SimplyThick® Thickening Gel Products Recall Due to Possible Presence of Bacteria

- Simply Thick, LLC is announcing a voluntary recall of its SimplyThick® thickening gel products due to failure to communicate with FDA a mechanism that will certify that harmful bacteria are destroyed during the manufacturing process.
- Products affected were manufactured since June 1, 2009 at a food processing plant (currently owned and operated by Thermo Pac, LLC) located in Stone Mountain, Georgia.
- SimplyThick® is a thickening agent used in the preparation of beverages to aid patients that have difficulty swallowing improve their fluid intake.

**SEQUESTERING ACTIONS**

- Following the action due dates in Product Recall Office Log # 1347 (available at http://vaww.recalls.ncps.med.va.gov/WebRecalls/Recalls.html), sequester and then return all remaining product at the CMOP/facility level with the affected lot numbers per manufacturer’s instructions. Please inform your Facility Recall Coordinator when completed.
- The affected lot numbers appear below:

<table>
<thead>
<tr>
<th>Description</th>
<th>Lot #</th>
<th>UPC</th>
<th>Econo #</th>
</tr>
</thead>
<tbody>
<tr>
<td>SIMPLY/T HONEY 240GM CS40 N/A</td>
<td>820513020004</td>
<td>1374982 (Mckesson Discontinued since September 2007)</td>
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<tr>
<td>SIMPLY/T HONEY 300MG CS100</td>
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<td>820513010001</td>
<td>2211167</td>
<td></td>
</tr>
</tbody>
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**PATIENT NOTIFICATION ACTIONS**

- Determine whether the affected product was dispensed to any patient(s) for home administration using a 12-month time frame. CMOP data (if available) will be provided by a CMOP representative to Pharmacy Chiefs.
- If an affected lot was dispensed to a patient(s) for home administration, then:
  - Identify the patient(s).
  - Contact patient(s) who may have received the affected product for home administration by any appropriate method.
    - This template can be altered according to site-specific needs.
  - Provide patient(s) in possession of the recalled product with instructions on the following:
- How to obtain a new supply of product.
- How to return the product being recalled to the pharmacy.
- When the correct product is received, patient should begin using the new product and return the recalled supply as instructed.
- Report any adverse reactions experienced with the use of this product to the VA ADERS program.

**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, gastrointestinal providers, 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 6/24/2011), communicate to PBM/VAMedSAFE that all patient notification actions have been completed via the Feedback tool: [http://vaww.national.cmop.va.gov/PBM/visn_drug_recalls_alerts/default.aspx](http://vaww.national.cmop.va.gov/PBM/visn_drug_recalls_alerts/default.aspx).