



DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
Rockville, MD 20857

April 14, 2005

Mr. Stephen D. Celestini
Salix Pharmaceuticals, Inc.
8540 Colonnade Center Drive
Suite 501
Raleigh, North Carolina 27615

FILE COPY

Dear Mr. Celestini:

Your petition requesting the Food and Drug Administration to establish guidance or regulations providing bioequivalence requirements for oral locally-acting gastrointestinal ("GI") drug products prior to approval of any generic versions of such drugs, was received by this office on 04/13/2005. It was assigned docket number 2005P-0146/CP 1 and it was filed on 04/14/2005. 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,

Lyle D. Jaffe
Division of Dockets Management
Office of Management Programs
Office of Management

2005 P-0146

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