DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration
Silver Spring MD 20993

NDA 200671/S-001

SUPPLEMENT APPROVAL

New Haven Pharmaceuticals, Inc.
Attention: Larry M. Dillaha, M.D.
Chief Operations Officer
116 Washington Avenue, 4th Floor
North Haven, CT 06473

Dear Dr. Dillaha:

Please refer to your Supplemental New Drug Application (sNDA) dated 11 September 2015, received 11 September 2015, submitted under section 505(b) of the Federal Food, Drug, and Cosmetic Act (FDCA) for DURLAZA (aspirin) Extended Release 162.5 mg Capsules.

This Changes Being Effected supplemental new drug application proposes the removal of the bolded box from the carton-container labeling stating "Dispense with Medication Guide" since there is no Medication Guide for this drug.

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.

CARTON AND IMMEDIATE CONTAINER LABELS
We acknowledge your 11 September 2015, submission containing final printed carton and container labels.

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, please call Alison Blaus, Regulatory Project Manager at (301) 796-1138.

Sincerely,

{See appended electronic signature page}

Mary Ross Southworth, PharmD
Safety Deputy Director
Division of Cardiovascular & Renal Products
Office of Drug Evaluation I
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/

ALISON L BLAUS
09/15/2015

MARY R SOUTHWORTH
09/15/2015