

# Enforcement Report

The FDA Enforcement Report is published weekly by the Food and Drug Administration, Department of Health and Human Services. It contains information on actions taken in connection with agency Regulatory activities.

## Selected Excerpts

August 9, 2006  
06-32

### RECALLS AND FIELD CORRECTIONS: DRUGS - CLASS II

#### PRODUCT

- a) Hydralazine Hydrochloride 100 mg tablets, 30 tablet box, NDC # 50111-397-01, Recall # D319-6;
- b) Hydralazine Hydrochloride 100 mg tablets, 250 tablet bag, NDC # 50111-397-01, Recall # D320-6

#### CODE

- a) Lot K43263R30, exp. 12/13/06;
- b) Lot K43263R25, exp. 12/13/06

#### RECALLING FIRM/MANUFACTURER

Heartland Repack Services LLC, Toledo, OH, by telephone and fax letter on July 14, 2006. Firm initiated recall is ongoing.

#### REASON

Packaging mix-up- The outer packaging is labeled as Hydralazine Hydrochloride, 100 mg tablets, but the unit dose blister strips inside the outer packaging may contain and be labeled as Benzotropine Mesylate, 0.5 mg tablets.

#### VOLUME OF PRODUCT IN COMMERCE

655/30 count boxes and 10/150 count bags

#### DISTRIBUTION

Nationwide

#### PRODUCT

Lorazepam Tablets, 2 mg, 30 tablet bingo cards, NDC # 61332-452-39, Recall # D-321-6

#### CODE

Lot # 452E0622, expiration date 4/30/2007

#### RECALLING FIRM/MANUFACTURER

*Recalling Firm:* Heartland repack Services LLC, Toledo, OH, by telephone on or about June 5, 2006.

*Manufacturer:* Sandoz, Inc, Broomfield, CO. Firm initiated recall is ongoing.

#### REASON

Lorazepam 1 mg tablets packaged and distributed as Lorazepam 2 mg tablets.

#### VOLUME OF PRODUCT IN COMMERCE

1,124 cards/30 tablets per card

#### DISTRIBUTION

Nationwide

### RECALLS AND FIELD CORRECTIONS: DRUGS - CLASS III

#### PRODUCT

Actonel® (risedronate sodium tablets), 35 mg, once a week, Rx only, NDC 0149-0472-02. Each

physician sample contains 1 tablet in a blister, sealed in a pouch, affixed to a sample card, Recall # D-322-6

**CODE**

Lot 328121, exp. date 12/2007

**RECALLING FIRM/MANUFACTURER**

Procter & Gamble Pharm, Inc., Norwich, NY, by letter on June 30, 2006. Firm initiated recall is ongoing.

**REASON**

Labeling: Incorrect package insert (older version) was sent instead of revised current version.

**VOLUME OF PRODUCT IN COMMERCE**

229,034 physician samples

**DISTRIBUTION**

Nationwide

**RECALLS AND FIELD CORRECTIONS: BIOLOGICS - CLASS II**

**PRODUCT**

Decavac Vaccine, 10 x 1 UD Syringe, NDC number: 49281-291-10, Recall # B-1611-6

**CODE**

Lot number: U1703AA, Expiration date: 7/11/07

**RECALLING FIRM/MANUFACTURER**

*Recalling Firm:* Amerisource Bergen, Chesterbrook, PA, by telephone on May 25, 2006, and by letter dated May 30, 2006.

*Manufacturer:* Sanofi Pasteur, Inc., Swifwater, PA. Firm initiated recall is complete.

**REASON**

Vaccines, that were stored under unacceptable temperatures, were distributed.

**VOLUME OF PRODUCT IN COMMERCE**

300 units

**DISTRIBUTION**

TX

**RECALLS AND FIELD CORRECTIONS: BIOLOGICS - CLASS III**

**RECALLING FIRM/MANUFACTURER**

American National Red Cross, Southern Region, Atlanta, GA, by facsimile transmissions and by letters dated November 17, 2004. Firm initiated recall is complete.

**REASON**

Red Cells, mislabeled as to M antigen phenotype, were distributed.

**VOLUME OF PRODUCT IN COMMERCE**

46 units

**DISTRIBUTION**

GA

**PRODUCT**

Package Insert which accompanies the Hematocrit and Metabolite QUALICHECK LEVEL 2 Quality Control of Hematocrits and Metabolites, used with the ABL 77/70/555 Blood Gas & Electrolyte Analyzers. The QC reagents are packaged in a box of 30 glass vials of (1.5 ml) per box. The package insert is packed one per box. Model #.S7180, Part Number: 944040, Recall # Z-1316-06 Package Insert which accompanies the Hematocrit and Metabolite QUALICHECK LEVEL 2 Quality Control of Hematocrits and Metabolites, used with the ABL 77/70/555 Blood Gas & Electrolyte Analyzers. The QC reagents are packaged in a box of 30 glass vials of (1.5 ml) per box. The package insert is packed one per box. Model #.S7180, Part Number: 944040, Recall # Z-1316-06

**CODE**

Lot # 15

**RECALLING FIRM/MANUFACTURER**

*Recalling Firm:* Radiometer America, Inc., Westlake, OH, by letter dated May 24, 2005.

*Manufacturer:* Radiometer Medical, Bronshoj, Denmark. Firm initiated recall is complete.

**REASON**

The package insert, which accompanied the QC reagents used with ABL blood gas analyzers, referenced incorrect control ranges for Hct (hematocrit) testing. The range stated on the package insert was too low to generate accurate Hct test results (The control ranges were acceptable for the glucose and lactate testing).

**VOLUME OF PRODUCT IN COMMERCE**

55 boxes

**DISTRIBUTION**

Nationwide, London, and Canada