NATIONAL PBM COMMUNICATION · January 20, 2011

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 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:

MEDLINE PRODUCT	DESCRIPTION	AFFECTED LOT NUMBER(S) AND INSTRUCTIONS
NON-STERILE KITS		
DYK1005488R	KIT, N/S RECOVERY	ALL LOTS IN INVENTORY
MINOR PROCEDURE TRAYS		
DYND10805	KIT, SPECI-CATH, FEMALE, 8FR, PVP, LUB, GLVS	ALL LOTS STARTING WITH 08, 09, 10 FOLLOWED BY A
DYND11008	TRAY, FOLEY CATH, SIL-ELAST, 18 FR, 10ML, BG	LETTER (A-Z) IN THE THIRD POSITION.
STERILE PROCEDURE TRAYS		
CDS981	CYSTO CDS	09JG1031
CDS981	CYSTO CDS	10EG1017
CDS981	CYSTO CDS	10GB5244

- 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, Pegasys, and TNKase.
- Private labeled alcohol prep pads, alcohol swabs, and/or alcohol swabsticks are:
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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	

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.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.

REFERENCES:

FDA Firm Press Release. http://www.fda.gov/Safety/Recalls/ucm239219.htm . (Accessed January 11, 2011).
FDA Firm Press Release. http://www.fda.gov/Safety/Recalls/ucm240131.htm . (Accessed January 19, 2011).

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/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.*