Our STN: BL 125777/117

SUPPLEMENT APPROVAL
August 6, 2025

Valneva Austria GmbH
Attention: Adam Friedman
Valneva USA, Inc.
4550 Montgomery Avenue
Bethesda, MD 20814

Dear Mr. Friedman:

We have approved your request received June 5, 2025, to supplement your Biologics License Application (BLA) submitted under section 351(a) of the Public Health Service Act for Chikungunya Vaccine, Live (IXCHIQ), manufactured at your Livingston, Scotland; Vienna, Austria and (b) (4) facilities, to include new safety information (NSI) regarding the increased risk of serious chikungunya-like illness, including hospitalization and death, in individuals 65 years of age and older, following vaccination with IXCHIQ in the "Highlights of Prescribing Information", the "Indications and Usage", "Warnings and Precautions", "Adverse Reactions", "Use in Specific Populations", and "Patient Counseling Information" sections in the Full Prescribing Information of the Package Insert, the Patient Package Insert, and carton labeling in accordance with section 505(o)(4) of the Federal Food, Drug, and Cosmetic Act (FDCA).

The review of this supplement was associated with our May 16, 2025, SAFETY LABELING CHANGE AND POSTMARKETING REQUIREMENT NOTIFICATION LETTER, notifying you of new safety information that we have determined should be included in the labeling for IXCHIQ. This information pertains to data from postmarketing safety analyses that suggest an increased risk of serious chikungunya-like illness, in individuals 65 years of age and older, following vaccination with IXCHIQ. FDA identified postmarketing reports describing serious adverse events consistent with chikungunya-like illness, including hospitalization and death, in individuals 65 years of age and older, following vaccination with IXCHIQ.

LABELING
Under 21 CFR 201.57(c)(18), patient labeling must be referenced in section 17 PATIENT COUNSELING INFORMATION. Patient labeling must be available and may either be reprinted immediately following the full prescribing information of the package insert or accompany the prescription product labeling.

We hereby approve the draft content of labeling Package Insert submitted under amendment 2, dated August 6, 2025, and the draft carton label submitted under amendment 2, dated August 6, 2025.

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 August 6, 2025. 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.

CARTON AND CONTAINER LABELS

Please electronically submit final printed carton label identical to the carton label submitted on August 6, 2025, 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 125777, 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)).

For each pending supplemental application for this BLA that includes proposed revised labeling, please submit an amendment to update the proposed revised labeling with the changes approved today.

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

Sincerely,

R. Douglas Pratt, MD
Deputy Director
Division of Clinical and Toxicology Review
Office of Vaccines Research and Review
Center for Biologics Evaluation and Research