Ms. Blessy Johns
U.S. Agent for Aurobindo Pharma Limited
Aurobindo Pharma USA, Inc.
279 Princeton-Hightstown Road
East Windsor, New Jersey 08520

Re: Docket No. FDA-2022-P-0069

June 30, 2022

Dear Ms. Johns:

This letter responds to your citizen petition received on January 11, 2022 (Petition). In the Petition, you request that the Food and Drug Administration (FDA) determine whether Micronor (norethindrone tablets, 0.35 milligram (mg)) has been withdrawn from sale for safety or efficacy reasons.

FDA has reviewed its records and determined that Micronor (norethindrone tablets, 0.35 mg) was not withdrawn from sale for reasons of safety or effectiveness. Thus, FDA will maintain Micronor (norethindrone tablets, 0.35 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) 796-3601.

Sincerely,

David Joy -S
Digitally signed by David Joy -S
Date: 2022.06.30 10:20:44 -04'00'

Nikki Mueller
Office of Regulatory Policy
Center for Drug Evaluation and Research

Enclosure

U.S. Food & Drug Administration
10903 New Hampshire Avenue
Silver Spring, MD 20993
w ww.fda.gov