

**CONTACT:** MICHAEL WEINKOWITZ, ESQUIRE  
LEVIN FISHBEIN SEDRAN & BERMAN  
PHONE 215 592-1500  
FAX 215 592-4663  
[MWINKOWITZ@LFSBLAW.COM](mailto:MWINKOWITZ@LFSBLAW.COM)

510 WALNUT STREET  
SUITE 500  
PHILADELPHIA, PA 19106  
PHONE 215 592-1500  
FAX 215 592-4663

**LEVIN, FISHBEIN,  
SEDRAN & BERMAN**

# Press Release

Nationwide Federal Class-Action Lawsuit Filed Against Manufacturers and Distributors of the Recalled Heart Drug Digitek®

On April 8, 2008, the FDA Announced a Class-I Recall of all lots of Bertek and UDL Laboratories Digitek® Tablets Manufactured and Distributed by Generic Drug-Maker Actavis and Mylan Pharmaceuticals because Tablets May Contain Up to Double the Dose of the Drug Digoxin

PHILADELPHIA, PA (May 9, 2008)

On April 8, 2008, the FDA and the Icelandic generic drug-maker Actavis announced a Class-I Recall of all lots of Bertek and UDL Laboratories Digitek®. Go to <http://www.fda.gov/medwatch/safety/2008/safety08.htm#Digitek>. Digitek® is a generic brand of the drug digoxin, used to treat heart conditions, including atrial fibrillation, atrial flutter and congestive heart failure. The Plaintiffs allege, consistent with the drug's label, that an overdose of Digitek®, or unwittingly taking a dose greater than the dose prescribed by a physician, can cause a host of severe and sometimes life-threatening injuries including cardiac, kidney, gastrointestinal and central nervous system injuries, and death.

A Class Action lawsuit was filed today in the United States District Court for the District of New Jersey by the nationally-recognized mass torts and personal injury law firm of LEVIN, FISHBEIN, SEDRAN & BERMAN based in Philadelphia, PA. The suit was filed against the drug companies that manufactured and distributed the defective drug on behalf of a nationwide class of patients who were prescribed, and unwittingly ingested, the recalled Digitek®. The Plaintiffs allege, among other claims, that Actavis Mylan

For Release 9 a.m. EDT, May 8, 2008

*more*

and their subsidiaries negligently and recklessly manufactured, tested, inspected and released a dangerous, misbranded and adulterated drug that contained a dose of digoxin that was higher than the dose on the drug's label. The Plaintiffs point to a detailed 7 page *Warning Letter* sent to Actavis by the Food and Drug Administration (FDA) in early 2007 following an inspection of a plant in New Jersey. In the *Warning Letter*, the FDA chastises the generic drug giant for several deviations from good manufacturing practices. According to the "*Warning Letter*," available on the FDA's website at [http://www.fda.gov/foi/warning\\_letters/archive/g6235d.htm](http://www.fda.gov/foi/warning_letters/archive/g6235d.htm):

Significant deficiencies were found in the operations of your firm's quality control unit, and as a result there is no assurance that many drug products manufactured and released into interstate commerce by your firm have the identity, strength, quality and purity that they purport to possess.

The *Warning Letter* catalogues a laundry list of manufacturing, testing and inspection violations resulting in strength, quality and purity flaws in many of the drugs including Digitek®. The Plaintiffs also allege that the drug makers put the public at further risk by delaying the recall of the misbranded and adulterated Digitek®, and then failing to provide the medical community and the public with full, complete and adequate information about the extent of the danger, including how many, and which lots of Digitek® contained amounts of unapproved digoxin; how long the drug-makers were manufacturing and producing the bad drug, how long it was supplied, sold, distributed and released into the stream of commerce and how many "reports of illness and injuries have been received."

**For more information about LEVIN, FISHBEIN, SEDRAN & BERMAN  
please visit on the Web at [www.lfsblaw.com](http://www.lfsblaw.com)**