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

2/21/2023

Re: Docket No. FDA-2022-P-2438

Dear Blessy Johns:

This letter responds to your citizen petition received on October 4, 2022, requesting that the Food and Drug Administration (FDA) determine whether Asacol HD (mesalamine) Delayed-Release Tablet, 800 Milligrams (mg), has been voluntarily withdrawn from sale for safety or effectiveness reasons.

FDA has reviewed its records and determined that Asacol HD (mesalamine) Delayed-Release Tablet, 800 mg, was not withdrawn from sale for reasons of safety or effectiveness. Thus, FDA will maintain Asacol HD (mesalamine) Delayed-Release Tablet, 800 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) 796-3600.

Sincerely,

Donna C. Tran -S

Digitally signed by Donna C. Tran -S
Date: 2023.02.21 08:50:57 -05'00'

Donna Tran
Office of Regulatory Policy
Center for Drug Evaluation and Research

Enclosure