November 12, 2024

Division of Dockets Management
Food and Drug Administration
Department of Health and Human Services
5630 Fishers Lane, Room 1061, HFA-305
Rockville, MD 20852

Subject: **Amendment to Docket ID FDA-2024-P-3571: ANDA Suitability Petition for Amlodipine and Benazepril Hydrochloride Oral Liquid**

Dear Sir or Madam:

Reference is made to the suitability petition (FDA-2024-P-3571), received by the FDA on 29 July 2024, seeking permission to file an ANDA for Amlodipine and Benazepril Hydrochloride Oral Liquid.

Reference is also made to the email communication from Kim-Yen Nguyen dated 08 November 2024, requesting the information detailed below as an amendment to the ANDA Suitability Petition to the Division of Dockets Management, for the Agency to complete review of the petition:

1. ***We note that your proposed drug product for this suitability petition is Amlodipine and Benazepril Hydrochloride Oral Liquid. Please clarify the proposed dosage form (i.e., solution, suspension, elixir, etc.) pursuant to 21 CFR 314.93(b).***

Petitioners Response:

As noted, the proposed drug product is a "liquid" dosage form intended for oral administration.

The Petitioner understands that "liquid" is an acceptable dosage form as recognized in the September 2024 edition of the FDA's Orange Book of Approved Drug Products with Therapeutic Equivalence Evaluations (noted in Appendix C: Uniform Terms – *Dosage Forms*), and the Structured Product Labeling (SPL) Resources (noted in Terminology – *Dosage Forms*).

The Petitioner anticipates that the "liquid" will be a solution, a suspension, or powder for suspension; ultimately to be administered to patients as an oral liquid.

Sincerely,

Seth D. DePuy Digitally signed by Seth D. DePuy
Date: 2024.11.12 09:39:04 -05'00'

Seth D. DePuy, PhD
Director, Regulatory Affairs
Premier Consulting
8000 Jarvis Avenue, Suite 100,
Newark, CA 94560
Telephone: 513-999-9854
Fax: 513-618-0964
seth.depuy@premierconsulting.com