



**FILE COPY**

August 23, 2013

Scott M. Lassman  
Klein, Kaplan & Becker LLP  
1140 19<sup>th</sup> Street, N.W., Suite 900  
Washington, D.C. 20036

Dear Mr. Lassman:

Your petition for reconsideration to the Food and Drug Administration on behalf of Novartis Pharmaceuticals Corporation requesting the Agency to strike Section III in its entirety or, in the alternative, to modify any conclusions in Section III based on mistaken inferences resting on prior incomplete information regarding the Petition's timing, was received by this office on 8/23/2013. It was assigned docket number FDA-2013-P-0247/PRC, and it was filed on 8/23/2013. 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 that reads "Karen Kennard".

Karen Kennard  
Director  
Division of Dockets Management  
FDA/Office of the Executive Secretariat (OES)