KVK | TECH

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RESPONSE TO PREA NON-COMPLAINCE LETTER AND DEFERRAL EXTENSION REQUESTED

September 16, 2021

Food and Drug Administration
Center for Drug Evaluation and Research
Division of Anesthesia, Analgesia, and Addiction Products
5901-B Ammendale Road
Beltsville, MD 20705-1266

Product Name:	**APADAZ™ (6.12 mg/325 mg benzhydrocodone/ acetaminophen combination tablet)**
NDA#:	**208653**
eCTD Sequence#	**0071**
Submission:	**Deferral Extension Request**
Sponsor:	**KVK Tech Inc.**

Dear Sir/Madam,

Reference is made to Investigational New Drug Application (IND) 108,038 for Benzhydrocodone HCl (KP201)/Acetaminophen (APAP) in accordance with Section 505B(d)(1) of the Federal Food, Drug and Cosmetics Act (FD&C Act) [21 U.S.C 355c(d)(1)], KVK-Tech, Inc., hereby submits a response to PREA Non-Compliance Letter and also requests a Deferral Extension. Furthermore, the Post Marketing Requirements (PMR) Waiver Request and Deferral Extension was requested as part of the submission made to the agency on 09/02/021 (NDA# 208653; Sequence 0069), the Sponsor has provided this request based on guidance received via email from Jaimin Patel, PharmD, Regulatory Project Manager (RPM), Anesthesiology, Addiction Medicine, and Pain Medicine, ORO, CDER, FDA on 07/15/2021 and reference guidance (FDA Guidance for Industry on How to Comply with the Pediatric Research Equity Act), A copy of email RPM is attached for your easy reference.

This amendment is submitted in response to PREA Non-Compliance Letter received via mail from Jaimin Patel, PharmD, Regulatory Project Manager (RPM), Anesthesiology, Addiction Medicine, and Pain Medicine, ORO, CDER, FDA on 09/10/2021. The PREA Non-Compliance Letter is attached here with this cover letter for ready reference.

The rationale for the delayed pediatric assessment and Deferral Extension request is briefly explained below.

Submission batches (b) (4) were manufactured, (b) (4)

FDA requested KVK Tech conduct a bioequivalence (BE) study. Due to COVID-19 pandemic,

we were not able to initiate this study as of today. However, we are considering CROs who can perform the required BE study.

In addition, [redacted] (b) (4) KVK has the capability to scale up for clinical studies if there is sufficient stability data that is within specification.

[redacted] (b) (4). At the present time, we do not have an independent, secure, rugged supply of Apadaz. Due to these reasons and the unforeseen delays associated [redacted] (b) (4) as described above, KVK requested timeline extension as part of the submission made to the agency on 09/02/021 (NDA# 208653; Sequence 0069) for conduct of the proposed pediatric clinical study.

KVK Tech verifies that [redacted] (b) (4) does not contain a proposed change to the product and is [redacted] (b) (4)

This submission has been prepared in the electronic Common Technical Document (eCTD) format and is being submitted through the FDA's WebTrader Electronic Submissions Gateway and checked for viruses using the FortiClient 6.0.9.0277 virus scanning software.

If there are any questions or concerns related to this NDA submission, please do not hesitate to contact me at:

Please direct all communications regarding this Submission to:

Meher Premkumar Tirunagari
Group Leader of Regulatory Affairs
KVK-TECH, INC.
110 Terry Drive, Newtown, PA 18940
Phone: (215) 579-1842, Fax: (215) 579-0746
E-mail: Regulatory@kvktech.com

Sincerely,

Meher Premkumar Tirunagari,

09/16/2021
Date

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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/

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