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## Mislabeled Butalbital-APAP-Caffeine tablets (Qualitest Pharmaceuticals announces voluntary recall)

### NOTICE

On June 24, 2011 Qualitest Pharmaceuticals announced a national voluntary retail-level recall of butalbital-acetaminophen-caffeine 50 mg-325 mg-40 mg tablets and hydrocodone-acetaminophen 7.5 mg-500 mg tablets secondary to the incorrect labeling of a butalbital-acetaminophen-caffeine bottle with a hydrocodone-acetaminophen label. To review the FDA's official press release please visit the agency's website at <http://www.fda.gov/Safety/Recalls/ucm260837.htm>.

### BACKGROUND

According to Qualitest Pharmaceuticals, this voluntary recall stems from the identification of a single bottle of butalbital-acetaminophen-caffeine tablets incorrectly labeled as hydrocodone-acetaminophen 7.5 mg-500 mg tablets (1000 count bottle) with lot number C0590909B. Secondary to the use of the same stock of labels for lot numbers C0590909A, C0400909A, and C0410909A, these batches may also be affected. According to the manufacturer, the products at question were shipped between November 13, 2009 and April 9, 2010 to wholesalers and pharmacies nationwide. Due to the fact that the identified bottles may contain incorrect substances, it is possible that patients intended to utilize hydrocodone-acetaminophen, may in fact, be inadvertently taking butalbital-caffeine-acetaminophen. While both products contain acetaminophen, the unintentional use of butalbital may result in adverse events such as lightheadedness, sedation, nausea, and dizziness. Furthermore, patients allergic to butalbital may experience hypersensitivity reactions. Though not as likely, adverse events associated with caffeine may include irritability, tremors, and difficulty sleeping. It is possible that patients who were utilizing hydrocodone-acetaminophen may experience an increase in pain or symptoms of withdrawal as a direct consequence of this labeling error.

### RECOMMENDED ACTION

Qualitest is currently notifying all pharmacies that may have received the mislabeled bottles in an effort to facilitate the return of the affected products. Patients who have received prescriptions for either medication manufactured by Qualitest will be contacted by their pharmacists and instructed to dispose of the affected product. Instructions for obtaining a replacement prescription will be provided. PMSI's Mail Order Pharmacy patients will be contacted in a similar fashion.

**Reference:** Butalbital, Acetaminophen, and Caffeine Tablets (USP 50mg, 325mg, 40mg) and Hydrocodone Bitartrate and Acetaminophen Tablets (USP 7.5mg, 500mg): Recall-Bottle Mislabeled. FDA MedWatch. <http://www.fda.gov/Safety/MedWatch/SafetyInformation/SafetyAlertsforHumanMedicalProducts/ucm260915.htm> <Accessed June 27, 2011>

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