



DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
Rockville MD 20857

FILE COPY

June 7, 2013

Peter J. Pitts
President
Center for Medicine in the Public Interest
757 Third Avenue
20th Floor
New York, NY 10017

Dear Mr. Pitts:

Your petition to the Food and Drug Administration requesting that FDA refrain from approving any new drug application ("NDA") or any supplemental new drug application ("sNDA") for Treanda® liquid bendamustine formulation unless and until the conditions specified in the Petition are satisfied, was received by this office on 06/07/2013. It was assigned docket number FDA-2013-P-0693/CP1, and it was filed on 06/07/2013. 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 black ink, reading "Gloria Ortega", is positioned above the printed name.

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