Recall of Triad Group Products Due to Potential for Infection: Sterile Lubricating Jelly & Alcohol Prep Pads/Swabs/Swabsticks

INFORMATION FOR PROVIDERS

- Due to FDA concerns regarding inadequate product sterilization and product contamination, which may lead to patient infection (especially in at risk populations, including immune suppressed and surgical patients), Triad Group is issuing a product recall for:
  - CERTAIN LOTS of STERILE LUBRICATING JELLY
  - ALL LOTS of ALCOHOL PREP PADS, ALCOHOL SWABS, and/or ALCOHOL SWABSTICKS

- Sterile Lubricating Jelly is a component of some catheter insertion trays assembled by Medline.
- Triad Group alcohol prep pads, alcohol swabs, and/or alcohol swabsticks are found in many commercially available drug and procedure kits, as well as private labels.
  - The FDA has not published a complete list of commercially available drug and procedure kits that contain the recalled alcohol prep pads, alcohol swabs, and/or alcohol swabsticks. To date, the commercially available drug kits known to contain the recalled alcohol prep pads, alcohol swabs, and/or alcohol swabsticks are Copaxone, Betaseron, Extavia, Boniva, Fuzeon, Nutropin A.Q. Pen, Pegasys, and TNKase.
  - Private labeled alcohol prep pads, alcohol swabs, and/or alcohol swabsticks are:
    - distributed nationwide to retail pharmacies;
    - packaged in individual packets;
    - sold in retail pharmacies in single boxes, each containing 100 packets;
    - identified by “Triad Group,” listed as the manufacturer;
    - also manufactured for third parties and use the names listed below in their packaging:

| Cardinal Health | Best Choice | Healthy Generations | Publix | Shoppers Drug |
| PSS Select | Care One | Kroger | Premier Value | Sunmark Up&Up |
| VersaPro | Discount Drug Mart | Leader | Quality Choice | Top Care |
| Boca/Ultilet | Equaline | Life Brand | Rite Aid | Triad |
| Moore Medical | Equate | Longs | Reli-On | Triad Sterile |
| Walgreens | Exchange Select | Major | Remedy RX | Uniprix |
| CVS | Exact | MEIJER | Rexall | Valu Plus |
| Conzellin | Good Sense | Medicine Shoppe | Safeway | Western Family |
| | Healthcare | Personelle | Select Brand |

- To date, FDA has received one report of a non-life-threatening skin infection related to the use of the recalled alcohol products.

FOR PHARMACY SERVICE

- This recall involves all Triad Group lots of Sterile Lubricating Jelly remaining, including all lot numbers beginning with the digits 7, 8, 9, and/or 0.
- Medline Industries, Inc., may have kits and/or packs containing the recalled Triad Group Sterile Lubricating Jelly, with the respective lot numbers for the Medline kits listed below:

<table>
<thead>
<tr>
<th>MEDLINE PRODUCT</th>
<th>DESCRIPTION</th>
<th>AFFECTED LOT NUMBER(S) AND INSTRUCTIONS</th>
</tr>
</thead>
<tbody>
<tr>
<td>NON-STERILE KITS</td>
<td>KIT, N/S RECOVERY</td>
<td>ALL LOTS IN INVENTORY</td>
</tr>
<tr>
<td>DYK1005488R</td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>MINOR PROCEDURE TRAYS</th>
<th>DESCRIPTION</th>
<th>AFFECTED LOT NUMBER(S) AND INSTRUCTIONS</th>
</tr>
</thead>
<tbody>
<tr>
<td>DYND10805</td>
<td>KIT, SPECI-CATH, FEMALE, 8FR, PVP, LUB, GLVS</td>
<td>ALL LOTS STARTING WITH 08, 09, 10 FOLLOWED BY A LETTER (A-Z) IN THE THIRD POSITION.</td>
</tr>
<tr>
<td>DYND11008</td>
<td>TRAY, FOLEY CATH, SIL-ELAST, 18 FR, 10ML, BG</td>
<td></td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>STERILE PROCEDURE TRAYS</th>
<th>DESCRIPTION</th>
<th>AFFECTED LOT NUMBER(S) AND INSTRUCTIONS</th>
</tr>
</thead>
<tbody>
<tr>
<td>CD5981</td>
<td>CYSTO CDS</td>
<td>09JG1031</td>
</tr>
<tr>
<td>CD5981</td>
<td>CYSTO CDS</td>
<td>10EG1017</td>
</tr>
<tr>
<td>CD5981</td>
<td>CYSTO CDS</td>
<td>10GB5244</td>
</tr>
</tbody>
</table>

- This recall also includes all lots of alcohol prep pads, alcohol swabs, and alcohol swabsticks manufactured by Triad Group.
- Triad Group alcohol prep pads, alcohol swabs, alcohol swabsticks are found in many commercially available drug and procedure kits, as well as private labels.
The FDA has not published a complete list of commercially available drug and procedure kits that contain the alcohol prep pads, alcohol swabs, and/or alcohol swabsticks. To date, the commercially available drug kits known to contain the recalled alcohol prep pads, alcohol swabs, and/or alcohol swabsticks are Copaxone, Betaseron, Extavia, Boniva, Fuzeon, Nutropin A.Q. Pen, Pegasyis, and TNKase.

Private labeled alcohol prep pads, alcohol swabs, and/or alcohol swabsticks are:
- distributed nationwide to retail pharmacies;
- packaged in individual packets;
- sold in retail pharmacies in single boxes, each containing 100 packets;
- identified by “Triad Group,” listed as the manufacturer;
- also manufactured for third parties and use the names listed below in their packaging:

Cardinal Health
Best Choice
Healthy Generations
Publix
Shoppers Drug
PSS Select
Care One
Kroger
Premier Value
Sunmark Up&Up
VersaPro
Discount Drug Mart
Leader
Quality Choice
Top Care
Boca/Ultilet
Equilibre
Life Brand
Rite Aid
Triad
Moore Medical
Equate
Longs
Reli-On
Triad Sterile
Walgreens
Exchange Select
Major
Remedy RX
Uniprix
CVS
Exact
MEIJER
Rexall
Valu Plus
Conzellin
Good Sense
Medicine Shoppe
Safeway
Western Family
Healthcare
Personelle
Select Brand

SEQUESTERING ACTIONS
- Follow the action due dates in Product Recall Office Log #807 and #812 [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.
- Since a complete list of commercially available drug kits affected by this recall is not available, inspect all commercial drug and procedure kits in facility inventory for the recalled items. Perform the following actions if the affected alcohol prep pads, alcohol swabs, and/or alcohol swabsticks are found:
  - Remove the affected alcohol prep pads, alcohol swabs, or alcohol swabsticks from the kit.
  - Provide a separately packaged alternative when dispensing to patients.
  - Include a notice to the patient explaining the action.

PATIENT NOTIFICATION ACTIONS
- Determine whether the affected lot numbers (refer to lot numbers provided above) were dispensed to any patient(s) for home administration. It is recommended to use a 12-month time frame for this determination. 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.recalls.ncps.med.va.gov/WebRecalls/Recalls.html. 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.

REFERENCES:

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, neurologists, geriatrics, urologists, and other surgical service, 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 2/03/2011), communicate to PBM/VA MedSAFE that all patient notification actions have been completed via the Feedback tool: http://vawww.national.cmop.va.gov/PBM/visn_drug_recalls_alerts/default.aspx.