



NDA 022523/S-002

**SUPPLEMENT APPROVAL  
RELEASE REMS REQUIREMENT**

Ortho-McNeil-Janssen Pharmaceuticals, Inc.  
c/o Johnson & Johnson Pharmaceutical Research & Development, L.L.C.,  
Attention: Ilona Scott  
Director, Global Regulatory Affairs  
920 Route 202 South  
Raritan, NJ 08869

Dear Ms. Scott:

Please refer to your Supplemental New Drug Application (sNDA) dated and received May 23, 2011, submitted under section 505(b) of the Federal Food, Drug, and Cosmetic Act (FDCA) for PANCREAZE (pancrelipase) Delayed-Release Capsules.

We acknowledge receipt of your amendment dated May 31, 2001, containing your risk evaluation and mitigation strategy (REMS) assessment.

This supplemental new drug application proposes to eliminate the requirement for the approved PANCREAZE (pancrelipase) 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 PANCREAZE (pancrelipase) was originally approved on April 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 PANCREAZE (pancrelipase).

We have determined that maintaining the Medication Guide as part of the approved labeling is adequate to address the serious and significant public health concern 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 to ensure that the benefits of PANCREAZE (pancrelipase) outweigh its risks, and a REMS for PANCREAZE (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/  
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JOYCE A KORVICK  
06/20/2011