

NATIONAL PBM COMMUNICATION · August 20, 2009

Barr Laboratories, Inc., Announces a Nationwide Voluntary Recall of a Specific Lot of Dextroamphetamine/Amphetamine 20mg Tablets Due to Weight Variability

- Barr Laboratories, Inc., is voluntarily recalling Dextroamphetamine Saccharate, Amphetamine Aspartate, Dextroamphetamine Sulfate and Amphetamine Sulfate (Mixed Salts of a Single Entity Amphetamine Product) 20mg Tablets, 100 count bottles, lot number 311756.
- The affected lot is being recalled due to excess tablet weight in some tablets which may lead to increased potency.
- Toxicities associated with an excess dose could include cardiovascular, neurologic, psychiatric and gastrointestinal reactions such as: palpitations, tachycardia, hypertension, headache, tremor, tic, dyskinesia, dizziness, blurred vision, sweating, insomnia, agitation, euphoria, mania, anxiety, restlessness, nausea, diarrhea, constipation, dry mouth, and decreased appetite.
- No adverse events have been reported to the FDA regarding the affected lot.
- The following product is being recalled:

Product	Description	Lot Numbers
Dextroamphetamine/Amphetamine 20mg Tablets	Oval peach colored tablet, debossed with b/973 on one side and 2/0 on the other side.	Only lot 311756 is affected by this recall. Barr distributed the affected lot between 06/11/09 and 06/16/09.

- Return all remaining product at the facility level with the affected lot number to McKesson, NOT as instructed in the product recall documents. Affected lots of in-house stock are to be sequestered within 24 hours of this notice. Please inform your Facility Recall Coordinator when the sequestering actions have been completed.
- Determine whether the affected medication (information provided above) was dispensed to any patient(s). The time frame for the distribution of the affected lot is noted above. A file containing the last 6 months of VAMC pharmaceutical prime vendor purchases is attached. This should only be used as a guide because it does not include direct purchases and drop shipments.
- If an affected product was dispensed to patients, then:
 - Identify the patient(s).
 - Contact patient(s) who may have received the affected product 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.
 - To continue taking the medication with the affected lot number until they receive a new supply. When correct medication is received, patient should begin taking the new medication and return the recalled supply as instructed.
- Report any adverse reactions experienced with the use of this medication to the VA ADERS program.
- Refer to <http://www.fda.gov/Safety/Recalls/ucm177321.htm> for further details regarding this recall.

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, mental health specialists, psychiatrists, sleep specialists, neurologists, and palliative care clinicians 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 09/03/2009), 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.