



OCT 11 2005

Food and Drug Administration  
Rockville MD 20857

Stephen D. Celestini  
Vice President and General Counsel  
Salix Pharmaceuticals, Inc.  
8540 Colonnade Center Drive  
Suite 501  
Raleigh, NC 27615

0228 5 OCT 13 P1:36

Re: Docket No. 2005P-0146/CP1

Dear Mr. Celestini:

I am writing to inform you that the Food and Drug Administration (FDA) has not yet resolved the issues raised in your citizen petition received on April 13, 2005. Your petition requests that the Agency establish guidance or regulations providing bioequivalence requirements for oral locally-acting gastrointestinal drug products prior to approval of any generic versions of such drugs, and that we require comparative clinical trials to establish bioequivalence of oral drug products containing balsalazide disodium.

FDA has been unable to reach a decision on your petition due to the need to address other Agency priorities. This interim response is provided in accordance with FDA regulations on citizen petitions (21 CFR 10.30(e)(2)). We will respond to your petition as soon as we have reached a decision on your request.

Sincerely,

Jane A. Axelrad

Associate Director for Policy  
Center for Drug Evaluation and Research

2005P-0146

LET 1