SUPPLEMENT APPROVAL

Our STN: BL 125280/251

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

October 4, 2018

Dear Mr. Allen:

We have approved your request dated December 04, 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: i) include an alternate primary immunization series of tw0 0.5 mL doses of IXIARO administered at 7 days apart for indivuduals 18 through 65 years of age, and ii) update the IXIARO package insert to include data to support the concomitant use of IXIARO primary immunization series, two 0.5 mL doses administered 28 days apart, with U.S.-licensed rabies vaccine (RabAvert®) administered for pre-exposure prophylaxis.

The review of this supplement was associated with the following National Clinical Trial (NCT) number: NCT01662440.

LABELING

We hereby approve the draft package insert labeling submitted under amendment 13, dated October 1, 2018.

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 that is identical to the package submitted on October 1, 2018, according to the guidance for industry titled *Providing Regulatory Submissions in Electronic Format — Certain Human Pharmaceutical Product Applications and Related Submissions Using the eCTD Specifications* at https://www.fda.gov/downloads/drugs/guidancecompliance regulatoryinformation/guidances/ucm333969.pdf.

All final labeling should be submitted as Product Correspondence to this BLA STN 125280/251 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.

We will include information contained in the above-referenced supplement in your BLA file.

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