

# MEDIXFACTS

Spring-Summer 2009

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Call your customer  
service rep at  
1-800-486-1811

The Pharmedix  
One-Write™  
Label will be re-  
turning late this  
Spring.

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PHARMEDIX CO. UNION CITY, CA.  
1-800-486-1811.

## Amoxicillin/ Cephalexin short- age

Due to a pending shortage of product created by FDA action against one of the main suppliers in the U.S. of Amoxicillin and Cephalexin, the price of these products will be increasing 30-50% after March 15th. We are notifying our clients of this increase in order to give you adequate time to stock up on these products at the old prices before our current inventory of product is exhausted. Call customer service for current expiration dates on the products you may need since amoxicillin and cephalexin products purchased in between Feb 1 and March 15th will not be returnable.

## Fuel Surcharge going down but not eliminated

The current fuel surcharge of \$ 3.75 per shipment will be decreasing to \$2.25 on Feb 15th. Despite the major decrease in gas prices, our carriers are still charging a reduced surcharge. If and when this charge disappears, we will suspend this charge.

## FDA THERAPEUTIC EQUIVALENCE EVALUATION CODES—THE ORANGE BOOK RATING

For the benefit of our clients, starting in February 15th 2009, *Pharmedix* will begin printing on each tray label of every prescription (Rx) medication that particular drug's FDA orange book bioequivalence rating. This project should take about 6-12 months to complete.

The FDA has a coding system for the therapeutic equivalence for drug products. This system is constructed to allow users to determine quickly whether the agency has evaluated a particular approved product as therapeutically equivalent to other pharmaceutically equivalent products (first letter) and to provide additional information on the basis of the FDA's evaluation (second letter). The two basic categories into which multisource drugs have been placed are indicated by the first letter as follows:

- A** Drug products that the FDA considers **to be therapeutically equivalent** to other pharmaceutically equivalent products, i.e. drugs for which:
1. There are no known or suspected bioequivalence problems. These are designated **AA, AN, AO, AP** or **AT** (the latter includes many Topicals, Ophthalmics, Otics, Parentals etc)
  2. Actual or potential bioequivalence problems have been resolved with adequate *in vitro* and/or *in vitro* evidence supporting bioequivalence. These are designated **AB**
- B** Drug products that the FDA at this time, considers **not to be therapeutically equivalent** to the other pharmaceutically equivalent products, i.e., drug products for which actual or potential bioequivalence problems have not been resolved by adequate evidence of bioequivalence. Often the problem is with specific dosage forms rather than the active ingredients. These are designated **BC, BD, BE, BN, BP, BR, BS, BT, BX, or B\***. For example, the new Albuterol HFA (Proair, Proventil, Ventolin) inhalers are currently rated BX meaning these products are NOT interchangeable.

At Pharmedix we only use A rated generics with few exceptions (see albuterol HFA above and Z rating below). Any competitor that says they only use AB rated generics does not understand the Orange Book rating codes. If they only carried AB rated generics, they would not be able to supply certain generics, like, for example, methocarbamol (generic Robaxin) or Hydrocodone/APAP (generic Vicodin), since all generics for these products are AA rated not AB rated. Another example is Gentamicin ophthalmic solution 0.3% for which all generic products are currently rated AT not AB.

In addition, many drug information databases designate some drugs with a **Z** rating. This rating is NOT a FDA rating but is used by these companies to designate (1) a pharmaceutical entity has been evaluated by the FDA but that particular manufacturer's product has not been (**ZA**); (2) nonprescription pharmaceuticals (e.g. aspirin) or older legend products (e.g. Belladonna Alkaloids + PB or plain Phenobarbital) that have never been evaluated by the FDA (**ZB**); or (3) single source drugs (e.g. divalproex sodium 250mg) that do not have a therapeutic equivalency rating in the Orange book (**ZC**). At *Pharmedix* we do not use ZA drugs but do use ZB and ZC products where these are the only products available.

For a more extensive explanation of the Orange Book Rating system, go to our website at [pharmedixRx.com](http://pharmedixRx.com) after March 1st and click on the FDA link and search for Orange Book or go to <http://www.fda.gov/cder/orange/default.htm>.

## **Sumatriptan (generic *Imitrex*™) now available !**

Sumatriptan (the generic for *Imitrex*) is now available. Sumatriptan 25mg, 50mg, and 100mg tablets are available in 9 pill patient dose cards and as injectable patient dose kits and refills. The price of this generic product is still high (only about a 15-20% reduction from the brand); however; the cost should begin to drop after the 180 day exclusivity period granted for the first generic product to market is over.