Department of Health and Human Services
Food and Drug Administration
Center for Biologics Evaluation and Research

MEMORANDUM

Suspension of Biologics License 1909

To file: IXCHIQ STN 125777

From: Vinayak Prasad, MD, MPH

Subject: Suspension of Biologics License under 21 CFR 601.6

Product: IXCHIQ (Chikungunya Vaccine, Live)

Applicant: Valneva Austria GmbH

Approved indication prior to suspension:

> For the prevention of disease caused by chikungunya virus (CHIKV) in individuals 18 years of age and older who are at high risk of exposure to CHIKV. This indication is approved under accelerated approval based on anti- CHIKV neutralizing antibody titers.
>
> The approved labeling includes the following limitations of use:
>
> Vaccination with IXCHIQ is not advisable for most U.S. travelers. For most U.S. travelers, the risk of exposure to CHIKV is low. The Centers for Disease Control and Prevention provides resources for assessing likelihood of exposure to CHIKV among travelers and laboratory workers (Chikungunya Vaccine Information for Healthcare Providers).
>
> The decision to administer IXCHIQ should take into consideration an individual's risk of severe or chronic disease outcomes if infected with CHIKV and risks of serious, severe, or prolonged chikungunya-like illness caused by vaccination with IXCHIQ (5.2, 6.1, 6.2), in addition to the risk of exposure to CHIKV. For travelers, factors to consider include level of disease activity at destination, duration of travel or residence, and likelihood of exposure to mosquitoes.

1. OBJECTIVES

This CBER Office of the Center Director (OCD) memorandum presents the rationale for the suspension of the biologics license for [IXCHIQ (Chikungunya Vaccine, Live)] under 21 CFR 601.6.

2. REGULATORY HISTORY

On November 9, 2023, FDA granted approval for IXCHIQ under accelerated approval pathway for active immunization for the prevention of disease caused by chikungunya virus in individuals 18 years of age and older who are at increased risk of exposure to chikungunya virus. At the time of approval, there was no evidence that IXCHIQ reduces the risk of acquiring the virus or severe disease of the virus, instead a surrogate endpoint was used. To date, no confirmatory study has demonstrated and quantified the vaccine effect.

On August 6, 2025, FDA approved a Safety Labeling Change sBLA that added new safety information in the IXCHIQ U.S. Prescribing Information (USPI). This included: 1) revision of the indication in the Indications and Usage section (Section 1) from "for use from individuals who are at *increased* risk" to "individuals who are at *high* risk of exposure to CHIKV"; 2) adding a new limitation of use to the Indications and Usage section (Section 1) stating that vaccination with IXCHIQ is not advisable for most U.S. travelers due to low risk of CHIKV exposure, and emphasizing the need for individualized benefit-risk assessment considering factors such as exposure risk, duration of travel, and patient-specific factors including age and comorbidities; 3) expanding the Warnings and Precautions section (Section 5.2) to state that serious chikungunya-like illness, resulting in hospitalization, including a case of encephalitis with fatal outcome, has been reported during postmarketing use with IXCHIQ and that individuals 65 years of age and older with one or more chronic medical conditions may have an increased risk for serious chikungunya-like illness following vaccination with IXCHIQ; 4) adding a new Postmarketing Experience section (Section 6.2) detailing serious adverse reactions observed in postmarketing surveillance, including chikungunya-like illness with complications such as encephalitis with fatal outcome, encephalopathy, aseptic meningitis, cardiac arrhythmias, and other serious manifestations; and 5) corresponding updates to the Geriatric Use (Section 8.5) and Patient Counseling (Section 17) sections to reflect these safety concerns.

As discussed below in the "Basis for Decision to Suspend Biologics License for IXCHIQ" section, following the August 6th safety labeling change (SLC), FDA became aware of more compelling evidence that this risk for serious chikungunya-like illness following IXCHIQ vaccination is not limited to older adults with chronic medical conditions. The available evidence now indicates serious chikungunya-like reactions may occur at any age, even in those at relatively low risk from the virus, and this reaction appears difficult to predict.

3. BACKGROUND

Please see Table 1 below on timeline of safety signal identification for IXCHIQ and

related actions.

Table 1. IXCHIQ safety signal timeline

April 16, 2025	CDC presented IXCHIQ VAERS data at ACIP, including six U.S. serious reports https://www.cdc.gov/acip/downloads/slides-2025-04-15-16/04-hills-chikungunya- 508.pdf
May 7, 2025	EMA starts review of Ixchiq (live attenuated chikungunya vaccine) | European Medicines Agency (EMA) and recommends temporarily restricting use to 12 – 64y (SAEs in older adults (62 – 89y) from La Reunion chikungunya outbreak)
May 9, 2025	FDA and CDC Recommend Pause in Use of Ixchiq (Chikungunya Vaccine, Live) in Individuals 60 Years of Age and Older While Postmarketing Safety Reports are Investigated
May 16, 2025	FDA issued SLC notification letter (STN 125777/96) based on new safety information
June 5, 2025	CBER receipt date for PAS-SLC (STN 125777/117)
June 5, 2025 – July 4, 2025	30-day discussion period for SLC
July 5, 2025 – August 3, 2025	30-day extension #1 of discussion period for SLC
July 11, 2025	Ixchiq: temporary restriction on vaccinating people 65 years and older to be lifted | European Medicines Agency (EMA)
August 4 – September 2, 2025	30-day extension #2 of discussion period for SLC
July 24, 2025	CBER Safety Working Group discussion of SLC
August 4, 2025	CBER Briefing for Dr. George Tidmarsh, Acting CBER Director
August 6, 2025	CBER approves the sBLA 125777/117 to include new safety information in accordance with section 505(o)(4) of the FDCA.
August 15, 2025	CBER queries the VAERS database and finds four additional serious adverse event reports.
August 21, 2025	CBER contacts Valneva to ask if company will voluntarily suspend distribution of the vaccine. Valneva did not indicate intent to voluntarily suspend distribution of the vaccine.

4. BASIS FOR DECISION TO SUSPEND BIOLOGICS LICENSE FOR IXCHIQ

As discussed further below, I have concluded that one of the grounds for suspension exists—namely, that the licensed product is not safe for its intended uses—and that by reason thereof there is a danger to health.

We also note the vaccine was approved under accelerated approval based on anti-CHIKV

neutralizing antibody titers—a surrogate endpoint considered "reasonably likely to predict clinical benefit" under section 506(c) of the FD&C Act—and the required postmarket confirmatory clinical trials to verify clinical benefit have not yet been completed. To date, the vaccine effectiveness has never been directly shown, and remains assumed. It has not been quantified.

The August 6th decision to approve a safety label change was based on VAERS data as of July 16, 2025. However, on August 14, 2025, CBER OCD requested an updated query of the VAERS database so CBER could remain up-to-date on adverse event reports in connection with the vaccine. The updated query of VAERS undertaken on August 15, 2025, identified reports not taken into consideration in the August 6, 2025 SLC. These reports revealed that from July 17, 2025 – August 15, 2025, there were 13 (4 US; and 9 foreign) non-serious reports and 4 foreign serious reports. The latter are summarized below.

The 4 reported foreign serious adverse events were:

- 70yo F experienced arthralgia and fever 2 days following IXCHIQ.
- 82yo M with history chronic bronchitis developed arthralgia, myalgia, asthenia 1 day after IXCHIQ vaccination.
- 72yo M with history TIA, DM developed vertigo, hypoaesthesia, paraesthesia 23 days after IXCHIQ vaccination.
- 55yo M with history hypertension developed symptoms 4 days after IXCHIQ vaccination, with fever, myalgia, arthralgia, headache, photosensitivity, and eye pain.

Notably the report of the 55-year-old male adds further evidence that safety concerns with this vaccine are not limited to the 65 years of age and older population. This case had reported symptoms clinically consistent with chikungunya-like illness with meningitis or encephalitis; PCR testing information was not reported. As of August 20, 2025, the patient outcome was reported as "recovering/resolving." This recent report, which we became aware of after the August 6th, 2025 SLC, together with the prior safety data, provide sufficient evidence that the vaccine is not safe for its intended use and it poses a danger to health such that the license needs to be suspended. This was the seventh report in an individual under the age of 65 and now six out of seven of these reports have been consistent with chikungunya-like illness. This case provided additional confirmation that this is a reaction which can occur in all currently-indicated ages, even in relatively healthy individuals, and poses a danger to health.

As of August 15, 2025, VAERS data for IXCHIQ included 38 serious adverse event (SAE) reports for 32 unique cases (7 U.S., 25 foreign), including 21 hospitalizations and 3 deaths. Most SAE reports (n = 24 (75%)) involved males and most individuals had at least one underlying condition. Age range for the 32 unique cases are as follows, and is compared with data described previously under IXCHIQ PAS-SLC memo (please see 125777/117):

Table 2. Total IXCHIQ SAE reports identified in VAERS prior to and since the August 6th, 2025, safety label change (SLC)

SAEs as of August 15, 2025 (n = 32)	SAEs as of July 16, 2025 (n = 28)
○ 28 – 59y: 5 ○ 60 – 64y: 2 ○ 65 – 70y: 6 ○ 70+: 19	○ 28 – 59y: 4 ○ 60 – 64y: 2 ○ 65 – 70y: 5 ○ 70+: 17

Most individuals (25 of 32) for whom SAEs were reported were individuals 65 years of age and older. However, there are 7 SAE reports in individuals 64 years of age and younger.

Many of the SAEs, including a case of encephalitis with fatal outcome, were consistent with chikungunya-like illness[1] (n = 26; age range 45 – 89 years), including 8 with (+) CHIKV testing[2] (incl 5 PCR (+) for vaccine strain)

- 17 with fever
- 9 without documented fever but with symptoms otherwise consistent
- 6 cases in individuals under 65 years of age

VAERS report details are provided in **Appendix 1** with reports among those under 65 years highlighted in pink.

Distribution data as of August 15th, 2025 (**Table 3**) corresponds to VAERS-reported SAE rate of 1/738 in adults ≥65 years of age and 1/4708 (7/32,949) in adults younger than 65 years of age. CDC recently published an estimated SAE rate based on VAERS reports from 2024 of 1/1267 or 86/100,000 (Hills Susan L, 2025). While not all SAEs can be causally linked to the vaccine, reported rates from VAERS have historically been underestimates of true rates. (Miller ER, 2020). The four new reports added to the prior 28 strengthen the evidence the vaccine-induced adverse reactions are occurring at a frequency which is not acceptable given the benefit-risk assessment discussed below (**Table 4** and **Table 5**). To date, five of the cases have been found to be positive for the vaccine strain of the virus, making causality for these reports nearly certain. Notably, none of the individuals younger than 65 years of age were reported to have had PCR testing, but with the addition of this most recent case since the SLC, six of the seven (86%) individuals younger than 65 years of age who were reported to have serious adverse events had reactions consistent with chikungunya-like illness.

[1] Given the broad definition of "chikungunya-like illness" this classification is based on reviewer assessment of individual reports, available information, and our best judgment. USPI, section 6.1 Clinical Trials Experience, defines chikungunya-like illness as IXCHIQ USPI (6.1):
Chikungunya-like illness was defined as fever (38 °C / 100.4 °F) and one or more of any of the following: arthralgia or arthritis, myalgia, headache, back pain, rash, lymphadenopathy, or certain neurological, cardiac or ocular symptoms, that occurred with an onset within 30 days after vaccination. Severe chikungunya-like illness reactions were those that prevented daily activity and/or required medical intervention.

[2] Tests included PCR, CSF IgM

Table 3. IXCHIQ distribution data, received from Valneva in response to information request dated August 15, 2025[3]

Distribution Data	U.S.	Outside U.S.	Worldwide total
Total doses distributed	(b) (4)	(b) (4)	(b) (4)
Total estimated doses administered	22,904	28,490	53,394
Total estimated doses administered in individuals 65 years of age and older	3,435	15,010	18,445
Total estimated doses administered in individuals <65 years of age	19,469	13,480	32,949

*IXCHIQ doses distributed and administered are estimates based on commercial channels and retail distribution and usage.

In July 2025, the CBER Division of Analytics and Benefit Risk Assessment (DABRA)/OBPV performed benefit-risk assessments for IXCHIQ in the context of the ongoing outbreak in La Reunion, which were referenced in the SLC memo dated August 6th, 2025, but are important to note here. This analysis concluded that the IXCHIQ was not likely to be a net benefit for individuals 12 through 64 years of age or individuals 65 years of age and older for a 1-month trip or 6-month trip to an outbreak area. The data for a favorable benefit-risk for prevention of deaths in individuals of any age were not demonstrated.

Table 4 Summary of Benefit-Risk for Travelers Visiting A Region During An Outbreak Similar to La Reunion in 2025

Risk Rate Approach	Duration of Travel	Age Group	Is the B-R favorable?	
			Prevented Hospitalizations vs SAEs?	Prevented Deaths vs VAERS reported Deaths (3)?
La Reunion Risk Rate	≤ 4 weeks	12 – 64	No	No
		65+	No	No
	6 months	12 – 64	No	No
		65+	No	No

Abbreviations: SAEs= serious adverse events
Assumes VE=97%, VE does not wane over course of travel and that the outbreak is similar to the characteristics of the 2025 La Reunion outbreak.

Table 5 Prevented Hospitalizations Compared to Vaccine-associated SAEs (per 100,000 administered doses) among Travelers Visiting a Region During an Outbreak Similar to La Reunion in 2025

Risk Rate Approach	Duration of Travel	Age Group	Prevented Hospitalizations	Vaccine-associated SAEs	Is B-R favorable?
La Reunion	≤ 4 weeks	12 – 64	7	485	No

[3] IR response under 125777/96, in response to IR dated August 15, 2025

Risk Rate	**6 months**	**65+**	37	250	No
		12 – 64	41	485	No
		65+	220	250	No

Abbreviations: SAEs= serious adverse events
Assumes VE=97%, VE does not wane over course of travel and that the outbreak is similar to the characteristics of the 2025 La Reunion outbreak.

Importantly, the above benefit-risk analyses assume a vaccine efficacy of 97%. However, to date, efficacy estimates have been based on immunogenicity data that have not been clinically validated; specifically, assumptions of IXCHIQ effectiveness have been based on the presence of alphavirus cross-neutralizing antibodies through Day 365 (Weber & Streblow, 2024).

Therefore, the above benefit-risk assessment considers best-case-scenario of vaccine efficacy and true vaccine efficacy may be substantially lower or even nil. For these reasons, CBER requested postmarketing randomized (Study 404) and observational (Study 402) studies to assess vaccine efficacy.

Additionally, CBER has performed benefit-risk analyses that consider lower vaccine-effectiveness (e.g. 90% to 25%). These rates include the lower bound of the confidence interval that CBER agreed to with the sponsor for a post marketing study. In other words, assumptions considered plausible to both parties. Under these assumptions, IXCHIQ was broadly consistent with a net-harm risk benefit profile even assuming a prolonged, year long epidemic, raging at the rate of La Reunion.

Based on substantial and immediate safety concerns including three deaths--one with high certainty attributable to IXCHIQ—in addition to numerous severe adverse events in adults consistent with chikungunya-like illness (including now 6 cases in adults younger than 65 years of age), there are reasonable grounds to believe the risks of the vaccine outweigh its benefits, and that it poses a danger to health. Therefore, CBER is suspending approval of IXCHIQ under 21 CFR 601.6.

6. SUMMARY, DECISION AND NEXT STEPS

In summary, I have decided to suspend approval of Valneva Austria GmbH's live-attenuated CHIK vaccine IXCHIQ under 21 CFR 601.6(a)[4] because I have concluded

[4] 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

that there are reasonable grounds to believe that one of the grounds for revocation exists— namely, that the licensed product is not safe for all of its intended uses—and that by reason thereof there is a danger to health. Beyond the reported three deaths, one with high certainty attributable to the vaccine, additional serious adverse events are consistent with chikungunya-like illness. Five cases, including one death, were found to be PCR positive for the vaccine strain of the virus, suggesting illness due to the vaccine strain. Since the FDA's last SLC, we have reviewed four additional SAEs reported to VAERS including one report of chikungunya-like illness in a middle-aged adult clinically consistent with meningitis/encephalitis. Following suspension of the license, CBER will propose withdrawal of the accelerated approval of the BLA for this vaccine pursuant to section 506(c)(3) of the FD&C Act.

References

FDA. (2025, May 9). *FDA and CDC Recommend Pause in Use of Ixchiq (Chikungunya Vaccine, Live) in Individuals 60 Years of Age and Older While Postmarketing Safety Reports are Investigated.* Retrieved from https://www.fda.gov/vaccines-blood-biologics/safety-availability-biologics/fda-and-cdc-recommend-pause-use-ixchiq-chikungunya-vaccine-live-individuals-60-years-age-and-older

Hills Susan L, S. R. (2025). Surveillance for adverse events following use of live attenuated chikungunya vaccine, United States, 2024, and the associated public health response in 2024 and 2025. . *Euro Surveill.* , 30(32):pii=2500543.

Miller ER, M. M. (2020). The reporting sensitivity of the Vaccine Adverse Event Reporting System (VAERS) for anaphylaxis and for Guillain-Barré syndrome. *Vaccine*, Nov 3;38(47):7458-7463.

Weber, W., & Streblow, Z. e. (2024). The approved live-attenuated chikungunya virus vaccine (IXCHIQ*) elicits cross-neutralizing antibody breadth extending to multiple athritogenic alphaviruses similar to the antibody breadthy following natural infection. . *Vaccines*, 12, 893.

(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.

Appendix 1: Tabulated Summaries of Postmarket Adverse Event Reports

Table 1: Individual case safety reports (ICSRs) for serious adverse events (N = 32 as of August 15, 2025)

ICSR	VAERS initial received date	US/ Foreign	Age (years) / Sex	Time to onset (days)	Adverse event	Fever (yes/ no)	Death (yes/no)	Underlying conditions	Chikungunya testing	Consistent with chikungunya-like illness (yes/no)
VAERS 2818780	12/31/2024	US	86M	2-3	Confusion, tachycardia	Yes	No	HTN, HLD, heart failure, diabetes, anemia, hypothyroidism, vitiligo	Blood: ChikV RNA (+)	Yes
VAERS 2776126	6/26/2024	US	83M	3	Encephalopathy, generalized weakness	Yes	No	HTN, HLD, CAD, CHF, CKD, AAA, atrial flutter, paroxysmal atrial fibrillation, Barrett's esophagus with high grade dysplasia, GERD, gout	No	Yes
VAERS 2799006	10/15/2024	US	77M	4	Encephalopathy	Yes	No	HTN, HLD, CAD, IgA deficiency, hypothyroidism, BPH	No	Yes
VAERS 2806067	11/7/2024	US	74M	3	Worsening and prolonged hypotension in background of underlying cardiomyopathy	No	No	CAD, cardiomyopathy	No	Yes
VAERS 2799807	10/17/2024	US	67M	4	Atrial flutter with rapid ventricular response, suspected small NSTEMI	Yes	No	HLD	No	Yes
VAERS 2803359	10/29/2024	US	68M	5	Aseptic meningitis	Yes	No	HTN, Dyslipidemia, hypothyroidism, prostate cancer	CSF: IgM and neutralizing antibodies (+), PCR (-)	Yes
VAERS 2839404	5/5/2025	Foreign	84M	2	Encephalitis	Yes	**Death**	CVD s/p MI w stent, HLD, DMII, asthma, sleep apnea	CSF and blood (+) for vaccine strain by PCR	Yes
VAERS 2839403	5/5/2025	Foreign	84M	2	Encephalopathy	Yes	No	HTN, CAD, diabetes, CKD, asthma, sleep apnea	Blood (+) for vaccine strain by PCR	Yes
VAERS 2839405	5/5/2025	Foreign	82M	4	Profound malaise, fall	Yes	No	Hypogammaglobulinemia, factor II mutation, reactive arthritis, ankylosing spondylitis, positional vertigo, pulmonary embolism, sleep apnea, BPH	Blood (+) for vaccine strain by PCR	Yes
VAERS 2840624	5/13/2025	Foreign	48M	1	Fatigue, myalgia, arthralgia	Yes	No	None reported	No	Yes
VAERS 2836601 and	4/17/2025	Foreign	64M	3	Arthralgia, elevated CRP	Yes	No	Thymoma, pericarditis, COPD	No	Yes

ICSR	VAERS initial received date	US/ Foreign	Age (years) / Sex	Time to onset (days)	Adverse event	Fever (yes/ no)	Death (yes/no)	Underlying conditions	Chikungunya testing	Consistent with chikungunya-like illness (yes/no)
2841255										
VAERS 2840903	5/14/2025	Foreign	89F	4	Myalgia, nausea, filmy vision, hyponatremia	Yes	No	Stent placement, hip prosthesis, lupus-like syndrome	No	Yes
VAERS 2840901	5/14/2025	Foreign	72M	6-8	Headache, malaise, cervicalgia, vertigo, asthenia, nausea	Unkno wn	No	HTN, HLD, COPD	No	Yes
VAERS 2841251	5/16/2025	Foreign	77M	8	Asthenia, acute kidney injury, aspiration pneumonia	Unkno wn	**Death**	Parkinson's disease, HTN, MI	No	No
VAERS 2841082	5/15/2025	Foreign	79F	5	Vertigo, nausea, confusion	Unkno wn	No	HTN	No	Yes
VAERS 2841083	5/15/2025	Foreign	62M	3	Fatigue, nausea, arthralgia, fall	Unkno wn	No	Marfan's syndrome, mitral valve repair, prostate cancer stage IV, diabetes	No	Yes
VAERS 2841253	5/16/2025	Foreign	80F	8	Thrombocytopenia, hemolysis, nephrotic syndrome	Unkno wn	No	Glaucoma	No	No
VAERS 2840900	5/14/2025	Foreign	67M	3	Malaise, fall, diarrhea	Yes	No	Not reported	No	Yes
VAERS 2842031	5/21/2025	Foreign	45F	4	Ventricular ectopy, pericardial effusion, amenorrhea, hot flush, asthenia	Unkno wn	No	Breast cancer, pneumothorax	No	Yes
VAERS 2842030	5/21/2025	Foreign	74M	4	Encephalopathy, skin eruption, arthralgia	Yes	No	HTN, dyslipidemia, heart valve disorders, atrial fibrillation, atria/mitral valve repair, annuloplasty, tobacco/alcohol/drug use,	Blood, CSF (-) by PCR	Yes
VAERS 2841785	5/20/2025	Foreign	88M	3	Aspiration pneumonia	Yes	**Death**	H/o head trauma with subsequent neurocognitive	Blood (+) for vaccine strain	No

ICSR	VAERS initial received date	US/ Foreign	Age (years) / Sex	Time to onset (days)	Adverse event	Fever (yes/ no)	Death (yes/no)	Underlying conditions	Chikungunya testing	Consistent with chikungunya-like illness (yes/no)
								disorder, ischemic stroke with hemiparesis, mixed dementia, Alzheimer's, anorexia, malnutrition, swallowing disorder, atrial fibrillation, hypertension, diabetes, dyslipidemia, hypertension, osteoporosis	by PCR	
VAERS 2842428	5/23/2025	Foreign	85M	4-17	Asthenia, fall, thrombocytopenia, lymphopenia, acute respiratory decompensation	Yes	No	HTN, diabetes, asthma, tobacco/alcohol use	Blood (+) for vaccine strain by PCR	Yes
VAERS 2841838	5/20/2025	US	28F	0	Acute adrenocortical insufficiency with hypotension, fever, tachycardia, diarrhea, vomiting, asthenia	Yes	No	Secondary adrenocortical insufficiency, Ehlers-Danlos, POTs, mast cell activation syndrome, migraines, GERD, ADHD		No
VAERS 2842738	5/27/2025	Foreign	47F	2	Fatigue, vertigo, agitation, delusions	Unkno wn	No	Depression, hypothyroidism, tendinitis, ear, nose, and throat infection, bladder distension, PTSD		Yes
VAERS 2842932	5/28/2025	Foreign	84M	3	Fever, malaise, fall, thrombocytopenia, hallucination, rash	Yes	No	Dementia with Lewy bodies, depression, COPD, aortic aneurysm	Blood PCR (+) , unknown if vaccine strain	Yes
VAERS 2843650	6/3/2025	Foreign	66F	3	Asthenia, arthralgia, headache, nausea,	Unkno wn	No	Vertigo, head injury, osteoarthritis, menopause,		Yes

ICSR	VAERS initial received date	US/ Foreign	Age (years) / Sex	Time to onset (days)	Adverse event	Fever (yes/ no)	Death (yes/no)	Underlying conditions	Chikungunya testing	Consistent with chikungunya-like illness (yes/no)
					vertigo, vision blurred			craniolacunia		
VAERS 2844709	6/12/2025	Foreign	69M	<17	Diplopia, decreased appetite, asthenia, myalgia	Unknown	No	None listed		Yes
VAERS 2842412 and 2844708	5/23/2025	Foreign	72M	0	Acute myocardial infarction	Unknown	No	Diabetes		No
VAERS 2851588*	7/29/2025	Foreign	55M	4	Headache, myalgia, arthralgia, photosensitivity, eye pain	Yes	No	HTN		Yes
VAERS 2850491*	7/21/2025	Foreign	82M	1	arthralgia, myalgia, asthenia	No	No	chronic bronchitis		Yes
VAERS 2850494*	7/21/2025	Foreign	72M	23	vertigo, hypoesthesia, paresthesia	No	No	TIA, DM		No
VAERS 2853518*	8/11/2025	Foreign	70F	2	arthralgia	Yes	No	None listed		Yes

*There is a lag between when a report is first received by the VAERS program, and when that report completes processing (i.e., “completed date” reflects when the report has been fully encoded and available in the VAERS extract so that it can be retrieved by querying VAERS). The four new SAE reports during July 17 – August 15, 2025, for VAERS IDs 2851588, 2850491, 2850494, and 2853518, were identified by manual screening of received reports as of August 15, 2025.

Cases reported in individuals under 65 years of age are highlighted in pink. Cases confirmed to be positive by PCR for the vaccine strain of the virus are highlighted in yellow.