August 4, 2022

Blessy Johns, US Agent
Aurobindo Pharma USA, Inc.
279 Princeton-Hightstown Road
East Windsor, NJ 08520

Sent via email to: bjohns@aurobindousa.com

Dear Petitioner:

Your submission requesting that the Commissioner of Food and Drug determine whether Lotensin® (benazepril hydrochloride, USP) 5 mg tablets; NDA 019851 of VALIDUS PHARMACEUTICALS LLC has been voluntarily withdrawn from sale for safety or efficacy reasons was received and processed under CFR 10.30 by this office on 08/03/2022.

It was assigned docket number FDA-2022-P-1785. Please refer to this docket number in future correspondence on this subject with the Agency.

Please note, the acceptance of the petition for filing is a procedural matter and in no way reflects the Agency's decision on the substantive merits of the petition.

Sincerely,

Karen P. Malvin -S
Digitally signed by Karen P. Malvin -S
Date: 2022.08.04 10:50:44 -04'00'

Karen Malvin
Acting Director
Dockets Management Staff
FDA/Office of Operations (OO)