U.S. FOOD & DRUG ADMINISTRATION

Matthew Weinberg, CEO
The Weinberg Group a ProPharma Group Company
1129 Twentieth St. N.W., Suite 600
Washington, DC 20036

March, 12, 2021

Re: Docket No. FDA-2020-P-1881

Dear Mr. Weinberg:

I am writing to inform you that the Food and Drug Administration (FDA) has not yet resolved the issues raised in your citizen petition received on September 15, 2020. Your petition requests that the Agency determine whether SERENTIL (mesoridazine besylate) tablet, approved under new drug application 016774, was withdrawn from sale for reasons of safety or effectiveness.

FDA has been unable to reach a decision on your petition due to the need to address other Agency priorities. This interim response is provided in accordance with FDA regulations on citizen petitions (21 CFR 10.30(e)(2)). We will respond to your petition as soon as possible given the numerous demands on the Agency's resources.

Sincerely,

Carol Bennett -S

Digitally signed by Carol Bennett -S
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Date: 2021.03.12 10:50:19-05'00'

Carol J. Bennett
Deputy Director
Office of Regulatory Policy
Center for Drug Evaluation and Research

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