DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration
Silver Spring MD 20993

NDA 200671/S-002

SUPPLEMENT APPROVAL

New Haven Pharmaceuticals, Inc.
Attention: Suzanne LoGalbo,
Chief Compliance Officer & Vice President, Regulatory Affairs
116 Washington Avenue, 4th Floor
North Haven, CT 06473

Dear Ms. LoGalbo:

Please refer to your Supplemental New Drug Application (sNDA) dated 15 September 2015, received 15 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 revisions to the carton and container labeling for DURLAZA. The proposed changes are as follows:

- The company logo was removed
- The color of the container labels for both the 30 and 90-count bottles was changed from purple to blue
- The statement "Professional Sample" was removed from the 30-count container label, resulting in the conversion of the 30-count professional sample label to a container label for a 30-count commercial bottle

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

Submit final printed carton and immediate container labels that are identical to the enclosed carton and immediate container labels, 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 200671/S-002**." Approval of this submission by FDA is not required before the labeling is used.

Marketing the productwith 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, please call:

Alison Blaus, RAC
Senior Regulatory Project Manager
(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/

MARY R SOUTHWORTH
09/30/2015