

Actavis Totowa (Formerly Known as Amide Pharmaceutical, Inc.) Recalls All Lots of Bertek and UDL Laboratories Digitek (Digoxin Tablets, USP) as a Precaution

25 April, 2008 - Actavis Totowa LLC, a United States manufacturing division of the international generic pharmaceutical company Actavis Group, is initiating a Class 1 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 is 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 illness 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 .