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COURT OF COMMON PLEAS  
PHILADELPHIA COUNTY

IN RE: DIGITEK LITIGATION

March Term, 2009

No. 5166

JURY TRIAL DEMANDED

**PLAINTIFFS' FIRST AMENDED GENERAL MASTER LONG-FORM  
COMPLAINT AND JURY DEMAND**

Pursuant to an Order by the Honorable Sandra M. Moss, the undersigned attorneys for plaintiffs in "Digitek" actions bring the First Amended General Master Long-Form Complaint against the following defendants:

Actavis Totowa, LLC  
1 New England Avenue  
Piscataway, NJ 08854

Actavis Inc  
60 Columbia Road, Building B

VALIDATION  
DATE: 12/04/09 TIME: 11:40  
TICKET NO: 576566  
CASE NO: 090305166  
TOTAL AMT: \$ 43.00  
REGISTER: Registrar 3 282 CH  
CASHIER: RJE  
CUSTOMER: Cash walk-in customer

Morristown, NJ 07960

Actavis Group hf  
Dalshraun 1. 220  
Hafnarfjodur, Iceland

Actavis Elizabeth, LLC  
200 Elmora Avenue  
Elizabeth, NJ 07207

Actavis, U.S.  
60 Columbia Road  
Morristown, NJ 07960

Mylan, Inc.  
1500 Corporate Drive  
Canonsburg, PA 15317

Mylan Laboratories, Inc.  
1500 Corporate Drive  
Canonsburg, PA 15317

Mylan Pharmaceuticals, Inc.  
781 Chestnut Ridge Road  
Morgantown, WV 26505

Mylan Bertek Pharmaceuticals, Inc.  
320 Lakeside Drive, Suite A  
Foster City, CA 94404

UDL Laboratories, Inc.  
1718 Northrock Court  
Rockford, IL 61103

**PLAINTIFFS**

1. Plaintiffs' file this Master Complaint in accordance with Case Management and Scheduling Order No. 1 and this Complaint applies to all cases (1) transferred to this Court in the Commonwealth of Pennsylvania for the In re: Digitek Products Liability Litigation; and (2) all related cases originally in this

Court.

2. Plaintiffs brings this action against the Defendants for design, manufacturing, producing, supplying, inadequately inspecting, testing, selling and distributing dangerous, defective, misbranded and adulterated Digitek® (digoxin tablets, USP)(hereinafter referred to as "Digitek") containing an amount of the drug's active ingredient, digoxin, different from the dose set forth on the label and in some cases exceeding the dose approved for medical treatment in humans. By reason of the wrongful conduct of the Defendants, and the dangers posed by the potential for overdoses of the drug, a massive, national recall of Digitek® tablets has been initiated in the United States.

### DEFENDANTS

#### THE "ACTAVIS DEFENDANTS"

3. Defendant Actavis Group hf is an international generic pharmaceutical company, with its principal place of business at Dalshraun 1 220 Hafnarfjodur, Iceland, and regularly conducts business throughout the United States and specifically in Pennsylvania, including but not limited to directing the operation and management of the other "Actavis Defendants," including Defendant Actavis Group, ehf, which is the parent of Defendants Actavis, Inc., Actavis Totowa, LLC (formerly known as Amide Pharmaceutical, Inc.), Actavis Elizabeth, LLC, and Actavis, US, in the design, development, manufacture, production, processing, compounding, formulating, testing, sale, marketing, labeling, packaging, dosing advertising, promotion, supply, releasing and/or

distribution of Digitek®.

4. Defendant Actavis Totowa, LLC (formerly known as Amide Pharmaceutical, Inc.) is a corporation organized and existing under the laws of Delaware with its principal place of business in New Jersey, and is a wholly-owned subsidiary, agent, and alter ego of Actavis Group hf.

5. Defendant Actavis, Inc. is a corporation organized and existing under the laws of Delaware with its principal place of business New Jersey, and is a wholly-owned subsidiary, agent, and alter ego of Actavis Group hf.

6. Defendant Actavis Elizabeth, LLC is a corporation organized and existing under the laws of Delaware with its principal place of business in New Jersey, and is a wholly-owned subsidiary, agent, and alter ego of Actavis Group hf.

7. Defendant Actavis, US is a corporation organized and existing under the laws of Delaware with its principal place of business in New Jersey, and is a wholly-owned subsidiary, agent, and alter ego of Actavis Group hf.

8. Defendants Actavis Group hf., Actavis Totowa (formerly known as Amide Pharmaceutical, Inc.) Actavis Inc., Actavis Elizabeth, LLC and Actavis U.S. are referred to hereinafter collectively as "Actavis" or "Actavis" Defendants" unless otherwise stated.

9. At material times hereto, the Actavis Defendants:

a. were, and are, engaged in the business of the design, development, manufacture, production, processing, compounding, formulating,

testing, sale, marketing, labeling, packaging, dosing advertising, promotion, supply, releasing and/or distribution of Digitek® in the United States either directly or indirectly through third-parties or related entities;

b. were, and are, in the business of profiting from the in the design, development, manufacture, production, processing, compounding, formulating, testing, sale, marketing, labeling, packaging, dosing advertising, promotion, supply, releasing and/or distribution of Digitek®;

c. conducted continuous and substantial business in the Commonwealth of Pennsylvania and,

d. acted and gained knowledge itself and by and through its various agents, servants, employees, and/or ostensible agents.

#### **THE "MYLAN DEFENDANTS"**

10. Defendant Mylan, Inc. is a corporation organized and existing under the laws of Pennsylvania with its principal place of business in New Jersey.

11. Defendant Mylan Laboratories, Inc. ("Mylan Laboratories") is a corporation organized and existing under the laws of Pennsylvania with its principal place of business in Pennsylvania and New Jersey.

12. Defendant Mylan Pharmaceuticals, Inc. ("Mylan Pharmaceuticals") is a corporation organized and existing under the laws of West Virginia with its principal place of in New Jersey and is a wholly-owned subsidiary, agent, and alter ego of Defendant Mylan, Inc.

13. Defendant Mylan Bertek Pharmaceuticals, Inc. ("Mylan Bertek") is a corporation organized and existing under the laws of Texas with its principal place of business in Texas and is a wholly-owned subsidiary, agent, and alter ego of Defendant Mylan, Inc.

14. Defendant UDL Laboratories, Inc. ("UDL") is a corporation organized and existing under the laws of Illinois with its principal place of business in Illinois and is a wholly-owned subsidiary, agent, and alter ego of Defendant Mylan, Inc.

15. Defendants Mylan Inc., Mylan Laboratories, Mylan Pharmaceuticals, Mylan Bertek and UDL are referred to hereinafter collectively as "Mylan" or the "Mylan Defendants," unless otherwise stated.

16. At material times hereto, the Mylan Defendants:

a. were, and are, engaged in the business of the design, development, manufacture, production, processing, compounding, formulating, testing, sale, marketing, labeling, packaging, dosing advertising, promotion, supply, releasing and/or distribution of Digitek® in the United States and Pennsylvania either directly or indirectly through third-parties or related entities;

b. were, and are, in the business of profiting from the design, development, manufacture, production, processing, compounding, formulating, testing, sale, marketing, labeling, packaging, dosing advertising, promotion, supply, releasing and/or distribution of Digitek®;

c. conducted continuous and substantial business in the

Commonwealth of Pennsylvania and,

d. acted and gained knowledge itself and by and through its various agents, servants, employees, and/or ostensible agents.

#### **JURISDICTION AND VENUE**

17. Jurisdiction over Defendants is based on 42 Pa. C.S.A § 5301 and is therefore proper in this Court.

18. Venue is proper pursuant to Pa. R.C.P. No. 2179. Defendants regularly conduct substantial business in Philadelphia County, Pennsylvania.

19. The amount in controversy exceeds, exclusive of interest and costs, the sum of fifty thousand (\$50,000.00) dollars.

#### **FACTUAL ALLEGATIONS**

##### **The Drug - Digitek® (digoxin tablets, USP)**

20. Digitek® is the brand-name of one of the cardiac glycosides, a closely related group of drugs having in common specific effects on the myocardium of the heart.

21. Digitek® is a registered trademark of Defendant Bertek Pharmaceuticals.

22. Digitek® is widely prescribed and used by millions of Americans to treat various heart conditions, including atrial fibrillation, atrial flutter and congestive heart failure.

23. Digitek® and digoxin are metabolized in the liver but excreted by the kidney.

24. Digitek® is approved only for sale and distribution in the United States in the following dosages:

Digitek® (digoxin tablets, USP) 0.125 mg, and,

Digitek® (digoxin tablets, USP) 0.250 mg

(collectively referred to hereinafter as the “approved dose”).

25. Each Digitek® tablet is approved by the United States Food and Drug Administration (“FDA”) only for sale and distribution if it contains the labeled amount of digoxin.

26. Digitek® tablets manufactured and produced with an amount of digoxin in less than or in excess of the labeled dose are not approved for sale or distribution in the United States (hereinafter “unapproved dose”).

### **THE FDA WARNING LETTERS**

#### **The August 15, 2006 FDA Warning Letter**

27. Upon information and belief, some of the Recalled Digitek® was designed, developed, manufactured, produced, processed, compounded, formulated, tested, sold, marketed, labeled, packaged, dosed, advertised, promoted, supplied, released and/or distributed from a plant in Little Falls, New Jersey owned by one or more of the Actavis Defendants, which was acquired in December 2005 as part of Actavis’ acquisition of another company’s generic business.

28. On or about August 15, 2006, the FDA issued a letter warning to the Actavis Defendants through defendant Actavis Totowa for failing to file periodic

safety reports at its solid oral dose manufacturing facility in Little Falls, New Jersey (hereinafter referred to as the "*August, 2006 Warning Letter*").

29. The *August, 2006 Warning Letter* is 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).

30. In the *August, 2006 Warning Letter*, the FDA warned the Actavis Defendants through Actavis Totowa that it had violated its adverse medical event reporting obligations, marketing drugs without proper clearance and causing at least 26 adverse drug experiences (ADEs) by not submitting periodic safety reports.

31. According to the FDA's *August 2006 Warning letter*, an FDA inspection between January and February 2006 revealed that there were six potentially serious and unexpected adverse drug events dating back to 1999 for products, including digoxin, that were not reported to the agency.

32. The FDA's *August 2006 Warning letter* also warned the Actavis Defendants through Actavis Totowa about not properly investigating serious and unexpected ADEs, not adequately reviewing ADE information, failing to file periodic safety reports which resulted in at least 26 ADEs which were never reported.

33. The FDA's *August 2006 Warning letter* also warned the Actavis Defendants through Actavis Totowa that it had not developed procedures for the surveillance, receipt, evaluation, and report of adverse events.

**The Revised Warning Letter About the Actavis Defendants' "Significant Deviations from the Current Good Manufacturing Practice Regulations"**

34. In or around February 1, 2007, the FDA issued a revised Warning Letter to the Actavis Defendants through Actavis Totowa (hereinafter "*Revised Warning Letter*") citing "significant deviations from the current Good Manufacturing Practice regulations."

35. The *Revised Warning letter* is 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).

36. In the *Revised Warning letter* the FDA noted several deviations from good manufacturing process, resulting in the adulteration of drug products manufactured by the Actavis Defendants, that were observed by the FDA during an inspection conducted July 10, 2006 to August 10, 2006.

37. According the FDA's *Revised Warning letter*:

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.

38. The deviation from good manufacturing process observed by the FDA were presented to Actavis Totowa on an FDA-483 (List of Inspections) at the close of the inspection on August 10, 2006.

39. The FDA's *Revised Warning letter* cited deficiencies in the operations of the Actavis Defendants' quality control unit, which included instances where

the unit failed to adequately investigate and resolve laboratory deviations and out-of-specification test results for drug products. Specifically, according to the

*Revised Warning letter:*

Our investigators observed numerous instances where the quality control unit failed to adequately investigate and resolve laboratory deviations and out-of-specification test results involving drug products that ultimately were released for distribution into interstate commerce. Additionally, our investigators uncovered out-of-specification test results in laboratory raw data that were not documented in laboratory notebooks, and found that products were released based on retesting without any justification for discarding the initial out-of-specification test results.

40. The FDA *Revised Warning letter* also pointed out significant deficiencies in the quality assurance department regarding investigating and correcting deviations found when testing products:

Numerous instances were observed where manufacturing process deviations occurred and in-process specifications were not met, yet there is no indication that action was taken promptly to investigate or to correct the deviations and the products were approved for release and distribution by your quality control unit. Additionally, instances were noted where your firm's quality control unit reviewed and approved test data and reports that were inaccurate and incomplete, and as such, did not follow established procedures. [CFR 211.22(a) and 21 CFR 211.22(d)]

41. The FDA *Revised Warning letter* stated that the FDA found during its inspection that analysts did not always document the preparation and testing of samples at the time they were done:

Master and batch production and control records were found to be deficient in that they did not include complete procedures for documenting the collection of samples. Although your firm's procedures require the collection of in-process blend uniformity samples of three times the weight of finished product tablets or capsules, master production records do not require, and batch records do not contain, documentation that the samples are being collected accordingly. [21 CFR 211.186 (b)(9) and 21 CFR 211.188(b)(10)]

42. The FDA found numerous discrepancies in which lab analysts inaccurately recorded electronic data in the laboratory notebooks, such actions resulted in adulterated products being entered into the stream of commerce:

There was a failure to check for accuracy the inputs to and outputs from the "Total Chrom Data Acquisition System," which is used to run your firm's HPLC instruments during analysis of drug products. For example, electronic data files were not routinely checked for accuracy and, as mentioned in the above observations, our investigators found numerous discrepancies between the electronic data files and documentation in laboratory notebooks. [21 CFR 211.68(b)]

43. The FDA also cited a failure to check for accuracy the input and outputs from a system used to run the high-performance liquid chromatography during analysis of drug products.

44. Among other deficiencies cited by the FDA in the *Revised Warning letter* were:

- e. failure of the quality control unit to recognize that some tablets did not meet in-process specifications;
- f. a lack of adequate procedures for conducting bulk product holding time studies; failure to identify and control rejected in-process

materials;

- g. not adequately qualifying select equipment; and,
- h. failure to establish and follow written procedures for

maintaining manufacturing equipment.

45. By way of example, the FDA states in the *Revised Warning letter*

that:

Your firm's cleaning validation studies were found to be inadequate and, as a result, there was no assurance that equipment is adequately cleaned between the manufacture of different drug products. [21 CFR 211.67(b)] For example:

a. Cleaning validation was performed for the process trains without evaluating for sample recovery for numerous products, including: Amidal Nasal Decongestant; Amigesic Caplets, 750mg; Carisoprodol and Aspirin Tablets, USP, 200mg/325mg; Carisoprodol Tablets, USP, 350mg; Chlorzoxazone Tablets, USP, 250mg and 500mg; Digoxin Tablets, USP, 0.25mg.

46. The FDA gave the Actavis Defendants, through Actavis Totowa, 15 working days to provide a written listing of all released lots of finished drug products that remain within specification that are associated with any out-of-specification test results during manufacture and to provide description of the actions taken to ensure that lots were suitable for release.

**The Manufacture, Production, Labeling, Distribution and Sale of Dangerous Digitek® Tablets Containing an Amount of Digoxin, different from the Labeled Dose**

47. The Defendants are drug companies, that upon information and belief, engaged in the design, development, manufacture, production, processing, compounding, formulating, testing, sale, marketing, labeling,

packaging, dosing, advertising, promotion, supply, releasing and/or distribution of Digitek® tablets containing an amount of digoxin, different than the dose on the label.

48. At all times relevant to this action, Defendants knew, and/or had reason to know, that the Recalled Digitek® was not safe for the patients for whom the drug was prescribed because it either contained an less than or an excess dose of digoxin which can cause serious medical problems, digoxin overdose, digitalis toxicity and, in certain patients, catastrophic injuries and death.

**The Class I-Recall in the United States And  
Defendants' Failure to Provide Full, Complete  
and Adequate Information About the Recalled Digitek®**

49. On or about April 25, 2008, the United States Food and Drug Administration ("FDA") announced a Class I Recall of all lots of Bertek and UDL Laboratories Digitek® (hereinafter "Recalled Digitek®"). The FDA announcement, available at <http://www.fda.gov/medwatch/safety/2008/safety08.htm#Digitek>, stated:

**DIGITEK (DIGOXIN TABLETS, USP)**

Audience: Cardiologists, family physicians, pharmacists, other healthcare professionals, patients

[Posted 04/28/2008] Actavis Totowa LLC notified healthcare professionals of a Class I nationwide recall of all strengths of Digitek, a drug used to treat heart failure and abnormal heart rhythms. The products are distributed by Mylan Pharmaceuticals Inc., under a "Bertek" label and by UDL Laboratories, Inc. under a "UDL" label. The product is being recalled due to the possibility that tablets with double the appropriate thickness may contain twice the approved level of active ingredient. The existence of double strength tablets poses a risk of digitalis toxicity in patents with renal failure. Digitalis toxicity can cause nausea, vomiting, dizziness,

low blood pressure, cardiac instability and bradycardia. Several reports of illnesses and injuries have been reported. Patients should contact their healthcare professional with questions.  
[April 25, 2008 - Press Release - Actavis Totowa LLC]

50. Class I Recalls are instituted only when there exists a reasonable probability that use of the product will cause serious injury or death.

51. The recall implicated Digitek tablets manufactured in a plant in Little Falls, New Jersey as early as 2006. Notably, on August 1, 2008, the Actavis Defendants announced a retail-level recall of all drugs manufactured at its Little Falls, New Jersey Plant. The expanded recall was prompted by yet another inspection at the facility which revealed that operations still did not meet the FDA's standards for good manufacturing practices. The recall implicated 65 different generic drugs all manufactured at the same facility that produced Digitek tablets.

52. After the August, 2008 recall, Defendant Actavis finally closed the New Jersey plants to institute "remediation" efforts. However, it sought to reopen the facilities, prompting the United States Justice Department to file a lawsuit in November, 2008 to force closure. Under a Consent Decree reached in December, 2008, the Actavis Defendants agreed to not distribute any products from the closed facilities until it has certified completion of certain enumerated requirements that demonstrate compliance with FDA's current good manufacturing practice and has passed follow-up FDA inspections of the facilities.





53. The Recalled Digitek® is an adulterated drug and its label and packaging are misbranded.

**Injuries from Digoxin Overdose, Digitalis Toxicity or from  
An Amount of Digoxin Less than the Labeled Dose**

54. Digoxin overdose and digitalis toxicity can cause serious and life-threatening personal injury, and death.

55. The Digitek® label states, in relevant parts, under "Precautions" that:

Use in Patients with Impaired Renal Function: Digoxin is primarily excreted by the kidneys; therefore, patients with impaired renal function require smaller than usual maintenance doses of digoxin. Because of the prolonged elimination half-life, a longer period of time is required to achieve an initial or new steady-state serum concentration in patients with renal impairment than in patients with normal renal function. If appropriate care is not taken to reduce the dose of digoxin, such patients are at high risk for toxicity, and toxic effects will last longer in such patients than in patients with normal renal function.

\* \* \*

Adults: *Cardiac*: Therapeutic doses of digoxin may cause heart block in patients with pre-existing sinoatrial or AV conduction disorders; heart block can be avoided by adjusting the dose of digoxin. Prophylactic use of a cardiac pacemaker may be considered if the risk of heart block is considered acceptable. High doses of digoxin may produce a variety of rhythm disturbances, such as first-degree, second-degree (Wenkebach), or third-degree heart block (including asystole); atrial tachycardia with block; AV dissociation; accelerated junctional (nodal) rhythm; unifocal or multifocal ventricular premature contractions (especially bigeminy or trigeminy); ventricular tachycardia; and ventricular fibrillation. Digoxin produces PR prolongation and ST segment depression which should not by themselves be considered digoxin toxicity. Cardiac toxicity can also occur at therapeutic doses in patients who have conditions which may alter their sensitivity to digoxin.

*Gastrointestinal*: Digoxin may cause anorexia, nausea, vomiting and diarrhea. Rarely, the use of digoxin has been associated with abdominal pain, intestinal ischemia and hemorrhagic necrosis of the intestines.

*CNS*: Digoxin can produce visual disturbances (blurred or yellow vision), headache, weakness, dizziness, apathy, confusion and mental disturbances (such as anxiety, depression, delirium and hallucination).

56. Non-approved, excessive doses of digoxin significantly increase the



likelihood that overdosed patients will experience the known side-effects and reactions that can result from the approved doses of digoxin. In other words, the risk and dangers of approved doses are enhanced by an overdose of digoxin.

57. Doses of digoxin less than and exceeding the dose prescribed by a physician for medical treatment can cause personal injury and death.

58. The Digitek® label states in relevant part that:

Massive Digitalis Overdosage: Manifestations of life-threatening toxicity include ventricular tachycardia or ventricular fibrillation, or progressive bradyarrhythmias, or heart block. The administration of more than 10 mg of digoxin in a previously healthy adult or more than 4 mg in a previously healthy child, or a steady-state serum concentration great than 10ng/mL often results in cardiac arrest.

DIGIBIND [Digoxin Immune Fab (Ovine)] should be used to reverse the toxic effects of ingestion of a massive overdose. The decision to administer DIGIBIND [Digoxin Immune Fab (Ovine)] to a patient who has ingested a massive dose of digoxin but who has not yet manifested life-threatening toxicity should depend on the likelihood that life-threatening toxicity will occur. Patients with massive digitalis ingestion should receive large doses of activated charcoal to prevent absorption and bind digoxin in the gut during enteroenteric recirculation. Emesis or gastric lavage may be indicated especially if ingestion has occurred within 30 minutes of the patient's presentation at the hospital. Emesis should not be induced in patients who are obtunded. If a patient presents more than 2 hours after ingestion or already has toxic manifestations, it may be unsafe to induce vomiting or attempt passage of a gastric tube, because such maneuvers may induce an acute vagal episode that can worsen digitalis-related arrhythmias.

Severe digitalis intoxication can cause a massive shift of potassium from inside to outside the cell, leading to life-threatening hyperkalemia. The administration of potassium supplements in the setting of massive intoxication may be hazardous and should be avoided. Hyperkalemia caused by massive digitalis toxicity is best treated with DIGIBIND [Digoxin Immune Fab (Ovine)]; initial treatment with glucose and insulin may also be required if hyperkalemia itself is acutely life-threatening.

59. The Digitek® label states, in relevant part, under "Adverse Events"

that:

In general, the adverse reactions of digoxin are dose dependent and occur at doses higher than those need to achieve a therapeutic effect. Hence, adverse reactions are less common when digoxin is used within the recommended dose range or therapeutic serum concentration range and when there is careful attention to concurrent medications an conditions.

Because some patients may be particularly susceptible to side effects with digoxin, the dosage of the drug should always be selected carefully and adjusted as the clinical conditions of the patient warrant. In the past, when high doses of digoxin were used and little attention was paid to the clinical status or concurrent medications, adverse reactions were more frequent and severe. Cardiac reactions accounted for about one-half, gastrointestinal disturbances about one-fourth and CNS and other toxicity for about one-fourth of these adverse reactions.

60. The Recalled Digitek® was adulterated, misbranded, defective, unreasonably dangerous and unfit for its intended uses. It contained amounts of Digoxin less than or more than the labeled dose. Defendants placed tens of thousands of patients, including Plaintiffs, unnecessarily at risk of serious injury and/or death and may have caused them to suffer personal injuries and harm, including medical expenses, anxiety and fear induced from ingesting the defective and misbranded drug.

61. Defendants knew or should have known about the manufacturing and production defects, misbranding and negligent sale and distribution of the Recalled Digitek® and had a duty to design, develop, manufacture, produce, process, compound, formulate, test, sell, market, label, package, dose, advertise, promote, supply, release and/or distribute only safe Digitek® with approved doses of digoxin and doses of digoxin that were consistent with the dose on the

- g. failed to investigate and/or use known and/or knowable reasonable alternative, manufacturing, production, testing and inspection processes for the recalled Digitek®;
- h. failed to warn Plaintiff of dangers known and/or reasonably suspected to Defendant to be associated with the recalled Digitek®;
- i. failed to make the recalled Digitek® reasonably safe;
- j. represented that the recalled Digitek® was reasonably safe for use for its intended purpose, when, in fact, it was not;
- k. manufactured the product such that it did not meet their own specifications and standards, as well as those of the FDA when it approved the drug;
- l. failed to timely conduct a recall of the recalled Digitek®, and when the recall was implemented, failed to implement the recall promptly and efficiently and failed to inform the medical community, and the public, including the Plaintiff of all the relevant information such that the significantly increased risk of harm was minimized to the fullest extent possible.

75. Defendants knew or should have known that recalled Digitek® caused unreasonably dangerous risks and side-effects, including death, of which Plaintiff, and Plaintiff's prescribing physicians would not be aware. Defendants

nevertheless marketed, advertised, supplied, released, sold and distributed the drug knowing that there were reasonably safer alternative products.

76. The defective design existed before the product left the control of Defendants.

77. The product did not undergo any substantial alteration before reaching Plaintiff.

78. Plaintiff and prescribing physicians were foreseeable users, who were not expected to know of the dangers of recalled Digitek® and who did not know of those dangers.

79. Reasonable consumers would not expect recalled Digitek® to be unreasonably dangerous.

80. Recalled Digitek's® risks of harm outweigh any potential utility.

81. Reasonably safer alternative products existed and were feasible to use, and they would have prevented or significantly reduced the risk of injury without substantially impairing the product's utility.

82. Recalled Digitek® significantly increases the risk of the known side-effects and reactions that can result from the approved doses of digoxin set forth above.

83. Recalled Digitek® was not approved by the FDA in the form ingested.

84. The above described outrageous and egregious conduct constitutes the wanton and willful disregard for health and safety for which punitive

damages as well as common law mandate exemplary damages to punish these Defendants and to deter these Defendants from such conduct in the future.

85. As a direct and proximate result of Defendants' reckless indifference to the rights of others, Plaintiff had and will continue to have, great physical pain and suffering, and great mental and emotional suffering, some or all of which may be permanent. As a direct and proximate result of the aforesaid, Plaintiff was, and will in the future be, obligated to spend various sums of money to treat, evaluate and care for Plaintiff's injuries; Plaintiff has sustained and will in the future sustain a loss of earnings and earning capacity; Plaintiff's enjoyment of life is impaired; Plaintiff is embarrassed and humiliated; all to Plaintiff's great loss.

**WHEREFORE**, Plaintiff demands judgment against Defendants for an amount in excess of \$50,000.00, compensatory damages and punitive damages as a jury may determine to be appropriate and necessary plus interest and costs.

**COUNT 2**  
**FAILURE TO ADEQUATELY WARN**

86. Plaintiffs incorporate by reference each preceding and succeeding paragraphs as though set forth fully at length herein.

87. At all relevant times, Defendants researched, developed, designed, tested, manufactured, inspected, labeled, and/or distributed, marketed, promoted, sold, and otherwise released into the stream of commerce the pharmaceutical, the Recalled Digitek®, and in the course of same, directly

advertised or marketed the product to FDA, consumers or persons responsible for consumers, and therefore had a duty to warn of the risks associated with the use of the Recalled Digitek®.

88. At all relevant times, the Recalled Digitek® was under the exclusive control of the Defendants as aforesaid, and was unaccompanied by appropriate warnings regarding all possible adverse side effects and complications associated with the use of the Recalled Digitek®, the dangers of inappropriately strong or weak doses and the comparative severity, duration and the extent of the risk of injury with such use.

89. At all relevant times, Defendants failed to timely and reasonably warn of material facts regarding the safety and efficacy of the Recalled Digitek® so that no reasonable medical care provider would have prescribed, or no consumer would have used, Digitek® had those facts been made known to such providers and consumers.

90. At all relevant times, Defendants egregious and intentional failure to perform or otherwise facilitate adequate testing in that such testing would have shown that the Recalled Digitek® posed serious and potentially life-threatening side effects and complications in tablets with more than, or less than, the labeled dose of digoxin respect to which full and proper warning accurately and fully reflecting the symptoms, scope and severity should have been made to medical care providers, the FDA and the public, including Plaintiff.

91. At all relevant times, the Recalled Digitek®, which was researched,

developed, designed, tested, manufactured, inspected, labeled, distributed, marketed, promoted, sold, and otherwise released into the stream of commerce by Defendants, was defective due to inadequate post-marketing warning and/or instruction because, after Defendants knew or should have known of the risk of serious and potentially life-threatening side effects and complications from the use of the Recalled Digitek®, Defendants failed to provide adequate warnings to medical care providers, the FDA and the consuming public, including Plaintiff, and continued to promote Digitek® aggressively.

92. As a direct and proximate result of Defendants' reckless indifference to the rights of others and negligence, the Plaintiff suffered severe and permanent physical injuries. Thereby, the Plaintiff has endured substantial emotional pain and suffering. The Plaintiff incurred significant expenses for medical care and treatment, and may continue to incur expenses in the future. Plaintiff suffered lost wages and earnings, and was otherwise physically and economically injured.

**WHEREFORE**, Plaintiff demands judgment against Defendants for an amount in excess of \$50,000.00, compensatory damages and punitive damages as a jury may determine to be appropriate and necessary plus interest and costs.

**COUNT 3**  
**PRODUCT LIABILITY - MANUFACTURING DEFECT**

93. Plaintiff incorporates by reference each preceding and succeeding paragraph as though set forth fully at length herein:

94. At all times material to this action, Defendants were engaged in the business of designing, developing, manufacturing, producing, testing, packaging, inspecting, promoting, marketing, distributing, supplying, labeling, releasing and/or selling the Recalled Digitek®.

95. At all times material to this action, the Recalled Digitek® was expected to reach, and did reach, consumers in the State of Pennsylvania and throughout the United States, without substantial change in the condition in which it was sold.

96. At all times material to this action, the Recalled Digitek® was designed, developed, manufactured, produced, tested, packaged, inspected, promoted, marketed, supplied, distributed, labeled, released and/or sold by Defendants in a defective and unreasonably dangerous condition at the time it was placed in the stream of commerce in ways which include, but are not limited to, one or more of the following particulars:

a. When placed in the stream of commerce, the Recalled Digitek® contained manufacturing defects which rendered the product unreasonably dangerous;

b. The manufacturing defects of the Recalled Digitek® occurred while the product was in the possession and control of Defendants;

c. The Recalled Digitek® was not made in accordance with Defendants'

specifications or performance standards and/or those specifications and standards approved by the FDA.

d. The manufacturing defects of the Recalled Digitek® existed before it left the control of Defendants due to their egregious and intentional conduct outlined in the many FDA observations and warning letters, which are described in the preceding and succeeding paragraphs and detail the outrageous and egregious conduct on the part of the Defendants regarding the maintenance and operation of their quality control/quality assurance lab ;

97. As a direct and proximate result of the acts and omissions of Defendants as aforesaid, Plaintiff was harmed as aforesaid.

**WHEREFORE**, Plaintiff demands judgment against Defendants for an amount in excess of \$50,000.00, compensatory damages and punitive damages as a jury may determine to be appropriate and necessary plus interest and costs.

**COUNT 4**  
**BREACH OF EXPRESS WARRANTY**

98. Plaintiffs incorporate by reference each preceding and succeeding paragraphs as though set forth fully at length herein.

99. At all relevant times, Defendants warranted that the Recalled Digitek® was safe and not defective and/or unreasonably dangerous as stated above and warranted that it continued a dose of digoxin that consistent with the dose set forth on its label and was otherwise safe for human ingestion.

100. At all relevant times, with reckless indifference to the rights of others, Defendant placed the Recalled Digitek® into the stream of commerce for sale and recommended its use to physicians, the FDA and consumers without adequately warning physicians, the FDA and consumers, including the Plaintiffs, of the risks associated with the use of the Recalled Digitek® and that it contained an amount of digoxin different than the labeled dose and sometimes exceeding the approved dose for human ingestion.

101. At all relevant times, Defendants had a duty to exercise reasonable care in the design, development, testing, manufacture, production, formulation, processing, compounding, labeling, packaging, inspections, supply, distribution, marketing, promotion, sale and release of the Recalled Digitek®, including a duty to:

- i. Ensure that the product did not cause the user unreasonably dangerous side-effects;
- j. Ensure that the product was labeled accurately;
- k. Ensure that the amount, strength and dose of the digoxin in the product was consistent with the that set forth on the label and to ensure that the does was approved by the FDA as a dose safe for use in humans;
  - l. Warn of dangerous and potentially fatal side-effects;and,
- m. Disclose adverse material facts when making representations to physicians, the FDA and the public at large, including

Plaintiffs.

102. When the Physicians of the Plaintiffs prescribed the Recalled Digitek® and the Plaintiffs decided to use the Recalled Digitek®, both Plaintiffs, and their physicians reasonably relied upon the Defendants and their agents to disclose known defects, risks, dangers and side-effects of the Recalled Digitek® and whether the Recalled Digitek® contained an dose of digoxin, consistent with its label, and not less than, or in excess of, the dose approved for ingestion by humans.

103. Plaintiffs' physician(s), the FDA and/or Plaintiffs had no knowledge of the falsity or incompleteness of the Defendants' statements and representations concerning the Recalled Digitek® when Plaintiffs' physician(s) prescribed and/or otherwise provided Recalled Digitek® and Plaintiffs purchased and used the Recalled Digitek® as designed, developed, tested, manufactured, produced, dosed, inspected, labeled, packaged, distributed, supplied, marketed, promoted, sold and otherwise released into the stream of commerce by the Defendants. Plaintiffs justifiably and detrimentally relied on the warranties and representations of Defendants in the purchase and use of the Recalled Digitek®.

104. At all relevant times, Defendants were under a duty to disclose the defective and unsafe nature of the Recalled Digitek® to physicians, the FDA, consumers and users, such as the Plaintiffs. Defendants had sole access to material facts concerning the defects, and Defendants knew that physicians, the

FDA and users, such as Plaintiffs, could not have reasonably discovered such defects.

105. By the egregious and intentional conduct alleged, Defendants, its agents and employees expressly warranted to Plaintiffs and their physicians(s) that the Recalled Digitek® was packaged and labeled accurately that it contained the approved dose of digoxin, that the drug was safe, merchantable and fit for the purpose intended.

106. This warranty was breached with reckless indifference because the Recalled Digitek® was misbranded, adulterated and did not contain the amount of digoxin as stated in the label and sometimes the approved dose for ingestion by humans, nor was it safe and effective as Defendants represented, and Plaintiffs were harmed as aforesaid.

107. As a direct and proximate result of Defendants' defective and unreasonably dangerous Recalled Digitek® and their breach of express warranty, Plaintiffs were harmed as aforesaid.

108. Defendants expressly warranted in their package inserts the amount of active ingredient in each tablet. Plaintiff relied on that express warranty when, in fact, the tablets were adulterated and did not comply with the package insert. Defendants breach of the express warranty caused serious personal injury to plaintiff.

**WHEREFORE**, Plaintiff demands judgment against Defendants for an amount in excess of \$50,000.00, compensatory damages as a jury may determine to be appropriate and necessary plus interest and costs.

**COUNT 5**  
**BREACH OF IMPLIED WARRANTY**

109. Plaintiffs incorporate by reference each preceding and succeeding paragraphs as though set forth fully at length herein.

110. The Defendants designed, developed, manufactured, marketed, produced, tested, inspected, distributed, supplied, released and sold the Recalled Digitek® for the treatment of certain cardiac heart problems.

111. At the time that the Defendants designed, developed, manufactured, marketed, produced, tested, inspected, distributed, supplied, released and sold the Recalled Digitek®, they knew of the use for which the subject product was intended and impliedly warranted it to be of merchantable quality and safe and fit for such use.

112. The Plaintiffs, individually and through their prescribing physician, reasonably relied upon the skill, superior knowledge and judgment of the Defendants.

113. The Plaintiffs were prescribed, purchased, and used the Recalled Digitek® for its intended purpose.

114. Due to the Defendants' egregious and intentional wrongful conduct as alleged herein, the Plaintiffs could not have known about the mislabeling,

misbranding, dose of digoxin different than the labeled dose, the nature of the risks and side-effects associated with the Recalled Digitek® until after they used it.

115. Contrary to the implied warranty for the subject product, the Recalled Digitek® was not of merchantable quality, and was not safe or fit for its intended uses and purposes, as alleged herein.

116. As a direct and proximate result of the acts and omissions of Defendants and the defective and unreasonably dangerous Recalled Digitek® and their breach of implied warranty, Plaintiffs were harmed as aforesaid, and Plaintiffs have suffered injuries and damages as aforesaid.

**WHEREFORE**, Plaintiff demands judgment against Defendants for an amount in excess of \$50,000.00, compensatory damages as a jury may determine to be appropriate and necessary plus interest and costs.

**COUNT 6**  
**MISREPRESENTATION AND SUPPRESSION BY DEFENDANTS**

117. Plaintiffs incorporate by reference each preceding and succeeding paragraphs as though set forth fully at length herein.

118. Defendants misrepresented to Plaintiffs and the medical community the safety and effectiveness of the Recalled Digitek® and/or fraudulently, intentionally and/or negligently concealed material information, including adverse information regarding the safety and effectiveness of the Recalled Digitek® and the dose of digoxin contained therein.

119. Defendants made misrepresentations and actively concealed adverse information at a time when the Defendants knew, or should have known, that the Recalled Digitek® had defects, dangers, and characteristics that were other than that what the Defendants had represented to Plaintiffs, the public, the FDA and the medical community generally. Specifically, Defendants misrepresented to and/or actively concealed from Plaintiffs, the FDA and, the medical community and consuming public that:

- i. Some doses of digoxin in the Recalled Digitek® was not a dose that was approved by the FDA;
- ii. The dose of the digoxin in the Recalled Digitek® was not what the label represented the dose to be;
- iii. Some of doses of digoxin in the Recalled Digitek® were less than or exceeded the labeled dose;
- iv. The dose of digoxin in the Recalled Digitek® was unsafe, hazardous and dangerous; and,
- v. Ingesting the Recalled Digitek® would result in an overdose or underdose.

120. The misrepresentations of and/or active concealment alleged were perpetuated directly and/or indirectly by Defendants. Many specific examples of misrepresentation were observed first hand by FDA investigators as revealed in their *Revised Warning letter* :

Our investigators observed numerous instances where the quality control unit failed to adequately investigate and resolve laboratory deviations and out-of-specification test results involving drug products that ultimately were released for distribution into interstate commerce. Additionally, our

investigators uncovered out-of-specification test results in laboratory raw data that were not documented in laboratory notebooks, and found that products were released based on retesting without any justification for discarding the initial out-of-specification test results.

Numerous instances were observed where manufacturing process deviations occurred and in-process specifications were not met, yet there is no indication that action was taken promptly to investigate or to correct the deviations and the products were approved for release and distribution by your quality control unit. Additionally, instances were noted where your firm's quality control unit reviewed and approved test data and reports that were inaccurate and incomplete, and as such, did not follow established procedures.

Instances were found where analysts aborted and failed to complete chromatographic testing runs after an out-of-specification test result was obtained. The chromatographic test data reflecting the out-of-specification test results were not recorded in laboratory notebooks.

Our investigators also uncovered numerous instances where out-of-specification test results obtained during the testing of your firm's drug products were not adequately investigated.

The audit trail for the laboratory data acquisition system does not indicate that the run was aborted and the analyst did not print the sample results or record the failing results in the laboratory notebook.

There was a failure to check for accuracy the inputs to and outputs from the "Total Chrom Data Acquisition System," which is used to run your firm's HPLC instruments during analysis of drug products.

Our investigators observed numerous instances where your firm's quality control unit either ignored or failed to recognize that some tablets that did not meet in-process specifications.

121. Defendants knew or should have known that these representations were false and made the representations with the intent or purpose that Plaintiffs would rely on them, leading to the use of the Recalled Digitek®.

122. At the time of Defendants' fraudulent misrepresentations, Plaintiffs were unaware of the falsity of the statements being made and believed them to be true. Plaintiffs had no knowledge of the information concealed and/or suppressed by Defendants.

123. Plaintiffs justifiably relied on and/or were induced by the misrepresentations and/or active concealment and relied on the absence of safety information which the Defendants did suppress, conceal or failed to disclose to the detriment of the Plaintiffs.

124. Defendants had a duty to warn Plaintiffs, the public, the FDA and the medical community, about the misbranding, adulteration and potential risks and complications associated with the Recalled Digitek® in a timely manner but failed to do so.

125. The misrepresentations and active fraudulent concealment by the Defendants constitutes a continuing tort against the Plaintiffs who ingested the Recalled Digitek®.

126. Defendants made the misrepresentations and actively concealed information about the defects and dangers of the Recalled Digitek® with the intention and specific desire that the healthcare professionals treating the Plaintiffs, the Plaintiffs, and the consuming public would rely on such or the absence of information in selecting and using the Recalled Digitek® as a medical treatment.

127. As a direct and proximate result of the fraudulent acts and omissions, suppression and misrepresentation of Defendants, Plaintiffs have suffered injuries and damages as aforesaid.

**WHEREFORE**, Plaintiff demands judgment against Defendants for an amount in excess of \$50,000.00, compensatory damages and punitive damages as a jury may determine to be appropriate and necessary plus interest and costs.

**COUNT 7**  
**NEGLIGENT MISREPRESENTATION**

128. Plaintiffs incorporate by reference each preceding and succeeding paragraphs as though set forth fully at length herein.

129. Defendants, in addition to knowing misrepresentations, made misrepresentations without any reasonable grounds for believing their statements to be true to Plaintiffs, other patients, and the medical community.

130. Defendants, through its misrepresentations, intended to induce justifiable reliance by Plaintiffs, other patients, and the medical community.

131. Defendants, through its labeling, marketing campaign and communications with treating physicians, was in a relationship so close to that of Plaintiffs and other patients that it approaches and resembles privity.

132. Defendants owes a duty to the medical community, Plaintiffs and other consumers, to conduct appropriate and adequate inspections and tests for all of their products, including the Recalled Digitek®, and to use safe and good

manufacturing and production practices, to provide appropriate and adequate information and warnings but they failed to do so.

133. Defendants failed to conduct appropriate or adequate inspections, tests on the Recalled Digitek®.

134. As a direct and proximate result of Defendants' negligent misrepresentations the Plaintiffs were harmed as aforesaid.

**WHEREFORE**, Plaintiff demands judgment against Defendants for an amount in excess of \$50,000.00, compensatory damages and punitive damages as a jury may determine to be appropriate and necessary plus interest and costs.

**COUNT 8**  
**WRONGFUL DEATH**

135. Plaintiffs incorporates by reference each preceding and succeeding paragraphs as though set forth fully at length herein.

136. As a direct and proximate result of the aforesaid, some of the Plaintiffs who ingested the defendant's product Digitek® were caused to contract the diseases and injuries described herein, causing extreme pain, suffering and mental anguish, and died as direct and proximate result of defendant's negligence, breach of implied and express warranties, failure to warn, and fraud as alleged herein.

**WHEREFORE**, Plaintiff demands judgment against Defendants for an amount in excess of \$50,000.00, compensatory damages and punitive damages as a jury may determine to be appropriate and necessary plus interest and costs.

**COUNT 9**  
**SURVIVAL ACTION**

137. Plaintiffs incorporates by reference each preceding and succeeding paragraphs as though set forth fully at length herein.

138. Plaintiffs bring this action on behalf of the Estates of their decedents under 42 Pa. C.S.A. § 8302, and the applicable decisional law.

139. Plaintiffs claim on behalf of said Estates damages suffered by the reason of the death of the decedents, including but not limited to and pain and suffering of Decedents prior to their deaths.

**WHEREFORE**, Plaintiff demands judgment against Defendants for an amount in excess of \$50,000.00, compensatory damages as a jury may determine to be appropriate and necessary plus interest and costs.

**COUNT 10**  
**LOSS OF CONSORTIUM**

140. Plaintiffs incorporates by reference each preceding and succeeding paragraphs as though set forth fully at length herein.

141. Plaintiffs' spouses, were at all times relevant herein, the husband/wife of the Plaintiff and as such, lived and cohabited with her.

142. By reason of the foregoing, Plaintiff's spouse has necessarily paid and has become liable to pay for medical aid, treatment and for medications and funeral expenses, and other liabilities.

143. By reason of the foregoing, Plaintiff's spouse has been caused, presently and in the future, the loss of the spouse's companionship, services,

society and the ability of said Plaintiff's spouse in said respect has been impaired and depreciated, and the marital association between husband and wife has been altered, and as such, the Plaintiff's spouse has been caused mental anguish and suffering.

**WHEREFORE**, Plaintiff demands judgment against Defendants for an amount in excess of \$50,000.00, compensatory damages and punitive damages as a jury may determine to be appropriate and necessary plus interest and costs.

**JURY TRIAL DEMANDED**

Plaintiff demands that all issues of fact of this case be tried to a properly impaneled jury to the extent permitted under the law.

**PRAYER FOR RELIEF**

**WHEREFORE**, Plaintiffs demand judgment against Defendants for damages including exemplary damages if applicable to which they are entitled by law, as well as all costs of this action, to the full extent of the law including:

1. judgment for Plaintiffs and against Defendants;
2. damages to compensate Plaintiffs for injuries sustained as a result of Digitek® use, past and future lost of income proven at trial;
3. judgment against Defendants for the damages resulting from Decedent's death, including, without limitations, Decedent's pecuniary injury, together with all hospital, medical and funeral expenses, as well as compensatory damages.
4. physical pain and suffering of the Plaintiffs; and any and all damages allowed under the law and laws or other statutes and laws that apply and for loss of consortium;

5. pre and post judgment interest at the lawful rate;
6. reasonable attorneys' fees and costs and expert fees;
7. restitution of all purchase costs that Plaintiffs for Digitek® disgorgement of Defendants' profits,
8. exemplary and punitive damages in an amount in excess of the jurisdictional limits, trebled on all applicable Counts;
9. all Bill of Costs elements;
10. a trial by jury on all issues of the case; and,
11. for any other relief as this court may deem equitable and just.

Respectfully submitted,

THE MILLER FIRM, LLC.

By:     /s/ Michael J. Miller    

By: Michael J. Miller, Esq.

Attorney ID No. 95102

By: Christopher A. Gomez, Esq.

Attorney ID No. 82899

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Bala Cynwyd, PA 19004

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**Attorneys for Plaintiff**

**CERTIFICATE OF SERVICE**

I hereby certify that a true and correct copy of Plaintiffs' First Amended General Master Long-Form Complaint was served by first class mail, postage prepaid on this 12th day of November, 2009 upon the following individuals:

Megan Grossman  
Walter H. Swayze, III  
Segal McCambridge Singer & Mahoney, Ltd.  
United Plaza  
30 S. 17<sup>th</sup> Street, Suite 1700  
Philadelphia, PA 19103

THE MILLER FIRM LLC

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