

## **Appendix A**

### **Risk Evaluation and Mitigation Strategy (REMS)**

**NDA 20-725**

### **CREON (pancrelipase) Delayed-Release Capsules**

Drug Class: Pancreatic Enzyme Products

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#### **1 Goals**

To ensure that the following serious risks are communicated to patients and caregivers:

- The risk of fibrosing colonopathy which may be mitigated by properly dosing CREON;
- The theoretical risk of transmission of viral disease to patients treated with a porcine-derived pancreatic enzyme product.

#### **2 REMS Elements**

##### **A. Medication Guide**

A Medication Guide (see attachment) will be a required element of the REMS for CREON. 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 CREON prescription. CREON container or package labels will include an instruction alerting the pharmacist to provide a Medication Guide to each patient to whom the product is dispensed, and stating how the Medication Guide is provided.

One copy of the Full Prescribing Information that includes a Medication Guide will be provided with each bottle of CREON. One additional copy of the Medication Guide will be supplied with the 12 count bottle, two additional Medication Guides will be supplied with the 100 count bottle and the 250 count bottle. The Full Prescribing Information, including the Medication Guide, will be available to download on the Internet at [www.CREON-US.com](http://www.CREON-US.com).

#### **B. Communication Plan**

The REMS for CREON does not include a Communication Plan.

#### **C. Elements to Assure Safe Use**

The REMS for CREON does not include Elements to Assure Safe Use.

#### **D. Implementation System**

Because this REMS for CREON does not include Elements to Assure Safe Use, an Implementation System is not required.

### **3 Assessment of the REMS for CREON**

#### **A. Timetable for Submission of Assessments**

The assessment interval period will close no earlier than 60 days prior to the date the respective assessment is due as noted below:

- 1<sup>st</sup> Assessment: [October 30, 2010] 18 months after NDA approval
- 2<sup>nd</sup> Assessment: [April 30, 2012] 3 years after NDA approval
- 3<sup>rd</sup> Assessment: [April 30, 2016] 7 years after NDA approval

The assessments will include an evaluation of the effectiveness of the Medication Guide in communicating the risks of CREON.