Ferrous Sulfate Tablets, 325 mg Labeled as Rugby Natural Iron Supplement: Recall - Bottle May Contain Meclizine HCl 25 mg Tablets

- On January 18, 2013, Advance Pharmaceutical Inc. recalled one lot of Ferrous Sulfate Tablets 325 mg because of a report that the bottle incorrectly contains Meclizine HCl 25 mg tablets instead.
- Inadvertently taking Meclizine HCl 25 mg instead of the intended Ferrous Sulfate 325 mg may pose risks of serious side effects in patients who use alcohol or other sedatives; patients with CNS conditions; patients with kidney or liver impairment; elderly patients; nursing infants whose lactating mothers received the drug; and newborns whose mothers received the drug immediately before childbirth.
- Dose-related and potentially life-threatening toxicities resulting from Meclizine accumulation include impaired alertness, drowsiness, confusion, low blood pressure, coma, and respiratory depression.

PRODUCT SEQUESTERING ACTIONS
- Details of affected lot include:
  - Product(s): Ferrous Sulfate 325mg (SGR) 100 Count.
  - Product Identification No(s): NDC 00536-5890-01.
  - Serial/Lot No(s): 12G468.
  - Expiration date for the lot: 07/14.
  - Manufacturer: Advance Pharmaceutical for Rugby Laboratories.
- Following the action due dates in Product Recall Office Log # 3347 (available at: http://vaww.recalls.ncps.med.va.gov/WebRecalls/Recalls.html), sequester and then return all remaining affected product at the CMOP/facility per manufacturer’s instructions. Please inform your FRC when completed.

PATIENT NOTIFICATION ACTIONS
- Determine whether the affected product(s) was dispensed to any patient(s) for home administration. Affected product was shipped between 09/21/2012 and 10/03/2012. VISNs with PPV purchases include: 1, 2, 3, 11, 17, 20, and 21. PPV sales data does not include lot number. VISNs 16, 17, and 18 had medical centers with prescriptions dispensed from CMOP with the affected lot number.
- If an affected lot(s) was dispensed to a patient(s) for home administration, then:
  - Identify the patient(s).
  - Contact patient(s) who may have received the affected product(s) 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.
  - If necessary, 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, patients should begin using the new product and return the recalled supply as instructed.
    - Patients should not continue to take the product until they obtain replacement product.
- Providers should continue to report any adverse reactions with the use of any iron supplement product(s) by entering the information into CPRS’ Allergies/ Adverse Reactions field and/or via local reporting mechanisms. Adverse events should also be reported, as appropriate, to the VA ADERS program and FDA MedWatch (1-800-FDA-1088, fax 1-800-FDA-0178, online at https://www.accessdata.fda.gov/scripts/medwatch/medwatch-online.htm, or by mail).

REFERENCES