November 28, 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-3573: ANDA Suitability Petition for Lisinopril and Hydrochlorothiazide Oral Liquid Oral Liquid**

Dear Sir or Madam:

Reference is made to the suitability petition (FDA-2024-P-3573), received by the FDA on 29 July 2024, seeking permission to file an ANDA for Lisinopril and Hydrochlorothiazide Oral Liquid.

Reference is also made to the email communication from Kim-Yen Nguyen dated 22 November 2024, requesting that, for the Agency to complete review of the petition, the information detailed below should be submitted to the Division of Dockets Management as an amendment to the ANDA Suitability Petition:

1. ***We note that your proposed drug product for this suitability petition is Lisinopril and Hydrochlorothiazide Oral Liquid. The FDA considers liquids, solutions, suspensions, and powder for suspension as four distinct dosage forms, each of which requiring separate suitability petitions. Please clarify and confirm the exact dosage form you are proposing for your drug product pursuant to 21 CFR 314.93(b).***

Petitioners Response:

The Petitioner acknowledges the Agency's feedback that liquids, solutions, suspensions, and powder for suspension are considered distinct dosage forms.

Pursuant to 21 CFR 314.93(b), the dosage form for the proposed drug product is a "liquid". The liquid is identical to the reference listed drug in active ingredient(s) and route of administration, and the proposed dosage strength(s) will cover the approved dosing range. It differs from the reference listed drug tablets only in dosage form.

Sincerely,

Seth D. DePuy Digitally signed by Seth D. DePuy
Date: 2024.11.28 09:41:26 -05'00'

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