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## FDA Says It Doesn't Know How Long Defective Digitek / Digoxin Pills Were Sold

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POSTED: Friday, May 02, 2008

FROM BLOG: [Drug Injury Watch](#) - Prescription Drug Side Effects News and Information from Attorney Tom Lamb

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### Actavis Says They Have Received 11 Complaints About Digitek Side Effects That Date Back To 2006

**(Posted by Tom Lamb at [DrugInjuryWatch.com](#))**

The facts surrounding a late April 2008 recall of Digitek (digoxin) pills that may have twice the usual active ingredient are becoming less clear as we learn more in the days following the FDA's April 28 announcement.

In a May 1, 2008 *Newsday.com* article, "[Pharmacists will call you: Digitek recalled](#)", by reporter Kathleen Kerr, we learn that the defective Digitek tablets may have been sold for more than a year:

"We had some concerns about the process," [Actavis Totowa spokesman John] LaRocca said. He said the company knew of no deaths linked to Digitek use but Actavis and the FDA had received 11 complaints about side effects since 2006.

As reported previously, [this improperly manufactured generic digoxin medication could lead to digitalis toxicity](#); patients with renal insufficiency are especially at risk.

According to *Californian* staff writer Emily Hagedorn, in her May 1, 2008 article "[Recall of heart drug worries Bakersfield family](#)", the FDA is still trying to get a handle on the magnitude and ramifications of this Digitek recall:

Considering it was voluntarily recalled Friday afternoon, it's too soon to tell how many people have suffered adverse reactions, said Sandy Walsh, spokeswoman for the Food and Drug Administration. She didn't know how long the defective pills were sold.... The FDA has inspected the manufacturer's facility since the error was discovered, she said.... While Actavis has 50 percent of the digoxin market, the FDA does not foresee a shortage from other manufacturers, Walsh said.


Going back to the *Newsday.com* May 1 article, we get some pharmacy perspective on the Digitek recall:

Joel Bassuk, pharmacist at Raindew Pharmacy in Manhasset, said he received the recall notice yesterday.... "They said to immediately examine your inventory and discontinue all lots," Bassuk said.... CVS spokesman Mike DeAngelis said the chain had removed all Digitek from its stores. "We went back to see which patients had prescriptions over the past 12 months and contacted them," DeAngelis said.

As always, we welcome information about emerging drug safety issues: [druginjury@gmail.com](mailto:druginjury@gmail.com). This situation, in particular, calls for such assistance from anyone who may know more about the extent of this apparent manufacturing problem whereby some digoxin pills may be too potent. At this juncture, at least, it seems we are not getting much in terms of "specifics" from Actavis, the drug manufacturer, nor the FDA about this Digitek recall.

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