DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration
Silver Spring MD 20993

NDA 202450/S-003

SUPPLEMENT APPROVAL

Forest Research Institute, Inc.
Harborside Financial Center
Plaza V, Suite 1900
New Jersey, NJ 07311

Attention: Amjad Inqbal, Pharm.D.
Director, Regulatory Affairs

Dear Dr. Iqbal:

Please refer to your Supplemental New Drug Application (sNDA) dated April 30, 2014, received April 30, 2014, submitted under section 505(b)of the Federal Food, Drug, and Cosmetic Act (FDCA) for Tudorza Pressair (aclidinium bromide) inhalation powder.

This "Changes Being Effected" supplemental new drug application proposes to add the word "Tudorza" to the carton and container labeling for the demonstration inhaler in the same font as "Pressair" on the currently approved demonstration inhaler label and packaging.

APPROVAL & LABELING

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 enclosed, agreed-upon labeling text and with the minor editorial revision listed below.

1. Revise the proposed carton and container labeling for the demonstration inhaler to include the established name, aclidinium bromide, in direct conjunction with the proprietary name, Tudorza Pressair.

CARTON AND IMMEDIATE CONTAINER LABELS

Submit final printed carton and immediate container labels that are identical to the submitted carton and immediate container labels, except with the revision listed above, as soon as they are available, but no more than 30 days after they are printed. Please submit these labels electronically according to the guidance for industry *Providing Regulatory Submissions in Electronic Format – Human Pharmaceutical Product Applications and Related Submissions Using the eCTD Specifications (June 2008)*. Alternatively, you may submit 12 paper copies, with 6 of the copies individually mounted on heavy-weight paper or similar material. For administrative purposes, designate this submission "**Final Printed Carton and Container Labels for approved NDA 202450/S-003**" Approval of this submission by FDA is not required before the labeling is used.

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

REPORTING REQUIREMENTS

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 Sadaf Nabavian, Senior Regulatory Project Manager, at (301) 796-2777.

Sincerely,

{See appended electronic signature page}

Badrul A. Chowdhury, MD, PhD
Director
Division of Pulmonary, Allergy, and Rheumatology Products
Office of Drug Evaluation II
Center for Drug Evaluation and Research

ENCLOSURE:
Carton and Container Labeling

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

/s/

BADRUL A CHOWDHURY
10/30/2014