

## NOTICE OF PROPOSED FSM PHARMACEUTICAL PRODUCT REGISTRATION REGULATIONS

Pursuant to the Authority vested upon the Secretary of the FSM Department of Health and Social Affairs, I am proposing the enclosed Permanent Regulations to implement Chapter 13 of Title 41 of the Code of the Federated States of Micronesia (Annotated), or the Safe Pharmaceutical Act. The purpose of the proposed Regulations is to establish a process for quality assessment and registration for all pharmaceutical products that will be imported for distributions, sale and or use in the Federated States of Micronesia.

Extra copies of the proposed Regulation can be obtained from the FSM Department of Health and Social Affairs and the FSM Pharmaceutical Unit. Any person interested in commenting on the proposed Regulation may do so by written submission to:

Hon. Marcus Samo  
Secretary  
FSM Department of Health & Social Affairs  
Palikir, Pohnpei  
Federated States of Micronesia  
Email: [health@fsmhealth.fm](mailto:health@fsmhealth.fm)

*All written submissions must be received by the Department of Health and Social Affairs within thirty (30) days of the posting of this notice, or no later than March 06, 2025.*

This proposed Regulation shall take effect upon approval by the President and compliance with Title 17 of the Code of the Federated States of Micronesia, which may be as soon as March 06, 2025. Affected persons should assume this amendment became effective on that date unless they learn otherwise. The actual date of effectiveness will be noted on the certified copy of the proposed Regulation to be filed with the FSM Register of Corporations (ROC) pursuant to 17 F.S.M.C. § 103(1).