DEVELOPMENT LLC

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September 27, 2024

Peter Stein, M.D., Director
Food and Drug Administration (FDA)
Center for Drug Evaluation and Research (CDER)
Office of New Drugs (OND)
Central Document Room (CDR)
5901-B Ammendale Road
Beltsville, MD 20705-1266

Potassium Phosphates Injection USP, 3 mM P/mL
NDA # 212121-0071
DEFERRAL EXTENSION REQUEST
RESPONSE TO PREA NON-COMPLIANCE LETTER

Dear Dr. Stein:

Reference is made to the CMP Development LLC ("CMP") New Drug Application (NDA) 212121 for Potassium Phosphates Injection USP, 3 mM P/mL approved by the Agency on September 19, 2019 as a source of phosphorus:

- in intravenous fluids to correct hypophosphatemia in adults and pediatric patients 12 years of age and older when oral or enteral replacement is not possible, insufficient or contraindicated and
- for parenteral nutrition in adults weighing at least 45 kg and pediatric patients 12 years of age and older weighing at least 40 kg when oral or enteral nutrition is not possible, insufficient or contraindicated.

The purpose of this letter is to respond to the FDA's Notification of Non-Compliance with PREA letter dated August 16, 2024 (Attachment 2). Reference is also made to the FDA deferral extension response letter received from Dr. Judith Racoosin dated August 14, 2024 (Attachment 1). Both Agency communications are provided for ease of reference in Appendix 1 (Sequence

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0068). CMP is hereby requesting an extension of the deferral for Final Report Submission until July 2026 in order to meet the Post Marketing Requirements (PMR) 3714-2 commitment.

(b) (4)

The information contained within this submission is considered confidential and we request that it not be disclosed outside of the Agency without our written authorization.

This submission has been compiled as per current eCTD specifications and is being submitted electronically via the Electronic Submissions Gateway. All information is contained within the sequence "0071" in the root folder "nda212121".

Should you have any questions regarding the content of this submission, please contact the undersigned via email (ellen.chrismon@cmppharma.com), or phone (252-753-7111).

Sincerely,

Ellen Chrismon

Ellen Chrismon
Regulatory Affairs Director
CMP Development LLC

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This is a representation of an electronic record that was signed electronically. Following this are manifestations of any and all electronic signatures for this electronic record.

/s/

GEORGE A MAKAR on behalf of FRANK A ANANIA
08/16/2024 10:42:20 AM