



NDA 020725/S-025

SUPPLEMENT APPROVAL

Abbvie Inc.
Attention: Jinrong Liu, PhD, MBA, RAC
Senior Manager, Regulatory Affairs
1 North Waukegan Rd
North Chicago, IL 60064

Dear Dr. Liu:

Please refer to your Supplemental New Drug Application (sNDA) dated and received December 18, 2017, and your amendments, submitted under section 505(b) of the Federal Food, Drug, and Cosmetic Act (FDCA) for CREON (pancrelipase) Delayed-Release Capsules.

This “Changes Being Effected” supplemental new drug application provides for carton and container labeling revised to include a bolded statement or appropriate alternative to the carton and container labels per 21 CFR 208.24(d): "ATTENTION PHARMACIST: Each patient is required to receive the enclosed Medication Guide".

APPROVAL & LABELING

We have completed our review of this supplemental application, as amended. 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 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 (May 2015, Revision 3)*. For administrative purposes, designate this submission “**Product Correspondence – Final Printed Carton and Container Labels for approved NDA 020725/S-025.**” 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 Grecia C. Edwards, Regulatory Business Process Manager, at (240) 402 - 1773.

Sincerely,

{See appended electronic signature page}

For:

David Lewis, PhD
Branch Chief, BII
Division of Post-Marketing Activities I
Office of Lifecycle Drug Products
Office of Pharmaceutical Quality
Center for Drug Evaluation and Research

Enclosure:

Carton and Container Labeling



Ramesh
Raghavachari

Digitally signed by Ramesh Raghavachari
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