IDPH
ILLINOIS DEPARTMENT OF PUBLIC HEALTH
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MEMORANDUM

TO: Local Health Department Administrators
VFC Medical Directors and Vaccine Coordinators
Illinois Vaccine Providers

FROM: IDPH Immunization Section

DATE: September 2, 2025

RE: **FDA Suspends Biologics License for IXCHIQ (Chikungunya Vaccine, Live)**

Key Points:

- FDA has suspended the biologics license for IXCHIQ (Chikungunya Vaccine, Live) due to significant safety concerns.
- This action does not impact Vimkunya (Chikungunya Vaccine, Recombinant), a virus-like particle (VLP) chikungunya vaccine, which remains licensed and recommended.

Background on IXCHIQ (Chikungunya Vaccine, Live)

- June 2025: IDPH shared updated ACIP recommendations along with an FDA safety communication restricting the use of IXCHIQ.
- August 6, 2025: FDA lifted the temporary pause on IXCHIQ and approved revised labeling:
  - Limited indication to adults at high risk of chikungunya exposure.
  - Clarified that vaccination is *not recommended* for most U.S. travelers.
  - Added new warnings for serious adverse reactions, including neurological and cardiac events, especially among older adults with chronic conditions.
- August 22, 2025: FDA's Center for Biologics Evaluation and Research (CBER) **suspended IXCHIQ's biologics license** after reports of serious adverse events, including:
  - 21 hospitalizations and 3 deaths
  - One death due to encephalitis caused by the vaccine strain**.**
  - Cases of chikungunya-like illness in vaccine recipients.
  - CBER concluded that "this vaccine is not safe and that continued administration to the public would pose a danger to health."

Valneva, the manufacturer of the vaccine, stated that the FDA's decision followed updated data from the Vaccine Adverse Event Reporting System, which included four new serious adverse events in older patients outside the U.S. The company noted these cases were consistent with previously observed clinical and post-marketing data. While the European Medicines Agency also paused use in older adults in May, it lifted the restriction in July.

Resources:

- FDA Update on the Safety of Ixchiq (Chikungunya Vaccine, Live)
- Valneva Announces FDA's Decision to Suspend License of Chikungunya Vaccine IXCHIQ® In the U.S.
- CIDRAP | FDA suspends license for chikungunya vaccine Ixchiq over serious safety concerns

Vimkunya (Chikungunya Vaccine, Recombinant)

Vimkunya, a virus-like particle chikungunya vaccine, remains FDA licensed and ACIP recommended**.** ACIP voted in favor of its use in April 2025, and recommendations were formally adopted by HHS on May 13, 2025**.**

ACIP Recommendations for use of Vimkunya (Chikungunya Vaccine, Recombinant):

1. ACIP recommends the virus-like particle chikungunya vaccine for persons aged ≥12 years traveling to a country or territory where there is a chikungunya outbreak. In addition, the virus-like particle chikungunya vaccine may be considered for persons aged ≥12 years traveling or taking up residence in a country or territory without an outbreak but with elevated risk for U.S. travelers if planning travel for an extended period of time, e.g., 6 months or more.
2. ACIP recommends the virus-like particle chikungunya vaccine for laboratory workers with potential for exposure to chikungunya virus.

Resource:

FDA | Vimkunya (Chikungunya Vaccine, Recombinant)

Contact Us for More Information:

For help, questions or feedback please contact the IDPH Immunization Section at dph.vaccines@illinois.gov or call 217-785-1455 and select option 2.