IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF NEW JERSEY

RICHARD GONTESKI, Individually and On Behalf of a Class of Similarly Situated Individuals,	) Civil Action No.
Plaintiff,	) Jury Trial Demanded
v.	)
HUAHAI US, INC., a New Jersey corporation, and ZHEJIANG HUAHAI PHARMACEUTICAL CO., LTD., a Chinese corporation,	)
Defendants.	)

CLASS ACTION COMPLAINT

Plaintiff, Richard Gonteski ("Plaintiff"), on behalf of himself and all others similarly situated, by and through his attorneys, 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 CASE

1. Plaintiff brings this class action on behalf of himself and all others similarly situated regarding the respective manufacturing, distribution, and sale of valsartan generic prescription medications adulterated with *N*-nitrosodimethylamine, a carcinogenic substance by Defendants, Huahai US, Inc. ("Huahai") and Zhejiang Huahai Pharmaceutical Co., Ltd. ("Zhejiang") (collectively, "Defendants").

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 Zhejiang's facility in China, certain generic formulations of Valsartan have become adulterated with an organic chemical known as *N*-nitrosodimethylamine ("NDMA").

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 Huahai, among others. The recall was due to the presence of NDMA 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 NDMA and are not fit for human consumption.

7. Plaintiff and the putative class (defined below) 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: (1) violation of New Jersey's Consumer Fraud Act; (2) strict products liability; (3) failure to warn; (4) breach of contract; (5) breach of implied warranty of merchantability; (6) unjust enrichment; (7) fraudulent concealment; (8) conversion; (9) negligence; and (10) gross negligence.

PARTIES

9. Plaintiff is an individual who is a citizen of New Jersey, domiciled in Riverside, Burlington County, New Jersey.

10. 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. Huahai is deemed to be a citizen of New Jersey.

11. On information and belief, Huahai conducts substantial business in the State of New Jersey 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. Huahai lists Valsartan as one of its products.

12. On information and belief, 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. Zhejiang is deemed to be a citizen of the People's Republic of China.

13. 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 (defined below); (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 that its 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.

JURISDICTION

14. On information and belief, at all times relevant herein Zhejiang exercised a high degree of control over its subsidiary, Huahai, and provided more than just standard administrative services to it.

15. On information and belief, at all times relevant herein Huahai and Zhejiang 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 in New Jersey.

16. On information and belief, at all times relevant herein Huahai and Zhejiang each transacted business in New Jersey.

17. On information and belief, at all times relevant herein Huahai and Zhejiang each carried on systematic business activity in New Jersey with a fair measure of permanence and continuity through, in part, efforts to market and sell their products in New Jersey, including the prescription drug, Valsartan.

18. On information and belief, at all times relevant herein Huahai and Zhejiang each delivered their products, including the prescription drug, Valsartan, into the stream of commerce with the expectation that it would be purchased by New Jersey consumers, including Plaintiff and putative class members.

19. On information and belief, at all times relevant herein Huahai and Zhejiang each purposefully directed activities at New Jersey and purposefully availed themselves of the privilege of conducting activities in New Jersey.

20. On information and belief, at all times relevant herein Huahai and Zhejiang each knew, or should have known, that their products, including the prescription drug, Valsartan, would ultimately be sold in New Jersey and throughout the United States.

21. On information and belief, at all times relevant herein Zhejiang, and Huahai each benefitted from New Jersey's system of laws, infrastructure and business climate for the sale of their products, including the prescription drug, Valsartan.

22. Defendants' manufacture, marketing, distribution and/or sale of the prescription drug, Valsartan, resulted in millions of dollars in sales of Valsartan to New Jersey consumers, as well as consumers nationwide, including Plaintiff and the putative class members.

23. Huahai and Zhejiang each committed a tortious act when Plaintiff and the putative class members purchased or consumed adulterated Valsartan contaminated with NDMA that had been manufactured, marketed, distributed, and sold by Defendants.

24. The tortious act injured Plaintiff and the putative class members in New Jersey and nationwide. The injuries and losses suffered by the Plaintiff and the putative class members arose out of the forum-related activities of Zhejiang and Huahai.

25. New Jersey has a strong interest in public safety, including the safety of prescription drugs sold by New Jersey entities. New Jersey also has a manifest interest in providing its residents with a convenient forum for redress of their injuries.

26. 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 it is a class action in which Plaintiff and some members of the putative class are citizens of states different from any Defendant. *See* 28 U.S.C. § 1332(d)(2)(A).

27. This Court has personal jurisdiction over Defendants because they conduct substantial business in New Jersey and Huahai is a citizen of New Jersey and resides within this District. Defendants have sufficient minimum contacts with the State of New Jersey and intentionally avail themselves of the consumers and markets within the State of New Jersey through the promotion and sale of their products, including Valsartan.

VENUE

28. 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.

BACKGROUND AND DEFENDANTS' CONDUCT

29. 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.

30. Due to manufacturing defects originating from overseas laboratories in China, certain generic formulations have become contaminated with NDMA.

31. At all times during the period alleged herein, Defendants each represented and warranted to consumers that their generic Valsartan products were therapeutically equivalent to and otherwise the same as Diovan, were otherwise fit for their ordinary uses, and were otherwise manufactured and distributed in accordance with applicable laws and regulations.

32. The Drug Price Competition and Patent Term Restoration Act of 1984 – more commonly referred to as the Hatch-Waxman Act – is codified at 21 U.S.C. § 355(j).

33. Brand drug companies submitting a New Drug Application ("NDA") are required to demonstrate clinical safety and efficacy through well-designed clinical trials. 21 U.S.C. § 355, *et seq.*

34. By contrast, generic drug companies submit an Abbreviated New Drug Application ("ANDA"). Instead of demonstrating clinical safety and efficacy, generic drug companies need only demonstrate bioequivalence to the brand or reference listed drug ("RLD"). Bioequivalence is the "absence of significant difference" in the pharmacokinetic profiles of two pharmaceutical products. 21 C.F.R. § 320.1(e).

35. The bioequivalence basis for ANDA approval is premised on the generally accepted proposition that equivalence of pharmacokinetic profiles of two drug products is accepted as evidence of therapeutic equivalence. In other words, if (1) the RLD is proven to be safe and effective for the approved indication through well-designed clinical studies accepted by the FDA, and (2) the generic company has shown that its ANDA product is bioequivalent to the RLD, then (3) the generic ANDA product must be safe and effective for the same approved indication as the RLD.

36. Generic drug manufacturers have an ongoing federal duty of sameness in their products. Under 21 U.S.C. § 355(j), the generic manufacturer must show the following things as relevant to this case: the active ingredient(s) are the same as the RLD, § 355(j)(2)(A)(ii); and, that the generic drug is "bioequivalent" to the RLD and "can be expected to have the same therapeutic effect," *id.* at (A)(iv). A generic manufacturer (like a brand manufacturer) must also

make "a full statement of the composition of such drug" to the FDA. *Id.* at (A)(vi); *see also* § 355(b)(1)(C).

37. A generic manufacturer must also submit information to show that the "labeling proposed for the new drug is the same as the labeling approved for the [RLD][.]" 21 U.S.C. § 355(j)(2)(A)(v).

38. Upon granting final approval for a generic drug, the FDA will typically state the generic drug is "therapeutically equivalent" to the branded drug. The FDA codes generic drugs as "A/B rated" to the RLD branded drug. Pharmacists, physicians, and patients can fully expect such generic drugs to be therapeutically interchangeable with the RLD, and generic manufacturers expressly warrant as much through the inclusion of the same labeling as the RLD delivered to consumers in each and every prescription of their generic products.

39. Under federal law, pharmaceutical drugs must be manufactured in accordance with "current Good Manufacturing Practices" ("cGMP(s)") to assure they meet safety, quality, purity, identity, and strength standards. *See* 21 U.S.C. § 351(a)(2)(B).

40. The FDA's cGMP regulations are found in 21 C.F.R. Parts 210 and 211. These detailed regulations set forth minimum standards regarding: organization and personnel (Subpart B); buildings and facilities (Subpart C); equipment (Subpart D); control of components and drug product containers and closures (Subpart E); production and process controls (Subpart F); packaging and label controls (Subpart G); holding and distribution (Subpart H); laboratory controls (Subpart I); records and reports (Subpart J); and returned and salvaged drug products (Subpart K). The FDA has worldwide jurisdiction to enforce these regulations if a facility is making drugs intended to be distributed in the United States.

41. Any drug not manufactured in accordance with cGMPs is deemed "adulterated" and may not be distributed or sold in the United States. *See* 21 U.S.C. §§ 331(a), 351(a)(2)(B).

42. Drugs are deemed to be adulterated if the manufacturer fails to comply with cGMPs to assure the drugs' safety, quality, purity, identity, and strength and/or if they are contaminated. *See* 21 U.S.C. § 351(a)(2)(A), (B). Federal law prohibits a manufacturer from directly or indirectly causing adulterated drugs to be introduced or delivered for introduction into interstate commerce. *See id.* § 331(a). States have enacting laws adopting or mirroring these federal standards.

43. Per federal law, cGMPs include "the implementation of oversight and controls over the manufacture of drugs to ensure quality, including managing the risk of and establishing the safety of raw materials, materials used in the manufacturing of drugs, and finished drug products." 21 U.S.C. § 351(j). Accordingly, it is a cGMP violation for a manufacturer to contract out prescription drug manufacturing without sufficiently ensuring continuing quality of the subcontractor's operations.

44. On May 15-19, 2017, the FDA inspected Zhejiang's Linhai City facilities. That inspection resulted in the FDA's finding that Zhejiang repeatedly re-tested out-of-specification ("OOS") samples until obtaining a desirable result. This practice allegedly dated back to at least September 2016, per the FDA's letter at the time.

45. This May 2017 inspection also resulted in the FDA's finding that "impurities occurring during analytical testing are not consistently documented/quantitated[.]" These findings were not made fully available to the public.

46. Further, for OOS sampling results, Zhejiang routinely invalidated these results without conducting any kind of scientific investigation into the reasons behind the OOS sample

result. In fact, in one documented instance, the OOS result was attributed to "pollution" in the environment surrounding the facility. Zhejiang's actions are consistent with systematic data manipulation designed to intentionally conceal and recklessly disregard the presence of harmful impurities such as NDMA.

47. The May 2017 inspection also found that Zhejiang's "facilities and equipment [were] not maintained to ensure [the] quality of drug product" manufactured at the facility. These issues included the FDA's finding that: equipment that was rusting and rust was being deposited into drug product; equipment was shedding cracking paint into drug product; there was an accumulation of white particulate matter; and black metallic particles were found in API batches.

48. NDMA is not an FDA-approved ingredient for branded Diovan or generic Valsartan. None of Defendants' Valsartan products (or any Valsartan product, for that matter) identifies NDMA as an ingredient on the products' labels or elsewhere.

49. The FDA maintains a list of "Approved Drug Products with Therapeutic Equivalence Evaluations," commonly referred to as the Orange Book.

50. The Orange Book is a public document; Defendants sought and received the inclusion of their products in the Orange Book upon approval of their Valsartan ANDAs.

51. In securing FDA approval to market generic Valsartan in the United States as an Orange Book-listed therapeutic equivalent to Diovan, Defendants were required to demonstrate that their generic Valsartan products were bioequivalent to brand Diovan.

52. Therapeutic equivalence for purposes of generic substitution is a continuing obligation on the part of the manufacturer. For example, according to the FDA's Orange Book,

therapeutic equivalence depends, in part, on the manufacturer's continued compliance with cGMPs.

53. By introducing their Valsartan products into the United States market under the name "Valsartan" as a therapeutic equivalent to Diovan and with the FDA-approved label that is the same as that of Diovan, Defendants represented and warranted to end users that their products are, in fact, the same as and are therapeutically interchangeable with Diovan.

54. Each Defendant's Valsartan products were accompanied by an FDA-approved label.

55. By presenting consumers with an FDA-approved Valsartan label, Defendants, as manufacturers, distributors, and sellers of Valsartan, made representations and express or implied warranties to consumers of the "sameness" of their products to Diovan, and that their products were consistent with the safety, quality, purity, identity, and strength characteristics reflected in the FDA-approved labels and/or were not adulterated.

56. The presence of NDMA in Defendants' Valsartan: (1) renders Defendants' Valsartan products non-bioequivalent (*i.e.*, not the same) to Diovan and, thus, non-therapeutically interchangeable with Diovan, thus breaching Defendants' express warranties of sameness; (2) was the result gross deviations from cGMPs, thus rendering Defendants' Valsartan products non-therapeutically equivalent to Diovan, breaching Defendants' warranties of sameness; and (3) results in Defendants' Valsartan containing an ingredient that is not also contained in Diovan, also breaching Defendants' warranty of sameness (and warranty that the products contained the ingredients listed on each Defendant's FDA-approved label).

57. Each Defendant willfully, recklessly, and/or negligently failed to ensure their Valsartan products' labels and other advertising or marketing statements accurately conveyed information about their products.

58. Due to its status as a probable human carcinogen as listed by both the IARC and the U.S. EPA, NDMA is not an FDA-approved ingredient in Valsartan. The presence of NDMA in Defendants' Valsartan means that Defendants have violated implied warranties to Plaintiff and the putative class members. The presence of NDMA in Defendants' Valsartan results in Defendants' Valsartan products being non-merchantable and not fit for its ordinary purposes (*i.e.*, as a therapeutically interchangeable generic version of Diovan), breaching Defendants' implied warranty of merchantability and/or fitness for ordinary purposes.

59. For these and other reasons, Defendants' Valsartan is therefore adulterated. *See* 21 U.S.C. § 351.

60. Adulterated Valsartan is essentially worthless. No consumer would purchase an adulterated Valsartan product or is even allowed to purchase an adulterated Valsartan product because it was illegally introduced into the United States. This is especially so given that alternative, non-adulterated Valsartan products or competing medications with the same approved indications were available from other manufacturers.

61. Plaintiff's and putative class members' causes of action accrued on the date the FDA announced the recall of Defendants' generic Valsartan products, which was on or about July 13, 2018.

62. Alternatively, any statute of limitation or prescriptive period is equitably tolled on account of fraudulent concealment. Defendants affirmatively concealed from Plaintiff and other putative class members their unlawful conduct. Defendants affirmatively strove to avoid

disclosing their knowledge of Zhejiang's cGMP violations with respect to Valsartan, and of the fact that their Valsartan products were adulterated and contaminated with NMDA and were not the same as brand Diovan.

63. For instance, neither Defendant revealed to the public that their Valsartan product contained NDMA or was otherwise adulterated or non-therapeutically equivalent to Diovan until the FDA's recall announcement in July 2018.

64. To the contrary, both Defendants continued to represent and warrant that their generic Valsartan products were the same as and therapeutically interchangeable with Diovan.

65. Because of this, Plaintiff and putative class members did not discover, nor could they discover through reasonable and ordinarily diligence, each Defendant's deceptive, fraudulent, and unlawful conduct alleged herein. Defendants' false and misleading explanations, or obfuscations, lulled Plaintiff and putative class members into believing that the prices paid for Valsartan were appropriate for what they believed to be non-adulterated drugs despite their exercise of reasonable and ordinary diligence.

66. As a result of Defendants' respective affirmative and other acts of concealment, any applicable statute of limitations affecting the rights of Plaintiff and putative class members has been tolled. Plaintiff and putative class members exercised reasonable diligence by, among other things, promptly investigating and bringing the allegations contained herein. Despite these or other efforts, Plaintiff and putative class members were unable to discover, and could not have discovered, the unlawful conduct alleged herein at the time it occurred or at an earlier time so as to enable this Complaint to be filed sooner.

67. Plaintiff seeks to pursue a class action against the Defendants for supplying, manufacturing, distributing, and ultimately selling Valsartan that was adulterated and defective

because it contained NDMA, which rendered the Valsartan adulterated, unsafe, and dangerous for consumption by humans ("the Adulterated Valsartan"), to Plaintiff and the putative class members.

68. 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.

69. 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.

70. 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.

71. NDMA is listed as a "priority toxic pollutant" in federal regulations. *See* 40 CFR § 131.36.

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

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

74. The FDA is an agency within the U.S. Department of Health and Human Services.

75. 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.

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

77. 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.

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

79. 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.

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

81. Zhejiang manufactured and/or supplied the Valsartan, and/or the Valsartan active pharmaceutical ingredient used in the manufacture of the Adulterated Valsartan that is subject to the Recall.

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

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

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

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

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

87. 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**
>
> | **Medicine** | **Company** |
> |---|---|
> | *Valsartan* | *Major Pharmaceuticals* |
> | *Valsartan* | *Solco Healthcare* |
> | *Valsartan* | *Teva Pharmaceuticals Industries Ltd* |
> | *Valsartan/Hydrochlorothiazide (HCTZ)* | *Solco Healthcare* |
> | *Valsartan/Hydrochlorothiazide (HCTZ)* | *Teva Pharmaceuticals Industries Ltd.* |

88. 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.)

89. 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.)

90. 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]

91. 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.

92. 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.

93. 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.

94. According to Huahai, it undertook recalls at the consumer level ***to protect human health.*** (Emphasis added.)

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

96. 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 Plaintiff and the putative class members because Defendants failed to have adequate quality control procedures in place to determine that Valsartan API was adulterated.

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

98. 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.

99. The Adulterated Valsartan is worthless.

100. Plaintiff and the putative class members suffered economic damages when they paid to purchase 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.

101. Had Defendants disclosed to 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.

102. 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.

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

CLASS ALLEGATIONS

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

105. Plaintiff bring Counts One through Ten 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 nationwide consumers who purchased Adulterated Valsartan that is subject to the Recall, as defined below (the "Class"):

> All persons or entities in the United States that purchased 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.

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

107. The rights of each member of the Class (the "Class Members") were violated in a similar fashion based upon the Defendants' uniform actions.

108. 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. Further, Plaintiff and all Class Members sustained monetary and economic injuries, including ascertainable loss, arising out of

Defendants' wrongful conduct by, *inter alia*, purchasing and/or consuming 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 or consumed the Adulterated Valsartan identified in the Lots. Plaintiff is advancing the same claims and legal theories on behalf of himself and all Class Members.

b. **Adequacy:** 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 all 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.

109. 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 Law and Fact:** Common questions of law and fact exist as to all members of the Class. These questions predominate over any questions affecting individual Class Members and 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 was a merchantable good 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 they sold the Adulterated Valsartan in the Lots;

vi. The date on which Defendants knew or reasonably should have known that the Adulterated Valsartan identified in the Lots was adulterated;

vii. Whether Defendants' recall notice was timely and/or sufficient;

viii. Whether Defendants breached the terms of an express and/or implied 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 ONE
Violation of New Jersey's Consumer Fraud Act ("NJCFA")
N.J.S.A. 56:8-1 *et seq*.

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

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

112. Plaintiff and other members of the class are "persons" within the meaning of N.J.S.A. 56:8-1(d).

113. Defendants' conduct alleged herein constitutes a "sale" within the meaning of N.J.S.A. 56:8-1(e).

114. The NJCFA declares unlawful "[t]he act, use or employment by any person of any unconscionable commercial practice, deception, fraud, false pretense, false promise, misrepresentation, or the knowing concealment, suppression, or omission of any material fact with intent that others rely upon such concealment, suppression or omission, in connection with the sale or advertisement of any merchandise or real estate, or with the subsequent performance of such person as aforesaid, whether or not any person has in fact been misled, deceived or damaged thereby[.]" N.J.S.A. 56:8-2.

115. Defendants have engaged in unfair, unlawful and deceptive acts in trade and commerce which have the capacity and tendency to deceive and, in fact, did deceive Plaintiff and the Class Members, and damaged Plaintiff and Class Members.

116. Defendants affirmatively misrepresented (and/or wrongfully concealed and omitted) that the Adulterated Valsartan was therapeutically equivalent to brand Diovan and/or was manufactured in compliance with cGMPs and/or was not adulterated. In fact, Defendants' Valsartan products were contaminated with NDMA resulting in the Adulterated Valsartan not being therapeutically equivalent to brand Diovan and not manufactured in compliance with cGMPs and, in fact, constituting adulterated pharmaceuticals.

117. Defendants committed unlawful, deceptive, and unconscionable trade practices by marketing, selling, and otherwise placing into the stream of commerce the Adulterated Valsartan products on the premise they were therapeutically equivalent to brand Diovan and/or manufactured in compliance with cGMPs and/or were not adulterated.

118. Defendants wrongfully concealed, suppressed, and omitted to disclose that the Adulterated Valsartan was not therapeutically equivalent to brand Diovan and/or not manufactured in compliance with cGMPs and/or was, in fact, adulterated.

119. Defendant's misrepresentations and omissions had the capacity to mislead Plaintiff and Class Members into believing that the Adulterated Valsartan (i) was therapeutically equivalent to brand Diovan, (ii) was manufactured in accordance with cGMPs, and/or (iii) was not adulterated and was legal to sell in the United States, when the opposite was true.

120. Had Defendants not made misrepresentations or not omitted such facts, the Adulterated Valsartan would not have been available to Plaintiff and the Class Members because, among other reasons, it would have been illegal for Defendants to even introduce the Adulterated Valsartan into the United States. Plaintiff and the Class Members suffered ascertainable loss as a result.

121. Because of Defendants' unlawful, deceptive, unfair, and unconscionable trade practices, Plaintiff and the Class Members have suffered injury and damages – an ascertainable loss – in an amount to be determined at trial. Pursuant to the NJCFA, this Court has the power to enjoin Defendants' conduct.

122. The NJCFA prohibits deceptive acts and practices in the sale of products, including the Adulterated Valsartan.

123. Plaintiff and the Class Members are "consumers," as defined under the NJCFA.

124. Defendants' conduct as alleged herein occurred in the course of "trade or commerce," as defined in the NJCFA.

125. 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.

126. In fact, the Adulterated Valsartan (a) did not have the characteristics, ingredients, uses or benefits represented, (b) was not safe for human consumption, (c) contained NDMA and (d) was adulterated. This offends public policy, has caused and continues to cause substantial injury to Plaintiff and the Class Members, and constitutes an unfair and deceptive trade practice.

127. 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 Plaintiff and the Class Members was safe for human consumption, when it was not.

128. Defendants' false representations were likely to deceive reasonable drug consumers, including Plaintiff and the Class Members.

129. Defendants intended for consumers, including 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 reasonably relied on such representations in making their decision to purchase the Adulterated Valsartan.

130. As a direct and proximate result of Defendants' deceptive and unfair trade 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.

131. Thus, Plaintiff and the Class Members have been aggrieved by Defendants' unfair and deceptive practices, in violation of the NJCFA.

132. Defendants' conduct violates the NJCFA and, pursuant to N.J.S.A 56:8-1, *et seq* Plaintiff and the Class Members are entitled to damages in an amount to be proven at trial, reasonable attorneys' fees, injunctive relief prohibiting Defendants' unfair and deceptive practices going forward, medical monitoring, and any other penalties or awards that may be appropriate under applicable law.

COUNT TWO
Strict Product Liability

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

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

135. 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.

136. 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.

137. 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.

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

139. 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.

140. 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.

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

142. 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.

143. 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.

144. 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.

145. 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.

146. 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.

147. 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.

148. 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.

149. 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.

150. 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.

151. 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 THREE
Failure to Warn

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

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

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

155. Defendants failed to adequately warn health care professionals and the public, including the Plaintiff, 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.

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

157. Defendants failed to perform or otherwise facilitate adequate testing or failed to reveal and/or concealed testing performed on the Valsartan.

158. As a direct and proximate cause of the Defendants' conduct, Plaintiff and the Class Members suffered economic loss.

159. Defendants' conduct was reckless and 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.

160. Upon information and belief, Defendants made a conscious decision not to notify the FDA, healthcare professionals and the public, thereby putting increased profits over 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 FOUR
Breach of Contract

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

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

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

164. 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 Adulterated Valsartan would not be adulterated with harmful and carcinogenic impurities such as NDMA.

165. Defendants represented that the Adulterated Valsartan was safe and unadulterated. 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.

166. 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.

167. Plaintiff and each Class Member relied on Defendants' representations that the Adulterated Valsartan would not be adulterated with harmful and carcinogenic impurities such as NDMA.

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

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

170. 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 FIVE
Breach of Implied Warranty of Merchantability

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

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

173. 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.

174. 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, contained NDMA, a carcinogen, and therefore unfit for human consumption. As a result, Plaintiff and the Class Members did not receive Valsartan as impliedly warranted by the Defendants to be merchantable.

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

176. Plaintiff did not alter the Adulterated Valsartan.

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

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

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

180. 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 SIX
Unjust Enrichment

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

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

183. 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.

184. Defendants voluntarily accepted and retained the conferred benefits by accepting payment for the Adulterated Valsartan.

185. 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 quality of the Adulterated Valsartan and the Adulterated Valsartan could not be used for the manner represented by Defendants.

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

187. Plaintiff and the Class Members do not have an adequate remedy at law against Defendants, in the alternative to the other causes of action alleged herein.

COUNT SEVEN
Fraudulent Concealment

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

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

190. 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.

191. Defendants knew or should have known that they should have disclosed such material facts to consumers such as Plaintiff and the Class Members.

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

193. 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 Defendants' Valsartan as early as 2012.

194. Upon information and belief, Defendants may have thus 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.

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

196. 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.

197. 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.

198. 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 EIGHT
Conversion

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

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

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

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

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

COUNT NINE
Negligence

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

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

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

207. 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.

208. 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 that was adulterated because it was contaminated by NDMA, a carcinogen; and

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

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

COUNT TEN
Gross Negligence

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

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

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

213. 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.

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

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

PRAYER FOR RELIEF

WHEREFORE, 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 statutory and punitive damages for the conduct alleged herein;

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

D. Awarding reasonable attorneys' fees and costs;

E. Awarding prejudgment and post-judgment interest; and

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: October 11, 2018

Respectfully submitted,

SHEPHERD, FINKELMAN, MILLER & SHAH, LLP

By: */s/ James C. Shah*

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Counsel for Plaintiff & Proposed Class

Exhibit A

Valsartan products under recall - Updated August 27, 2018				
Company	Product	NDC	Lot	Expiration
Teva Pharmaceuticals labeled as Major Pharmaceuticals	Valsartan 80mg 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	07/2018 to 01/2020
	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	1196936A	09/2018
			1238463A	05/2019
			1270617A	10/2019
	Valsartan 40mg Tablets, 90 count bottle	0591-2167-19	1196934M	09/2018
			1238462M	05/2019
			1268429A	10/2019
	Valsartan 80mg Tablets, 90 count bottle	0591-2168-19	1175947M	07/2018
			1175948M	07/2018
			1177115A	07/2018
			1219361A	02/2019
			1240434M	05/2019
			1250704M	05/2019
	Valsartan 80mg Tablets, 1000 count bottle	0591-2168-10	1177114A	07/2018
			1219360M	02/2019
			1250706A	05/2019
	Valsartan 160mg Tablets, 90 count bottle	0591-2169-19	1177880A	07/2018
			1220831A	02/2019
			1263941A	08/2019
	Valsartan 160mg Tablets, 1000 count bottle	0591-2169-10	1175922M	07/2018
			1220826M	02/2019
			1236294M	05/2019
			1240427M	05/2019
			1270616A	08/2019
	Valsartan 320mg Tablets, 90 count bottle	0591-2170-19	1208002A	10/2018
			1247282M	05/2019
			1263944M	08/2019
	Valsartan 320mg Tablets, 500 count bottle	0591-2170-05	1208000M	10/2018
			1208001M	10/2018
			1240425A	06/2019
	Valsartan and Hydrochlorothiazide (HCTZ) 80mg/12.5mg Tablets, 90 count bottle	0591-2315-19	1191191M	08/2018
			1191192M	08/2018

EXHIBIT A

Company	Product	NDC	Lot	Expiration
			1191193M	08/2018
			1191194M	08/2018
			1191195M	08/2018
			1238466M	06/2019
			1238467M	06/2019
			1253261M	07/2019
			1256125M	07/2019
			1277709M	09/2019
	Valsartan and Hydrochlorothiazide (HCTZ) 160mg/12.5mg Tablets, 90 count bottle	0591-2316-19	1191160M	09/2018
			1191161M	09/2018
			1191162A	09/2018
			1219363M	02/2019
			1219364M	02/2019
			1219365A	02/2019
			1225613A	02/2019
			1233944M	04/2019
			1233945M	04/2019
			1253253M	07/2019
			1253254M	07/2019
	Valsartan and Hydrochlorothiazide (HCTZ) 160mg/25mg Tablets, 90 count bottle	0591-2317-19	1191164M	09/2018
			1191165M	09/2018
			1191166M	09/2018
			1191167A	10/2018
			1225612M	02/2019
			1250717M	07/2019
			1256111M	07/2019
			1288798M	10/2019
	Valsartan and Hydrochlorothiazide (HCTZ) 320mg/12.5mg Tablets, 90 count bottle	0591-2318-19	1191185M	09/2018
			1191186M	09/2018
			1225615M	02/2019
			1233948M	02/2019
			1250718M	08/2019
			1253257M	07/2019
	Valsartan and Hydrochlorothiazide (HCTZ) 320mg/25mg Tablets, 90 count bottle	0591-2319-19	1191188M	09/2018
			1191189M	09/2018
			1191190M	09/2018
			1199220M	08/2018
			1217576M	01/2019
			1217577M	01/2019
			1217578M	01/2019
			1220832M	01/2019
			1220833M	02/2019
			1247283M	06/2019
			1247284M	06/2019
			1247285M	06/2019
			1247286M	06/2019
			1247287A	06/2019
			1280632M	10/2019
			1280633M	10/2019
AvKARE (Teva/Actavis)	Valsartan and Hydrochlorthiazide (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

Company	Product	NDC	Lot	Expiration
			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 Hydrochlorothizaide (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 Tablets, 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
RemedyRepack Inc. (Prinston/Solco)	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 (Teva/Actavis & Prinston/Solco)	Valsartan 80mg Tablets, 90 count bottle	54569-6582-1	342B17019	09/2019
			342B17018	08/2019
			342B17004	02/2019
			342B17002	11/2018
	Valsartan 80mg Tablets, 30 count bottle	54569-6582-0	342B17003	11/2018
			342B17004	02/2019
	Valsartan 160mg Tablets, 90 count bottle	54569-6583-1	343B17056	08/2019
			343B17053	08/2019
			343B17024	03/2019
			343B17016	02/2019
	Valsartan 160mg Tablets, 30 count bottle	54569-6583-0	343B17019	02/2019
			343B17023	03/2019
			343B17056	08/2019
	Valsartan and Hydrochlorothiazide (HCTZ) 160mg/12.5mg Tablets, 30 count bottle	54569-6480-0	1233944M	04/2019

Company	Product	NDC	Lot	Expiration
			1253253M	07/2019
	Valsartan and Hydrochlorothiazide (HCTZ) 160mg/12.5mg Tablets, 90 count bottle	54569-6480-1	1253253M	07/2019
	Valsartan and Hydrochlorothiazide (HCTZ) 320mg/25mg Tablets, 30 count bottle	54569-6488-0	1191188M	09/2018
			1191189M	09/2018
			1217576M	01/2019
			1247283M	06/2019
			1247285M	06/2019
Bryant Ranch Prepack Inc. (Teva/Actavis)	Valsartan 80mg 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	10/2018
			109004	12/2018
	Valsartan 320mg Tablets, 90 count bottle	63629-6905-2	114319	10/2018
			109004	12/2018
	Valsartan 320mg Tablets, 90 count bottle	71335-0567-2	120879	10/2019
H J Harkins Company Inc. dba Pharma Pac (Prinston/Solco)	Valsartan 160mg Tablets, 90 count bottle	76519-1158-9	VSA000OV	02/2019
Northwind Pharmaceuticals (Teva/Actavis)	Valsartan 80mg Tablets, 30 count bottle	51655-652-52	UT48310002	10/2018
	Valsartan 160mg Tablets, 30 count bottle	51655-460-52	UT48320002	07/2018
			UT48320003	05/2019
	Valsartan 320mg Tablets, 30 count bottle	51655-654-52	UT48100001	09/2019
	Valsartan and Hydrochlorothiazide (HCTZ) 160mg/12.5mg Tablets	51655-950-52	UTB23790003	02/2019
Hetero Labs, Inc. labeled as 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		
	Valsartan 160mg Tablets, 90 count bottle	31722-747-90		
	Valsartan 320mg Tablets, 90 count bottle	31722-748-90		
NuCare Pharmaceuticals Inc. (Prinston/Solco)	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
RemedyRepack, Inc. (Hetero/Camber)	Valsartan 80mg Tablets , 90 count bottle	61786-0791-19	B0335344-081717	08/2018
			B0363364-110917	11/2018
			B0391225-012218	01/2019
			B0408458-030618	03/2019
			B0384871-010318	01/2019
			B0436862-051518	05/2019
	Valsartan 160mg Tablets, 90 count bottle	61786-0792-19	B0335344-081717	08/2018
			B0363364-110917	11/2018
			B0391225-012218	01/2019
			B0408458-030618	03/2019
			B0384871-010318	01/2019
			B0436862-051518	05/2019
	Valsartan 320mg Tablets, 90 count bottle	61786-0793-19	B0362988-110917	10/2018
			B0432265-050318	05/2019
			B0450321-061218	06/2019
			B0450322-061218	05/2019
			B0408652-030718	02/2019
AvKARE (Hetero/Camber)	Valsartan 40mg Tablets	50268-783-15	All lots	07/2018 - 06/2020
	Valsartan 80mg Tablets	50268-784-15		
	Valsartan 160mg Tablets	50268-785-15		
	Valsartan 320mg Tablets	50268-786-13		
Preferred Pharmaceuticals, Inc. (Hetero/Camber)	Valsartan 320mg Tablets, 90 count bottle	68788-6882-9	G2017F	10/2018

Company	Product	NDC	Lot	Expiration
Torrent Pharmaceuticals Limited	Amlodipine, Valsartan and Hydrochlorothiazide (HCTZ) 10mg/320mg/25mg Tablets, 30 count bottle	13668-325-30	BBX2C007	08/2018
			BBX2D001	12/2018
			BBX2D002	12/2018
			BBX2D003	03/2019
			BBX2D004	03/2019
			BBX2D005	03/2019
			BBX2D006	03/2019
			BBX2D007	03/2019
			BBX2D008	03/2019
			BBX2D009	03/2019
			BBX2D010	04/2019
			BBX2D011	04/2019
			BBX2D012	05/2019
			BBX2D013	05/2019
			BBX2D014	08/2019
			BBX2D015	10/2019
			BBX2D016	10/2019
			BBX2D017	10/2019
			BBX2D018	10/2019
			BBX2D019	10/2019
			BBX2D020	10/2019
			BBX2D021	10/2019
			BBX2D022	10/2019
			BBX2D023	10/2019
			BBX2D024	11/2019
			BBX2D025	11/2019
			BBX2D026	11/2019
			BBX2E001	01/2020
			BBX2E002	01/2020
			BBX2E003	01/2020
			BBX2E004	01/2020
			BBX2E005	01/2020
	Amlodipine, Valsartan and Hydrochlorothiazide (HCTZ) 10mg/160mg/25mg Tablets, 30 count bottle	13668-328-30	BBX9D001	02/2019
			BBX9D002	03/2019
			BBX9D003	07/2019
			BBX9D004	11/2019
			BBX9E001	01/2020
	Amlodipine, Valsartan and Hydrochlorothiazide (HCTZ) 5mg/160mg/12.5mg Tablets, 30 count bottle	13668-326-30	BBY1C002	09/2018
			BBY1D001	05/2019
			BBY1E001	12/2019
			BBY1E002	03/2020
			BBY1E003	03/2020
	Amlodipine, Valsartan and Hydrochlorothiazide (HCTZ) 10mg/160mg/12.5mg Tablets, 30 count bottle	13668-327-30	BBY2D001	02/2019
			BBY2D002	11/2019
			BBY2E001	03/2020
	Amlodipine, Valsartan and Hydrochlorothiazide (HCTZ) 5mg/160mg/25mg Tablets, 30 count bottle	13668-329-30	BBY4D001	04/2019
			BBY4D002	04/2019
			BBY4D003	06/2019
			BBY4D004	11/2019
			BBY4E001	01/2020
	Amlodipine and Valsartan 5mg/160mg Tablets, 30 count bottle	13668-207-30	BV53C004	08/2018
			BV53C005	08/2018
			BV53C006	11/2018
			BV53D001	02/2019

Company	Product	NDC	Lot	Expiration
			BV53D002	02/2019
			BV53D003	09/2019
			BV53D004	10/2019
	Amlodipine and Valsartan 10mg/160mg Tablets, 30 count bottle	13668-206-30	BV65C002	09/2018
			BV65C003	10/2018
			BV65C004	11/2018
			BV65D001	08/2019
			BV65D002	10/2019
	Amlodipine and Valsartan 10mg/320mg Tablets, 30 count bottle	13668-204-30	BV77C001	10/2018
			BV77C009	08/2018
			BV77C010	08/2018
			BV77D001	02/2019
			BV77D002	02/2019
			BV77D003	02/2019
			BV77D004	02/2019
			BV77D005	02/2019
			BV77D006	02/2019
			BV77D007	02/2019
			BV77D008	05/2019
			BV77D009	08/2019
			BV77D010	09/2019
			BV77D011	09/2019
			BV77D012	09/2019
			BV77D013	10/2019
	Amlodipine and Valsartan 5mg/320mg Tablets, 30 count bottle	13668-205-30	BV84C006	08/2018
			BV84C007	08/2018
			BV84C008	08/2018
			BV84C009	08/2018
			BV84C011	10/2018
			BV84D001	01/2019
			BV84D002	01/2019
			BV84D005	02/2019
			BV84D006	02/2019
			BV84D007	02/2019
			BV84D008	05/2019
			BV84D009	05/2019
			BV84D010	10/2019
			BV84E001	12/2019
	Valsartan 80mg Tablets, 90 count bottle	13668-068-90	BV46C003	08/2018
			BV46C006	08/2018
			BV46C007	09/2018
			BV46C008	10/2018
			BV46C009	10/2018
			BV46C010	10/2018
			BV46C011	11/2018
			BV46C012	11/2018
	Valsartan 160mg Tablets, 90 count bottle	13668-069-90	BV47C003	08/2018
			BV47C004	08/2018
			BV47C005	09/2018
			BV47C006	09/2018
			BV47D001	12/2018
	Valsartan 320mg Tablets, 90 count bottle	13668-070-90	BV48D001	12/2018
			BV48D002	12/2018
RemedyRepack, Inc. (Torrent)	Amlodipine, Valsartan and Hydrochlorothiazide (HCTZ) 10mg/320mg/25mg Tablets	70518-1220-00	B0476653-080218	08/2019

JS 44 (Rev. 06/17)

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

RICHARD GONTESKI

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

(c) Attorneys *(Firm Name, Address, and Telephone Number)*
James C. Shah,
SHEPHERD, FINKELMAN, MILLER & SHAH, LLP
475 White Horse Pike, Collingswood, NJ 08107 Ph: 856-858-1770

DEFENDANTS

HUAHAI US, INC., and
ZHEJIANG HUAHAI PHARMACEUTICAL CO., LTD.

County of Residence of First Listed Defendant Middlesex
(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
- ☐ 3 Federal Question *(U.S. Government Not a Party)*
- ☐ 2 U.S. Government Defendant
- ☒ 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)*

(For Diversity Cases Only)

	PTF	DEF		PTF	DEF
Citizen of This State	☒ 1	☐ 1	Incorporated *or* Principal Place of Business In This State	☐ 4	☒ 4
Citizen of Another State	☐ 2	☐ 2	Incorporated *and* Principal Place of Business In Another State	☐ 5	☐ 5
Citizen or Subject of a Foreign Country	☐ 3	☐ 3	Foreign Nation	☐ 6	☐ 6

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

Click here for: Nature of Suit Code Descriptions.

CONTRACT	TORTS		FORFEITURE/PENALTY	BANKRUPTCY	OTHER STATUTES
☐ 110 Insurance	PERSONAL INJURY	PERSONAL INJURY	☐ 625 Drug Related Seizure of Property 21 USC 881	☐ 422 Appeal 28 USC 158	☐ 375 False Claims Act
☐ 120 Marine	☐ 310 Airplane	☐ 365 Personal Injury - Product Liability	☐ 690 Other	☐ 423 Withdrawal 28 USC 157	☐ 376 Qui Tam (31 USC 3729(a))
☐ 130 Miller Act	☐ 315 Airplane Product Liability	☐ 367 Health Care/ Pharmaceutical Personal Injury Product Liability		PROPERTY RIGHTS	☐ 400 State Reapportionment
☐ 140 Negotiable Instrument	☐ 320 Assault, Libel & Slander	☐ 368 Asbestos Personal Injury Product Liability		☐ 820 Copyrights	☐ 410 Antitrust
☐ 150 Recovery of Overpayment & Enforcement of Judgment	☐ 330 Federal Employers' Liability	PERSONAL PROPERTY	LABOR	☐ 830 Patent	☐ 430 Banks and Banking
☐ 151 Medicare Act	☐ 340 Marine	☒ 370 Other Fraud	☐ 710 Fair Labor Standards Act	☐ 835 Patent - Abbreviated New Drug Application	☐ 450 Commerce
☐ 152 Recovery of Defaulted Student Loans (Excludes Veterans)	☐ 345 Marine Product Liability	☐ 371 Truth in Lending	☐ 720 Labor/Management Relations	☐ 840 Trademark	☐ 460 Deportation
☐ 153 Recovery of Overpayment of Veteran's Benefits	☐ 350 Motor Vehicle	☐ 380 Other Personal Property Damage	☐ 740 Railway Labor Act	SOCIAL SECURITY	☐ 470 Racketeer Influenced and Corrupt Organizations
☐ 160 Stockholders' Suits	☐ 355 Motor Vehicle Product Liability	☐ 385 Property Damage Product Liability	☐ 751 Family and Medical Leave Act	☐ 861 HIA (1395ff)	☐ 480 Consumer Credit
☐ 190 Other Contract	☐ 360 Other Personal Injury		☐ 790 Other Labor Litigation	☐ 862 Black Lung (923)	☐ 490 Cable/Sat TV
☐ 195 Contract Product Liability	☐ 362 Personal Injury - Medical Malpractice		☐ 791 Employee Retirement Income Security Act	☐ 863 DIWC/DIWW (405(g))	☐ 850 Securities/Commodities/ Exchange
☐ 196 Franchise				☐ 864 SSID Title XVI	☐ 890 Other Statutory Actions
				☐ 865 RSI (405(g))	☐ 891 Agricultural Acts
					☐ 893 Environmental Matters
					☐ 895 Freedom of Information Act
REAL PROPERTY	CIVIL RIGHTS	PRISONER PETITIONS	IMMIGRATION	FEDERAL TAX SUITS	☐ 896 Arbitration
☐ 210 Land Condemnation	☐ 440 Other Civil Rights	**Habeas Corpus:**	☐ 462 Naturalization Application	☐ 870 Taxes (U.S. Plaintiff or Defendant)	☐ 899 Administrative Procedure Act/Review or Appeal of Agency Decision
☐ 220 Foreclosure	☐ 441 Voting	☐ 463 Alien Detainee	☐ 465 Other Immigration Actions	☐ 871 IRS—Third Party 26 USC 7609	☐ 950 Constitutionality of State Statutes
☐ 230 Rent Lease & Ejectment	☐ 442 Employment	☐ 510 Motions to Vacate Sentence			
☐ 240 Torts to Land	☐ 443 Housing/ Accommodations	☐ 530 General			
☐ 245 Tort Product Liability	☐ 445 Amer. w/Disabilities - Employment	☐ 535 Death Penalty			
☐ 290 All Other Real Property	☐ 446 Amer. w/Disabilities - Other	**Other:**			
	☐ 448 Education	☐ 540 Mandamus & Other			
		☐ 550 Civil Rights			
		☐ 555 Prison Condition			
		☐ 560 Civil Detainee - Conditions of Confinement			

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 - Transfer ☐ 8 Multidistrict Litigation - Direct File

VI. CAUSE OF ACTION

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

Brief description of cause:
Fraudulent sale of adulterated product

VII. REQUESTED IN COMPLAINT:

☒ CHECK IF THIS IS A **CLASS ACTION** UNDER RULE 23, F.R.Cv.P.

DEMAND $

CHECK YES only if demanded in complaint:
JURY DEMAND: ☒ Yes ☐ No

VIII. RELATED CASE(S) IF ANY

(See instructions):

JUDGE _____ DOCKET NUMBER _____

DATE
10/11/2018

SIGNATURE OF ATTORNEY OF RECORD
/s/James C. Shah

FOR OFFICE USE ONLY

RECEIPT # _____ AMOUNT _____ APPLYING IFP _____ JUDGE _____ MAG. JUDGE _____

INSTRUCTIONS FOR ATTORNEYS COMPLETING CIVIL COVER SHEET FORM JS 44

Authority For Civil Cover Sheet

The JS 44 civil cover sheet and the information contained herein neither replaces nor supplements the filings and service of pleading 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. Consequently, a civil cover sheet is submitted to the Clerk of Court for each civil complaint filed. The attorney filing a case should complete the form as follows:

I.(a) **Plaintiffs-Defendants.** Enter names (last, first, middle initial) of plaintiff and defendant. If the plaintiff or defendant is a government agency, use only the full name or standard abbreviations. If the plaintiff or defendant is an official within a government agency, identify first the agency and then the official, giving both name and title.

(b) **County of Residence.** For each civil case filed, except U.S. plaintiff cases, enter the name of the county where the first listed plaintiff resides at the time of filing. In U.S. plaintiff cases, enter the name of the county in which the first listed defendant resides at the time of filing. (NOTE: In land condemnation cases, the county of residence of the "defendant" is the location of the tract of land involved.)

(c) **Attorneys.** Enter the firm name, address, telephone number, and attorney of record. If there are several attorneys, list them on an attachment, noting in this section "(see attachment)".

II. **Jurisdiction.** The basis of jurisdiction is set forth under Rule 8(a), F.R.Cv.P., which requires that jurisdictions be shown in pleadings. Place an "X" in one of the boxes. If there is more than one basis of jurisdiction, precedence is given in the order shown below.
United States plaintiff. (1) Jurisdiction based on 28 U.S.C. 1345 and 1348. Suits by agencies and officers of the United States are included here.
United States defendant. (2) When the plaintiff is suing the United States, its officers or agencies, place an "X" in this box.
Federal question. (3) This refers to suits under 28 U.S.C. 1331, where jurisdiction arises under the Constitution of the United States, an amendment to the Constitution, an act of Congress or a treaty of the United States. In cases where the U.S. is a party, the U.S. plaintiff or defendant code takes precedence, and box 1 or 2 should be marked.
Diversity of citizenship. (4) This refers to suits under 28 U.S.C. 1332, where parties are citizens of different states. When Box 4 is checked, the citizenship of the different parties must be checked. (See Section III below**; NOTE: federal question actions take precedence over diversity cases.**)

III. **Residence (citizenship) of Principal Parties.** This section of the JS 44 is to be completed if diversity of citizenship was indicated above. Mark this section for each principal party.

IV. **Nature of Suit.** Place an "X" in the appropriate box. If there are multiple nature of suit codes associated with the case, pick the nature of suit code that is most applicable. Click here for: Nature of Suit Code Descriptions.

V. **Origin.** Place an "X" in one of the seven boxes.
Original Proceedings. (1) Cases which originate in the United States district courts.
Removed from State Court. (2) Proceedings initiated in state courts may be removed to the district courts under Title 28 U.S.C., Section 1441. When the petition for removal is granted, check this box.
Remanded from Appellate Court. (3) Check this box for cases remanded to the district court for further action. Use the date of remand as the filing date.
Reinstated or Reopened. (4) Check this box for cases reinstated or reopened in the district court. Use the reopening date as the filing date.
Transferred from Another District. (5) For cases transferred under Title 28 U.S.C. Section 1404(a). Do not use this for within district transfers or multidistrict litigation transfers.
Multidistrict Litigation – Transfer. (6) Check this box when a multidistrict case is transferred into the district under authority of Title 28 U.S.C. Section 1407.
Multidistrict Litigation – Direct File. (8) Check this box when a multidistrict case is filed in the same district as the Master MDL docket.
PLEASE NOTE THAT THERE IS NOT AN ORIGIN CODE 7. Origin Code 7 was used for historical records and is no longer relevant due to changes in statue.

VI. **Cause of Action.** Report the civil statute directly related to the cause of action and give a brief description of the cause. **Do not cite jurisdictional statutes unless diversity.** Example: U.S. Civil Statute: 47 USC 553 Brief Description: Unauthorized reception of cable service

VII. **Requested in Complaint.** Class Action. Place an "X" in this box if you are filing a class action under Rule 23, F.R.Cv.P.
Demand. In this space enter the actual dollar amount being demanded or indicate other demand, such as a preliminary injunction.
Jury Demand. Check the appropriate box to indicate whether or not a jury is being demanded.

VIII. **Related Cases.** This section of the JS 44 is used to reference related pending cases, if any. If there are related pending cases, insert the docket numbers and the corresponding judge names for such cases.

Date and Attorney Signature. Date and sign the civil cover sheet.