September 15, 2020

Division of Dockets Management
Department of Health and Human Services
Food and Drug Administration
5630 Fishers Lane, Room 1061
Rockville, MD 20852

CITIZEN PETITION

Dear Sir/Madam,

The undersigned, The Weinberg Group, submits this petition to section 21 CFR § 314.161 of the Federal Food, Drug and Cosmetic (FD&C) Act, in accordance with the 21 CFR § 10.25 (a) and § 10.30 to request the Food and Drug Administration (FDA) to determine whether the Reference Listed Drug (RLD), Serentil (mesoridazine besylate) tablet under the New Drug Application (NDA) 016774, was withdrawn for safety and/or effectiveness reasons.

A. Action Requested

The petitioner requests the FDA to determine whether Novartis' Serentil (mesoridazine besylate) tablet approved under NDA 016774 was withdrawn for safety and/or effectiveness reasons.

B. Statement of Grounds

On March 26, 2018, the Federal Register announced the withdrawal of 38 NDAs including Serentil (mesoridazine besylate) under NDA 016774 due to notification from the holders of the applications that the drug products would no longer be marketed (83 FR 7738). Serentil (mesoridazine besylate) under NDA 016774 is also listed in the discontinued section of the Approved Drug Products with Therapeutic Equivalence Evaluations, commonly referred to as the "Orange Book," without any determination as to whether the Listed Drug was withdrawn from the market for safety/effectiveness reasons.

C. Environmental Impact

The petitioner claims a categorical exclusion from the requirement of an environmental assessment or environmental impact statement pursuant to 21 CFR § 25.31.

D. Economic Impact

Pursuant to 21 CFR § 10.30(b), upon request by the Commissioner, the Petitioner will submit economic impact information.

E. Certification

The undersigned certifies that to the best of its knowledge, this petition includes all information and views on which the petition relies, and that it includes representative data and information known to the Petitioner which are unfavorable to the petition.

Sincerely,

Matthew Weinberg
CEO, The Weinberg Group
a ProPharma Group Company