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In reply please refer to: V2-447-3/DS/MT/1

Your reference: P-04983

Fujian Yamei Industry & Trade Co. Ltd
Attn: Mr. Jack Chen
Room 2001, Building C2, Fuli Center
Taijiang District
350002 Fazhou
China

12 September 2025

Dear Mr. Chen:

WHO Prequalification Unit – Vector Control Products Assessment

Vector Control Product Prequalification: Suspension

Product Name	Product ID	Product Type
Yahe 4.0	P-04983	Insecticide-Treated Net (ITN)

According to the established procedures for the prequalification of vector control products, the World Health Organization (WHO) reserves the right to terminate this procedure for a specific product if the applicant is not able to provide the required information or implement the corrective actions within a specified time period, or if the information supplied is inadequate to complete this procedure, or when serious safety and/or quality concerns arise.

There is uncertainty regarding the quality of the product Yahe 4.0 (Product ID: P-04983), and it cannot be determined that the data submitted to WHO to support the prequalification decision as published in World Health Organization Public Assessment Report (WHOPAR) is still applicable to the current product as formulated and manufactured. Based on information obtained by WHO, there is insufficient evidence to ensure that if the product were to be produced at the declared manufacturing site, that the resulting product could be considered the same as what was declared and assessed through the prequalification procedures. Therefore, the prequalification decision has been suspended and the status of the product on the published list of prequalified ITNs has been updated.

The product, Yahe 4.0, was accepted for assessment on 23 May 2022 and was under assessment at the time of the publication of the WHO Guidelines for prequalification assessment of ITNs (December 2023). The product was assessed based on the requirements in place at the time of its submission. The product was prequalified on 11 November 2024 in accordance with the established procedures for prequalification of vector control products. With the implementation of the new guidelines, all manufacturers of ITNs are required to submit updated product dossiers to demonstrate compliance with the prequalification requirements. WHO officially notified Fujian Yamei Industry & Trade Co. Ltd of the requirement for submission of an updated product dossier for reassessment of the product Yahe 4.0 on 5 December 2024 and sent a follow up request on 9 January 2025. Fujian Yamei Industry & Trade Co. Ltd has not provided any response to this request.

During an on-site inspection of the declared manufacturing facility, discrepancies were identified between the declared formulation and manufacturing process and the intended production process. Furthermore, critical non-conformities were identified in the quality management system. The product assessment team sent a Notice to Address Nonconformities to Fujian Yamei Industry & Trade Co. Ltd on 5 June 2025. The applicant's response on 29 August 2025 failed to provide the information needed to ensure that the product dossier was reflective of the intended production process. Furthermore, it was confirmed that the applicant was delinquent in responding to requests from the PQT Inspections Team to

address the critical non-conformities identified in the inspection report resulting in the site being deemed “non-compliant” until the deficiencies are addressed.

Currently, the following points are considered outstanding and responses from the applicant are awaited:

1. Request from PQT/INSP for corrective and preventative actions (CAPAs) to address the non-conformities identified in the inspection report.
2. All points identified in the 5 June 2025 Notice to Address Nonconformities letter
3. All points identified in the 5 December 2024 and 9 January 2025 requests for submission of information and data generation plan to comply with the implementation plan of the new ITN guideline.

The decision to reinstate the prequalification status of the product, thereby lifting the suspension, requires that Fujian Yamei Industry & Trade Co. Ltd address the open points above and that the information provided results in:

1. the determination of compliance of the manufacturing site with the established requirements,
2. positive assessment outcomes of information to be submitted in response to the letters dated 5 December 2024, 9 January 2025, and 5 June 2025, which must also include the 5 batch phys/chem study generated using product samples produced per the updated formulation and manufacturing process, and
3. acceptance of the proposed timelines for generation of other data/information required to comply with the implementation plan for reassessment of ITNs.

It must be noted that should the ownership of this product be transferred to a new legal manufacturer, this new owner must acknowledge the suspended status of the product and commit to addressing all relevant requirements enabling the reinstatement of the prequalification decision for the product.

For further information regarding the status of this product and in the case of questions arising in relation to the prequalification process, please use the email address - **pqvectorcontrol@who.int** - ensuring that any such email mentions the corresponding product name and reference number.

Your cooperation is appreciated.

Yours sincerely,



Mr Dominic Schuler
Team Lead, Vector Control Products Assessment
Prequalification Unit
Regulation and Prequalification Department