## *NATIONAL PBM COMMUNICATION · May 31, 2011*

# *ADDENDUM: Recall of ADDITIONAL LOTS of Various Adhesive Remover Wipes/Skin Prep Protective Wipes Due to Potential Microbial Contamination*

- On May 19, 2011, PBM issued a NATIONAL PBM COMMUNICATION addressing Smith & Nephew, Inc.'s voluntary product recall for specific lots of various adhesive remover wipes/skin prep protective wipes used in wound management for the following reasons:
  - The manufacture of these products occurred at the same facility as Triad wipe products, swabs, and swab sticks recalled earlier this year; and
  - Potential for bacterial contamination exists.
- Recently, additional lots have been identified.

***SEQUESTERING ACTIONS***

- Following the action due dates in Product Recall Office Log # 1148 (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 affected lot number(s) per manufacturer's instructions. Please inform your Facility Recall Coordinator when completed.
- Additional affected lot number(s) are listed below:

| DESCRIPTION | LOT # | NDC | UPC | ECONO# |
|---|---|---|---|---|
| REMOVE Universal Adhesive Remover Wipes, Box of 50, Product# 403100 | 0E145, 0E146, 0E210, 0E211, 0G138, 0H135, 0H248, 0J232, 0L147, 0M176, 0M177, 1A117, 1B112, 0E194, 1B128 | 08026403100 | 04056511566 | 1254036 |
| SKIN PREP NO STING Protective Wipes, Box of 50, Product# 420600 | 9L170, 9K150, 9K151 | 08026420600 | 04056511673 | 2236206 |
| SKIN-PREP Protective Wipes, Box of 50, Product# 420400 | 0D169, 0D182, 0D200, 0F164, 0F165, 0F183, 0F184, 0H117, 0J124, 0L227, 0L241, 0M200, 1A246, 1A247, 1A248, 1A257, OD190, OF182, OG137, OJ293, O6K120, 1A258 | 08026420400 | 04056511452 | 1468701 |
| REMOVE Universal Adhesive Remover Wipes, Box of 50, SMITH&NEPH PROD NUMB 59403125 | OF242, OG116, OJ233, 1A106, 1A182 | N/A | N/A | McKesson does not stock |
| SKIN-PREP Protective Wipes, Box of 50, SMITH&NEPH PROD NUMB 59420425 | OG117, OG225, OJ147, OM198 | N/A | N/A | McKesson does not stock |
| UNI-SOLVE Adhesive Remover Wipes, Box of 50, Product# 402300 | 0F198, 0F223, 1B130, 1A103, 1B131, 1B132 | 08026402300 | 04056511565 | 1469352 |
| PERI-PREP Wipes, Box of 50, Product# 5132 | OC232, OG243 | | | |
| SKIN-PREP Protective Wipes, Box of 1000, Product# 420471 | OD149, OF184, OJ127, OM109, 1A277, 9M165 | | | |
| REMOVE Universal Adhesive Remover Wipes, Box of 50, Product# 403120 | OL163, 1A193 | | | |

***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(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 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) with instructions on the following:
    - How to obtain a new supply of product.
    - How to return the product being recalled to the pharmacy.
    - Not to continue using the product with the affected lot number. 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 handle this agent (e.g.,* ***pharmacy staff, and other medical specialties who may use adhesive remover wipes/skin prep protective wipes,*** *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 06/14/2011), 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.*