NDA 017581/S-116, NDA 018164/S-066 and NDA 20067/S-025

SUPPLEMENT APPROVAL

Atnahs Pharma Us Limited
c/o Parexel International
Attention: Nupur Dutta Chowdhury
Regulatory Affairs Consultant
2520 Meridian Parkway, 200
Durham, NC 27713

Dear Nupur Dutta Chowdhury:

Please refer to your supplemental New Drug Application(s) (sNDA) submitted under section 505(b) of the Federal Food, Drug, and Cosmetic Act (FDCA), and all amendments, for the following products:

Supplemental Application	Product Information	Submit Date	FDA Received Date
NDA 017581/S-116	Naprosyn (naproxen) Tablets	November 9, 2023	November 9, 2023
NDA 018164/S-066	Anaprox DS (naproxen sodium) Tablets	November 8, 2023	November 8, 2023
NDA 20067/S-025	EC Naprosyn (naproxen delayed release) Tablets	November 7, 2023	November 7, 2023

These “Changes Being Effected” supplemental new drug applications provide for changes to bottle label and carton label of as follows:
• 'Usual Dosage: See package insert’ changed to ' Recommended Dosage: See Prescribing Information'
• “PHARMACIST: DISPENSE THE ACCOMPANYING MEDICATION GUIDE TO EACH PRESCRIPTION” changed to: “PHARMACIST: DISPENSE THE ACCOMPANYING MEDICATION GUIDE TO EACH PATIENT.”
• 'Store at 15°-30°C (59°- 86°F)' change to: ‘Store at 15° to 30°C (59° to 86°F)’
• Added expiration date format (YYYY-MM)
• Remove 'Made in Mexico'
• Added Human-readable and machine-readable (2D data matrix barcode)
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APPROVAL & LABELING

We have completed our review of these supplemental applications, as amended. They are approved, effective on the date of this letter, for use as recommended in the enclosed agreed-upon labeling.

CARTON AND CONTAINER LABELS

Submit final printed carton and container labels that are identical to enclosed carton and 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 – Certain Human Pharmaceutical Product Applications and Related Submissions Using the eCTD Specifications*. For administrative purposes, designate this submission "**Product Correspondence – Final Printed Carton and Container Labels for approved NDA 017581/S-116.**" Approval of this submission by FDA is not required before the labeling is used.

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 Teicher Agosto, Regulatory Business Process Manager, at (240) 402 - 3777.

Sincerely,

{See appended electronic signature page}

Gurpreet Gill-Sangha, Ph.D.
Supervisor
Division of Product Quality Assessment II
Office of Product Quality Assessment I
Office of Pharmaceutical Quality
Center for Drug Evaluation and Research

Enclosure(s):
Carton and Container Labeling

Gurpreet
Gill Sangha

Digitally signed by Gurpreet Gill Sangha
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