DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration
Silver Spring MD 20993

NDA 22205/S-001

SUPPLEMENT APPROVAL

Salix Pharmaceuticals, Inc.
Attention: Benjamin Burgin, RAC
Senior Manager, Regulatory Affairs
8510 Colonnade Center Dr.
Raleigh, NC 27615

Dear Mr. Burgin:

Please refer to your Supplemental New Drug Application (sNDA) dated and received September 11, 2013, submitted under section 505(b) of the Federal Food, Drug, and Cosmetic Act (FDCA) for Giazo (balsalazide disodium) tablets, 1.1 g.

This "Changes Being Effected" supplemental new drug application proposes to revise the 6 count sample carton and bottle label by removing the statement "Take this medication with food" in accordance with the prescribing information which states that Giazo may be taken "with or without food".

We acknowledge your September 11, 2013, submission containing final printed carton and container labels.

We have completed our review of this supplemental application. It is approved, effective on the date of this letter, for use as recommended in the labeling submitted on September 11, 2013.

We remind you that you must comply with reporting requirements for an approved NDA (21 CFR 314.80 and 314.81).

If you have any questions, call Heather Buck, Regulatory Project Manager, at (301) 796-1413.

Sincerely,

{See appended electronic signature page}

Joyce Korvick, M.D., M.P.H.
Deputy Director for Safety
Division of Gastroenterology and Inborn Errors Products
Office of Drug Evaluation III
Center for Drug Evaluation and Research

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/s/

JOYCE A KORVICK
12/16/2013