

**DEPARTMENT OF VETERANS AFFAIRS VETERAN HEALTH ADMINISTRATION (VHA)
PHARMACY BENEFITS MANAGEMENT SERVICES (PBM) & MEDICAL ADVISORY PANEL (MAP)
VA CENTER FOR MEDICATION SAFETY (VAMedSAFE)**

NATIONAL PBM COMMUNICATION · June 10, 2011

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:

Description	Lot #	UPC	Econo #
SIMPLY/T HONEY 240GM CS40	N/A	82051302004	1374982 (McKesson Discontinued since September 2007)
SIMPLY/T HONEY 30GM CS100	0041, 0042, 0043, 0046, 0047, 0081, 0082, 0084, 0085, 0095, 0096, 0123, 0124, 0125, 0130, 0144, 0145, 0146, 0193, 0194, 0195, 0216, 0217, 0218, 0228, 0229, 0230, 0235, 0256, 0257, 0258, 0284, 0285, 0286, 0287, 0298, 0299, 0319, 0320, 0321, 0322, 0340, 0341, 0362, 0363, 1003, 1004, 1005, 1006, 1026, 1027, 1052, 1053, 1054, 1081, 1082, 1083, 1101, 1102, 1103, 1104, 1118, 1122, 1123, 1124, 9152, 9153, 9189, 9190, 9216, 9222, 9223, 9251, 9252, 9253, 9264, 9265, 9313, 9314, 9315, 9321, 9322, 9342, 9343, 9344	82051302001	3770450
SIMPLY/T HONEY 30GM CT100	0041, 0042, 0043, 0046, 0047, 0081, 0082, 0084, 0085, 0095, 0096, 0123, 0124, 0125, 0130, 0144, 0145, 0146, 0193, 0194, 0195, 0216, 0217, 0218, 0228, 0229, 0230, 0235, 0256, 0257, 0258, 0284, 0285, 0286, 0287, 0298, 0299, 0319, 0320, 0321, 0322, 0340, 0341, 0362, 0363, 1003, 1004, 1005, 1006, 1026, 1027, 1052, 1053, 1054, 1081, 1082, 1083, 1101, 1102, 1103, 1104, 1118, 1122, 1123, 1124, 9152, 9153, 9189, 9190, 9216, 9222, 9223, 9251, 9252, 9253, 9264, 9265, 9313, 9314, 9315, 9321, 9322, 9342, 9343, 9344	82051302001	2211993
SIMPLY/T NECTAR 120GM CS80	N/A	82051301004	1376078 (McKesson Discontinued since September 2007)
SIMPLY/T NECTAR 15GM CS200	0004, 0005, 0047, 0048, 0049, 0060, 0061, 0062, 0063, 0082, 0083, 0097, 0098, 0099, 0116, 0117, 0118, 0119, 0120, 0123, 0152, 0153, 0154, 0155, 0187, 0188, 0189, 0190, 0191, 0193, 0214, 0215, 0216, 0235, 0236, 0237, 0277, 0278, 0279, 0280, 0281, 0282, 0291, 0292, 0293, 0294, 0299, 0305, 0306, 0313, 0314, 0315, 0319, 0320, 0321, 0322, 0340, 0341, 0362, 0363, 0364, 1003, 1004, 1005, 1006, 1015, 1018, 1019, 1020, 1024, 1025, 1045, 1046, 1047, 1048, 1049, 1054, 1055, 1080, 1081, 1082, 1101, 1102, 1103, 1104, 1105, 1117, 1118, 1129, 1130, 1131, 1132, 9188, 9189, 9208, 9209, 9210, 9211, 9215, 9216, 9244, 9245, 9246, 9251, 9265, 9266, 9267, 9292, 9293, 9294, 9295, 9313, 9320, 9321, 9341, 9342, 9345	82051301001	3777810
SIMPLY/T NECTAR 15GM CT200	0004, 0005, 0047, 0048, 0049, 0060, 0061, 0062, 0063, 0082, 0083, 0097, 0098, 0099, 0116, 0117, 0118, 0119, 0120, 0123, 0152, 0153, 0154, 0155, 0187, 0188, 0189, 0190, 0191, 0193, 0214, 0215, 0216, 0235, 0236, 0237, 0277, 0278, 0279, 0280, 0281, 0282, 0291, 0292, 0293, 0294, 0299, 0305, 0306, 0313, 0314, 0315, 0319, 0320, 0321, 0322, 0340, 0341, 0362, 0363, 0364, 1003, 1004, 1005, 1006, 1015, 1018, 1019, 1020, 1024, 1025, 1045, 1046, 1047, 1048, 1049, 1054, 1055, 1080, 1081, 1082, 1101, 1102, 1103, 1104, 1105, 1117, 1118, 1129, 1130, 1131, 1132, 9188, 9189, 9208, 9209, 9210, 9211, 9215, 9216, 9244, 9245, 9246, 9251, 9265, 9266, 9267, 9292, 9293, 9294, 9295, 9313, 9320, 9321, 9341, 9342, 9345	82051301001	2211167

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.
 - A sample letter can be found at: <http://vaww.national.cmop.va.gov/PBM/Other%20Documents%20and%20Resources/Recall%20Patient%20Letter%20Template.doc>
 - 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.cmap.va.gov/PBM/visn_drug_recalls_alerts/default.aspx.