U.S. FOOD & DRUG ADMINISTRATION

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

February 6, 2023

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

Dear Ms. Johns:

This letter responds to your citizen petition received on August 3, 2022, requesting that the Food and Drug Administration (FDA) determine whether Lotensin (benazepril hydrochloride) tablets, 5 milligrams (mg), were withdrawn from sale for reasons of safety or effectiveness.

FDA has reviewed its records and determined that Lotensin (benazepril hydrochloride) tablets, 5 mg, were not withdrawn from sale for reasons of safety or effectiveness. Thus, FDA will maintain Lotensin (benazepril hydrochloride) tablets, 5 mg, in the "Discontinued Drug Product List" section of *Approved Drug Products With Therapeutic Equivalence Evaluations* (the Orange Book).

Enclosed is a copy of the *Federal Register* notice that announces the FDA determination. If you require any further information, please feel free to call me at (301) 796-4455.

Sincerely,

Nisha P. Shah -S

Digitally signed by Nisha P. Shah -S
Date: 2023.02.06 13:28:49 -05'00'

Nisha Shah
Office of Regulatory Policy
Center for Drug Evaluation and Research

Enclosure

U.S. Food & Drug Administration
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Silver Spring, MD 20993
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