January 11, 2022

To,

Division of Dockets Management (HFA-305)
Food and Drug Administration
Department of Health and Human Services
5630 Fishers Lane, Room 1061
Rockville, MD 20852

CITIZEN PETITION

Dear Sir/Madam,

The undersigned submits this Citizen Petition electronically under Section 505(j) of the Federal Food, Drug, and Cosmetic Act and 21 CFR 10.25(a), 10.30 and 21 CFR parts 314.122 and 314.161, requesting the Commissioner of the Food and Drug Administration to provide a determination whether the listed drug product has been withdrawn for safety or effectiveness reasons.

A. Action Requested

Aurobindo Pharma Limited requests the Food and Drug Administration (FDA) to determine whether **MICRONOR** (Norethindrone Tablets 0.35 mg); **NDA 016954** of Janssen Pharmaceuticals Inc. has been voluntarily withdrawn from sale for safety or efficacy reasons.

B. Statement of Grounds

The Food and Drug Administration maintains a list of drug products, which are eligible for submission as Abbreviated New Drug Applications (ANDA's) in the *Approved Drug Products with Therapeutic Equivalence Evaluations, referred to as the Orange Book*). It contains all FDA approved drug products. **MICRONOR** (Norethindrone Tablets 0.35 mg); **NDA 016954** of Janssen Pharmaceuticals Inc. was considered as "listed drug product" in the orange book. **MICRONOR** (Norethindrone Tablets 0.35 mg); **NDA 016954** of Janssen Pharmaceuticals Inc. now appears in the discontinued section of the Orange Book (enclosed as ***Annexure-I***).

Under FDA regulation, drugs are withdrawn from the list if the Agency withdraws or suspends approval of the drug product's application for reasons of safety or effectiveness, or if the FDA determines that the listed drug was withdrawn or withheld from sale for reasons of safety or effectiveness (21 CFR 314.162). The regulation also provides that the Agency must

make a determination as to whether a listed drug is withdrawn from sale for reasons of safety or effectiveness before an ANDA that refers to that listed drug may be approved (21 CFR 314.161(a)(1)). Because the product appears in the discontinued section of the Orange Book, it is requested that FDA determine whether Janssen Pharmaceuticals Inc.'s decision to discontinue marketing of **MICRONOR** (Norethindrone Tablets 0.35 mg); **NDA 016954** of Janssen Pharmaceuticals Inc. was for reasons of safety or effectiveness.

C. Environmental Impact

A claim for categorical exclusion of the requirements for an environmental assessment is made pursuant to 21 C.F.R. 25.31(a) and 25.15(d).

D. Economic Impact Statement

Pursuant to 21 C.F.R. 10.30(b), economic impact information is submitted only when requested by the Commissioner. This information will be promptly provided, if so requested.

E. Certification

The undersigned certifies that, to the best knowledge and belief of the undersigned, this petition includes all information and views on which the petition relies, and that it includes representative data and information known to the petitioner which is unfavorable to the petition.

Sincerely yours,

Blessy Johns

Digitally signed by Blessy Johns
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