Our STN: BL 125682/40

SUPPLEMENT APPROVAL
PMR FULFILLED

June 30, 2023

Sanofi Pasteur, Inc.
Attention: Michael F. Stirr
Discovery Drive
Swiftwater, PA 18370-0187

Dear Mr. Stirr:

We have approved your request received May 31, 2022, to supplement your Biologics License Application (BLA) submitted under section 351(a) of the Public Health Service Act for Dengue Tetravalent Vaccine, Live (DENGVAXIA) manufactured at your Swiftwater, Pennsylvania location to include safety and efficacy data that support the use of DENGVAXIA in individuals 6 through 16 years of age with laboratory-confirmed previous dengue infection and living in endemic areas.

The review of this supplement was associated with the following National Clinical Trial (NCT) numbers: NCT01373281, NCT01374516, NCT00842530, NCT01983553.

LABELING

We hereby approve the draft content of Package Insert labeling submitted under amendment 20, dated June 23, 2023, and the draft carton label submitted May 31, 2022.

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. Content of labeling must be identical to the Package Insert submitted on June 23, 2023. 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.

U.S. Food & Drug Administration
10903 New Hampshire Avenue
Silver Spring, MD 20993
www.fda.gov

CARTON AND CONTAINER LABELS

Please electronically submit final printed carton label identical to the carton label submitted on May 31, 2022, 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, STN BL 125682, at the time of use 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 REQUIREMENTS

This submission fulfills your postmarketing requirements (PMRs) #1, #2 and #3 identified in the May 1, 2019, approval Letter for BLA STN 125682/0 for Dengue Tetravalent Vaccine, Live (DENGVAXIA). The requirements addressed in this submission are as follows:

1. Deferred study CYD14 to evaluate the safety and effectiveness of DENGVAXIA in children 2 to < 9 years of age.

   Final Protocol Submission: January 28, 2011

   Study Completion Date: November 21, 2017

   Final Report Submission: April 1, 2020

2. Deferred study CYD23 to evaluate the safety and effectiveness of DENGVAXIA in children 4 to < 9 years of age.

   Final Protocol Submission: May 27, 2011

   Study Completion Date: September 10, 2013

   Final Report Submission: April 1, 2020

3. Deferred study CYD57 to evaluate the safety and effectiveness of DENGVAXIA in children 4 to < 9 years of age.

   Final Protocol Submission: October 18, 2013

   Study Completion Date: February 19, 2016

   Final Report Submission: April 01, 2020

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 are waiving the pediatric study requirement for ages 6 months to < 2 years because there is evidence strongly suggesting that the biological product would be unsafe in this pediatric group.

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 supplement in your BLA file.

Sincerely,

Joseph G. Toerner, M.D., M.P.H
Acting Deputy Director - Clinical
Division of Vaccines and
Related Products Applications
Office of Vaccines
Research and Review
Center for Biologics
Evaluation and Research