Our STN: BL 125597/123

SUPPLEMENT APPROVAL
[PMR/PMC FULFILLED]

Emergent Travel Health, Inc.
Attention: Suzanne Kiani
300 Professional Drive
Gaithersburg, MD 20879

December 23, 2020

Dear Ms. Kiani:

We have approved your request submitted March 31, 2020, received April 1, 2020, to supplement your Biologics License Application (BLA) under section 351(a) of the Public Health Service Act for Cholera Vaccine, Live, Oral (Vaxchora), manufactured at your (b) (4), location, to expand the usage to include children 2 to <18 years of age.

The review of this supplement was associated with the following National Clinical Trial (NCT) number(s): NCT03220737.

LABELING
We hereby approve the draft package insert labeling submitted under amendment #19, dated December 7, 2020, and the draft carton and container labeling submitted under amendment #6, dated August 28, 2020.

CONTENT OF LABELING

As soon as possible, but no later than 14 days from the date of this letter, please submit the final content of labeling (21 CFR 601.14) in Structured Product Labeling (SPL) format via the FDA automated drug registration and listing system, (eLIST) as described at http://www.fda.gov/ForIndustry/DataStandards/StructuredProductLabeling/default.htm. Information on submitting SPL files using eLIST may be found in the guidance for industry *SPL Standard for Content of Labeling Technical Qs and As* at http://www.fda.gov/downloads/Drugs/GuidanceComplianceRegulatoryInformation/Guidances/UCM072392.pdf.

The SPL will be accessible via publicly available labeling repositories.

PACKAGE AND CONTAINER LABELS

Please electronically submit final printed package and container labels that are identical to the package and container labels submitted on August 28, 2020, according to the guidance for industry *Providing Regulatory Submissions in Electronic Format — Certain Human Pharmaceutical Product Applications and Related Submissions Using the eCTD Specifications* at https://www.fda.gov/regulatory-information/search-fda-guidance-

documents/providing-regulatory-submissions-electronic-format-certain-human-pharmaceutical-product-applications.

All final labeling should be submitted as Product Correspondence to this BLA 125597 at the time of use (prior to marketing) and include implementation information on Form FDA 356h.

ADVERTISING AND PROMOTIONAL LABELING

You may submit two draft copies of the proposed introductory advertising and promotional labeling with Form FDA 2253 to the Advertising and Promotional Labeling Branch at the following address:

Food and Drug Administration
Center for Biologics Evaluation and Research
Document Control Center
10903 New Hampshire Ave.
WO71–G112
Silver Spring, MD 20993-0002

You must submit copies of your final advertising and promotional labeling at the time of initial dissemination or publication, accompanied by Form FDA 2253 (21 CFR 601.12(f)(4)).

All promotional claims must be consistent with and not contrary to approved labeling. You should not make a comparative promotional claim or claim of superiority over other products unless you have substantial evidence or substantial clinical experience to support such claims (21 CFR 202.1(e)(6)).

Please submit an amendment to all pending supplemental applications for this BLA that include revised labeling incorporating a revised content of labeling that includes these changes.

FULFILLED POSTMARKETING REQUIREMENT/COMMITMENTS

This submission fulfills your postmarketing requirement PMR #1 identified in the June 10, 2016, approval letter for BLA STN 125597/0 for Cholera Vaccine, Live, Oral. The requirement addressed in this submission is as follows:

1. Deferred pediatric study (PXVX-VC-200-006) under PREA for active immunization against disease caused by *V. cholerae* serogroup O1 in pediatric patients ages 2 years to less than 18 years traveling to cholera-affected areas. This study will evaluate the safety and immunogenicity of VAXCHORA in this age group.

PEDIATRIC REQUIREMENTS

Under the Pediatric Research Equity Act (PREA) (21 U.S.C. 355c), all applications for new active ingredients, new indications, new dosage forms, new dosing regimens, or new routes of administration are required to contain an assessment of the safety and effectiveness of the product for the claimed indication in pediatric patients unless this requirement is waived, deferred, or inapplicable.

We note that you have fulfilled the pediatric study requirement for all relevant pediatric age groups for this application.

We will include information contained in the above-referenced supplements in your BLA files.

Sincerely,

Doran L. Fink, M.D., Ph.D.
Deputy Director - Clinical
Division of Vaccines
and Related Products Applications
Office of Vaccines
Research and Review
Center for Biologics
Evaluation and Research