



NDA 020725/S-014

**SUPPLEMENT APPROVAL
RELEASE REMS REQUIREMENT**

Abbott Products, Inc.
Attention: Adam E. Allgood, Pharm.D., R.Ph.
Director, Regulatory Affairs
901 Sawyer Road
Marietta, GA 30062

Dear Dr. Allgood:

Please refer to your Supplemental New Drug Application (sNDA) dated April 29, 2011, received April 29, 2011, submitted under section 505(b) of the Federal Food, Drug, and Cosmetic Act (FDCA) for CREON (pancrelipase) delayed-release capsules.

We also acknowledge receipt of your risk evaluation and mitigation strategy (REMS) assessment dated October 28, 2010.

This supplemental new drug application proposes to eliminate the requirement for the approved REMS.

We have completed our review of this supplemental application, as amended. It is approved, effective on the date of this letter.

RISK EVALUATION AND MITIGATION STRATEGY REQUIREMENTS

The REMS for CREON (pancrelipase) was originally approved on April 30, 2009, and the most recent REMS modification was approved on August 12, 2010. The REMS consists of a Medication Guide and a timetable for submission of assessments of the REMS.

You propose that FDA no longer require a REMS for CREON (pancrelipase).

We have determined that maintaining the Medication Guide as part of the approved labeling is adequate and meets the standard in 21 CFR 208.1. Therefore, it is no longer necessary to include the Medication Guide as an element of the approved REMS, and a REMS is no longer necessary to ensure that the benefits of CREON (pancrelipase) outweigh its risks. Therefore, we agree with your proposal and a REMS for CREON (pancrelipase) is no longer required.

We remind you that the Medication Guide will continue to be part of the approved labeling in accordance with 21 CFR 208.

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 Jagjit Grewal, Regulatory Project Manager, at (301) 796-0846.

Sincerely,

{See appended electronic signature page}

Joyce Korvick, M.D., M.P.H.
Deputy Director for Safety
Division of Gastroenterology and Inborn
Errors Products
Office of Drug Evaluation III
Center for Drug Evaluation and Research

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/s/

JOYCE A KORVICK
05/09/2011