SUPPLEMENT APPROVAL
PMR FULFILLED

Our STN: BL 125280/235

Valneva Austria GmbH
Attention: John Allen
910 Clopper Road
Suite 160S
Gaithersburg MD 20878

Dear Mr. Allen:

We have approved your request dated June 16, 2017, to supplement your Biologics License Application (BLA) submitted under section 351(a) of the Public Health Service Act (42 U.S.C. 262) for Japanese Encephalitis Virus Vaccine, Purified, Inactivated, Adsorbed (IXIARO), manufactured at your Livingston, United Kingdom facility to include the data from study IC51-322, and long-term pediatric studies IC51-325 and IC51-324 to update the package insert. Under this approval, we are also approving the recommendation of a booster dose at least 11 months after completion of the primary vaccination series for individuals <17 years of age who are at risk of continued exposure or re-exposure to Japanese encephalitis virus.

The review of this supplement was associated with the following National Clinical Trial (NCT) number(s): NCT01296360, NCT01246479, NCT01047839.

LABELING
We hereby approve the draft package insert labeling submitted under Amendment 10, dated April 03, 2018.

Please provide your final content of labeling including the carton and container labels in Structured Product Labeling (SPL) format. All final labeling should be submitted as Product Correspondence to BLA STN 125280 at the time of use (prior to marketing) and include implementation information on Form FDA 356h.

In addition, please submit the final content of labeling (21 CFR 601.14) in 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.

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#1 identified in the October 14, 2010, approval letter for BLA STN 125280/19 for IXIARO. The requirement addressed in this submission is as follows:

1. IC51-325: Long Term Immunogenicity And Safety With Or Without A Booster Dose Following Primary Vaccination With The Japanese Encephalitis Vaccine IC51 (IXIARO®) In A Pediatric Population In JEV-Endemic Countries. An open-label, randomized follow-up study to evaluate use of a booster dose of IXIARO administered to a subset of children who received a primary series of IXIARO in Study IC51-323.

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 supplement in your BLA file.

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