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

April 8, 2022

Re: Docket No. FDA-2022-P-0077

Dear Ms. Johns:

This letter responds to your citizen petition received on January 14, 2022, requesting that the Food and Drug Administration (FDA) determine whether Nasonex (mometasone furoate) nasal spray, 0.05 milligram (mg)/spray (50 microgram (mcg)), approved under new drug application (NDA) 020762 and held by Organon LLC (subsidiary of Merck Sharp and Dohme Corp.) was withdrawn from sale for safety or effectiveness reasons.

FDA has reviewed its records and determined that Nasonex (mometasone furoate) nasal spray, 0.05 mg/spray (50 mcg), was not withdrawn from sale for reasons of safety or effectiveness. Thus, FDA will maintain Nasonex (mometasone furoate) nasal spray, 0.05 mg/spray (50 mcg), 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) 402-9674.

Sincerely,

Sungjoon Chi -S

Digitally signed by Sungjoon Chi -S
DN: c=US, o=U.S. Government, ou=HHS, ou=FDA, ou=People, cn=Sungjoon Chi -S, 0.9.2342.19200300.100.1.1=2001541263
Date: 2022.04.08 08:03:36 -04'00'

Sungjoon Chi
Office of Regulatory Policy
Center for Drug Evaluation and Research

Enclosure