DEPARTMENT OF VETERANS AFFAIRS VETERAN HEALTH ADMINISTRATION (VHA)
PHARMACY BENEFITS MANAGEMENT SERVICES (PBM) & MEDICAL ADVISORY PANEL (MAP)
VA CENTER FOR MEDICATION SAFETY (VAMedSAFE)

NATIONAL PBM COMMUNICATION · June 30, 2011

RECALL DUE TO MISLABELING: Butalbital, Acetaminophen, and Caffeine Tablets, USP 50mg/325mg/40mg (Four Lots)and Hydrocodone Bitartrate and Acetaminophen Tablets, USP 7.5mg/500mg (Four Lots)

- Qualitest Pharmaceuticals is voluntarily recalling four lots of Butalbital, Acetaminophen, and Caffeine Tablets USP, 50mg/325mg/40mg, and four lots of Hydrocodone Bitartrate and Acetaminophen Tablets, USP 7.5mg/500mg due to incorrect labeling.
- An individual bottle of Butalbital, Acetaminophen, and Caffeine Tablets USP, 50mg/325mg/40mg, 500 count was found incorrectly labeled with a Hydrocodone Bitartrate and Acetaminophen Tablets, USP 7.5mg/500mg, 1000 count label.
- For patients naïve to butalbital, unintentional administration may result in sedation, confusion, lightheadedness, dizziness, and nausea, as well as possible hypersensitivity reactions in those with an allergy to butalbital. Furthermore, patients on hydrocodone for chronic pain who inadvertently receive the mislabeled medications may experience suboptimal control of pain and withdrawal symptoms.
- No injuries have been reported to date.

SEQUESTERING ACTIONS

- Following the action due dates in Product Recall Office Log # 1411 (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.
- The affected lot numbers appear below:
  - **Butalbital, Acetaminophen, and Caffeine Tablets, USP, 50mg/325mg/40mg, NDC 0603-2544-28 500 count, Lot Numbers C0390909A, C0400909A, C0410909A, C0590909B.** Tablet Description: white, round shaped tablets, debossed "2355" on one side, and debossed "V" on the reverse side.
  - **Hydrocodone Bitartrate and Acetaminophen Tablets, USP 7.5mg / 500mg, NDC 0603-3882-32, 1000 count, Lot Numbers C0390909A, C0400909A, C0410909A, C0590909B.** Tablet Description: white with green specks, capsule-shaped, scored tablets, debossed "3594" on one side and debossed "V" on the reverse side.

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 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) in possession of the recalled product with instructions on the following:
    - How to obtain a new supply of product.
    - How to return the product being recalled to the pharmacy.
    - 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 Recall – Firm Press Release: Qualitest Pharmaceuticals Issues Voluntary, Nationwide Retail Level Recall of Four Lots of Butalbital, Acetaminophen, and Caffeine Tablets, USP 50mg/325mg/40mg and Four Lots of Hydrocodone Bitartrate and Acetaminophen Tablets, USP 7.5mg/500. http://www.fda.gov/Drugs/DrugSafety/ucm245085.htm .(Accessed 06/29/11).

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, pain clinic staff, and pharmacy staff,*** *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 07/15/2011), 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.*