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

March 15, 2024

Re: Docket No. FDA-2024-P-0827

Dear Ms. Johns:

This letter responds to your citizen petition received on February 14, 2024, requesting that the Food and Drug Administration (FDA) determine whether Duexis (ibuprofen and famotidine) tablet, 800 milligrams (mg) ibuprofen and 26.6 mg famotidine, under the new drug application 022519, held by Horizon Medicines LLC, has been voluntarily withdrawn from sale for safety or efficacy reasons.

FDA has reviewed its records and determined that Duexis (ibuprofen and famotidine) tablet, 800 mg and 26.6 mg, was not withdrawn from sale for reasons of safety or effectiveness. Thus, FDA will maintain Duexis (ibuprofen and famotidine) tablet, 800 mg and 26.6 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 (240) 402-9201.

Sincerely,

Grace L. St Vincent -S

Digitally signed by Grace L. St Vincent -S
Date: 2024.03.15 09:40:16 -04'00'

Grace St.Vincent
Office of Regulatory Policy
Center for Drug Evaluation and Research

Enclosure