Matthew Weinberg
CEO
The Weinberg Group
A ProPharma Group Company
1129 Twentieth Street, NW, Suite 600
Washington, DC 20036

Re: Docket No. FDA-2020-P-1881 April 1, 2021

Dear Mr. Weinberg:

This letter responds to your citizen petition received on September 15, 2020, requesting that the Food and Drug Administration (FDA) determine whether Serentil (mesoridazine besylate) tablet under new drug application 016774 was withdrawn from sale for safety or efficacy reasons.

FDA has reviewed its records and determined that Serentil (mesoridazine besylate) tablets, 10 milligrams (mg), 25 mg, 50 mg, and 100 mg, was not withdrawn from sale for reasons of safety or effectiveness. Thus, FDA will maintain Serentil (mesoridazine besylate) tablets, 10 mg, 25 mg, 50 mg, and 100 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 (240) 402-4191.

Sincerely,

Ayako Sato -S

Digitally signed by Ayako Sato -S
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Ayako Sato
Office of Regulatory Policy
Center for Drug Evaluation and Research

Enclosure