DEPARTMENT OF HEALTH & HUMAN SERVICES Public Health Service

Food and Drug Administration
Silver Spring MD 20993

September 15, 2020

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

Dear Petitioner:

Your petition to the Commissioner of Food and Drug Administration requesting the FDA to determine whether Novartis' Serentil (mesoridazine besylate) tablet approved under NDA 016774 was withdrawn for safety and/or effectiveness reasons was received by this office on 09/15/2020.

It was assigned docket number FDA-2020-P-1881. Please refer to this docket number in future correspondence on this subject with the Agency.

Please note that the acceptance of the petition for filing is a procedural matter and in no way reflects an agency decision on the substantive merits of the petition.

Sincerely,

Dynna Gorham-bigby -S
Digitally signed by Dynna Gorham-bigby -S
Date: 2020.09.16 15:50:46 -04'00'

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