U.S. FOOD & DRUG ADMINISTRATION

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

January 25, 2023

Re: Docket No. FDA-2022-P-1785

Dear Ms. Johns:

I am writing to inform you that the Food and Drug Administration (FDA) has not yet resolved the issues raised in your citizen petition received on August 3, 2022. Your petition requests that FDA determine whether LOTENSIN (benazepril hydrochloride) tablets, 5 milligrams, held by Validus Pharmaceuticals LLC, has been voluntarily withdrawn from the commercial market or withdrawn from sale for reasons of safety and/or effectiveness.

FDA has been unable to reach a decision on your petition due to the need to address other Agency priorities. This interim response is provided in accordance with FDA regulations on citizen petitions (21 CFR 10.30(e)(2)). We will respond to your petition as soon as possible given the numerous demands on the Agency's resources.

Sincerely,

Carol Bennett -S

Digitally signed by Carol Bennett -S
Date: 2023.01.25 11:44:53 -05'00'

Carol J. Bennett
Deputy Director
Office of Regulatory Policy
Center for Drug Evaluation and Research

U.S. Food & Drug Administration
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