NATIONAL PBM ALERT

July 17, 2008

**DEPARTMENT OF VETERANS AFFAIRS - VETERANS HEALTH ADMINISTRATION (VHA)
PHARMACY BENEFITS MANAGEMENT SERVICES (PBM), MEDICAL ADVISORY PANEL (MAP),
AND CENTER FOR MEDICATION SAFETY PSCI (VA MedSAFE),
Nationwide Recall of Sodium Polystyrene Sulfonate Suspension, USP (15g/60ml)
(NDC 0054-0165-51; Lot 856396A Expiration April 2010, and Lot 856693A Expiration May 2010)**

I. ISSUE

Roxane Laboratories, Inc. announced that it is conducting a voluntary nationwide recall of Sodium Polystyrene Sulfonate Suspension, USP, 15g/60ml unit dose bottles (NDC 0054-0165-51; Lot 856396A Expiration April 2010, and Lot 856693A Expiration May 2010) due to potential yeast contamination.

II. BACKGROUND

Sodium Polystyrene Sulfonate Suspension is used in the management of patients with hyperkalemia. According to the manufacturer, a sample from one of the recalled lots (856396A Expiration April 2010) tested positive for yeast; the contamination was felt to be due to one lot of high-density polyethylene bottles from a supplier. Sodium Polystyrene Sulfonate Suspension Lot 856693A Expiration May 2010 has not tested positive for yeast; however, this product is also part of the recall as a precaution, since the same bottles were used for this lot. The manufacturer states that there have been no adverse events reported that were related to the recalled lots.

III. DISCUSSION

The concern with potential yeast contamination with the affected lot numbers of Sodium Polystyrene Sulfonate Suspension is the potential for yeast infections, especially in immunocompromised patients (e.g., patients undergoing bone marrow or stem cell transplants; organ transplantation; patients receiving multiple immunosuppressive therapies or chemotherapy; patients with profound neutropenia, a dysfunctional spleen, or who have undergone a splenectomy; patients with HIV/AIDS) as they may be at an increased risk for opportunistic infections and sepsis.

IV. VA MEDSAFE RECOMMENDATIONS *reinforce those of the manufacturer and FDA and include*:

- Determine whether the affected lot numbers of Sodium Polystyrene Sulfonate Suspension, USP, 15 g/60 ml unit dose bottles (NDC 0054-0165-51; Lots 856396A Expiration April 2010, and Lot 856693A Expiration May 2010) were dispensed to the patient and if so, identify the patients who may have received the affected product and determine the most appropriate method of notifying the patient (use/modify accompanying patient letter, phone call, other) with instructions on how to return the affected product and receive a new prescription.
- Patients should be advised to contact their Healthcare Provider or seek medical care if symptoms of yeast infection develop (e.g., fever, skin rash, oral thrush).
- All remaining product with the affected lot numbers at the facility/CMOP level should be returned as instructed in the FDA Recall notice (see link below).
- Further information regarding the affected lots of Sodium Polystyrene Sulfonate Suspension safety issue can be accessed via the following link: Roxane Laboratories, Inc. Initiates a Nationwide Voluntary Recall of Two Manufacturing Lots of Sodium Polystyrene Sulfonate Suspension in the US and Puerto Rico.

V. REFERENCES

1. FDA Recall-Firm Press Release: Roxane Laboratories, Inc. Initiates a Nationwide Voluntary Recall of Two Manufacturing Lots of Sodium Polystyrene Sulfonate Suspension in the US and Puerto Rico
2. Patterson TF. Advances and challenges in management of invasive mycoses. Lancet 2005;366:1013-25.