Paul Keller, PhD; Katherine Berkhausen

#### FDA ATTENDEES

Sudhakar Agnihothram, PhD	CBER/OVRR/DVRPA/RRB2
Marie Anderson	CBER/OCBQ/DCM/BDDCB
Noel Baichoo, PhD	CBER/OCBQ/DBSQC
Katherine Berkhausen	CBER/OVRR/DVRPA/RRB2
Dennis Cato	CBER/OCBQ/DIS/BMB
Maryna Eichelberger, PhD	CBER/OCBQ/DBSQC
John Eltermann, PhD	CBER/OCBQ/DMPQ
Darcie Everett, MD, MPH	CBER/OVRR/DVRPA/CRB2
Meghan Ferris, MD, MPH	CBER/OVRR/DVRPA/CRB2
Timothy Fritz, PhD	CBER/OVRR/DVRPA/RRB2
Sara Gagneten, PhD	CBER/OVRR/DVP
Margaret Gomez-Lorenzo, MD	CBER/OBE/DE/AEB
Marion Gruber, PhD	CBER/OVRR
Jie He, PhD	CBER/OCBQ/DMPQ/BII
Lei Huang, PhD	CBER/OBE/DB/VEB
Andrea Hulse, MD	CBER/OVRR/DVRPA/CRB2
Bhanu Kannan	CBER/OCBQ/DIS/BMB
Paul Keller, PhD	CBER/OVRR/DVRPA/RRB2
Jennifer Kirk, PhD	CBER/OBE/DB/VEB
Tsai-Lien Lin, PhD	CBER/OBE/DB/VEB
Anthony Lorenzo	CBER/OCBQ/DMPQ/BII
Marian Major, PhD	CBER/OVRR/DVP/LHV
Loris McVittie, PhD	CBER/OVRR/DVRPA
Manette Niu, MD	CBER/OBE
Rakesh Pandey, PhD	CBER/OVRR/DVRPA/RRB2

Twanda Scales	CBER/OCBQ/DCM/APLB
Daphne Stewart	CBER/OVRR/DVRPA/RMSB
Lauren Siltz, PhD	CBER/OVRR/DVP/LHV
Lisa Stockbridge, PhD	CBER/OCBQ/DCM/APLB
Ching-Long Sun, PhD	CBER/OVRR/DVRPA/TOX
Konstantin Virnik, PhD	CBER/OVRR/DVRPA/RRB2

## APPLICANT ATTENDEES

Francisco Diaz-Mitoma MD	(Chief Medical Officer, VBI Vaccines Inc.)
Jeff Baxter	(President and Chief Executive Officer, VBI Vaccines B.V)
Vlad Popovic, MD	(VP, Clinical Development and Medical Affairs, VBI Vaccines Inc.)
Tehseen Salimi	(Vice President, Medical Affairs, VBI Vaccines Inc.)
Johanna Spaans	(Director, Regulatory Affairs, North America, VBI Vaccines Inc.)
Nathalie Machluf	(VP, Regulatory Affairs, Europe & ROW, SciVac Ltd./VBI Vaccines Inc.)
Avi Mazaltov	(SciVac General Manager and Head of Global Manufacturing)
Doug Chambers	(QA VP, SciVac Ltd).
Oren Milani	(QA Director, SciVac Ltd).
Nell Beattie	(Chief Business Officer, VBI Vaccines Inc.)
Misha Nossov	VP, Market Access and Commercial, VBI Vaccines Inc.)
Alka Chaudhari	(Project Manager-Regulatory Affairs, VBI Vaccines Inc.)
Christina Vessely	(CMC, Biologics Consulting Group, Inc.)
Vince Narbut	(CMC, Biologics Consulting Group, Inc.)
Kelly Reich	(Regulatory Project Manager, US Agent, Biologics Consulting Group, Inc.)

## BACKGROUND

BLA 125737/0 was submitted on November 30, 2020, for Hepatitis B Vaccine (recombinant).

Proposed indication: Prevention of infection caused by all known subtypes of the hepatitis B virus in adults 18 years and older.

PDUFA goal date: November 30, 2021.

In preparation for this meeting, FDA issued the Late-Cycle Meeting Materials on August 24, 2021.

## DISCUSSION

### 1. Discussion of Substantive Review Issues

At this time CBER does not have any substantive review issues to discuss.

### 2. Information Requests (IR)

One IR was outstanding at the time the agenda was communicated:

- IR #16: August 11, 2021; regarding *in vivo* potency assay – response expected by September 6, 2021.

Two IRs were issued after the meeting agenda was finalized, but before the Late-Cycle Meeting teleconference was held:

- August 31, 2021; DMPQ IR including 5 items relating to Media Fill Studies and Shipping Validations; response expected by September 13, 2021
- August 31, 2021; IR regarding low number of postmarketing reports available between 2016 and 2021; response expected by September 7, 2021.

### 3. Risk Management Actions

CBER has not identified any issues related to risk management. We do not believe that a risk management action is needed at this time.

### 4. Postmarketing Requirements/Postmarketing Commitments

CBER intends to communicate to the applicant regarding Post Marketing Requirements by October 31, 2021.

### 5. Major Labeling Issues

The package insert, carton and container labels are being reviewed. CBER is working towards providing labeling comments before October 31, 2021.

### 6. Review Plans

CBER intends to take action on this application no later than November 30, 2021.

### 7. Applicant Questions

Applicant questions were addressed by email prior to the meeting. The applicant indicated that CBER's responses were clear and that they did not have any additional questions for discussion.

### 8. Wrap-up and Action Items

CBER intends to communicate regarding Post Marketing Requirements by October 31, 2021.

CBER intends to provide labeling comments before October 31, 2021.

CBER intends to take action on this application no later than November 30, 2021.

This application has not yet been fully reviewed by the signatory authorities, Division Directors and Review Committee Chair and therefore, this meeting did not address the final regulatory decision for the application.