ANDA 083722/S-029, S-031, and S-034

CHANGES BEING EFFECTED/
PRIOR APPROVAL SUPPLEMENT
APPROVAL

International Medication Systems, Limited
1886 Santa Anita Ave.
South El Monte, CA 91733
Attention: Gisela Sharp
Associate Director, Regulatory Affairs

Dear Gisela Sharp:

This letter is in reference to your supplemental abbreviated new drug applications (sANDAs), submitted pursuant to section 505(j) of the Federal Food, Drug, and Cosmetic Act (FD&C Act) for Phytonadione Injectable Emulsion USP, 1 mg/0.5 mL.

Reference is also made to any amendments submitted prior to the issuance of this letter.

The sANDAs, submitted as "Changes Being Effected/Prior Approval Supplement," provide for:

Supplement	Sub-Type	Received Date	Purpose
S-029	CBE-0	October 29, 2013	Revised labeling to include a revised tertiary packaging configuration for 10 units instead of 25 units.
S-031	CBE-0	June 4, 2018	Revised labeling to be in accordance with the reference listed drug (RLD), AquaMEPHYTON, NDA 012223/S-041, approved on March 7, 2018.
S-034	PAS	July 17, 2023	New SurGuard2 Safety Hypodermic Needle for Assembly of the 3 mL SurGuard Saf-T-Jet® Injector.

We have completed the review of these sANDAs, as amended, and they are **approved**.

COMPENDIAL STANDARDS

A drug with a name recognized in the official United States Pharmacopeia or official National Formulary (USP-NF) generally must comply with the compendial standard for strength, quality, and purity, unless the difference in strength, quality, or purity is plainly stated on its label (see FD&C Act § 501(b), 21 USC 351(b)). FDA typically cannot share application-specific information contained in submitted regulatory filings with third parties, which includes USP-NF. To help ensure that a drug continues to comply with compendial standards, application holders may work directly with USP-NF to revise official USP monographs. More information on the USP-NF is available on USP's website as https://www.uspnf.com/.

REQUIREMENTS AND RECOMMENDATIONS POST APPROVAL

Under applicable statutes, regulations, and guidances, your ANDA may be subject to certain requirements and recommendations post approval, including requirements regarding changes to approved ANDAs, postmarketing reporting, promotional materials, and annual facility fees, among others. For information on post-approval requirements and recommendations for ANDAs and a list of resources for ANDA holders, we refer you to https://www.fda.gov/drugs/abbreviated-new-drug-application-anda/requirements-and-resources-approved-andas.

Sincerely yours,

{See appended electronic signature page}

For Edward M. Sherwood
Director
Office of Regulatory Operations
Office of Generic Drugs
Center for Drug Evaluation and Research

Catherine Poole

Digitally signed by Catherine Poole
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