Nitroglycerin (Nitrostat®) Recall Due to Packaging Error

- Pfizer Inc., is voluntarily recalling the following medicines due to incorrect packaging:
  - Nitrostat® 0.4 mg, LOT V100670
  - Nitrostat® 0.6 mg, LOT V100546

- Four-pack cartons of Nitrostat® 0.4 mg, LOT V100670 may contain bottles of Nitrostat® 0.6 mg, LOT V100546, which are not marketed in the United States.
- No other lot number(s) are affected by this recall.
- According to Pfizer, patients who inadvertently take Nitrostat® 0.6 mg instead of Nitrostat® 0.4 mg may experience adverse effects that are temporary and medically reversible, with serious outcomes a remote possibility.

**SEQUESTERING ACTIONS**

- Following the action due dates in Product Recall Office Log # 1291 (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 number per manufacturer’s instructions. Please inform your Facility Recall Coordinator when completed.
- Determine whether the affected lot number(s) (refer to lot number[s] provided above) 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.

**PHARMACY ACTIONS**

- If an affected lot(s) was dispensed to a/multiple 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 medication.
      - How to return the medication being recalled to the pharmacy.
- Providers should continue to report any adverse events with nitroglycerin by entering the information into CPRS’ Allergies/Adverse Reactions field and/or via local reporting mechanisms. Facilities should continue to report adverse events into VA ADERS and to the FDA (as appropriate).

**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 and cardiologists, 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 receipt (due 06/09/2011), communicate to PBM/VAMedSAFE that all actions have been completed via the Feedback tool: http://vaww.national.cmop.va.gov/PBM/visn_drug_recalls_alerts/default.aspx.