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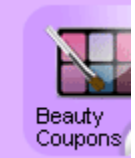
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Extent Of Digitek Recall Remains A Mystery Ten Days Later; Patients Are Left In The Dark

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POSTED: Tuesday, May 06, 2008

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

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Heart Medication Sold By Mylan Was Made In Actavis Plant That Received FDA Letter About Manufacturing Problems Over A Year Ago

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

[News about the April 2008 Digitek recall](#) came first in the form of a brief company press release dated April 25, which was followed by an FDA MedWatch Safety Alert posted April 28 on the agency's web site.

As of May 5, ten days later, there had been little additional information from Actavis Totowa, the drug manufacturer, and none from the FDA, about the possible extent of the Digitek recall.

Meanwhile, patients are being contacted by their pharmacists who, admittedly, know nothing more about the situation than what was set forth in the April 25 half-page press release about this "Class 1 nationwide recall of Digitek (digoxin pills, USP, all strengths)".

Understandably, patients are asking how far back in time they have been getting and taking Digitek pills that may have contained double the intended dose of active ingredient.

The latest news about the extent of the Digitek recall comes from a May 6, 2008 article, "[Double-strength digoxin recalled in US](#)", by Phil Taylor, which is posted online at [In-PharmaTechnologist.com](#) ("Breaking News on Pharmaceutical Technology"), of London, UK.

Because we do not want to misconstrue in any manner the intriguing information developed by Mr. Taylor in his May 6 article, we provide this extended excerpt:

A spokesperson for the company told [in-PharmaTechnologist.com](#) that the investigation into the problem was still ongoing, but at the moment there was no further information on what caused it and how many tablets were involved.

This is not the first time that there have been manufacturing problems

at the Actavis Totowa facility in New Jersey, which was acquired as part of the takeover of Amide Pharmaceuticals by Actavis in May 2005, although the spokesperson said these earlier issues were entirely unrelated to the current incident.


Just over a year ago Actavis Totowa was sent a warning letter by the FDA after an agency inspection revealed that drugs products manufactured in the facility were 'adulterated'.

The quality control unit at the site came under criticism from the agency, which said it failed to reliably establish the identity, strength, quality and purity of drug products manufactured and released onto the market. The FDA inspectors also noticed a general lack of investigation of out-of-specification test results, as well as a lack of sufficient documentation of the results.

It is understood, however, that all these 'Form 483' issues have since been resolved to the agency's satisfaction.

Hopefully Actavis and/or the FDA will be making an official announcement, soon, about how far back in time the Digitek pills sold under the "Bertek" and "UDL" labels may have been double-strength tablets. Until then, many patients and their families are left wondering if possibly related symptoms were caused by the use of these double-strength Digitek tablets.

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