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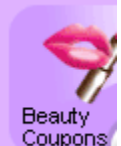
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Recall Notice For Digitek Marketed Under Bertek Label Goes Back To March 2006

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POSTED: Monday, May 12, 2008

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

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North Carolina Board Of Pharmacy Has Posted A Copy Of The Bertek Digitek Drug Recall Notice On Its Web Site

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

The [home page of the North Carolina Board of Pharmacy \(NCBOP\)](#) currently shows a May 5, 2008 news item about the Digitek recall which includes a link to this document, which they describe as the "recall notice":

[Urgent: Drug Recall -- Digitek® \(digoxin tablets, USP\)](#)

- Recall initiated by the manufacturer: Actavis Totowa LLC (formerly known as Amide Pharmaceuticals, Inc.)
- Product Distributed by: Mylan Pharmaceuticals, Inc. under a "Bertek" Label

Therein, we are told that this Digitek recall, at least for Bertek tablets, goes back all the way to March 2006, more than two years before [the April 2008 announcements by Actavis and the FDA](#):

Mylan Pharmaceuticals Inc. is continuing a voluntary recall of the Actavis Totowa recall of Digitek® (digoxin tablets, USP). This product is being recalled 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. **Product was distributed nationwide between March 2006 and April 2008.**

(Emphasis added.)

The NCBOP May 5 news item also reminds North Carolina pharmacists that because digoxin is a so-called "Narrow Therapeutic Index" drug, they have special obligations

under North Carolina law:

A prescription for a narrow therapeutic index drug shall be refilled using only the same drug product by the same manufacturer that the pharmacist last dispensed under the prescription, unless the prescriber is notified by the pharmacist prior to the dispensing of another manufacturer's product, and the prescriber and the patient give documented consent to the dispensing of the other manufacturer's product. For purposes of this subsection, the term "refilled" shall include a new prescription written at the expiration of a prescription which continues the patient's therapy on a narrow therapeutic index drug.

N.C.G.S. Section 90-85.28(b1).

In their May 2008 news item, the NCBOP acknowledged that the Digitek recall is "unusual" as concerns pharmacist-compliance with this NC statute:


Board staff understands that the Digitek recall will require switching some patients to a different manufacturer's digoxin product. Compliance with the letter of N.C.G.S. Section 90-85.28(b1) may prove difficult in certain circumstances. In the unusual circumstances of this recall, it is critical to ensure that patients continue to receive their medication. Accordingly, where switching a patient to a different manufacturer's digoxin product is necessary because of the recall, pharmacists must counsel affected patients on the switch, the reason for it, and possible side effects/therapeutic changes that could be associated with the change. Moreover, pharmacists must contact the patient's prescriber to alert of the change so that monitoring of digoxin levels and therapeutic effect can, if necessary, begin.

Interestingly, the Digitek recall notice posted on the North Carolina Board of Pharmacy (NCBOP) web site makes no mention of the Digitek pills marketed under the "UDL" label and distributed by [UDL Laboratories, Inc.](#) -- part of Mylan Laboratories, Inc. which also includes Mylan Pharmaceuticals, Inc.

One reason may be that UDL apparently provided Digitek in pharmaceutical unit dose packaging for hospitals, nursing homes, and other healthcare institutions, only. As such, perhaps that aspect of the Digitek recall is not a matter of concern for the NCBOP.

Let us know if you have any news or information about the Digitek recall that we can share.

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