DEPARTMENT OF HEALTH & HUMAN SERVICES Public Health Service

Food and Drug Administration
Silver Spring MD 20993

January 14, 2022

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 NASONEX® (mometasone furoate monohydrate) Nasal Spray, 0.05 mg/Spray (50 mcg); NDA 020762 of ORGANON LLC (Subsidiary of MERCK SHARP AND DOHME CORP) has been voluntarily withdrawn from sale of safety or efficacy reasons was received and processed under CFR 10.30 by this office on 01/14/2022.

It was assigned docket number FDA-2022-P-0077. 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: 2022.01.18 10:36:02 -05'00'

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