DEPARTMENT OF HEALTH & HUMAN SERVICES Public Health Service

Food and Drug Administration
Silver Spring MD 20993

January 11, 2021

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

Sent via email to: bjohns@aurobindousa.com

Dear Petitioner:

Your submission requesting that the Commissioner of the Food and Drug Administration to determine whether MICRONOR (Norethindrone Tablets 0.35 mg); NDA 016954 of Janssen Pharmaceuticals Inc. has been voluntarily withdrawn from sale of safety or efficacy reasons was received and processed under CFR 10.30 by this office on 01/11/2022.

It was assigned docket number FDA-2022-P-0069. Please refer to this docket number in future correspondence on this subject with the Agency.

Also, note that the acceptance of the petition for filing is a procedural matter and in no way reflects the agency's decision on the substantive merits of the petition.

Sincerely,

Dynna Gorham-Bigby

Digitally signed by Dynna Gorham-Bigby
Date: 2022.01.11 16:11:03 -05'00'

Dynna Bigby
Supervisory Administrative Proceedings Officer
Dockets Management Staff
FDA/Office of Operations (OO)