

**CENTER FOR DRUG EVALUATION AND  
RESEARCH**

*APPLICATION NUMBER:*  
**022523Orig1s000**

**REMS**

**NDA 022523**

**PANCREAZE (pancrelipase)**

Delayed-Release Capsules

Manufactured by:  
Nordmark Arzneimittel GmbH & Co. KG  
25436 Uetersen, Germany

Marketed and Distributed by:  
McNeil Pediatrics, Division of Ortho-McNeil-Janssen Pharmaceuticals, Inc.  
Titusville, NJ 08560

1-800-526-7736

**I. GOALS**

To inform patients about the serious risks associated with the use of Pancreaze, including the risk of fibrosing colonopathy and the theoretical risk of transmission of porcine viral disease.

**II. REMS ELEMENTS**

**A. Medication Guide**

A currently approved Medication Guide will be dispensed with each PANCREAZE Delayed-Release Capsules prescription in accordance with 21 CFR 208.24.

To comply with 21 CFR 208.24, sufficient numbers of the Medication Guide will be provided to ensure that a copy can be provided with each dispensed PANCREAZE prescription.

Container and carton labels for PANCREAZE will include an instruction alerting the pharmacist to provide a Medication Guide to each patient to whom the product is dispensed.

One copy of the Full Prescribing Information (which includes a medication guide) will be provided with each bottle of PANCREAZE. The Full Prescribing Information, including the Medication Guide, will be available to download on the Internet at: [www.rxforsafety.com](http://www.rxforsafety.com).

The Medication Guide is appended to this REMS.

## **B. Timetable For Submission Of Assessments**

Ortho-McNeil-Janssen Pharmaceuticals, Inc. will submit REMS assessments to FDA 18 months, 3 years, and 7 years from the date of initial approval of the REMS. To facilitate inclusion of as much information as possible while allowing reasonable time to prepare the submission, the reporting interval covered by each assessment should conclude no earlier than 60 days before the submission date for that assessment.

Ortho-McNeil-Janssen Pharmaceuticals, Inc. will submit each assessment so it will be received by the FDA on or before the due date.

Application  
Type/Number

Submission  
Type/Number

Submitter Name

Product Name

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NDA-22523

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ORIG-1

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JOHNSON &  
JOHNSON  
PHARMACEUTICA  
L RESEARCH &  
DEVELOPMENT  
LLC

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Pancrelipase Microtablets

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/s/  
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JULIE G BEITZ  
04/12/2010