August 22, 2025

Thomas Lingelbach
Valneva Austria GmbH
Campus Vienna Biocenter 3
1030 Vienna, Austria
FB-Nr: FN 389960 x / HG Wien

Dear Mr. Lingelbach,

I am writing regarding your vaccine IXCHIQ STN 125777. Based on the Center for Biologics Evaluation and Research (CBER)'s review of VAERS reports, including 32 serious adverse event (SAE) reports(7 U.S., 25 foreign), including 21 hospitalizations and 3 deaths, I have determined under FDA's regulation at 21 CFR 601.6 that there are reasonable grounds to believe that one of the grounds for biologics license suspension under 21 CFR 601.6 exist—namely, that your vaccine is not safe for all of its intended uses—and that by reason thereof is a danger to health.[1] Specifically, your live-attenuated vaccine appears to be causing chikungunya-like illness in vaccine recipients, including severe cases with encephalopathy, encephalitis, and even at least one fatal outcome. One death and four SAE reports were PCR positive for the vaccine strain of the chikungunya virus. 26 reported SAEs in total were consistent with chikungunya-like illness. On July 29th there was yet another SAE report consistent with chikungunya like-illness where the individual had symptoms potentially consistent with meningitis or encephalopathy. This was in a 55-year-old male in whom the only known underlying medical condition was hypertension.

We acknowledge that CBER approved your sBLA with safety labeling changes to IXCHIQ's labeling on August 6, 2025. However, the August 6th decision to approve the sBLA was based on VAERS data as of July 16, 2025. On August 15, 2025, CBER became aware of 4 additional serious adverse events that were reported in the July 17, 2025, through August 15, 2025, time period. These additional serious adverse events included the July 29th SAE in the 55-year-old male described above. My decision to suspend your biologics license is based on this new safety information together with the information previously known to CBER.

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[1] 21 CFR 601.6(a) provides:

> Whenever the Commissioner has reasonable grounds to believe that any of the grounds for revocation of a license exist and that by reason thereof there is a danger to health, the Commissioner may notify the licensed manufacturer that the biologics license is suspended and require that the licensed manufacturer do the following:
> (1) Notify the selling agents and distributors to whom such product or products have been delivered of such suspension, and
> (2) Furnish to the Center for Biologics Evaluation and Research or the Center for Drug Evaluation and Research, complete records of such deliveries and notice of suspension.

The Commissioner has delegated this authority to the Director of CBER. See FDA Staff Manual Guide 1410.203.

This letter confirms the telephone conversation in which notice was given that pursuant to 21 CFR 601.6(a), the U.S. license for IXCHIQ (license number 1909) has been suspended, as of the time and date indicated below. Instructions were given at that time not to ship the product subject to license in interstate commerce.

In accordance with the regulations governing suspension of a biologics license under 21 CFR 601.6, you are required to: 1) give notice of this suspension to the selling agents and distributors to whom licensed products have been delivered within the 60 days prior to this suspension; and 2) furnish to the Office of Compliance and Biologics Quality, Center for Biologics Evaluation and Research, complete records of such deliveries and notices of suspension.

All communication with the Office of Compliance and Biologics Quality should be directed to the attention of Melissa Mendoza, Director, Office of Compliance and Biologics Quality. She may be reached at (301) 796-8707 and melissa.medoza@fda.hhs.gov. You are advised that Valneva Austria GmbH no longer holds an unsuspended license for your IXCHIQ vaccine and that unless and until otherwise notified, introduction or delivery for introduction into interstate commerce of such product is a violation of section 351(a) of the Public Health Service Act (42 U.S.C. 262(a)). Additionally, any shipments made during the suspension of license may constitute a violation of the Federal Food, Drug, and Cosmetic Act (FD&C Act). See, for example, 21 U.S.C. 33l(a). Criminal penalties may be imposed for such violations of the Public Health Service Act and FD&C Act. No shipments labeled with U.S. license number 1909 may be made during the suspension of license.

CBER will propose withdrawal of the accelerated approval of the IXCHIQ BLA pursuant to section 506(c)(3) of the FD&C Act (21 U.S.C. 356(c)(3)) unless you notify the CBER Director, Dr. Vinayak Prasad, within 10 working days of receipt of this letter to request that the matter of withdrawal be held in abeyance pending resolution of the matters involved. The appropriate state officials will also be notified of your suspension.

Sincerely,

Vinayak Prasad, MD, MPH
Director
Center for Biologics Evaluation and Research
Vinayak.prasad@fda.hhs.gov
Tel: (240) 461-0179

Effective Date: August 22, 2025 Time: 1:35 PM EST