January 28, 2022

RESPONSE TO PREA NON-COMPLIANCE LETTER

Jessica J. Lee, M.D., MMSc
Director, Division of Gastroenterology
Office of Drug Evaluation III
Center for Dru Evaluation and Research
Food and Drug Administration
10903 New Hampshire Avenue
Silver Spring, MD 20993

Benuvia Therapeutics Inc.
444 South Ellis Street
Chandler, AZ 85224

www.benuvia.com

Re: NDA 205525: SYNDROS® (Dronabinol) Oral Solution, CII
S0138: DEFERRAL EXTENSION REQUESTED

Dear Dr. Lee:

Reference is made to Benuvia Therapeutics Inc.'s New Drug Application for Dronabinol Oral Solution (SYNDROS®). Reference is also made to a PREA Non-Compliance Letter dated 16 December 2021 (Ref ID 4905893) in which the Division requested a response within 45 calendar days.

The Sponsor hereby submits a deferral extension request on the grounds that the pediatric formulation being developed should be tested for safety and exposure in adults prior to testing in pediatric subjects. The Sponsor therefore submits synopses for an adult pharmacokinetic study in healthy volunteers and a pediatric safety, tolerability, pharmacokinetic and efficacy evaluation in patients with chemotherapy-induced nausea and vomiting. The Sponsor requests Agency feedback on the strategy and synopses before submitting final protocols for both studies. Further, an update on the development of the (b) (4) pediatric formulation with timelines is also provided.

Included in this submission are the following documents:

- (b) (4)
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The Sponsor plans to adhere to the following timelines to meet the PREA commitments for this program:

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- Final protocol for Adult Bioavailability Study (PMR-3044-a) within 3 weeks of receiving FDA feedback on the included synopsis.
- Final protocol for Pediatric Pharmacokinetic Study (PMR-3044-b) within 3 weeks of receiving FDA feedback on the included synopsis.
- Pediatric Formula Optimization: September 2022
- GMP batch manufactured/released for use in clinical study by 31 December 2022
- Commencement of Adult Bioavailability Study: January 2023.

If this proposal if acceptable to the Agency, the Sponsor plans to submit a request for a Release and Reissue of the current post marketing requirements.

Please note, the contents of this amendment are classified as trade secret and/or commercially confidential.

If you have any questions regarding this submission, please contact me by email at lthelen@benuvia.com.

Sincerely,

Lisa Thelen

Digitally signed by Lisa Thelen
Date: 2022.01 27 12:49:56 -07'00'

Lisa Thelen
Manager, Commercial Regulatory Affairs
Benuvia Therapeutics Inc.

cc: Maureen Dewey, M.P.H. Senior Regulatory Project Manager

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The IT point of contact for this submission is:

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