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

October 2, 2024

Re: Docket No. FDA-2024-P-2314

Dear Ms. Johns:

This letter responds to your citizen petition received on May 9, 2024, requesting that the Food and Drug Administration (FDA) determine whether Augmentin XR (amoxicillin; clavulanate potassium) Extended-release Tablets, 1 gram (gm); equivalent to (EQ) 62.5 milligram (mg) base, new drug application 050785, held by US Antibiotics, LLC, was voluntarily withdrawn for reasons of safety or effectiveness.

FDA has reviewed its records and determined that Augmentin XR (amoxicillin; clavulanate potassium) Extended-release Tablets, 1 gm; EQ 62.5 mg base, was not withdrawn from sale for reasons of safety or effectiveness. Thus, FDA will maintain Augmentin XR (amoxicillin; clavulanate potassium) Extended-release Tablets, 1 gm; EQ 62.5 mg base, 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) 796-0110.

Sincerely,

Awo Archampong-gray -S

Digitally signed by Awo Archampong-gray -S
Date: 2024.10.02 13:05:35 -04'00'

Awo Archampong-Gray
Office of Regulatory Policy
Center for Drug Evaluation and Research

Enclosure

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