



NDA 20-725/S-007

**SUPPLEMENT APPROVAL**

Abbott Laboratories  
Attention: Adam Allgood, PharmD., RPh  
Assistant Director, Regulatory Affairs  
901 Sawyer Road  
Marietta, GA 30062

Dear Dr. Allgood:

Please refer to your Supplemental New Drug Application (sNDA) dated February 5, 2010, received February 12, 2010, submitted pursuant to section 505(b)(2) of the Federal Food, Drug, and Cosmetic Act (FDCA) for Creon (pancrelipase) Delayed-Release Capsules.

We also acknowledge receipt of your amendments dated February 24, March 10, August 3, August 10, and August 11, 2010, and your risk evaluation and mitigation strategy (REMS) assessment dated February 24, 2010.

This supplemental new drug application provides for proposed modifications to the approved REMS, which consists of revising the Medication Guide for consistency with the Medication Guide for NDA 22-210 Zenpep (pancrelipase) Delayed-Release Capsules, as well as updating manufacturer information.

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.

As soon as possible, but no later than 14 days from the date of this letter, submit, using the FDA automated drug registration and listing system (eLIST), the content of labeling [21 CFR 314.50(l)] in structured product labeling (SPL) format, as described at <http://www.fda.gov/ForIndustry/DataStandards/StructuredProductLabeling/default.htm>, that is identical to the enclosed labeling text and include the labeling changes proposed in any pending "Changes Being Effected" (CBE) supplements. Upon receipt, we will transmit that version to the National Library of Medicine for public dissemination. For administrative purposes, please designate this submission, "**SPL for approved NDA 20-725/S-007.**"

We request that the revised labeling approved today be available on your website within 10 days of receipt of this letter.

## **RISK EVALUATION AND MITIGATION STRATEGY REQUIREMENTS**

The REMS for Creon (pancrelipase) Delayed-Release Capsules was originally approved on April 30, 2009. The REMS consists of a Medication Guide and a timetable for submission of assessments of the REMS. Your proposed modifications to the REMS consist of revisions to the Medication Guide.

Your proposed modified REMS, submitted on August 11, 2010, and appended to this letter, is approved.

The timetable for submission of assessments of the REMS will remain the same as that approved on April 30, 2009.

There are no changes to the REMS assessment plan described in our April 30, 2009, letter.

Assessments of an approved REMS must include, under section 505-1(g)(3)(B) and (C), information on the status of any postapproval study or clinical trial required under section 505(o) or otherwise undertaken to investigate a safety issue. With respect to any such postapproval study, you must include the status of such study, including whether any difficulties completing the study have been encountered. With respect to any such postapproval clinical trial, you must include the status of such clinical trial, including whether enrollment has begun, the number of participants enrolled, the expected completion date, whether any difficulties completing the clinical trial have been encountered, and registration information with respect to requirements under subsections (i) and (j) of section 402 of the Public Health Service Act. You can satisfy these requirements in your REMS assessments by referring to relevant information included in the most recent annual report required under section 506B and 21 CFR 314.81(b)(2)(vii) and including any material or significant updates to the status information since the annual report was prepared. Failure to comply with the REMS assessments provisions in section 505-1(g) could result in enforcement action.

In addition to the assessments submitted according to the timetable included in the approved REMS, you must submit a REMS assessment and may propose a modification to the approved REMS when you submit a supplemental application for a new indication for use as described in section 505-1(g)(2)(A) of FDCA.

Prominently identify submissions containing the REMS assessments or proposed modifications of the REMS with the following wording in bold capital letters at the top of the first page of the submission as appropriate:

**NDA 20-725  
REMS ASSESSMENT**

**NEW SUPPLEMENT FOR NDA 20-725 - PRIOR APPROVAL SUPPLEMENT  
PROPOSED REMS MODIFICATION  
REMS ASSESSMENT**

**NEW SUPPLEMENT (NEW INDICATION FOR USE)  
FOR NDA 20-725  
REMS ASSESSMENT  
PROPOSED REMS MODIFICATION (if included)**

If you do not submit electronically, please send 5 copies of REMS-related submissions.

**PROMOTIONAL MATERIALS**

You may request advisory comments on proposed introductory advertising and promotional labeling. To do so, submit the following, in triplicate, (1) a cover letter requesting advisory comments, (2) the proposed materials in draft or mock-up form with annotated references, and (3) the package insert to:

Food and Drug Administration  
Center for Drug Evaluation and Research  
Division of Drug Marketing, Advertising, and Communications  
5901-B Ammendale Road  
Beltsville, MD 20705-1266

You must submit final promotional materials and package insert, accompanied by a Form FDA 2253, at the time of initial dissemination or publication [21 CFR 314.(b)(3)(i)]. Form FDA 2253 is available at <http://www.fda.gov/opacom/morechoices/fdaforms/cder.html>; instructions are provided on page 2 of the form. For more information about submission of promotional materials to the Division of Drug Marketing, Advertising, and Communications (DDMAC), see <http://www.fda.gov/AboutFDA/CentersOffices/CDER/ucm090142.htm>.

**LETTERS TO HEALTH CARE PROFESSIONALS**

If you decide to issue a letter communicating important safety-related information about this drug product (i.e., a “Dear Health Care Professional” letter), we request that you submit, at least 24 hours prior to issuing the letter, an electronic copy of the letter to this NDA, to CDERMedWatchSafetyAlerts@fda.hhs.gov, and to the following address:

MedWatch Program  
Office of Special Health Issues  
Food and Drug Administration  
10903 New Hampshire Ave  
Building 32, Mail Stop 5353  
Silver Spring, MD 20993

**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 Heather Buck, Regulatory Project Manager, at (301) 796-1413.

Sincerely,

*{See appended electronic signature page}*

Joyce Korvick, M.D.  
Deputy, Safety  
Office of Drug Evaluation III  
Center for Drug Evaluation and Research

ENCLOSURE(S):   REMS  
                          Package Insert  
                          Medication Guide

Application Type/Number	Submission Type/Number	Submitter Name	Product Name
NDA-20725	SUPPL-7	ABBOTT PRODUCTS INC	CREON/MINIMICROSPHERE)PA NCRELIPASE D-R C

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**This is a representation of an electronic record that was signed electronically and this page is the manifestation of the electronic signature.**

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/s/

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JOYCE A KORVICK  
08/12/2010