



# U.S. Food and Drug Administration



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## ***Recall -- Firm Press Release***

FDA posts press releases and other notices of recalls and market withdrawals from the firms involved as a service to consumers, the media, and other interested parties. FDA does not endorse either the product or the company.

### **Actavis Totowa (formerly known as Amide Pharmaceutical, Inc.) recalls all lots of Bertek and UDL Laboratories Digitek® (digoxin tablets, USP) as precaution**

**Contact:**

Stericycle customer service  
1-888-276-6166

**FOR IMMEDIATE RELEASE** -- Morristown, NJ -- April 25, 2008 -- Actavis Totowa LLC, a United States manufacturing division of the international generic pharmaceutical company Actavis Group, is initiating a Class I nationwide recall of Digitek® (digoxin tablets, USP, all strengths) for oral use. The products are distributed by Mylan Pharmaceuticals Inc., under a "Bertek" label and by UDL Laboratories, Inc. under a "UDL" label.

The voluntary all lot recall is due to the possibility that tablets with double the appropriate thickness may have been commercially released. These tablets may contain twice the approved level of active ingredient than it appropriate.

Digitek® is used to treat heart failure and abnormal heart rhythms. The existence of double strength tablets poses a risk of digitalis toxicity in patients with renal failure. Digitalis toxicity can cause nausea, vomiting, dizziness, low blood pressure, cardiac instability and bradycardia. Death can also result from excessive Digitalis intake. Several reports of illnesses and injuries have been received.

Actavis manufactures the products for Mylan and the products are distributed by Mylan and UDL under the Bertek and UDL labels. Bertek and UDL are affiliates of Mylan.

**Any customer inquiries related to this action should be addressed to Stericycle customer service at 1-888-276-6166 with representatives available Monday through Friday, 8 am to 5 pm EST. Additional information about the voluntary recall can also be found at [www.actavis.us](http://www.actavis.us).**

**Retailers who have this product are urged to return the product to their place of purchase. If consumers have medical questions, they should contact their health care providers.**

This recall is being conducted with the knowledge of the Food and Drug Administration.

Any adverse reactions experienced with the use of this product, and/or quality problems should also be reported to the FDA's MedWatch

Program by phone at 1-800-FDA-1088, by Fax at 1-800-FDA-0178, by mail at MedWatch, FDA, 5600 Fishers Lane, Rockville, MD 20852-9787, or on the MedWatch website at [www.fda.gov/medwatch](http://www.fda.gov/medwatch).

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