



Our STN: BL **125597/0**

Pax Vax Bermuda Ltd.
Attention: Mr. Mark Metlz
Clarendon House
2 Church Street
Hamilton, Bermuda HM 11

Dear Mr. Meltz:

Attached is a copy of the memorandum summarizing your March 31, 2016, Late-Cycle teleconference with CBER. This memorandum constitutes the official record of the teleconference. If your understanding of the 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 Dr. Kelsy Hoffman or Ms. Christina Houck at 301-796-2640.

Sincerely Yours,

Wellington Sun, M.D.
Director
Division of Vaccines and
Related Products Applications
Office of Vaccines
Research and Review
Center for Biologics
Evaluation and Research

Late-Cycle Meeting Summary

Meeting Date and Time: March 31, 2016 at 11:30AM-1:00PM EST
Meeting Location: Teleconference

Application Number: 125597/0
Product Name: Vaxchora®, Cholera Vaccine, Live, Oral
Proposed Indications: Active immunization against disease caused by *V. cholerae* serogroup O1 in adults 18 years of age and older

Applicant Name: PaxVax Bermuda Limited
Meeting Chair: Goutam Sen, Ph.D.
Meeting Recorder: Kelsy Hoffman, Ph.D.

FDA ATTENDEES

Sang Ahnn, Ph.D., Biostatistics Reviewer, DB/OBE
Marie Anderson, Ph.D., M.S., Quality Control Reviewer (LRP, Testing), DBSQC/OCBQ
Deepa Arya, M.D., M.P.H., M.B.A., Epidemiology Reviewer, DE/OBE
Lokesh Bhattacharyya, Ph.D., Chief, LACBRP/DBSQC
Jennifer Bridgewater, M.P.H., Associate Director for Regulatory Policy, DBPAP/OVRR
Drusilla Burns, Ph.D., Deputy Division Director, DBPAP/OVRR
CAPT Jon Daugherty, Ph.D., Regulatory Review Branch I Chief, DVRPA/OVRR
Alfred Del Grosso, Ph.D., Product/CMC Reviewer, DBSQC/OCBQ
Nicolette deVore, PhD, Senior Scientist and Project Manager for Counterterrorism and Emerging Threats Preparedness, IOD/CBER
Christine Drabick, M.S., BiMo Reviewer, DIS/OCBQ
Oluchi Elekwachi, Pharm.D., M.P.H., Advertising and Promotional Labeling Reviewer, DCM/OCBQ
Karen Farizo, M.D., Associate Director for Medical Policy and Vaccine Safety, OVRR
Theresa Finn, Ph.D., Associate Director for Regulatory Policy, OVRR
Marion Gruber, Ph.D., Director, OVRR
Erik Henchal, Ph.D., Associate Director for Management and Scientific Affairs, OVRR
LCDR Kelsy Hoffman, Ph.D., Regulatory Project Manager, DVRPA/OVRR
Patricia Holobaugh, M.S., Branch Chief, DIS/OCBQ
Dale Horne, Ph.D., Vaccine Evaluation Branch Chief, DB/OBE
Simleen Kaur, M.S., Quality Control Reviewer (Microbiology), DBSQC/OCBQ
CAPT Craig Zinderman, M.D., M.P.H., Associate Director for Product Safety, DE/OBE
Loris McVittie, Ph.D., Deputy Director, DVRPA/OVRR
Tina Khoie Mongeau, M.D., M.P.H., Medical Officer, DVRPA/OVRR
Laurie P. Norwood, Ph.D., Deputy Director, DMPQ/OCBQ
Manuel Osorio, Ph.D., Serology Assay Reviewer, DBPAP/OVRR
Roger Plaut, Ph.D., CMC Reviewer, DBPAP/OVRR
David Rouse, MS, Senior Scientist for Counterterrorism and Emerging Threats Preparedness, IOD/CBER
Goutam Sen, Ph.D., Chair, DVRPA/OVRR

Jay Slater, M.D., Director, DBPAP/OVRR
LCDR Matthew Steele, Ph.D., Regulatory Review Branch I Acting Team Leader,
DVRPA/OVRR
Scott Stibitz, Ph.D., Laboratory Chief, DBPAP/OVRR
Wellington Sun, M.D., Director, DVRPA/OVRR
Deborah Trout, Manufacturing Team Leader, DMPQ/OCBQ
Freyja Williams, B.S., Consultant Serology Assay Reviewer, DBPAP/OVRR
Lihan Yan, Ph.D., Statistical Team Leader, DB/OBE

EASTERN RESEARCH GROUP (ERG) ATTENDEES

Christopher Sese, Contractor, Eastern Research Group

APPLICANT ATTENDEES

Grace Benedict, Director Regulatory Affairs
Fiona Cameron, Regulatory Affairs Consultant
Lisa Danzig, VP Clinical Development and Medical Affairs
Martin Dearden, Vice President Quality
Marc Gurwith, Chief Medical Officer
Volker Niedan, Head Quality Control
Amish Patel, Director Product Development
Paul Shabram, Vice President Operations
Jon Smith, Chief Scientific Officer
Tom Yonker, Vice President Project Management

BACKGROUND

BLA 125597/0 was submitted on October 16, 2015, for Vaxchora, Cholera Vaccine, Live, Oral

Proposed indication(s): Active immunization against disease caused by *V. cholerae* serogroup O1 in adults 18 years of age and older

PDUFA goal date: June 15, 2016

In preparation for this meeting, FDA issued the Late-cycle Meeting Materials on March 18, 2016.

DISCUSSION

1. Discipline Review Letters

No Discipline Review letters have been issued to date.

2. Substantive Review Issues to be discussed during the LCM

There are no substantive review issues for discussion for the following disciplines: Chemistry, Manufacturing and Controls (CMC), Clinical and Statistical.

For inspections: Inspections are ongoing. A final recommendation is pending at this time.

Amendment: There are no current amendments related to a substantive review issue.

3. Advisory Committee Meeting

An Advisory Committee meeting is not planned.

4. Risk Management Actions (e.g., REMS)

We have not identified any issues related to risk management. At this time we do not believe that a risk management action (e.g., REMS) is needed.

LCM AGENDA

1. Introductory Comments (CBER-RPM/Chair)

Welcome, Introductions, Objectives of the meeting

2. Discussion of Substantive Review Issues

No substantive review issues have been identified to date for discussion.

3. Information Requests (IR's)- Information requests sent, for which a response has not yet been received:

A. CMC IR sent February 26, 2016

B. CMC IR sent March 25, 2016

4. Postmarketing Requirements/Postmarketing Commitments

We anticipate the necessity for one or more Postmarketing Requirements.

5. Major labeling issues

No labeling issues have been identified at this time.

CBER stated that labeling comments will be communicated to PaxVax prior to May 15, 2016.

6. Review Plans

- a. First Labeling Comments to Applicant: May 15, 2016
- b. Action Due: We will take action on this application no later than June 15, 2016

7. Applicant Questions

On March 28, 2016, Pax Vax Bermuda Limited confirmed that they have no questions or discussion items for this meeting.

8. Wrap-up and Action Items

No additional discussion occurred during this meeting.

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.