DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
Rockville MD 20857

FILE COPY

April 18, 2013

Linda G. Young, RPh, JD
Vice President, Regulatory Affairs
Salix Pharmaceuticals, Inc.
8510 Colonnade Center Drive
Raleigh, NC 27615

Dear Dr. Young:

Your petition to the Food and Drug Administration requesting an amendment to the existing criteria for how to demonstrate bioequivalence for mesalamine extended release capsules and refrain from approving any abbreviated new drug application (ANDA) for mesalamine without resolving the issues raised in the citizen petition, was received by this office on 04/18/2013. It was assigned docket number FDA-2013-P-0470/CP1, and it was filed on 04/18/2013. 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,

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