DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
Rockville, MD 20857

NDA 11-870/S-039

Salix Pharmaceuticals, Inc.
Jill Kompa, MS., RAC
1700 Perimeter Park Drive
Morrisville, NC 27560

Dear Ms. Kompa:

Please refer to your supplemental new drug application dated February 16, 2007, received February 20, 2007 submitted under section 505(b) of the Federal Food, Drug, and Cosmetic Act for Diuril® (chlorothiazide) 250 mg/5mL Oral Suspension.

This "Changes Being Effected" supplemental new drug application provides for changes in the **PRECAUTIONS,** *Drug Interactions* section to amend the interaction with non-steroidal anti-inflammatory drugs (NSAIDS) to include selective cyclooxygenase-2 (COX-2) inhibitors. Additionally, a caution was added for the concomitant use of NSAIDS (including selective COX-2 inhibitors) with diuretics, angiotensin II receptor antagonists or ACE inhibitors in patients with compromised renal function.

We have completed our review of this application and it is approved, effective on the date of this letter, for use as recommended in the agreed-upon labeling text.

If you issue a letter communicating important information about this drug product (i.e., a "Dear Health Care Professional" letter), we request that you submit a copy of the letter to this NDA and a copy to the following address:

MEDWATCH
Food and Drug Administration
5515 Security Lane
HFD-001, Suite 5100
Rockville, MD 20852

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

Within 21 days of the date of this letter, submit content of labeling [21 CFR 314.50(l)] in structured product labeling (SPL) format, as described at http://www.fda.gov/oc/datacouncil/spl.html, that is identical in content to the submitted labeling text. Upon receipt, we will transmit that version to the National Library of Medicine for public dissemination.

Marketing the product with SPL that is not identical to the approved labeling text may render the product misbranded and an unapproved new drug.

If you have any questions, please call Mr. John David, Regulatory Project Manager at (301) 796-1059.

Sincerely,

{See appended electronic signature page}

Norman Stockbridge, M.D., Ph.D.
Director
Division of Cardiovascular and Renal Products
Office of Drug Evaluation I
Center for Drug Evaluation and Research

This is a representation of an electronic record that was signed electronically and this page is the manifestation of the electronic signature.

/s/

Norman Stockbridge

8/6/2007 11:41:49 AM