Creon Delayed-Release Capsules Recall - Possible Presence of Different Strength Capsule(s) Other than Labelled in Bottle

- AbbVie Inc., is conducting a voluntary recall of one lot of Creon Delayed-Release Capsules due to the presence of a capsule of Creon that may be a different strength than labelled. The incorrect strength is not stated.
- The manufacturer states that exposure to the product is not likely to cause adverse health consequences.
- Creon is a combination of porcine-derived lipases, proteases, and amylases indicated for the treatment of exocrine pancreatic insufficiency due to cystic fibrosis, chronic pancreatitis, pancreatectomy, or other conditions.

PRODUCT SEQUESTERING ACTIONS
- This patient level recall involves the following product:

<table>
<thead>
<tr>
<th>PRODUCT NAME</th>
<th>STRENGTH</th>
<th>NDC NUMBER</th>
<th>LOT NUMBER</th>
<th>EXPIRATION DATE</th>
</tr>
</thead>
<tbody>
<tr>
<td>Creon Delayed-Release Capsules</td>
<td>24,000 USP units of lipase; 76,000 USP units of protease; 120,000 USP units of amylase.</td>
<td>0032-1224-07</td>
<td>1020156</td>
<td>03/21/2016</td>
</tr>
</tbody>
</table>

- This specific lot was packaged on June 21, 2014 and distributed within the U.S. between July 9, 2014 and August 26, 2014.
- Following the action due dates in Product Recall Office Log # 8644 (available at: http://vaww.recalls.ncps.med.va.gov/WebRecalls/Recalls.html), sequester and then return all remaining affected product at the CMOP/facility per manufacturer’s instructions. Please inform your Facility Recall Coordinator when completed.

PATIENT NOTIFICATION ACTIONS
- Determine whether the affected product(s) was dispensed to any patient(s) for home administration. CMOP data (if available) will be provided by a CMOP representative to Pharmacy Chiefs.
- If an affected lot(s) was dispensed to a patient(s) for home administration, then:
  - Identify the patient(s).
  - Contact patient(s) who may have received the affected product(s) for home administration by any appropriate method.
    - A sample letter can be found at: https://vaww.cmopnational.va.gov/cmop/PBM/Other%20Documents%20and%20Resources/Recall%20Patient%20Letter%20Template.doc
- Provide patient(s) in possession of the recalled product with instructions on the following:
  - How to return the product being recalled to the pharmacy.
  - How to obtain a new supply of product.
  - When the correct product is received, patients should begin using the new product and return the recalled supply as instructed.
- Providers should continue to report any adverse reactions with the use of Creon Delayed-Release Capsules by entering the information into CPRS’ Allergies/Adverse Reactions field and/or via local reporting mechanisms. Adverse events should also be reported, as appropriate, to the VA ADERS program and FDA MedWatch (1-800-FDA-1088, fax 1-800-FDA-0178, online at https://www.accessdata.fda.gov/scripts/medwatch/medwatch-online.htm, or by mail).

REFERENCES:

FEEDBACK NOTIFICATION ACTIONS:
- Facility Director (or physician designee): Report completion of actions to the VISN Director.
- Facility COS and Chief Nurse Executives: Forward this document to all appropriate providers who prescribe this agent (e.g., primary care providers, internal medicine, gastrointestinal specialists, and pharmacy staff, including contract providers, etc.). In addition, forward to the Associate Chief of Staff (ACOS) for Research and Development (R&D). Forward to other VA employees as deemed appropriate. Report completion of actions to the Facility Director.
- ACOS for R&D: Forward this document to Principal Investigators (PIs) who have authority to practice at the facility and to your respective Institutional Review Board (IRB).
- VISN Directors: Within 10 business days of issue (due 10/20/2014), communicate to PBM/VAMedSAFE that all product sequestration actions have been completed via the Feedback tool: https://vaww.cmopnational.va.gov/cmop/PBM/visn_drug_recalls_alerts/default.aspx.