

**UNITED STATES DISTRICT COURT  
FOR THE EASTERN DISTRICT OF MISSOURI  
EASTERN DIVISION**

JAMES JONES, individually and on behalf )  
of all others similarly situated, )

Plaintiff, )

vs. )

Civil Action No. \_\_\_\_\_

ZHEJIANG HUAHAI PHARMACEUTICAL )  
CO., LTD., a Chinese corporation; PRINSTON )  
PHARMACEUTICAL, INC., a Delaware )  
corporation; SOLCO HEALTHCARE U.S., )  
LLC, a Delaware limited liability company; and )  
HUAHAI US, INC., a New Jersey corporation; )

**JURY TRIAL DEMANDED**

Defendants. )

**CLASS ACTION COMPLAINT**

Plaintiff, James Jones, on behalf of himself and all others similarly situated, by and through his attorney, Lanny Darr, alleges as follows upon personal knowledge as to facts pertaining to himself, and upon information and belief based on the investigation of his counsel as to all other matters.

**NATURE OF THE ACTION**

1. Plaintiff brings this class action on behalf of himself and all others similarly situated regarding Defendants’ respective manufacturing, distribution, and sale of valsartan generic prescription medications adulterated with *N*-nitrosodimethylamine, a carcinogenic substance.

2. Valsartan is a prescription medication mainly used for the treatment of high blood pressure and congestive heart failure.

3. Due to manufacturing defects originating in Defendant Zhejiang Huahai Pharmaceutical Co., Ltd.'s facility in China, certain generic formulations of valsartan have become adulterated with an organic chemical known as *N*-nitrosodimethylamine.

4. On July 13, 2018, the U.S. Food & Drug Administration ("FDA") announced a voluntary recall of several brands of valsartan-containing generic medications, including those manufactured and distributed by Defendants Solco, Princeton, and Huahai. The recall was due to the presence of *N*-nitrosodimethylamine in the recalled products.

5. Generic drugs such as valsartan are marketed and sold to consumers such as Plaintiff when the brand-name version of the drug comes off patent, and other competitors are able to seek approval for, market, and sell bioequivalent versions of the brand-name drug. These generic equivalents, such as valsartan, are supposed to be of equal quality and equal safety.

6. Plaintiff and the putative class members were injured by the full purchase price of their valsartan-containing medications and incidental medical expenses. These medications are worthless, as they are contaminated with carcinogenic and harmful *N*-nitrosodimethylamine and are not fit for human consumption.

7. Plaintiff and the putative class members were advised to cease using their valsartan-containing medications.

8. Plaintiff brings this action both individually and on behalf of the putative class members for equitable relief and to recover economic damages and restitution for: (i) violation of Missouri Merchandising Practices Act, Mo. Ann. Stat. §§ 407.010 *et seq.*; (ii) strict products liability; (iii) failure to warn; (iv) breach of contract; (v) breach of implied warranty of merchantability; (vi) unjust enrichment; (vii) fraudulent concealment; (viii) conversion; (ix) negligence; and (x) gross negligence.

**PARTIES**

9. Plaintiff James Jones (“Plaintiff”) is an individual who is a citizen of Missouri, domiciled in The City of St. Louis, Missouri.

10. On information and belief, Defendant Zhejiang Huahai Pharmaceutical Co., Ltd. (“Zhejiang”) is a corporation organized and existing under the laws of the People’s Republic of China, and it maintains its principal place of business at Xunqiao, Linhai, Zhejiang 317024, China.

11. Zhejiang touts on its website that: (a) It is a large scaled modern pharmaceutical group that integrates formulations, APIs (Active Pharmaceutical Ingredients) and intermediates; (b) It has 11 subsidiary entities in the United States, Shanghai, Hangzhou, and Linhai; (c) It occupies an area of 800,000 square meters, and has a staff of 3,400; (d) Its formulation workshops are designed in strict compliance with the international cGMP standard; (e) It is the first pharmaceutical company in China that has passed United States FDA approval; (f) It ensures that production is operated in accordance with good manufacturing practices and product quality meets the required specifications; and (g) It is equipped with state-of-the-art devices ensuring high quality raw materials, final products and in process intermediates.

12. Defendant Huahai US, Inc. (“Huahai”) is a corporation organized and existing under the laws of the state of New Jersey, and it maintains its principal place of business at 2001 Eastpark Boulevard, Cranbury, New Jersey.

13. On information and belief, Huahai conducts substantial business in the state of Missouri and manufactures, markets and/or distributes valsartan for use in generic drugs, including the prescription drug valsartan which is the subject of this litigation, by incorporating valsartan manufactured in China by Zhejiang. According to Huahai’s website, it is a wholly-

owned subsidiary of Zhejiang focusing on the sales and marketing of APIs and Intermediates, and lists valsartan as one of its products.

14. Defendant Princeton Pharmaceutical, Inc. (“Princeton”) is a corporation organized and existing under the laws of the state of Delaware, and it maintains its principal place of business at 2002 Eastpark Boulevard Cranbury, New Jersey.

15. On information and belief, Princeton conducts substantial business in the state of Missouri and manufactures, markets and/or distributes generic drugs, including the prescription drug valsartan which is the subject of this litigation, by incorporating valsartan manufactured in China by Zhejiang.

16. Defendant Solco Healthcare U.S., LLC (“Solco”) is a limited liability company organized under the laws of the state of Delaware, and it maintains its principal place of business at 2002 Eastpark Boulevard, Cranbury, New Jersey.

17. On information and belief, Princeton is the sole member of Solco. According to Princeton’s website, Solco is the U.S. sales and marketing “division” of Princeton.

18. On information and belief, Solco conducts substantial business in the state of Missouri by marketing and distributing generic drugs, including the prescription drug valsartan which is the subject of this litigation.

19. Defendant Solco touts on its website that it “is an industry leader in marketing and distributing generic pharmaceuticals,” and that it “currently markets 38 products,” which “are manufactured in state-of-the-art GMP facilities in China using the highest quality assurance standards that meet the FDA regulatory requirements.”

20. Defendant Solco’s website further states that it is “a fully owned subsidiary of Princeton Pharmaceutical, Inc. and Zhejiang Huahai Pharmaceutical....”

**JURISDICTION & VENUE**

21. On information and belief, at all times relevant herein Zhejiang exercised a high degree of control over its subsidiaries, including Princeton, Solco, and Huahai, and provided more than just standard administrative services to them.

22. On information and belief, at all times relevant herein Zhejiang, Huahai, Princeton and Solco were agents of each other and/or worked in concert with each other on the development, obtaining of regulatory approval, supplying, manufacturing, marketing, distribution and/or sale of generic drugs, including the prescription drug valsartan, throughout the United States and including Missouri.

23. On information and belief, at all times relevant herein Zhejiang, Huahai, Princeton, and Solco each transacted business in Missouri.

24. On information and belief, at all times relevant herein Zhejiang, Huahai, Princeton, and Solco carried on systematic business activity in Missouri with a fair measure of permanence and continuity through, in part, efforts to market and sell their products in Missouri, including the prescription drug valsartan.

25. On information and belief, at all times relevant herein Zhejiang, Huahai, Princeton, and Solco delivered their products, including the prescription drug valsartan, into the stream of commerce with the expectation that they would be purchased by Missouri consumers, including Plaintiff and putative class members.

26. On information and belief, at all times relevant herein Zhejiang, Huahai, Princeton, and Solco purposefully directed activities at Missouri and purposefully availed themselves of the privilege of conducting activities in Missouri.

27. On information and belief, at all times relevant herein Zhejiang, Huahai, Princeton, and Solco knew or should have known that their products, including the prescription drug valsartan, would ultimately be sold in Missouri.

28. Zhejiang, Huahai, Princeton, and Solco each benefitted from Missouri's system of laws, infrastructure and business climate for the sale of their products, including the prescription drug valsartan.

29. Defendants' manufacture, marketing, distribution and/or sale of the prescription drug valsartan resulted in many millions of dollars in sales to Missouri consumers, including Plaintiff and the putative class members.

30. Zhejiang, Huahai, Princeton, and Solco committed a tortious act in Missouri when the Plaintiff and the putative class members purchased or consumed adulterated valsartan contaminated with an organic chemical known as *N*-nitrosodimethylamine ("NDMA").

31. The tortious act injured Plaintiff and the putative class members in Missouri. The injuries and losses suffered by the Plaintiff and the putative class members arose out of the forum related activities of Zhejiang, Huahai, Princeton, and Solco.

32. Missouri has a strong interest in public safety, including the safety of prescription drugs sold to Missouri residents. Missouri also has a manifest interest in providing its residents with a convenient forum for redress of their injuries.

33. Zhejiang, Huahai, Princeton and Solco share a close business relationship. For example, it appears that Huahai, Princeton and Solco share corporate officers, one of whom also appears to be a corporate officer of Zhejiang.

34. Other examples of the close interrelationship between Zhejiang, Huahai, Princeton and Solco include the following:

- a. Jun Du, sometimes referred to as Du Jun, appears to be the initial registered agent of Huahai, appears to be a Vice Chairman of Zhejiang and appears to be, or to have been, a CEO of Huahai and Solco;
- b. Hai Wang appears to be, or to have been, Solco's President, Princeton's Vice President of Business Development and Marketing and a co-founder and senior management team member of Huahai.
- c. Xiaodi Guo appears to be, or to have been, Princeton's Vice President of Research & Development, a Huahai Director and a former Executive Vice President of Huahai.
- d. Chris Keith appears to be Solco's Senior Vice President of Marketing and Business Development and to be part of the senior management team at Princeton. Prior to joining Solco, it appears that Chris Keith was Princeton's Vice President of Marketing and Business Development.
- e. Huahai calls Princeton a "spin-off" from its business operations, while Princeton calls Solco a subsidiary. According to Solco, it is a subsidiary of both Princeton and Zhejiang.
- f. Huahai, Princeton and Solco share the same corporate address in Cranbury, New Jersey.

35. This Court has subject matter jurisdiction over this class action pursuant to 28 U.S.C. § 1332, as amended by the Class Action Fairness Act of 2005, because the matter in controversy exceeds \$5 million, exclusive of interest and costs, and is a class action in which Plaintiff and some members of the putative class are citizens of states different than Defendants. See 28 U.S.C. § 1332(d)(2)(A).

36. This Court has personal jurisdiction over Defendants because Defendants conduct substantial business in Missouri and within this District. Defendants have sufficient minimum contacts with the State of Missouri and intentionally avail themselves of the consumers and markets within the State of Missouri through the promotion and sale of their products, including valsartan.

37. Venue is proper in this District pursuant to 28 U.S.C. § 1391(b)(2) because a substantial part of the acts giving rise to Plaintiff's claims occurred in this District and because Defendants are subject to personal jurisdiction within this District.

### **FACTS COMMON TO ALL CLAIMS**

38. Valsartan is a generic prescription drug mainly used to treat hypertension, high blood pressure, congestive heart failure and to prevent heart attacks and strokes. It was originally marketed and sold under the brand name Diovan.

39. Plaintiff seeks to pursue a class action against the Defendants for supplying, manufacturing, distributing, and ultimately selling valsartan to Plaintiff and the putative class members which was adulterated and defective because it contained NDMA, which rendered the valsartan adulterated, unsafe, and dangerous for consumption by humans ("the Adulterated Valsartan").

40. On information and belief, NDMA is not currently produced in pure form or commercially used in the United States, except for research purposes. On information and belief, NDMA was formerly used in the production of, among other things, liquid rocket fuel.

41. The United States EPA classifies NDMA as a B2 (probable human) carcinogen, based on the induction of tumors in both rodents and non-rodent mammals exposed to NDMA by various routes.



42. According to the EPA, in animal studies of various species including rats and mice, exposure to NDMA has caused tumors primarily of the liver, respiratory tract, kidney and blood vessels.

43. NDMA is listed as a “priority toxic pollutant” in federal regulations. *See* 40 CFR § 131.36.

44. The U.S. Department of Health and Human Services states that NDMA is reasonably anticipated to be a human carcinogen (DHHS 2011).

45. The American Conference of Governmental Industrial Hygienists has classified NDMA as a Group A3 confirmed animal carcinogen with unknown relevance to humans (ACGIH 2012).

46. The U.S. Food & Drug Administration (“FDA”) is an agency within the U.S. Department of Health and Human Services.

47. The FDA protects the public health by assuring the safety, effectiveness, and security of human and veterinary drugs, vaccines and other biological products for human use, and medical devices.

48. On or about July 13, 2018, the FDA announced a voluntary recall of several brands of drugs containing valsartan, including those supplied, manufactured, distributed and/or sold by Defendants (“the Recall”).

49. The Adulterated Valsartan is composed of certain specific lots (“the Lots”). The FDA has issued a list of the Lots that are subject to the Recall.

50. Defendants supplied, manufactured, marketed, distributed and/or sold, respectively, the Lots of Adulterated Valsartan that are subject to the Recall.

51. Plaintiff and the putative class members purchased and ingested Adulterated Valsartan from the Lots subject to the Recall that were supplied, manufactured, distributed and/or sold by the Defendants.

52. According to the Recall, the Lots of the Adulterated Valsartan identified on the Recall List contained NDMA.

53. Zhejiang supplied the valsartan used in the manufacture of the Adulterated Valsartan that is subject to the Recall.

54. In addition to the Recall in the United States, prescription drugs containing valsartan have been recalled in approximately 21 other countries.

55. According to the FDA, numerous valsartan-containing prescriptions medications are subject to the Recall, including those identified on **Exhibit A** hereto.

56. Pursuant to his prescription, Plaintiff purchased what he subsequently learned was Adulterated Valsartan from a Drug Depot, a mail order pharmacy.

57. Plaintiff consumed Adulterated Valsartan pursuant to his prescription on a daily basis prior to the Recall.

58. The Adulterated Valsartan purchased and consumed by Plaintiff was included in the Lots subject to the Recall.

59. Plaintiff stopped consuming the Adulterated Valsartan, at least in part, because he learned that it contained NDMA.

60. According to the FDA on or about July 17, 2018:

The companies listed below are recalling all lots of non-expired products that contain the ingredient valsartan supplied to them by Zhejiang Huahai Pharmaceuticals, Linhai, China. Not all valsartan-containing medicines distributed in the United States have valsartan active pharmaceutical ingredient (API) supplied by this specific company. Zhejiang Huahai has stopped

distributing its valsartan API and the FDA is working with the affected companies to reduce or eliminate the valsartan API impurity from future products.

### **Recalled Products**

<b>Medicine</b>	<b>Company</b>
Valsartan	Major Pharmaceuticals
Valsartan	Solco Healthcare
Valsartan	Teva Pharmaceuticals Industries Ltd
Valsartan/Hydrochlorothiazide (HCTZ)	Solco Healthcare
Valsartan/Hydrochlorothiazide (HCTZ) Ltd.	Teva Pharmaceuticals Industries

61. On or about July 17, 2018, the FDA issued a press release. According to that press release:

The U.S. Food and Drug Administration is alerting health care professionals and patients of a voluntary recall of several drug products containing the active ingredient valsartan, used to treat high blood pressure and heart failure. ***This recall is due to an impurity, N-nitrosodimethylamine (NDMA), which was found in the recalled products.*** However, not all products containing valsartan are being recalled. ***NDMA is classified as a probable human carcinogen (a substance that could cause cancer) based on results from laboratory tests. The presence of NDMA was unexpected and is thought to be related to changes in the way the active substance was manufactured.***

The FDA's review is ongoing and has included investigating the levels of NDMA in the recalled products, assessing the possible effect on patients who have been taking them and what measures can be taken to reduce or eliminate the impurity from future batches produced by the company.

The FDA is committed to maintaining our gold standard for safety and efficacy. That includes our efforts to ensure the quality of drugs and the safe manner in which they're manufactured," said FDA Commissioner Scott Gottlieb, M.D. "When we identify lapses in the quality of drugs and problems with their manufacturing that have the potential to create risks to patients, we're committed to taking swift action to alert the public and help facilitate the removal of the products from the market. As we seek the removal of certain drug products today, our drug shortages team is also working hard to ensure patients' therapeutic needs are met in the United States with an adequate supply of unaffected medications." [Emphasis added].

62. On or about July 17, 2018, the FDA determined that Health professionals should know that:

The FDA has determined *the recalled valsartan products pose an unnecessary risk to patients*. Therefore, *FDA recommends patients use valsartan-containing medicines made by other companies or consider other available treatment options for the patient's medical condition*. If you have medication samples from these companies, *quarantine the products and do not provide them to patients*. [Emphasis added].

63. On or about July 17, 2018 according to Janet Woodcock, M.D., director of the FDA's Center for Drug Evaluation and Research:

“We have carefully assessed the valsartan-containing medications sold in the United States, and we've found that the valsartan sold by these specific companies does not meet our safety standards. This is why *we've asked these companies to take immediate action to protect patients*....” [Emphasis added]

64. On or about August 3, 2018, Plaintiff's pharmacy sent a letter to Plaintiff advising him that: (a) He may have received a prescription for valsartan or valsartan/HCTZ and advising him of an important voluntary recall concerning the product (b) The recall was due to the detection of a trace amount of an unexpected impurity, NDMA, in an active pharmaceutical ingredient by the manufacturer-Zhejiang Huahai Pharmaceutical Co. Ltd. in the manufacture of the subject product lots; (c) Suggesting that he discuss a replacement treatment and prescription options with his healthcare professional; and (d) NDMA is classified as a probable human carcinogen.

65. On August 21, 2018, Huahai posted information on its Internet website. According to that post, a review of manufacturing and optimization processes in early June 2018 resulted in the discovery of NDMA, an impurity, in its valsartan. According to Huahai, NDMA is a carcinogen.

66. Huahai has publicly stated that it isolated its storage of valsartan API on hand, suspended its further release and manufacture, and notified the FDA and other regulatory agencies of its findings.

67. Huahai also notified its customers and instructed them to suspend the further use of its valsartan API. Huahai then initiated a voluntary recall and provided periodic updates to both regulatory agencies and customers.

68. According to Huahai, it undertook recalls at the consumer level *to protect human health*. [Emphasis added].

69. At all times relevant herein Defendants intended to and did convey to Plaintiff and the putative class members that its prescription drug valsartan was of the quality necessary to be utilized for its intended purpose.

70. At all times relevant herein Defendants were negligent in supplying, manufacturing, marketing, distributing and/or selling the Adulterated Valsartan as a prescription drug safe for consumption by the Plaintiff and the putative class members because they failed to have adequate quality control procedures in place to determine that valsartan API was adulterated.

71. As a result of failing to maintain appropriate quality control procedures, Defendants failed to detect NDMA in the Adulterated Valsartan.

72. Defendants made false and misleading representations and, prior to the Recall, failed to disclose to Plaintiff or the putative class members that the Adulterated Valsartan was contaminated with NDMA.

73. The Adulterated Valsartan is worthless.

74. Plaintiff and the Class Members suffered economic damages when they purchased Adulterated Valsartan. Plaintiff and the putative class members would not have purchased the worthless Adulterated Valsartan from Defendants if they had known that it was contaminated with NDMA.

75. Had Defendants disclosed to the Plaintiff and the putative class members that the Adulterated Valsartan was contaminated with NDMA, Plaintiff and the putative class members would not have purchased the Adulterated Valsartan.

76. Plaintiff and the putative class members are subject to increased risk of cancer and disease as a result of their consumption of the Adulterated Valsartan.

77. Plaintiff and the putative class members need medical monitoring as a result of their consumption of the Adulterated Valsartan.

#### **CLASS ALLEGATIONS**

78. Plaintiff and each putative class member purchased and/or ingested Adulterated Valsartan that was subject to the Recall.

79. Plaintiff bring Counts I through X below, both individually and as a class action, pursuant to FED. R. CIV. P. 23(a), 23(b)(2) and/or 23(b)(3), on behalf of a class of Missouri consumers who purchased and/or consumed Adulterated Valsartan that is subject to the Recall, as defined below (the "Class"):

All persons or entities who, while in Missouri, purchased and/or consumed Adulterated Valsartan identified in the Lots subject to the Recall. Excluded from the Class are: (1) Defendants, and any entity in which any Defendant has a controlling interest, or which has a controlling interest in any Defendant; (2) Defendants' respective legal representatives, assigns and successors; and (3) the judge(s) to whom this action is assigned and any member of the judge's immediate family.

80. Plaintiff reserves the right to redefine the Class prior to class certification.

81. The rights of each member of the Class (the “Class Members”) were violated in a similar fashion based upon the Defendants’ uniform actions.

82. These and other questions of law or fact which are common to the Class Members predominate over any questions affecting only individual members of the Class.

a. **Typicality:** Plaintiff’s claims are typical of the claims of the Class Members since Plaintiff and all Class Members purchased and/or consumed the Adulterated Valsartan identified in the Lots while in Missouri. Further, Plaintiff and all Class Members sustained monetary and economic injuries arising out of Defendants’ wrongful conduct by, *inter alia*, purchasing the Adulterated Valsartan identified in the Lots (either out-of-pocket or via co-payments made to their pharmacy or healthcare professionals) and they unknowingly purchased Adulterated Valsartan. Had this material information, *i.e.* that the prescription valsartan was adulterated, been disclosed to Plaintiff and the Class Members, they would not have purchased the Adulterated Valsartan identified in the Lots. The Plaintiff is advancing the same claims and legal theories on behalf of himself and all Class Members.

b. **Adequacy:** The Plaintiff is an adequate representative of the Class because his interests do not conflict with the interests of the respective Class Members that he seeks to represent; Plaintiff has retained counsel competent and highly experienced in complex class action litigation and they intend to prosecute this action vigorously. The interests of the Class will be fairly and adequately protected by Plaintiff and his counsel.

c. **Superiority:** A class action is superior to other available means of fair and efficient adjudication of the claims of Plaintiff and Class Members. The injury suffered

by each individual Class member is relatively small in comparison to the burden and expense of individual prosecution of the complex and extensive litigation necessitated by Defendants' conduct. It would be virtually impossible for members of the Class to individually and effectively redress the wrongs done to them. Even if the members of the Class could afford such individual litigation, the court system could not. Individualized litigation presents a potential for inconsistent or contradictory judgments. Individualized litigation also increases the delay and expense to all parties, and to the court system, presented by the complex legal and factual issues of the case. By contrast, the class action device presents far fewer management difficulties, and provides the benefits of single adjudication, an economy of scale, and comprehensive supervision by a single court.

d. **Ascertainability:** Class members are readily ascertainable and can be identified by Defendants' records.

83. This action has been brought and may be properly maintained as a class action for the following reasons:

a. **Numerosity:** Members of the Class are so numerous that their individual joinder is impracticable. Plaintiff is informed and believes that the proposed Class contains thousands of individuals or entities that purchased Adulterated Valsartan identified in the Lots, either out-of-pocket or via co-payments. The Class is therefore sufficiently numerous to make joinder impracticable, if not impossible. The precise number of Class members is unknown to Plaintiff at this time.

b. **Existence and Predominance of Commons Questions of Fact and Law:** Common questions of law and fact exist as to all members of the Class. These



questions predominate over any questions affecting individual Class members. These common legal and factual questions include, but are not limited to, the following:

- i. Whether the Adulterated Valsartan identified in the Lots met the Defendants' warranties;
- ii. Whether the Adulterated Valsartan identified in the Lots were merchantable goods at the time of sale;
- iii. Whether the Adulterated Valsartan identified in the Lots was fit for its intended purpose;
- iv. Whether Defendants made fraudulent, false, deceptive, and/or misleading statements in connection with the sale of the Adulterated Valsartan identified in the Lots;
- v. Whether Defendants omitted material information when it sold the Adulterated Valsartan;
- vi. The date on which Defendants knew or reasonably should have known that the Adulterated Valsartan was adulterated;
- vii. Whether Defendants' recall notice was timely and/or sufficient;
- viii. Whether Defendants' breached the terms of the express warranty.
- ix. The appropriate nature of class-wide equitable relief; and
- x. The appropriate measurement of restitution and/or measure of damages to award to Plaintiff and the Class Members.

**COUNT I**  
**VIOLATION OF MISSOURI MERCHANDISING PRACTICES ACT**

84. Plaintiff hereby incorporates by reference the allegations contained in all preceding paragraphs of this Complaint as if fully set forth herein.

85. Plaintiff brings this claim individually and on behalf of the Class Members.

The acts and practices engaged in by Defendant, and described herein, constitute unlawful, unfair and/or fraudulent business practices in violation of the Missouri Merchandising Practices Act, Mo. Ann. Stat. §§ 407.010 *et seq.*

86. Defendant engaged in unlawful practices including deception, false promises, misrepresentation, and/or the concealment, suppression, or omission of material facts in connection with the sale, distribution or advertisement of the Adulterated Valsartan in violation of Mo. Rev. Stat. § 407.020.

87. Plaintiffs purchased the Adulterated Valsartan, a product that was falsely represented, as stated above, in violation of the Missouri Merchandising Practices Act and as a result Plaintiffs suffered economic damages in that the product they and other class members purchased was worth less than the product they thought they had purchased had Defendant's representations been true.

88. Defendants' conduct as alleged herein occurred in the course of trade or commerce.

89. Defendants misrepresented the characteristics of the Adulterated Valsartan, the ingredients in the Adulterated Valsartan, the uses or benefits of the drug, that the Adulterated Valsartan was safe for human consumption, that the Adulterated Valsartan did not contain NDMA, and that the Adulterated Valsartan was not adulterated.

90. In fact, the Adulterated Valsartan did not have the characteristics, ingredients, uses or benefits represented, it was not safe for human consumption, it did contain NDMA and was adulterated. This offends public policy, and has caused substantial injury to Plaintiff and the Class Members.

91. Upon information and belief, and given the fact that Defendants were responsible for designing, supplying, manufacturing, distributing and/or selling the Adulterated Valsartan to Plaintiff and the Class Members, Defendants knew or should have known at all relevant times that the valsartan was adulterated because it contained NDMA and was not safe for human consumption. Nonetheless, Defendants falsely represented that the Adulterated Valsartan purchased by the Plaintiff and the Class Members was safe for human consumption when it was not.

92. Defendants intended for consumers, including the Plaintiff and the Class Members, to rely on their representations that the Adulterated Valsartan was safe for human consumption when choosing to purchase the drug. Plaintiff and the Class Members relied on such representations in making their decision to purchase the Adulterated Valsartan.

93. As a direct and proximate result of Defendants' practices, Plaintiff and the Class Members suffered actual damages, including monetary losses for the purchase price of the Adulterated Valsartan which was not safe for human consumption and was worthless, and incidental medical expenses.

**COUNT II**  
**STRICT PRODUCT LIABILITY**

94. Plaintiff hereby incorporates by reference the allegations contained in all preceding paragraphs of this Complaint as if fully set forth herein.

95. Plaintiff brings this claim individually and on behalf of the Class Members.

96. At all times relevant to this action, Defendants designed, tested, manufactured, packaged, marketed, distributed, promoted, and/or sold the Adulterated Valsartan, placing the drug into the stream of commerce.

97. At all times material, the Adulterated Valsartan was designed, tested, inspected, manufactured, assembled, developed, labeled, sterilized, licensed, marketed, advertised, promoted, sold, packaged, supplied and/or distributed by Defendants in a defective and unreasonably dangerous condition to consumers, including Plaintiff and the Class Members.

98. The Adulterated Valsartan was expected to reach, and did reach, users and/or consumers, including Plaintiff, and Class Members without substantial change in the defective and unreasonably dangerous condition in which it was manufactured and sold.

99. The Adulterated Valsartan was unreasonably dangerous because it was adulterated and contaminated by NDMA, a carcinogen.

100. The Adulterated Valsartan was defective in that it neither bore, nor was packaged with, nor accompanied by, warnings adequate to alert consumers, including Plaintiff and the Class Members, to the risks described herein, including, but not limited to, the risk of serious injury and/or death.

101. The Adulterated Valsartan was not accompanied by adequate labeling, instructions for use and/or warnings to fully apprise the medical, pharmaceutical and/or scientific communities, and users and/or consumers of the drug, including Plaintiff and the Class Members, of the potential risks associated with its use, thereby rendering Defendants liable to Plaintiff and the Class Members.

102. The Adulterated Valsartan was unsafe for normal or reasonably anticipated use.

103. The Adulterated Valsartan was defective in formulation because when the drug left the hands of the Defendants, it was unreasonably dangerous and more dangerous than an ordinary consumer would expect.

104. The Adulterated Valsartan was also defective and unreasonably dangerous in that the foreseeable risk of injuries from consuming the Adulterated Valsartan exceeded the benefits associated with the formulation of the Adulterated Valsartan.

105. The Adulterated Valsartan is unreasonably dangerous; a) in construction or composition; b) in design; c) because an adequate warning about it was not provided; and d) because the Adulterated Valsartan did not conform to an express warranty about the product.

106. The Adulterated Valsartan as manufactured, distributed, supplied, and/or sold by the Defendants was also defective due to inadequate testing before exposing Plaintiff and the Class Members to it.

107. The Adulterated Valsartan as manufactured, distributed, supplied and/or sold by Defendants was defective and after Defendants knew or should have known of the risk of injuries from use and/or ingestion, they failed to provide adequate warnings to the medical community and the consumers, to whom they were directly marketing and advertising; and, further, they continued to affirmatively promote Adulterated Valsartan as safe and effective.

108. In light of the potential and actual risk of harm associated with the consumption of the Adulterated Valsartan, a reasonable person who had actual knowledge of this potential and actual risk of harm would have concluded that the Adulterated Valsartan should not have been marketed in that condition.

109. Although Defendants knew or should have known of the defective nature of the Adulterated Valsartan, they continued to manufacture, market, distribute and/or sell it so as to maximize sales and profits at the expense of the public health and safety. Defendants thus acted with conscious and deliberate disregard of the foreseeable harm caused by the Adulterated Valsartan.

110. Plaintiff and the Class Members could not, through the exercise of reasonable care, have discovered the risk of serious injury and/or death associated with and/or caused by their consumption of the Adulterated Valsartan.

111. As a direct and proximate result of Defendants' conduct, Plaintiff and the Class Members purchased or consumed Adulterated Valsartan, and, as a result, Plaintiff and the putative class members suffered harm and loss.

112. Information provided by the Defendants to the medical community and to consumers concerning the safety and efficacy of the Adulterated Valsartan, especially the information contained in the advertising and promotional materials, did not accurately reflect the serious and potentially fatal side effects resulting from consumption of the Adulterated Valsartan.

**COUNT III**  
**FAILURE TO WARN**

113. Plaintiff hereby incorporates by reference the allegations contained in all preceding paragraphs of this Complaint as if fully set forth herein.

114. Plaintiff brings this claim individually and on behalf of the Class Members.

115. Defendants violated a state-law duty of care by failing to report known risks associated with the consumption of the Adulterated Valsartan.

116. Defendants failed to adequately warn health care professionals and the public, including the Plaintiff and the Class Members and their physicians, of the true risks of the Adulterated Valsartan, including the risks associated with the consumption of NDMA, a carcinogen. Defendants owed a duty to exercise ordinary care. Defendants breached their duty to exercise ordinary care to supply, manufacture, distribute, and/or sell valsartan to Plaintiff and the Class Members that was not adulterated.

117. Defendants failed to timely and reasonably warn of material facts regarding the safety and efficacy of the Adulterated Valsartan.

118. Defendants failed to perform or otherwise facilitate adequate testing, or failed to reveal and/or concealed testing performed on the valsartan.

119. As a direct and proximate cause of the Defendants' conduct, Plaintiff and the class members suffered economic loss.

120. Defendants' conduct was reckless. Defendants risked the lives and health of consumers, including Plaintiff and the Class Members, based on the suppression of knowledge relating to the safety and efficacy problems associated with the Adulterated Valsartan.

121. Upon information and belief, Defendants made a conscious decision not to notify the FDA, healthcare professionals, and the public, thereby putting increased profits over the public safety, including the safety of the Plaintiff and the Class Members. Defendants' actions and omissions as alleged herein demonstrate an utter disregard for human safety, warranting the imposition of punitive damages.

#### COUNT IV

#### **BREACH OF CONTRACT**

122. Plaintiff hereby incorporates by reference the allegations contained in all preceding paragraphs of this Complaint as if fully set forth herein.

123. Plaintiff brings this claim individually and on behalf of the Class Members.

124. Plaintiff, and each Class Member, formed a contract with the Defendants at the time they purchased the Adulterated Valsartan medication.

125. The terms of the contract include the promises and affirmations of fact in the advertising, and on the packaging and labeling for the medicine, including that the valsartan

would not contain harmful and carcinogenic impurities such as NDMA. Defendants represented that the valsartan was safe. The promises and affirmations of fact became part of the basis of the bargain and are a part of the contract between Plaintiff, the Class Members and the Defendants.

126. Defendants also represented that the Adulterated Valsartan was safe, efficacious and fit for its intended purposes, that it was of merchantable quality, that it did not produce any unwarned-of dangerous side effects, and that it was adequately tested.

127. Plaintiff, and each Class Member, relied on Defendants' representations that their valsartan would not contain harmful and carcinogenic impurities such as NDMA.

128. Plaintiff and each Class Member performed all conditions precedent pursuant to their contract with Defendants.

129. Defendants breached the contract because the Adulterated Valsartan was adulterated and contaminated with the carcinogen NDMA.

130. Plaintiff would not have purchased the Adulterated Valsartan if he had known that it was adulterated and contaminated with the carcinogen NDMA.

131. None of the Class Members would have purchased the Adulterated Valsartan if they had known that it was adulterated and contaminated with the carcinogen NDMA.

132. Plaintiff and each of the Class Members have been damaged in the amount of the purchase price of the Adulterated Valsartan and consequential economic damages, including incidental medical expenses, resulting therefrom.

**COUNT V**  
**BREACH OF IMPLIED WARRANTY OF MERCHANTABILITY**

133. Plaintiff hereby incorporates by reference the allegations contained in all preceding paragraphs of this Complaint as if fully set forth herein.

134. Plaintiff brings this claim individually and on behalf of the Class Members.



135. Defendants as the designers, manufacturers, distributors and/or sellers of the Adulterated Valsartan impliedly warranted that the Adulterated Valsartan purchased by Plaintiff and the Class Members was safe for human consumption, that the Adulterated Valsartan was not adulterated, and that the Adulterated Valsartan did not contain NDMA, a carcinogen.

136. Defendants breached the warranty implied in the contract for the sale of the valsartan because the Adulterated Valsartan could not pass without objection in the trade under the contract description, it was not of the quality described, and it was unfit for its intended and ordinary purpose because it was adulterated, containing NDMA, a carcinogen, and therefore unfit for human consumption. As a result, the Plaintiff and the Class Members did not receive valsartan as impliedly warranted by the Defendants to be merchantable.

137. Plaintiff and the Class Members purchased the Adulterated Valsartan in reliance on the Defendants' implied warranties of fitness for a particular purpose.

138. Plaintiff did not alter the Adulterated Valsartan.

139. The Class Members did not alter the Adulterated Valsartan.

140. The Adulterated Valsartan was defective when it left the exclusive control of the Defendants.

141. The Adulterated Valsartan was defectively manufactured and unfit for its intended purpose and the Plaintiff and Class Members did not receive the Adulterated Valsartan as warranted.

142. As a direct and proximate result of the Defendants' breach of the implied warranty, Plaintiff and the Class Members have been harmed and injured because (a) they would not have purchased the Adulterated Valsartan containing the carcinogen NDMA if they had known that such valsartan was adulterated and contained a carcinogen; (b) the Adulterated

Valsartan does not have the characteristics, ingredients, uses, or benefits as promised by the Defendants; (c) the Adulterated Valsartan has never been tested for human consumption; (d) the Adulterated Valsartan has never been tested for efficacy; and (e) the Adulterated Valsartan is worthless.

**COUNT VI**  
**UNJUST ENRICHMENT**

143. Plaintiff hereby incorporates by reference the allegations contained in all preceding paragraphs of this Complaint as if fully set forth herein.

144. Plaintiff brings this claim individually and on behalf of the Class Members.

145. Plaintiff and the Class Members conferred a benefit on Defendants by purchasing the Adulterated Valsartan, which was worthless, adulterated, dangerous, and contained NDMA, a carcinogen.

146. It is inequitable and unjust for Defendants to retain the revenues obtained from purchases of the Adulterated Valsartan by Plaintiff and the Class Members because Defendants misrepresented the qualities of the Adulterated Valsartan and the Adulterated Valsartan could not be used in the manner represented by Defendants.

147. Accordingly, because Defendants will be unjustly enriched if it is allowed to retain such funds, Defendants must pay restitution to Plaintiff and the Class Members in the amount which Defendants were unjustly enriched by each purchase of the Adulterated Valsartan.

**COUNT VII**  
**FRAUDULENT CONCEALMENT**

148. Plaintiff hereby incorporates by reference the allegations contained in all preceding paragraphs of this Complaint as if fully set forth herein.

149. Plaintiff brings this claim individually and on behalf of the Class Members.

150. Defendants had a duty to disclose material facts to Plaintiff and the Class Members that they were in fact manufacturing, distributing and/or selling valsartan that was adulterated, contained NDMA, a carcinogen, and that the Adulterated Valsartan was unfit for human consumption.

151. Defendants had superior knowledge such that the purchases of the Adulterated Valsartan by Plaintiff and the Class Members were inherently unfair.

152. Upon information and belief, Defendants possessed knowledge of the material facts. Reports from government entities reveal that NDMA may have been part of the make-up of valsartan since at least as far back as 2012.

153. Upon information and belief, Defendants may have withheld their knowledge of the contamination for approximately six years before finally disclosing the issue in July 2018. During that time, Plaintiff and the Class Members purchased and/or consumed the Adulterated Valsartan without knowing that they were consuming NDMA, a carcinogen.

154. Defendants failed to discharge their duty to disclose material facts.

155. Upon information and belief, Defendants, with scienter and/or an intent to defraud, intended to hide from Plaintiff and the Class Members that they were purchasing and consuming Adulterated Valsartan that was contaminated by NDMA, a carcinogen, rendering the medicine unfit for human consumption.

156. Plaintiff and the Class Members reasonably relied on Defendants' failure to disclose insofar as they would not have purchased the Adulterated Valsartan manufactured, distributed and/or sold by Defendants had they known it was contaminated with NDMA and thus adulterated.

157. As a direct and proximate result of Defendants' fraudulent concealment, Plaintiff and the Class Members suffered damages in the amount of money paid for the Adulterated Valsartan and incidental medical expenses.

**COUNT VIII**  
**CONVERSION**

158. Plaintiff hereby incorporates by reference the allegations contained in all preceding paragraphs of this Complaint as if fully set forth herein.

159. Plaintiff brings this claim individually and on behalf of the members of the Class Members.

160. Defendants exercised control over the money paid by the Plaintiff and the Class Members which is inconsistent with the right of the Plaintiff and the Class Members to possession of the money paid to purchase the Adulterated Valsartan.

161. Plaintiff and the Class Members have a right to possession of the money paid to purchase the Adulterated Valsartan.

162. Demand for return of their money by the Plaintiff or the Class Members would be futile.

**COUNT IX**  
**NEGLIGENCE**

163. Plaintiff hereby incorporates by reference the allegations contained in all preceding paragraphs of this Complaint as if fully set forth herein.

164. Plaintiff brings this claim individually and on behalf of the Class Members.

165. The Defendants supplied, manufactured, distributed and/or sold valsartan as a drug for consumption by the Plaintiff and the Class Members.

166. The Defendants had a duty to exercise ordinary care to supply, manufacture, distribute and/or sell valsartan to Plaintiff and the Class Members that was not adulterated.

167. The Defendants breached their duty of care owed to the Plaintiff and the Class Members by:

a. Supplying, manufacturing, distributing and/or selling valsartan to Plaintiff and the Class Members valsartan that was adulterated because it was contaminated by NDMA, a carcinogen;

b. Failing to maintain appropriate quality control procedures thereby allowing NDMA to contaminate valsartan purchased and/or consumed by Plaintiff and Class Members;

168. Defendants' breach of the duty of care proximately caused damage to Plaintiff and the Class Members.

**COUNT X**  
**GROSS NEGLIGENCE**

169. Plaintiff hereby incorporates by reference the allegations contained in all preceding paragraphs of this Complaint as if fully set forth herein.

170. Defendants' conduct resulted in an extreme risk to the Plaintiff and the Class Members.

171. Upon information and belief, the Defendants should have known of the extreme risk to the Plaintiff and the Class Members but continued with their conduct anyway.

172. The Defendants' conduct was more than just negligence, it amounts to gross negligence and amounted to recklessness or aggravated negligence resulting from an extreme departure from the ordinary standard of care owed to Plaintiff and the Class Members.

173. The Defendants' conduct was so unreasonable and dangerous that it was highly probable that harm would result.

174. The Defendants' conduct created circumstances constituting an imminent or clear and present danger.

WHEREFORE, the Plaintiff requests judgment against the Defendants, jointly and severally as follows:

A. Determine that the claims alleged herein may be maintained as a class action under Rule 23(a), (b)(2), and/or (b)(3) of the Federal Rules of Civil Procedure, and issue an order certifying the Class as defined above and designating Plaintiffs' counsel as counsel for the Class;

B. Awarding Plaintiff and the Class Members judgment in the amount of their economic losses as well as punitive damages for the conduct alleged herein;

C. Allowing for medical monitoring for the Plaintiff and Class Members;

- D. Awarding reasonable attorney's fees and costs;
- E. Awarding prejudgment and postjudgment interest;
- F. Any and all other relief, both legal and equitable, that the Court may deem just and appropriate.

**DEMAND FOR JURY TRIAL**

Plaintiff, both individually and on behalf of the Class, hereby demands a jury trial pursuant to Federal Rule of Civil Procedure 38(b) on all issues so triable in this action.

Dated: September 11, 2018

Respectfully submitted,

JAMES JONES

By: /s/ Lanny Darr  
Lanny Darr (#42038)  
Darr Law Offices, Ltd.  
307 Henry Street, Suite 406  
Alton, IL 62002  
Phone: (618)208-6828  
Fax: (618)433-8519  
darr@darrfirm.com

<b>EXHIBIT A</b>				
Company	Product	NDC	Lot	Expiration
Teva Pharmaceuticals labeled as Major Pharmaceuticals	Valsartan 80 mg Tablets	0904-6594- 61	T01795	05/2019
			T01807	05/2019
			T01712	02/2019
			T01625	02/2019
			T01596	02/2019
			T01500	02/2019
			T01466	07/2018
			T01270	07/2018
	Valsartan 160mg Tablets	0904-6595- 61	T01646	05/2019
			T01788	05/2019
			T01668	05/2019
			T01524	02/2019
			T01269	07/2018
	Prinston Pharmaceutical Inc. labeled as Solco Healthcare LLC.	Valsartan 40mg Tablets, 30 count bottle	43547-367- 03	All lots
Valsartan 80mg Tablets, 90 count bottle		43547-368- 09		
Valsartan 160mg Tablets, 90 count bottle		43547-369- 09		
Valsartan 320mg Tablets, 90 count bottle		43547-370- 09		



	Valsartan and Hydrochlorothiazide (HCTZ) 80mg/12.5mg Tablets, 90 count bottle	43547-311-09		
	Valsartan and Hydrochlorothiazide (HCTZ) 160mg/12.5mg Tablets, 90 count bottle	43547-312-09		
	Valsartan and Hydrochlorothiazide (HCTZ) 160mg/25mg Tablets, 90 count bottle	43547-313-09		
	Valsartan and Hydrochlorothiazide (HCTZ) 320mg/12.5mg Tablets, 90 count bottle	43547-314-09		
	Valsartan and Hydrochlorothiazide (HCTZ) 320mg/25mg Tablets, 90 count bottle	43547-315-09		
Teva Pharmaceuticals USA labeled as Actavis	Valsartan 40mg Tablets, 30 count bottle	0591-2167-30	1196936 A	09/2018
			1238463 A	05/2019
			1270617 A	10/2019
	Valsartan 40mg Tablets, 90 count bottle	0591-2167-19	1196934 M	09/2018
			1238462 M	05/2019
			1268429 A	10/2019

Valsartan 80mg Tablets, 90 count bottle	0591-2168- 19	1175947 M	07/2018
		1175948 M	07/2018
		1177115 A	07/2018
		1219361 A	02/2019
		1240434 M	05/2019
		1250704 M	05/2019
Valsartan 80mg Tablets, 1000 count bottle	0591-2168- 10	1177114 A	07/2018
		1219360 M	02/2019
		1250706 A	05/2019
Valsartan 160mg Tablets, 90 count bottle	0591-2169- 19	1177880 A	07/2018
		1220831 A	02/2019
		1263941 A	08/2019
Valsartan 160mg Tablets, 1000 count bottle	0591-2169- 10	1175922 M	07/2018
		1220826 M	02/2019
		1236294 M	05/2019

		1240427 M	05/2019
		1270616 A	08/2019
Valsartan 320mg Tablets, 90 count bottle	0591-2170- 19	1208002 A	10/2018
		1247282 M	05/2019
		1263944 M	08/2019
Valsartan 320mg Tablets, 500 count bottle	0591-2170- 05	1208000 M	10/2018
		1208001 M	10/2018
		1240425 A	06/2019
Valsartan and Hydrochlorothiazide (HCTZ) 80mg/12.5mg Tablets, 90 count bottle	0591-2315- 19	1191191 M	08/2018
		1191192 M	08/2018

		1191193 M	08/2018
		1191194 M	08/2018
		1191195 M	08/2018
		1238466 M	06/2019
		1238467	06/2019

		M	
		1253261 M	07/2019
		1256125 M	07/2019
		1277709 M	09/2019
Valsartan and Hydrochlorothiazide (HCTZ) 160mg/12.5mg Tablets, 90 count bottle	0591-2316-19	1191160 M	09/2018
		1191161 M	09/2018
		1191162 A	09/2018
		1219363 M	02/2019
		1219364 M	02/2019
		1219365 A	02/2019
		1225613 A	02/2019
		1233944 M	04/2019
		1233945 M	04/2019
		1253253 M	07/2019
		1253254 M	07/2019

Valsartan and Hydrochlorothiazide (HCTZ) 160mg/25mg Tablets, 90 count bottle	0591-2317-19	1191164 M	09/2018
		1191165 M	09/2018
		1191166 M	09/2018
		1191167 A	10/2018
		1225612 M	02/2019
		1250717 M	07/2019
		1256111 M	07/2019
		1288798 M	10/2019
Valsartan and Hydrochlorothiazide (HCTZ) 320mg/12.5mg Tablets, 90 count bottle	0591-2318-19	1191185 M	09/2018
		1191186 M	09/2018
		1225615 M	02/2019
		1233948 M	02/2019
		1250718 M	08/2019
		1253257 M	07/2019
Valsartan and Hydrochlorothiazide	0591-2319-19	1191188 M	09/2018

(HCTZ) 320mg/25mg  
Tablets, 90 count bottle

1191189 M	09/2018
1191190 M	09/2018
1199220 M	08/2018
1217576 M	01/2019
1217577 M	01/2019
1217578 M	01/2019
1220832 M	01/2019
1220833 M	02/2019
1247283 M	06/2019
1247284 M	06/2019
1247285 M	06/2019
1247286 M	06/2019
1247287 A	06/2019
1280632 M	10/2019
1280633 M	10/2019

AvKARE	Valsartan and Hydrochlorothiazide (HCTZ) 80mg/12.5mg Tablets, 90 count bottle	42291-884-90	17349	08/2018
			18395	08/2018
			19221	06/2019
			20029	06/2019
			20158	07/2019
			20843	07/2019

			21411	09/2019
	Valsartan and Hydrochlorothiazide (HCTZ) 160mg/12.5mg Tablets, 90 count bottle	42291-885-90	17325	09/2018
			17856	09/2018
			18396	09/2018
			18702	02/2019
			19020	02/2019
			19222	02/2019
			20030	04/2019
			20381	04/2019
	Valsartan and Hydrochlorothiazide (HCTZ) 320mg/12.5mg Tablets, 90 count bottle	42291-886-90	17780	09/2018
			18029	09/2018
			18398	09/2018
			18723	09/2018
			19017	02/2019
			19224	02/2019

		20032	08/2019
		20289	08/2019
		21076	08/2019
		21382	08/2019
Valsartan and Hydrochlorothiazide (HCTZ) 160mg/25mg Tablets, 90 count bottle	42291-887-90	17307	09/2018
		17857	09/2018
		18397	09/2018
		18722	09/2018
		19016	10/2018
		19223	02/2019
		20031	07/2019
		20382	07/2019
		21281	07/2019
Valsartan and Hydrochlorothiazide (HCTZ) 320mg/25mg Tablet, 90 count bottle	42291-888-90	17308	09/2018
		18158	09/2018
		18539	01/2019
		19021	01/2019
		19225	01/2019
		20033	06/2019
		20290	06/2019
		20565	06/2019



			21369	10/2019
Remedy Repack	Valsartan and Hydrochlorothiazide (HCTZ) 320mg/12.5mg Tablet, 90 count bottle	70518-0925-0	B0383153-122917	12/2018
	Valsartan and Hydrochlorothiazide 160mg/12.5mg Tablets, 90 count bottle	70518-0607-0	B0318652-070617	07/2018
A-S Medication Solutions LLC	Valsartan 80mg Tablets	54569-6582-1	342B17019	09/2019
			342B17018	08/2019
			342B17004	02/2019
			342B17002	11/2018
	Valsartan 80mg Tablets	54569-6582-0	342B17003	11/2018
			342B17004	02/2019
	Valsartan 160mg Tablets	54569-6583-1	343B17056	08/2019
			343B17053	08/2019
			343B17024	03/2019
			343B17016	02/2019
54569-6583-0		343B17019	02/2019	

			343B170 23	03/2019
			343B170 56	08/2019
	Valsartan and Hydrochlorothiazide (HCTZ) 160mg/12.5mg Tablets	54569-6480-0	1233944 M	04/2019
			1253253 M	07/2019
		54569-6480-1	1253253 M	07/2019
	Valsartan and Hydrochlorothiazide (HCTZ) 320mg/25mg Tablets	54569-6488-0	1191188 M	09/2018
			1191189 M	09/2018
			1217576 M	01/2019
			1247283 M	06/2019
			1247285 M	06/2019
Bryant Ranch Prepack Inc.	Valsartan 80 mg Tablets, 28 count bottle	63629-6922-4	111158	02/2019
	Valsartan 80mg Tablets, 60 count bottle	63629-6922-3	111158	02/2019
	Valsartan 80mg Tablets, 90 count bottle	63629-6922-2	111158	02/2019
	Valsartan 320 mg Tablets, 28 count bottle	63629-6905-3	114319	10/2018
109004			12/2018	

	Valsartan 320mg Tablets, 30 count bottle	63629-6905- 1	114319 109004	10/2018 12/2018
	Valsartan 320mg Tablets, 90 count bottle	63629-6905- 2	114319 109004	10/2018 12/2018
	Valsartan 320mg Tablets, 90 count bottle	71335-0567- 2	120879	10/2019
H J Harkins Company Inc. dba Pharma Pac	Valsartan 160mg Tablets, 90 count bottle	76519-1158- 9	VSA000 OV	02/2019
Proficient Rx LP	Valsartan and Hydrochlorothiazide (HCTZ) 320mg/12.5mg Tablets, 90 count bottle	71205-004- 90	All lots	09/2018 to 07/2019
Northwind Pharmaceuticals	Valsartan 80mg Tablets, 30 count bottle	51655-652- 52	UT48310 002	10/2018
	Valsartan 160mg Tablets	51655-460- 52	UT48320 002	07/2018
			UT48320 003	05/2019
	Valsartan 320mg Tablets, 30 count bottle	51655-654- 52	UT48100 001	09/2019
	Valsartan and Hydrochlorothiazide (HCTZ) 160mg/12.5mg Tablets	51655-950- 52	UTB237 90003	02/2019
Camber Pharmaceuticals, Inc.	Valsartan 40mg Tablets, 30 count bottle	31722-745- 30	All lots	07/2018 - 06/2020
	Valsartan 80mg Tablets, 90 count bottle	31722-746- 90	All lots	07/2018 - 06/2020

	Valsartan 160mg Tablets, 90 count bottle	31722-747- 90	All lots	07/2018 - 06/2020
	Valsartan 320mg Tablets, 90 count bottle	31722-748- 90	All lots	07/2018 - 06/2020
NuCare Pharmaceuticals Inc.	Valsartan and Hydrochlorothiazide (HCTZ) 160mg/12.5mg Tablets, 90 count bottle	68071-4311- 9	U01779	04/2019
	Valsartan and Hydrochlorothiazide (HCTZ) 160mg/25mg Tablets, 30 count bottle	68071-2119- 3	T11443	02/2019
	Valsartan and Hydrochlorothiazide (HCTZ) 320mg/25mg Tablets, 30 count bottle	68071-4183- 3	T11577	06/2019

JS 44 (Rev. 12/12)

CIVIL COVER SHEET

The JS 44 civil cover sheet and the information contained herein neither replace nor supplement the filing and service of pleadings or other papers as required by law, except as provided by local rules of court. This form, approved by the Judicial Conference of the United States in September 1974, is required for the use of the Clerk of Court for the purpose of initiating the civil docket sheet. (SEE INSTRUCTIONS ON NEXT PAGE OF THIS FORM.)

I. (a) PLAINTIFFS

James Jones, individually and on behalf of all other similarly situated,

(b) County of Residence of First Listed Plaintiff (EXCEPT IN U.S. PLAINTIFF CASES)

(c) Attorneys (Firm Name, Address, and Telephone Number) Darr Firm, Lanny Darr, 307 Henry Street, Suite 406, Alton, IL 62002 618-208-6828

DEFENDANTS

Zhejiang Huahai Pharmaceutical Co., Ltd., a Chinese corporation; Prinston Pharmaceutical, Inc., a Delaware corporation; Solco Healthcare U.S., LLC, a Delaware limited liability company, and Huahai US, Inc., a New Jersey corporation;

County of Residence of First Listed Defendant Foreign (IN U.S. PLAINTIFF CASES ONLY)

NOTE: IN LAND CONDEMNATION CASES, USE THE LOCATION OF THE TRACT OF LAND INVOLVED.

Attorneys (If Known)

II. BASIS OF JURISDICTION (Place an "X" in One Box Only)

- 1 U.S. Government Plaintiff, 2 U.S. Government Defendant, 3 Federal Question (U.S. Government Not a Party), 4 Diversity (Indicate Citizenship of Parties in Item III)

III. CITIZENSHIP OF PRINCIPAL PARTIES (Place an "X" in One Box for Plaintiff and One Box for Defendant)

Table with columns for Plaintiff (PTF) and Defendant (DEF) citizenship and incorporation status. Includes options for Citizen of This State, Citizen of Another State, Citizen or Subject of a Foreign Country, and Foreign Nation.

IV. NATURE OF SUIT (Place an "X" in One Box Only)

Large table with categories: CONTRACT, REAL PROPERTY, TORTS, CIVIL RIGHTS, PRISONER PETITIONS, FORFEITURE/PENALTY, LABOR, IMMIGRATION, LABOR, SOCIAL SECURITY, FEDERAL TAX SUITS, OTHER STATUTES. Includes numerous sub-categories and checkboxes for specific suit types.

V. ORIGIN (Place an "X" in One Box Only)

- 1 Original Proceeding, 2 Removed from State Court, 3 Remanded from Appellate Court, 4 Reinstated or Reopened, 5 Transferred from Another District (specify), 6 Multidistrict Litigation

VI. CAUSE OF ACTION

Cite the U.S. Civil Statute under which you are filing (Do not cite jurisdictional statutes unless diversity): 28 USC 1332

Brief description of cause: Missouri Merchandising Practices Act, Mo. Ann. Stat. 407.010 et. seq.

VII. REQUESTED IN COMPLAINT:

CHECK IF THIS IS A CLASS ACTION UNDER RULE 23, F.R.Cv.P. DEMAND \$ 5,000,000.00 CHECK YES only if demanded in complaint. JURY DEMAND: X Yes [ ] No

VIII. RELATED CASE(S) IF ANY

(See instructions): JUDGE DOCKET NUMBER

DATE 09/11/2018 SIGNATURE OF ATTORNEY OF RECORD /s/Lanny Darr

FOR OFFICE USE ONLY

RECEIPT # AMOUNT APPLYING IFP JUDGE MAG. JUDGE

UNITED STATES DISTRICT COURT  
EASTERN DISTRICT OF MISSOURI

	)	
	)	
	)	
Plaintiff,	)	
	)	
v.	)	Case No.
	)	
	)	
Defendant,	)	
	)	

**ORIGINAL FILING FORM**

**THIS FORM MUST BE COMPLETED AND VERIFIED BY THE FILING PARTY WHEN INITIATING A NEW CASE.**

THIS SAME CAUSE, OR A SUBSTANTIALLY EQUIVALENT COMPLAINT, WAS PREVIOUSLY FILED IN THIS COURT AS CASE NUMBER \_\_\_\_\_ AND ASSIGNED TO THE HONORABLE JUDGE \_\_\_\_\_.

THIS CAUSE IS RELATED, BUT IS NOT SUBSTANTIALLY EQUIVALENT TO ANY PREVIOUSLY FILED COMPLAINT. THE RELATED CASE NUMBER IS \_\_\_\_\_ AND THAT CASE WAS ASSIGNED TO THE HONORABLE \_\_\_\_\_. THIS CASE MAY, THEREFORE, BE OPENED AS AN ORIGINAL PROCEEDING.

NEITHER THIS SAME CAUSE, NOR A SUBSTANTIALLY EQUIVALENT COMPLAINT, HAS BEEN PREVIOUSLY FILED IN THIS COURT, AND THEREFORE MAY BE OPENED AS AN ORIGINAL PROCEEDING.

**The undersigned affirms that the information provided above is true and correct.**

Date: 09/11/2018

/s/Lanny Darr  
Signature of Filing Party

AO 440 (Rev. 12/09) Summons in a Civil Action

UNITED STATES DISTRICT COURT
for the

Eastern District of Missouri

James Jones, individually and on behalf of all other similarly situated,

Plaintiff

Zhejiang Huahai Pharmaceutical Co., Ltd., a Chinese corporation; Prinston Pharmaceutical, Inc., a Delaware corporation; Solco Healthcare U.S., LLC, a Delaware limited liability company; Defendant and Huahai US, Inc., a New Jersey corporation;

Civil Action No.

SUMMONS IN A CIVIL ACTION

To: (Defendant's name and address)

PRINSTON PHARMACEUTICAL, INC.
Through its registered agent:
AMERICAN INCORPORATORS LTD.
1013 CENTRE ROAD SUITE 403-A
WILMINGTON, DE 19805

A lawsuit has been filed against you.

Within 21 days after service of this summons on you (not counting the day you received it) — or 60 days if you are the United States or a United States agency, or an officer or employee of the United States described in Fed. R. Civ. P. 12 (a)(2) or (3) — you must serve on the plaintiff an answer to the attached complaint or a motion under Rule 12 of the Federal Rules of Civil Procedure. The answer or motion must be served on the plaintiff or plaintiff's attorney, whose name and address are:

Lanny Darr
307 Henry Street
Suite 406
Alton, IL 62002

If you fail to respond, judgment by default will be entered against you for the relief demanded in the complaint. You also must file your answer or motion with the court.

CLERK OF COURT

Date:

Signature of Clerk or Deputy Clerk



AO 440 (Rev. 12/09) Summons in a Civil Action (Page 2)

Civil Action No. \_\_\_\_\_

**PROOF OF SERVICE**

*(This section should not be filed with the court unless required by Fed. R. Civ. P. 4 (l))*

This summons for *(name of individual and title, if any)* \_\_\_\_\_  
was received by me on *(date)* \_\_\_\_\_.

I personally served the summons on the individual at *(place)* \_\_\_\_\_  
\_\_\_\_\_ on *(date)* \_\_\_\_\_; or

I left the summons at the individual's residence or usual place of abode with *(name)* \_\_\_\_\_  
\_\_\_\_\_, a person of suitable age and discretion who resides there,  
on *(date)* \_\_\_\_\_, and mailed a copy to the individual's last known address; or

I served the summons on *(name of individual)* \_\_\_\_\_, who is  
designated by law to accept service of process on behalf of *(name of organization)* \_\_\_\_\_  
\_\_\_\_\_ on *(date)* \_\_\_\_\_; or

I returned the summons unexecuted because \_\_\_\_\_; or

Other *(specify)*: \_\_\_\_\_

My fees are \$ \_\_\_\_\_ for travel and \$ \_\_\_\_\_ for services, for a total of \$ \_\_\_\_\_ 0.00 \_\_\_\_\_.

I declare under penalty of perjury that this information is true.

Date: \_\_\_\_\_

\_\_\_\_\_  
*Server's signature*

\_\_\_\_\_  
*Printed name and title*

\_\_\_\_\_  
*Server's address*

Additional information regarding attempted service, etc:



AO 440 (Rev. 12/09) Summons in a Civil Action

UNITED STATES DISTRICT COURT

for the

Eastern District of Missouri

James Jones, individually and on behalf of all other similarly situated,

Plaintiff

Zhejiang Huahai Pharmaceutical Co., Ltd., a Chinese corporation; Prinston Pharmaceutical, Inc., a Delaware corporation; Solco Healthcare U.S., LLC, a Delaware limited liability company; Defendant and Huahai US, Inc., a New Jersey corporation;

Civil Action No.

SUMMONS IN A CIVIL ACTION

To: (Defendant's name and address)

SOLCO HEALTHCARE U.S., LLC
Through its registered agent:
AMERICAN INCORPORATORS LTD.
1013 CENTRE ROAD SUITE 403-A
WILMINGTON, DE 19805

A lawsuit has been filed against you.

Within 21 days after service of this summons on you (not counting the day you received it) — or 60 days if you are the United States or a United States agency, or an officer or employee of the United States described in Fed. R. Civ. P. 12 (a)(2) or (3) — you must serve on the plaintiff an answer to the attached complaint or a motion under Rule 12 of the Federal Rules of Civil Procedure. The answer or motion must be served on the plaintiff or plaintiff's attorney, whose name and address are:

Lanny Darr
307 Henry Street
Suite 406
Alton, IL 62002

If you fail to respond, judgment by default will be entered against you for the relief demanded in the complaint. You also must file your answer or motion with the court.

CLERK OF COURT

Date:

Signature of Clerk or Deputy Clerk

AO 440 (Rev. 12/09) Summons in a Civil Action (Page 2)

Civil Action No. \_\_\_\_\_

**PROOF OF SERVICE**

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This summons for *(name of individual and title, if any)* \_\_\_\_\_  
was received by me on *(date)* \_\_\_\_\_.

I personally served the summons on the individual at *(place)* \_\_\_\_\_  
\_\_\_\_\_ on *(date)* \_\_\_\_\_; or

I left the summons at the individual's residence or usual place of abode with *(name)* \_\_\_\_\_  
\_\_\_\_\_, a person of suitable age and discretion who resides there,  
on *(date)* \_\_\_\_\_, and mailed a copy to the individual's last known address; or

I served the summons on *(name of individual)* \_\_\_\_\_, who is  
designated by law to accept service of process on behalf of *(name of organization)* \_\_\_\_\_  
\_\_\_\_\_ on *(date)* \_\_\_\_\_; or

I returned the summons unexecuted because \_\_\_\_\_; or

Other *(specify)*: \_\_\_\_\_.

My fees are \$ \_\_\_\_\_ for travel and \$ \_\_\_\_\_ for services, for a total of \$ \_\_\_\_\_ 0.00 \_\_\_\_\_.

I declare under penalty of perjury that this information is true.

Date: \_\_\_\_\_

\_\_\_\_\_  
*Server's signature*

\_\_\_\_\_  
*Printed name and title*

\_\_\_\_\_  
*Server's address*

Additional information regarding attempted service, etc:

AO 440 (Rev. 12/09) Summons in a Civil Action

UNITED STATES DISTRICT COURT

for the

Eastern District of Missouri

James Jones, individually and on behalf of all other similarly situated,

Plaintiff

Zhejiang Huahai Pharmaceutical Co., Ltd., a Chinese corporation; Prinston Pharmaceutical, Inc., a Delaware corporation; Solco Healthcare U.S., LLC, a Delaware limited liability company; Defendant and Huahai US, Inc., a New Jersey corporation;

Civil Action No.

SUMMONS IN A CIVIL ACTION

To: (Defendant's name and address)

HUAHAI US, INC.
Through its registered agent:
Jun Du
2002 Eastpark Blvd
Cranbury, NJ 08512

A lawsuit has been filed against you.

Within 21 days after service of this summons on you (not counting the day you received it) — or 60 days if you are the United States or a United States agency, or an officer or employee of the United States described in Fed. R. Civ. P. 12 (a)(2) or (3) — you must serve on the plaintiff an answer to the attached complaint or a motion under Rule 12 of the Federal Rules of Civil Procedure. The answer or motion must be served on the plaintiff or plaintiff's attorney, whose name and address are:

Lanny Darr
307 Henry Street
Suite 406
Alton, IL 62002

If you fail to respond, judgment by default will be entered against you for the relief demanded in the complaint. You also must file your answer or motion with the court.

CLERK OF COURT

Date:

Signature of Clerk or Deputy Clerk

AO 440 (Rev. 12/09) Summons in a Civil Action (Page 2)

Civil Action No. \_\_\_\_\_

**PROOF OF SERVICE**

*(This section should not be filed with the court unless required by Fed. R. Civ. P. 4 (l))*

This summons for *(name of individual and title, if any)* \_\_\_\_\_  
was received by me on *(date)* \_\_\_\_\_.

I personally served the summons on the individual at *(place)* \_\_\_\_\_  
\_\_\_\_\_ on *(date)* \_\_\_\_\_; or

I left the summons at the individual's residence or usual place of abode with *(name)* \_\_\_\_\_  
\_\_\_\_\_, a person of suitable age and discretion who resides there,  
on *(date)* \_\_\_\_\_, and mailed a copy to the individual's last known address; or

I served the summons on *(name of individual)* \_\_\_\_\_, who is  
designated by law to accept service of process on behalf of *(name of organization)* \_\_\_\_\_  
\_\_\_\_\_ on *(date)* \_\_\_\_\_; or

I returned the summons unexecuted because \_\_\_\_\_; or

Other *(specify)*: \_\_\_\_\_.

My fees are \$ \_\_\_\_\_ for travel and \$ \_\_\_\_\_ for services, for a total of \$ \_\_\_\_\_ 0.00 \_\_\_\_\_.

I declare under penalty of perjury that this information is true.

Date: \_\_\_\_\_

\_\_\_\_\_  
*Server's signature*

\_\_\_\_\_  
*Printed name and title*

\_\_\_\_\_  
*Server's address*

Additional information regarding attempted service, etc:

UNITED STATES DISTRICT COURT  
EASTERN DISTRICT OF MISSOURI  
EASTERN DIVISION

James Jones, individually and on  
behalf of all others similarly situated

\_\_\_\_\_, )  
Plaintiff (s), )

Y.  
Zhejiang Huahai Pharmaceutical Co., Ltd., a )  
Chinese corporation; Prinston Pharmaceutical, )  
Inc., a Delaware corporation; Solco Healthcare )  
U.S., LLC, a Delaware limited liability company; )  
and Huahai US, Inc., a New Jersey corporation; )  
Defendant(s). )

Case No.

NOTICE OF INTENT TO USE  
PROCESS SERVER

Comes now Plaintiff \_\_\_\_\_ and notifies the court of the intent to use  
(Plaintiff or Defendant)

Kimberly Ryan, Delaware Attorney Services, LLC

(name and address of process server)

3516 Silverside Road, Unit 16

Wilmington, DE 19810

To serve:

Prinston Pharmaceutical, Inc. and Solco Healthcare U.S., LLC in the

(name of defendants to be served by this process server)

above-styled cause. The process server listed above possesses the

requirements as stated in Rule 4 of the Federal Rules of Civil Procedure.

The undersigned affirms the information provided above is true and correct.

09/11/2018

(date)

/s/Lanny Darr

(attorney for Plaintiff)

\_\_\_\_\_  
(attorney for Defendant)



UNITED STATES DISTRICT COURT  
EASTERN DISTRICT OF MISSOURI  
EASTERN DIVISION

James Jones, individually and on  
behalf of all others similarly situated

\_\_\_\_\_, )  
Plaintiff (s), )

Y  
Zhejiang Huahai Pharmaceutical Co., Ltd., a )  
Chinese corporation; Prinston Pharmaceutical, )  
Inc., a Delaware corporation; Solco Healthcare )  
U.S., LLC, a Delaware limited liability company; )  
and Huahai US, Inc., a New Jersey corporation; )  
Defendant(s). )

Case No.

NOTICE OF INTENT TO USE  
PROCESS SERVER

Comes now Plaintiff \_\_\_\_\_ and notifies the court of the intent to use  
(Plaintiff or Defendant)

Miranda Platt, DGR Legal, Litigation Department  
(name and address of process server)

1359 Littleton Road

Morris Plains, NJ 07950

To serve:  
Huahai US, Inc. \_\_\_\_\_ in the  
(name of defendants to be served by this process server)

above-styled cause. The process server listed above possesses the  
requirements as stated in Rule 4 of the Federal Rules of Civil Procedure.

The undersigned affirms the information provided above is true and correct.

09/11/2018  
(date)

/s/Lanny Darr  
(attorney for Plaintiff)

\_\_\_\_\_  
(attorney for Defendant)