



DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
Rockville MD 20857

FILE COPY

May 10, 2013

William Franzblau, Esq.
Vice President, Legal Affairs
Prometheus Laboratories Inc.
9410 Carroll Park Drive
San Diego, CA 92121

Dear Mr. Franzblau:

Your petition to the Food and Drug Administration requesting FDA to provide meaningful direction to industry engaged in negotiating single shared Risk Evaluation and Mitigation Strategies (REMS) through notice and comment rulemaking establishing the standards and processes for single shared REMS and waivers from the requirement for a single shared REMS, was received by this office on 05/10/2013. It was assigned docket number FDA-2013-P-0572/CP1, and it was filed on 05/10/2013. 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 in that it in no way reflects an agency decision on the substantive merits of the petition.

Sincerely,

A handwritten signature in cursive script, reading "Gloria Ortega", is positioned above the typed name.

Gloria Ortega
Administrative Proceedings Officer
Division of Dockets Management
FDA/Office of the Executive Secretariat (OES)