IN THE UNITED STATES DISTRICT COURT
FOR THE EASTERN DISTRICT OF TENNESSEE
CHATTANOOGA DIVISION

LOREN LEWIS, individually and on behalf of a class of similarly situated individuals,	)	Case No.
Plaintiff,	)	
v.	)	COMPLAINT – CLASS ACTION
ZHEJIANG HUAHAI PHARMACEUTICAL CO., LTD., a Chinese corporation and HUAHAI US, INC., a New Jersey corporation,	)	**JURY DEMAND**
Defendants.	)	

CLASS ACTION COMPLAINT

Plaintiff, Loren Lewis, on behalf of herself and all others similarly situated, by and through her attorneys, Glassman, Wyatt, Tuttle & Cox, P.C., alleges as follows upon personal knowledge as to facts pertaining to herself, and upon information and belief based on the investigation of her counsel as to all other matters.

NATURE OF THE CASE

1. Loren Lewis ("Plaintiff") brings this class action on behalf of herself and all others similarly situated regarding Defendants' respective manufacturing, distribution, and sale of valsartan containing an Active Pharmaceutical Ingredient 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 the Defendants. 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 patent for the brand-name version of the drug expires, 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 paying the full purchase price of their valsartan-containing medications and paying for incidental medical expenses. These medications are worthless because they are contaminated with carcinogenic and harmful *N*-nitrosodimethylamine and are not fit for human consumption.

7. 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) violations of the Tennessee Products Liability Act, T.C.A. § 29-28-101, *et seq.*; (ii) failure to warn; (iii) breach of contract; (iv) breach of implied warranty of merchantability; (v) unjust enrichment; (vi) fraudulent concealment; (vii) conversion; (viii) negligence; and (ix) gross negligence.

PARTIES

8. Plaintiff is an individual who is a citizen of Tennessee, domiciled in Sequatchie County, Tennessee.

9. 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.

10. On its website, Zhejiang touts 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.

11. 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.

12. On information and belief, Huahai conducts substantial business in the state of Tennessee 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.

JURISDICTION AND VENUE

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

14. On information and belief, at all times relevant herein Zhejiang and Huahai 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 Tennessee.

15. On information and belief, at all times relevant herein Zhejiang and Huahai both transacted business in Tennessee.

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

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

18. On information and belief, at all times relevant herein Zhejiang and Huahai purposefully directed activities at Tennessee and purposefully availed themselves of the privilege of conducting activities in Tennessee.

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

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

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

22. Zhejiang and Huahai committed a tortious act in Tennessee when the Plaintiff and the putative class members purchased or consumed adulterated valsartan contaminated with an organic chemical known as *N*-nitrosodimethylamine ("NDMA") (hereinafter referred to as the "Adulterated Valsartan").

23. The tortious act injured Plaintiff and the putative class members in Tennessee. The injuries and losses suffered by the Plaintiff and the putative class members arose out of the forum related activities of Zhejiang and Huahai.

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

25. Zhejiang and Huahai share a close business relationship. For example, it appears that Jun Dun, sometimes referred to as Dun Jun, was the initial registered agent of Huahai, appears to be, or to have been, CEO of Huahai and also appears to be a Vice Chairman of Zhejiang.

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 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).

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

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.

FACTUAL ALLEGATIONS

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. Plaintiff seeks to pursue a class action against the Defendants for manufacturing, supplying, distributing, and ultimately selling Adulterated Valsartan to Plaintiff and the putative class members which was adulterated and defective because it contained NDMA and/or a second impurity, N-Nitrosodithylamine ("NDEA"), a known animal and suspected human carcinogen, which rendered the valsartan adulterated, unsafe, and dangerous for consumption by humans.

31. 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.

32. 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.

33. 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.

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

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

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

37. The European Medicines Agency has explained that NDMA is an unexpected impurity that was not detected by routine tests by Zhejiang and that the change in manufacturing process which led to the impurity was introduced in 2012 and is believed to have produced NDMA as a side product. As such, valsartan may have been contaminated since 2012.

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

39. 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.

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

41. The Defendants manufactured, supplied, distributed, and/or sold the Active Pharmaceutical Ingredient valsartan used in the manufacture of the Adulterated Valsartan.

42. In addition to the Recall in the United States, prescription drugs containing valsartan have been recalled in more than 20 other countries.

43. According to the FDA, numerous valsartan-containing prescriptions medications are subject to the Recall.

44. Plaintiff purchased Adulterated Valsartan from a pharmacy located in Dunlap, Sequatchie County, Tennessee.

45. Plaintiff consumed Adulterated Valsartan in Tennessee prior to the Recall.

46. 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.* |

47. 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].

48. 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].

49. 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]

50. 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.

51. 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.

52. 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.

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

54. The FDA is authorized to perform inspections under Federal Food, Drug and Cosmetic Act. A Form FDA 483 letter is a form used by the FDA to document and communicate concerns discovered during such an inspection.

55. The FDA conducted an inspection of Zhejiang's operations between July 23, 2018 to July 28, 2018 and again between July 30, 2018 to August 3, 2018.

56. On August 3, 2018, the FDA, through Investigators Cheryl Clausen and Joel Hustedt, issued a Form FDA 483 letter confirming observations made during the aforementioned inspection and communicating concerns discovered during the inspection relating to Zhejiang's quality management systems, validation procedures, manufacturing processes and product

specifications. The FDA also criticized Zhejiang's investigation and testing procedures. **Exhibit A.**

57. According to the FDA's 483 letter dated August 3, 2018, the FDA observed (1) The change control system to evaluate all changes that may affect the production and control of intermediates or Active Pharmaceutical Ingredients (APIs) is not adequate; (2) Validation of production processes, cleaning procedures, analytical methods, and in-process control test procedures are not always adequate; (3) The system for managing quality to ensure confidence that the API will meet its intended specifications for quality and purity is not adequate in that Zhejiang's quality unit lacks written procedures and the authority and responsibility to ensure all critical deviations are thoroughly investigated; (4) The quality unit does not always fulfill the responsibilities of the quality unit to release or reject all APIs; (5) Cleaning procedures do not contain sufficient details to enable operators to clean each type of equipment in a reproducible and effective manner; (6) Equipment used in the manufacture of intermediates and APIs should be of appropriate design and adequate size, and suitably located for its intended use, cleaning and maintenance; (7) Schedules and procedures for preventative maintenance of equipment are not adequate or do not exist; (8) Substances associated with the operation of equipment, such as lubricants, heating fluids or coolants are not always food grade lubricants and oils; (9) Sampling plans and test procedures are not always scientifically sound and appropriate to ensure raw materials, intermediates and APIs conform to established standards of quality; (10) Zhejiang's ongoing testing program to monitor the stability characteristics of APIs to confirm appropriate storage conditions and retest dates is not adequate; and (11) Production deviations are not always reported and evaluated and critical deviations are not always investigated and the conclusions recorded.

58. On September 13, 2018, the FDA updated the agency's investigation surrounding valsartan by announcing that NDEA, another impurity, was found in several batches of valsartan-containing medications.

59. On September 14, 2018, CNN reported that the FDA found yet another cancer causing impurity in three lots of Valsartan containing medications. CNN was reporting on a September 13, 2018, press release from the FDA, which indicated that this second impurity, N-Nitrosodithylamine ("NDEA") is a known animal and suspected human carcinogen.

60. On or about September 28, 2018, to protect U.S. patients, the FDA placed Zhejiang on an import alert, halting imports from the company until Zhejiang is able to determine how impurities were introduced into its API and until it remediates its quality systems. The FDA's import alert stops all API made by Zhejiang and finished drug products made using Zhejiang's API from legally entering the United States. At the same time, the FDA reminded manufacturers that it is their responsibility to develop and use suitable methods to detect impurities, including when they make changes to their manufacturing processes and that if a manufacturer detects new or higher levels of impurities, they should fully evaluate the impurities and take action to ensure the product is safe for patients. (https://www.fda.gov/DrugSafety/ucm613916htm)

61. As part of the FDA's ongoing investigation into the presence of impurities in valsartan products it performed tests that identified NDMA and NDEA in certain valsartan products. The FDA's analyses reflect the average levels of NDMA present in a single tablet based on the strength of the tested drug product within the lots tested. Because the change in the manufacturing process which led to the impurities was introduced in 2012, it is highly likely that

additional batches, not tested by the FDA and not identified in any recall, were contaminated by NDMA and/or NDEA.

62. The FDA previously estimated that if 8,000 people took the highest valsartan dose (320 mg) containing NDMA from the recalled batches daily for four years, there may be one additional case of cancer over the lifetimes of the 8,000 people. The FDA's estimate was based on the highest daily dose, however many people may have taken lower doses, and therefore, according to the FDA, their risks would theoretically be less. This assessment, in part, led to the FDA's decision to recall valsartan.

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

64. At all times relevant herein Defendants were negligent in manufacturing, supplying, marketing, distributing and/or selling the valsartan API as 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 the valsartan API was adulterated.

65. As a result of failing to maintain appropriate manufacturing processes, quality control procedures, validation procedures, cleaning procedures, failing to utilize equipment of appropriate design and size, failing to employ schedules and procedures for preventative maintenance of equipment, failing to employ substances associated with the operation of its equipment that are food grade lubricants and oils, utilizing sampling plans and test procedures that are not scientifically sound, failing to monitor the stability characteristics of APIs to confirm appropriate storage conditions and retest dates and failing to report, evaluate, investigate and record conditions related to production deviations, Defendants caused valsartan API to be

contaminated by NDMA and/or NDEA and failed to detect NDMA and/or NDEA in the Adulterated Valsartan.

66. 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 and/or NDEA.

67. The Adulterated Valsartan is worthless.

68. 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 and/or NDEA.

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

70. 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.

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

CLASS ALLEGATIONS

72. Plaintiff and each putative class member purchased and/or ingested Adulterated Valsartan.

73. 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 Tennessee consumers who purchased Adulterated Valsartan, as defined below (the "Class"):

> All persons or entities who, while in Tennessee, purchased and/or consumed Adulterated Valsartan. 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.

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

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

76. 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 while in Tennessee. Further, Plaintiff and all Class Members sustained monetary and economic injuries arising out of Defendants' wrongful conduct by, *inter alia*, purchasing and/or consuming the Adulterated Valsartan (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, *ie*. that the prescription valsartan was adulterated, been disclosed to Plaintiff and the Class Members, they would not have purchased or consumed the Adulterated Valsartan. The Plaintiff is advancing the same claims and legal theories on behalf of herself and all Class Members.

b. Adequacy: The Plaintiff is an adequate representative of the Class because her interests do not conflict with the interests of the respective Class Members that she 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 her 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.

77. 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, 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 met the Defendants' warranties;

ii. Whether the Adulterated Valsartan were merchantable goods at the time of sale;

iii. Whether the Adulterated Valsartan was fit for their intended purpose;

iv. Whether Defendants made fraudulent, false, deceptive, and/or misleading statements in connection with the sale of the Adulterated Valsartan;

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 the Tennessee Products Liability Act, T.C.A. §§ 29-28-101, *et seq.*, ("TPLA")

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

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

80. Under the TPLA, a manufacturer or seller is liable for damages caused by a product that is "in a defective condition or unreasonably dangerous at the time it left the control of the manufacturer or seller." T.C.A. § 29-28-101(a).

81. Defendants' Adulterated Valsartan is a "product" under the TPLA. T.C.A. § 29-28-101(b)(5).

82. Defendants are "manufacturers" and/or "sellers" under the TPLA. T.C.A. § 29-28-101(b)(4), (7).

83. "Defective condition" under the TPLA means a condition of a product that renders it unsafe for normal or anticipatable consumption. T.C.A. § 29-28-101(b)(2).

84. "Unreasonably dangerous" under the TPLA means that a product is dangerous to an extent beyond that which would be contemplated by the ordinary consumer who purchases it, with the ordinary knowledge common to the community as to its characteristics, or that the product, because of its dangerous condition, would not be put on the market by a reasonably prudent manufacturer or seller, assuming that the manufacturer or seller knew of its dangerous condition. T.C.A. § 29-28-101(b)(8).

85. 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.

86. 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.

87. 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.

88. Defendants' Adulterated Valsartan was in a defective condition when it left Defendants' control because it was contaminated by NDMA, a carcinogen and/or NDEA.

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

90. Defendants' Adulterated Valsartan was also in a defective condition when it left Defendants' control because 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.

91. Additionally, Defendant's Adulterated Valsartan was unreasonably dangerous when it left Defendants' control because it was contaminated by NDMA, a carcinogen and/or NDEA.

92. An ordinary drug consumer would be unable to determine whether Defendants' Adulterated Valsartan was contaminated by NDMA or NDEA.

93. 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.

94. 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.

95. No reasonably prudent manufacturer or seller would put the NDMA-contaminated or NDEA-contaminated Adulterated Valsartan on the market if such manufacturer or seller knew of the contamination.

96. 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.

97. 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.

98. In light of the potential and actual risk of harm associated with the consumption of the Adulterated Valsartan, no reasonably prudent person who had actual knowledge of this potential and actual risk of harm would have concluded that the Adulterated Valsartan should have been marketed in that condition.

99. 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.

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

101. 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.

102. Information provided by the Defendants to the medical community and to consumers concerning the safety and efficacy of the Adulterated Valsartan did not accurately reflect the serious health and potentially fatal side effects resulting from consumption of the Adulterated Valsartan.

COUNT II: Failure to Warn

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

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

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

106. 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 and/or NDEA. Defendants owed a duty to exercise ordinary care. Defendants breached their duty to exercise ordinary care to manufacture, supply, distribute, and/or sell valsartan to Plaintiff and the Class Members that was not adulterated.

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

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

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

110. 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.

111. 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 III: Breach of Contract

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

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

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

115. 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 and NDEA. 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.

116. 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.

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

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

119. Defendants breached the contract because the Adulterated Valsartan was adulterated and contaminated with the carcinogen NDMA or NDEA.

120. Plaintiff would not have purchased the Adulterated Valsartan if she had known that it was adulterated and contaminated with the carcinogen NDMA or NDEA.

121. 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 or NDEA.

122. 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 IV: Breach of Implied Warranty of Merchantability

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

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

125. 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 or NDEA.

126. 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, or NDEA 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.

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

128. Plaintiff did not alter the Adulterated Valsartan.

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

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

131. 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.

132. 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 or NDEA 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 V: Unjust Enrichment

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. Plaintiff brings this unjust enrichment claim to the extent the Court finds that there was no contractual relationship between Plaintiff and/or the Class Members and Defendants.

136. 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 or NDEA.

137. Defendants accepted, retained, and appreciated such non-gratuitous benefits conferred by Plaintiff and the Class Members.

138. 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.

139. 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 which Defendants were unjustly enriched by each purchase of the Adulterated Valsartan.

COUNT VI: Fraudulent Concealment

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

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

142. 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, or NDEA and that the Adulterated Valsartan was unfit for human consumption.

143. Defendants knew or should have known that they had a duty to disclose such material facts to consumers such as Plaintiff and the Class Members.

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

145. 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.

146. 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 or NDEA.

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

148. 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, or NDEA rendering the medicine unfit for human consumption.

149. 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 or NDEA and thus adulterated.

150. 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 VII: Conversion

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

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

153. 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.

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

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

COUNT VIII: Negligence

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

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

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

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

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

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

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

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

COUNT XI: Gross Negligence

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

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

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

165. 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.

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

167. Defendants were indifferent to such probable harm.

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

PRAYER FOR RELIEF

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 post judgment 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: October 16, 2018

Respectfully submitted,

By: /s/ Edwin E. Wallis III
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EDWIN E. WALLIS III (TN #23950)
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Attorneys for Loren Lewis

EXHIBIT A

DEPARTMENT OF HEALTH AND HUMAN SERVICES
FOOD AND DRUG ADMINISTRATION

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NAME AND TITLE OF INDIVIDUAL TO WHOM REPORT IS ISSUED

TO: Mr. Jun Dun, Executive Vice President

FIRM NAME	STREET ADDRESS
Zhejiang Huahai Pharmaceutical Co., Ltd.	Coastal Industrial Zone, Chuannan No. 1 Branch
CITY, STATE AND ZIP CODE	TYPE OF ESTABLISHMENT INSPECTED
Linhai, Zhejiang Province 317016 China	manufacturer

THIS DOCUMENT LISTS OBSERVATIONS MADE BY THE FDA REPRESENTATIVE(S) DURING THE INSPECTION OF YOUR FACILITY. THEY ARE INSPECTIONAL OBSERVATIONS; AND DO NOT REPRESENT A FINAL AGENCY DETERMINATION REGARDING YOUR COMPLIANCE. IF YOU HAVE AN OBJECTION REGARDING AN OBSERVATION, OR HAVE IMPLEMENTED, OR PLAN TO IMPLEMENT CORRECTIVE ACTION IN RESPONSE TO AN OBSERVATION, YOU MAY DISCUSS THE OBJECTION OR ACTION WITH THE FDA REPRESENTATIVE(S) DURING THE INSPECTION OR SUBMIT THIS INFORMATION TO FDA AT THE ADDRESS ABOVE. IF YOU HAVE ANY QUESTIONS, PLEASE CONTACT FDA AT THE PHONE NUMBER AND ADDRESS ABOVE.

DURING AN INSPECTION OF YOUR FIRM (I) (WE) OBSERVED:

QUALITY SYSTEM
OBSERVATION 1

The change control system to evaluate all changes that may affect the production and control of intermediates or Active Pharmaceutical Ingredients (APIs) is not adequate. Specifically,

a) you do not always conduct a formal risk assessment for critical changes to evaluate the potential impact of proposed changes on the quality of intermediates or APIs. Critical Change Request PCRC-11025 was initiated November 27, 2011 and closed November 29, 2011, for the stated purpose of making changes to the (b) (4) manufacturing process to (b) (4) the current (b) (4) ((b) (4) % - (b) (4) %) of the known isomer impurity (b) (4) (b) (4) in the final API and (b) (4) batch yields (current batch yield (b) (4) - (b) (4) per batch).

i) you did not conduct and document a formal risk assessment for Change Request PCRC-11025 to evaluate the potential impact of proposed changes on the quality of the intermediates or the final API for this critical change to your validated manufacturing process prior to your quality unit approving the change.

ii) you hired an outside laboratory to conduct a small lab scale research project. Based on the results of a lab scale research project you initiated validation on a commercial scale to change your validated manufacturing process without conducting pilot scale or other small scale batches. Your Deputy Director of Manufacturing stated you have commercial experience and since you only changed the (b) (4) there was no need to conduct pilot scale trial batches before instituting critical changes on a commercial scale.

You initiated validation on a commercial scale without conducting a formal risk assessment to evaluate the potential impact of changes to your validated manufacturing process on the quality of intermediates and APIs. You do not have a quality agreement with the outside laboratory you used to perform a lab scale research project requiring (prior to initiating testing and reporting results): qualification of all instruments used to conduct tests; validation of all software used with qualified instruments to conduct tests; calibration of all applicable measurement devices against traceable standards prior to use; use of official standards as appropriate; if applicable, establishing system suitability prior to testing samples and processing data; and validation of all test methods used for testing.

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	Cheryl Clausen	Cheryl Clausen, Investigator Joel Hustedt, Investigator	08/03/2018

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b) you do not have an adequate change control system requiring scientific judgement to determine what additional testing and validation studies are appropriate to justify changes to a validated manufacturing process. You do not always have data to support approval of changes to validated processes.

i) You did not identify specific parameters and specify acceptance criteria for those parameters prior to implementing changes, as part of critical Change Request PCRC-11025, to use to evaluate if the implemented changes (b) (4) the isomer (b) (4) of (b) (4) and (b) (4) the batch yield.

ii) Additional testing requirements associated with critical changes are not always based on sound scientific judgement. Change Request PCRC-11025 included changing (b) (4) in your validated manufacturing process. Additional testing requirements associated with these changes were limited to three validation batches and a commitment to conduct additional testing on (b) (4) batches a (b) (4)

c) you do not have an adequate classification procedure for determining the level of testing, validation, and documentation needed to justify changes to a validated process. You do not consistently classify changes. You do not always increase testing, validation, and the documentation required to justify changes to a validated process based on the classification of a proposed change. Amendment to Drug Master File (b) (4) USP (Process (b) (4) DMF# (b) (4) dated December 10, 2013 indicates the amendment was submitted for minor changes for drug substance manufacturing. Amendment to Drug Master File (b) (4) USP (Process (b) (4)) DMF# (b) (4) contradicts your internal Change Request PCRC-11025 which lists change control classification as critical change.

d) written change control procedures should provide for the identification, documentation, appropriate review, and approval of changes in raw materials, specifications, analytical methods, facilities, support systems, equipment (including computer hardware), processing steps, labeling and packaging materials, and computer software. Any proposals for GMP relevant changes should be drafted, reviewed, and approved by the appropriate organizational units and reviewed and approved by the quality unit. Your quality unit does not always follow your written procedure for change control. Your written procedure Change Control System SMP-018.05 effective December 30, 2017 section 5.3.6 (3) specifies QA shall reject the change if the action cannot meet predetermined expectations. Critical Change Request PCRC-11025 did not include acceptance criteria with predetermined expectations. (b) (4) Product Development Report-01 dated April 13, 2012 Table 8 includes (b) (4) isomer impurity (specification < (b) (4) %) from three batches manufactured according to the validated manufacturing process (results range from (b) (4) % - (b) (4) %) and Table 10 includes (b) (4) isomer impurity from the three

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validation batches manufactured using a different (b) (4) (results range from (b) (4) % - (b) (4) %). The product development report is silent regarding evaluation of the ability of the implemented changes to (b) (4) isomer (b) (4) (b) (4) Product Development Report-01 did not compare the batch weights from batches manufactured immediately before the change to the validated manufacturing process and the first batches manufactured after implementing changes to the manufacturing process.

OBSERVATION 2

Validation of production processes, cleaning procedures, analytical methods, and in-process control test procedures are not always adequate. Specifically,

a) your manufacturing processes are not always capable of consistently producing final products meeting all product quality specifications. Deviation No. DCB18-17017 was initiated for OOS genotoxic impurity (b) (4) (b) (4) ppm (specification < (b) (4) ppm) in (b) (4) batch (b) (4) Repeat test results included OOS results. As a corrective action you reprocessed (b) (4) batch (b) (4) by (b) (4) the (b) (4) step in your manufacturing process. You did not investigate corrective actions to your manufacturing process or to the manufacturing batch record to improve product consistency and manufacturing reproducibility, and to reduce the level of (b) (4) in the (b) (4) intermediate crude. You did not develop a prevent action plan to prevent future OOS (b) (4) levels in the intermediate crude and final API.

Between December 16, 2016 and August 22, 2017 you initiated 17 OOS investigations for (b) (4) impurity in (b) (4) Of the 17 OOS investigations initiated for (b) (4) impurity in (b) (4) you attributed 13 OOS results to lab related errors, 5 OOS results to production errors, and 2 OOS results to a combination of lab and production errors. You reprocessed all 17 (b) (4) batches you investigated for OOS (b) (4) impurity.

b) written validation protocols are not always adequate.

i) Your Process Validation Protocol for (b) (4) Process (b) (4) Workshop (b) (4) CNVP-11-075 and Process Validation Protocol for Crude (b) (4) Step (b) (4) PVC-18012(P) do not include the specific parameters with acceptance criteria to establish your manufacturing process is not only consistent and reproducible but able to fulfill the purpose for changing your validated manufacturing process.

ii) Neither Process Validation Protocol for (b) (4) Process (b) (4) Workshop (b) (4) CNVP-11-075 nor

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Process Validation Protocol for Crude (b) (4) Step (b) (4) PVC-18012(P) specified the number of manufacturing batches to be manufactured as part of validation of your manufacturing process or discussed the number of validation batches to manufacture based on the complexity of the process or the magnitude of the process change.

iii) Neither Process Validation Protocol for (b) (4) Process (b) (4) Workshop (b) (4) CNVP-11-075 nor Process Validation Protocol for Crude (b) (4) Step (b) (4) PVC-18012(P) included a sampling plan designed to demonstrate the consistency and reproducibility of your manufacturing process through batch uniformity data.

c) you do not always initiate investigations during process validation. (b) (4) process validation batch (b) (4) est results for Diastereo-isomer (b) (4) % (specification < (b) (4) %) were OOT (Out-of-Trend) compared to the other (b) (4) validation batches with Diasterio-isomer results ranging from (b) (4) % to (b) (4) %. You did not initiate an investigation to identify the CPP(s) (Critical Process Parameter), non-critical process parameter(s), raw material(s), or other influences which could impact Diastereo-isomer results in an effort to improve the quality and consistency of (b) (4) (the product from the (b) (4) synthesis step in the manufacture of (b) (4) .

d) you do not have sufficient data to demonstrate your in-house test methods, used for Assay and Related Substance testing of (b) (4) are at least equivalent to USP Monograph test methods. (b) (4) USP Method and In-house Method Qualification Comparison Research Report VLDor-10-099 (R) version 2 effective August 29, 2014 does not include data showing you tested known concentrations of (b) (4) and spiked (b) (4) samples and then compared the results from your in-house test method with results from tested known concentrations of (b) (4) and spiked (b) (4) samples using the USP method to verify your in-house test results at least meet the acceptance criteria of the USP methods.

e) you do not have validated cleaning procedures. Cleaning procedures for (b) (4) -203-1 and (b) (4) 204-3 in workshop (b) (4) used in the manufacture of crude (b) (4) are not validated in that you do not have data to demonstrate the cleaning procedure is effective following manufacture of (b) (4) consecutive batches. The most recent cleaning validation study, CVD-18015 (R), approved in July 2018, is based on (b) (4) consecutive batches. The 2016 equipment use log for (b) (4) -203-1 shows (b) (4) consecutive batches were manufactured before cleaning. The 2016 equipment use log for (b) (4) -204-3 shows (b) (4) consecutive batches were manufactured before cleaning. Your Quality Assurance Director verbally confirmed no rinse samples were analyzed following either of these cleanings.

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OBSERVATION 3

The system for managing quality to ensure confidence that the API will meet its intended specifications for quality and purity is not adequate in that your quality unit lacks written procedures and the authority and responsibility to ensure all critical deviations are thoroughly investigated. Specifically,

a) you release finished APIs manufactured from crude intermediates with OOS levels of genotoxic impurities without conducting a thorough investigation. Deviation No. DCB18-17025 initiated December 13, 2017 and closed April 16, 2018 was initiated for OOS (b) (4) impurity (b) (4) ppm (specification < (b) (4) ppm) in (b) (4) batch (b) (4) You identified the root cause as an equipment failure which impacted intermediate crude (b) (4) batch (b) (4) during (b) (4) You reprocessed (b) (4) batch (b) (4) Intermediate crude (b) (4) batch (b) (4) was also used in (b) (4) API final batch (b) (4) You did not reprocess batch (b) (4) made from OOS intermediate crude (b) (4) batch (b) (4) . You did not open an investigation, or conduct additional testing on batch (b) (4) Your QA Director stated batch (b) (4) met the product release specification for Related Substance (b) (4)

b) major Deviation DD (b) (4) 17003 was initiated August 2, 2017 and closed September 11, 2017 for (b) (4) batches (b) (4) and (4) with OOS results for a single unknown impurity (specification < (b) (4) %). You confirmed OOS results for (b) (4) batches (b) (4) single unknown impurity (b) (4) %, and (b) (4) single unknown impurity (b) (4) %.

i) you did not identify a root cause for the single unknown impurity results in batches (b) (4) and (b) (4) You stated the root cause was probably due to occasional fluctuation in your manufacturing process. You did not attempt to identify this single unknown impurity. You did not attempt to identify the source of fluctuations in your manufacturing process for (b) (4)

ii) you did not develop an adequate Corrective Action and Preventive Action (CAPA) plan. The CAPA you listed on Deviation Investigation Report Form for Deviation DD (b) (4) 17003 included: discarding both batches, and following-up on the next (b) (4) batches to see if a similar issue occurs. You did not review your manufacturing process and manufacturing batch records to determine if your manufacturing process and manufacturing batch records could be revised to reduce process variation. You did not interview employees to determine if employees consistently and reproducibly follow your manufacturing instructions.

iii) you did not conduct a thorough risk assessment. Your risk assessment consisted of answering (b) (4) generic

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questions: yes, no, or NA (Not Applicable). Deviation DD(b) (4) 17003 investigation did not include documentation showing a more thorough risk assessment was conducted by your risk management team. Your written procedure for Quality Risk Management SMP-023.03 effective November 1, 2017 section 7.1.3 specifies a risk management team should be established when solving major risk issues, and section 7.1.5 of the same procedure specifies to select different tools according to the risk category. Quality Risk Management SMP-023.03 section 8.3 specifies all activities should be defined and documented. Quality Risk Management SMP-023.03 does not specify which risk management methods and tools to use in association with specific deviation categories.

c) you do not always thoroughly document investigations. your written procedure Deviation Investigation Management System SMP-017.05 effective January 1, 2018 section 6.4.2 specifies the investigation should be well documented including the quality risk assessment (the same specification as included in version SMP-17.04 effective May 30, 2016). Deviation Investigation Management System SMP-017.05 like SMP-017.04 does not specify which risk management methods and tools to use in association with specific deviation categories.

d) you do not always thoroughly investigate deviations before closing the deviation. Deviation DCB02-17002 was initiated October 10, 2017 and closed February 1, 2018 for single unknown impurity (specification (b) (4) %) (b) (4) intermediate (b) (4) batches (b) (4) (b) (4) %) and (b) (4) (b) (4) %). The Deviation Investigation Report states unspecified impurity at RRT (Relative Retention Time) (b) (4) is an in-process impurity observed in other batches but at levels not more than (b) (4) %. You did not identify a root cause. Your corrective action plan included: use LC-MS to identify the impurity, conduct further investigations once the impurity is identified, and conduct a lab trial study to determine if reprocessing removes the impurity. You did not develop a preventive action plan. You did not identify the single unknown impurity. You reprocessed (b) (4) intermediate (b) (4) batches (b) (4) and (b) (4) and assigned the reprocessed batches final API batch numbers (b) (4) and (b) (4) You then closed the investigation without identifying the single unknown impurity.

e) you do not always follow your written procedures. Returned Products Management Procedure SMP-012.02 effective October 30, 2013 defines a quality-related issue as any non-compliance to physical, chemical or microbiological feature. You classified Return No. RC-18006 as not quality related for (b) (4) batches (b) (4) and (b) (4) returned for not complying with customer PSD specifications, a

SEE REVERSE OF THIS PAGE	EMPLOYEE(S) SIGNATURE	EMPLOYEE(S) NAME AND TITLE (Print or Type)	DATE ISSUED
	CAC	Cheryl Clausen, Investigator Joel Hustedt, Investigator	08/03/2018

DISTRICT OFFICE ADDRESS AND PHONE NUMBER	DATE(S) OF INSPECTION
Food and Drug Administration, ORA OPQO HQ 12420 Parklawn Drive, RM 2032 Rockville, MD 20857 Industry Information: www.fda.gov/oc/industry	07/23/2018 - 07/28/2018, 07/30/2018-08/03/2018 FEI NUMBER 3003885745

NAME AND TITLE OF INDIVIDUAL TO WHOM REPORT IS ISSUED

TO: Mr. Jun Dun, Executive Vice President

FIRM NAME	STREET ADDRESS
Zhejiang Huahai Pharmaceutical Co., Ltd.	Coastal Industrial Zone, Chuannan No. 1 Branch
CITY, STATE AND ZIP CODE	TYPE OF ESTABLISHMENT INSPECTED
Linhai, Zhejiang Province 317016 China	manufacturer

physical feature. The Treatment Record section and closure date on Return No. RC-18006 were left blank.

OBSERVATION 4

The quality unit does not always fulfill the responsibilities of the quality unit to release or reject all APIs. Specifically, (b) (4) batch (b) (4) ((b) (4) designates the batch was (b) (4)) did not meet your customer's specification for PSD (Particle Size Distribution (b) (4) – (b) (4) µm). The actual PSD values were not reported on the CoA (Certificate Analysis for the batch. The quality unit did not complete a Product Release Form rejecting the batch for not meeting the customer's PSD specification with instructions for handling the batch.

(b) (4) batch (b) (4) was (b) (4) a (b) (4) time and the batch number was changed to batch (b) (4) ((b) (4) µm). The quality unit completed a Product Release Form and identified the batch as released without further instructions for handling the batch. Yet (b) (4) batch (b) (4) was (b) (4) a (b) (4) time. After (b) (4) batch (b) (4) was (b) (4) a (b) (4) time PSD results were (b) (4) µm. The quality unit completed a Product Release Form releasing the batch a second time.

FACILITIES AND EQUIPMENT SYSTEM

OBSERVATION 5

Cleaning procedures do not contain sufficient details to enable operators to clean each type of equipment in a reproducible and effective manner. Specifically, your cleaning procedures are inadequate in that three of the three (b) (4) examined during the inspection contained visible residue or apparent foreign material. (b) (4) (b) (4) 102-1 contained apparent white particulate matter and what appeared to be a red-colored metallic particle. (b) (4) 102-2 contained apparent white residue. (b) (4) II-250 also contained apparent white residue along the length of the (b) (4)

OBSERVATION 6

Equipment used in the manufacture of intermediates and APIs should be of appropriate design and adequate size, and suitably located for its intended use, cleaning, and maintenance. This is a repeat observation. Specifically, a) you do not maintain equipment in a good state of repair. The end of the (b) (4) in (b) (4) II-250 is not adequately repaired. The repaired area on the (b) (4) consists of (b) (4) different colored unidentified materials: (b) (4) Your Engineering Supervisor stated the (b) (4) material is the (b) (4) repair material and the (b) (4) material is the (b) (4) of the same repair material.

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	CK	Cheryl Clausen, Investigator Joel Hustedt, Investigator	08/03/2018

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Food and Drug Administration, ORA OPQO HQ 12420 Parklawn Drive, RM 2032 Rockville, MD 20857 Industry Information: www.fda.gov/oc/industry	07/23/2018 - 07/28/2018, 07/30/2018-08/03/2018 FEI NUMBER 3003885745

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Zhejiang Huahai Pharmaceutical Co., Ltd.	Coastal Industrial Zone, Chuannan No. 1 Branch
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Linhai, Zhejiang Province 317016 China	manufacturer

Only a small portion of the (b) (4) covered the repaired area. The durability of the (b) (4) in the absence of the (b) (4) is unknown. The (b) (4) material is unknown.

b) you do not have adequate lighting in (b) (4) to inspect (b) (4) after cleaning to ensure no visible residue remains.

c) you do not have an adequate (b) (4) sealing machine to seal (b) (4) API (b) (4) bags. (b) (4) sealing machine (b) (4) -811 does not have sufficient controls for pressure and time to ensure proper sealing. You do not conduct leak tests to check bag seals prior to final product approval and release.

OBSERVATION 7
Schedules and procedures for preventive maintenance of equipment are not adequate or do not exist. Specifically,

a) you do not have a written procedure describing how to conduct a (b) (4) test to verify the integrity of the interior surface of the (b) (4) in your manufacturing workshops. (b) ( ) are used in the manufacture of crude in workshops (b) (4) and (b) (4).

b) you do not have a written procedure describing how to perform repairs to the interior surfaces of (b) (4) (b) (4) Repairs to interior surfaces of (b) (4) are made by your employees without written instructions for how to make those repairs.

c) you do not have a record showing a (b) (4) test was performed immediately following a repair to the (b) (4) of the (b) (4) in (b) (4) II-250. (b) (4) II-250 is used in the manufacture of crude (b) (4)

OBSERVATION 8
Substances associated with the operation of equipment, such as lubricants, heating fluids or coolants are not always food grade lubricants and oils. Specifically, you use (b) (4) in all of your (b) (4) reactors in Workshop (b) (4) You do not test (b) (4) prior to release for use for (b) (4) a potential toxic contaminant. Rather than preventing potential finished API contamination from (b) (4) by testing (b) (4) for (b) (4) prior to approval and release, your QA Director stated you periodically monitor your finished product APIs for (b) (4) contamination.

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Food and Drug Administration, ORA OPQO HQ 12420 Parklawn Drive, RM 2032 Rockville, MD 20857 Industry Information: www.fda.gov/oc/industry	07/23/2018 - 07/28/2018, 07/30/2018-08/03/2018
	FEI NUMBER 3003885745

NAME AND TITLE OF INDIVIDUAL TO WHOM REPORT IS ISSUED

TO: Mr. Jun Dun, Executive Vice President

FIRM NAME	STREET ADDRESS
Zhejiang Huahai Pharmaceutical Co., Ltd.	Coastal Industrial Zone, Chuannan No. 1 Branch
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LABORATORY SYSTEM
OBSERVATION 9

Sampling plans, and test procedures are not always scientifically sound and appropriate to ensure raw materials, intermediates and APIs conform to established standards of quality.

a) you do not always have scientifically sound reasons for invalidating OOS results for lab related reasons. This is a repeat observation. Complaint No. CC-16008 received September 13, 2016 for (b) (4) batches (b) (4) ((b) (4) ppm (b) (4) impurity) and (b) (4) ((b) (4) ppm (b) (4) impurity) failing to meet (b) (4) impurity specification < (b) (4) ppm identifies the complaint as a quality complaint for product quality attribute. Your Vice President of Analytical Operations stated a Single Quadrupole LC-MS is not as sensitive as a Triple Quadrupole LC-MS and sometimes it gives false positive results. Your customer tested (b) (4) batches (b) (4) and (b) (4) using a Triple Quadrupole LC-MS. You sent samples of (b) (4) and (b) (4) to an outside laboratory to test using a Triple Quadrupole LC-MS. Your customer provided you with their LC-MS test method. The outside laboratory used a Triple Quadrupole LC-MS but did not follow the test method provided by your customer.

You do not have a quality agreement with this outside laboratory requiring all equipment used for testing is qualified, any software used with the instrument is validated, and the test method used is validated prior to reporting results. You used results from this outside laboratory for (b) (4) batches (b) (4) and (b) (4) to invalidate the OOS results reported by your customer. After your customer returned (b) (4) batches (b) (4) and (b) (4) you reprocessed the batches and assigned the reprocessed batches new batch numbers (b) (4) and (b) (4) Finished API batches (b) (4) and (b) (4) were then sold to other customers.

b) you do not have scientifically sound sampling plans.

i) Sampling Procedure for API Raw Material QC-026-9 effective September 30, 2017 includes sampling instructions designed to obscure non-homogenous raw material batches. As an example, section 5.6 specifies to sample the (b) (4) of (b) (4) compartment in the tanker and (b) (4) the compartment sample and then (b) (4) the (b) (4) samples from (b) (4) the compartments. You do not have data establishing inter-batch and intra-batch homogeneity for key starting materials.

ii) Sampling procedures lack sufficient details describing how to collect samples to ensure the sampling

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Food and Drug Administration, ORA OPQO HQ 12420 Parklawn Drive, RM 2032 Rockville, MD 20857 Industry Information: www.fda.gov/oc/industry	07/23/2018 - 07/28/2018, 07/30/2018-08/03/2018
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NAME AND TITLE OF INDIVIDUAL TO WHOM REPORT IS ISSUED

TO: Mr. Jun Dun, Executive Vice President

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procedure is consistently and reproducibly followed. Sampling Procedure for APIs QA-005-5 effective August 30, 2017 is silent regarding which drums to sample or how to collect samples from the sampled drums.

c) you do not have data to support reduced testing for genotoxic and other impurities. During process validation for (b) (4) you committed to testing the final API validation batches for elemental impurities and residual solvents, (b) (4) After the three (b) (4) validation batches you test (b) (4) batches (b) (4) for elemental impurities and residual solvents. During process validation for (b) (4) you tested the finished API validation batches for potential genotoxic impurity (b) (4) After the validation batches you test (b) (4) batches (b) (4) for potential genotoxic impurity (b) (4)

OBSERVATION 10

Your on-going testing program to monitor the stability characteristics of APIs to confirm appropriate storage conditions and retest dates is not adequate. Specifically,

a) you subjected (b) (4) API samples to conditions expected to cause degradation (forced degradation). You did not conduct full product release testing on those forced degradation samples, using validated test methods, to identify the specific product release test(s) that are stability indicating. Instead you included forced degradation samples in three HPLC test method validations for Related Substance, Assay and (b) (4) impurity. Not all potential product degradants can be identified by HPLC test methods. Product release tests for (b) (4) include tests for identification of Residual Solvents by GC-FID. You did not test forced degradation samples for Residual Solvents by GC-FID.

b) you do not always appropriately add stability study samples to your stability study program. Deviation investigation DCB02-17002 was initiated for (b) (4) intermediate (b) (4) batches (b) (4) single unknown impurity (b) (4) % (specification < (b) (4) %) and (b) (4) single unknown impurity (b) (4) %. You reprocessed the batches. You assigned the following batch numbers to the finished APIs made from the aforementioned (b) (4) intermediate (b) (4) batches: (b) (4) and (b) (4) You did not add batches (b) (4) and (b) (4) to your stability study program.

SEE REVERSE OF THIS PAGE	EMPLOYEE(S) SIGNATURE	EMPLOYEE(S) NAME AND TITLE (*Print or Type*)	DATE ISSUED
	CRC	Cheryl Clausen, Investigator Joel Hustedt, Investigator	08/03/2018

DEPARTMENT OF HEALTH AND HUMAN SERVICES
FOOD AND DRUG ADMINISTRATION

DISTRICT OFFICE ADDRESS AND PHONE NUMBER	DATE(S) OF INSPECTION
Food and Drug Administration, ORA OPQO HQ 12420 Parklawn Drive, RM 2032 Rockville, MD 20857 Industry Information: www.fda.gov/oc/industry	07/23/2018 - 07/28/2018, 07/30/2018-08/03/2018 **FEI NUMBER** 3003885745

NAME AND TITLE OF INDIVIDUAL TO WHOM REPORT IS ISSUED

TO: Mr. Jun Dun, Executive Vice President

FIRM NAME	STREET ADDRESS
Zhejiang Huahai Pharmaceutical Co., Ltd.	Coastal Industrial Zone, Chuannan No. 1 Branch
CITY, STATE AND ZIP CODE	**TYPE OF ESTABLISHMENT INSPECTED**
Linhai, Zhejiang Province 317016 China	manufacturer

PRODUCTION SYSTEM

OBSERVATION 11

Production deviations are not always reported and evaluated and critical deviations are not always investigated and the conclusions recorded. Specifically,

a) your production operators do not always follow batch production instructions for critical processing parameters. At approximately (b) (4) on July 24, 2018, the temperature monitor for (b) (4) II-201 used in the manufacture of (b) (4) crude (b) (4) batch (b) (4) displayed (b) (4) degrees C. The manufacturing batch record for (b) (4) crude (b) (4) showed the manufacturing process for intermediate (b) (4) from chemical synthesis (b) (4) step was at step (b) (4) in the manufacturing process. The batch record identifies the parameters for this step as (b) (4) °C -(b) (4) °C maintained for (b) (4) The batch record also identifies this (b) (4) time duration as critical. The previous batch record entry recorded at (b) (4) lists a temperature of (b) (4) °C. The temperature for step (b) (4) is controlled by a manual (b) (4)

b) on July 25, 2018 in workshop (b) (4) a production employee was observed recording a value of (b) (4) liters for the amount of (b) (4) at step (b) (4) in the batch manufacturing record during the production of crude (b) (4) batch (b) (4) The flowmeter for the (b) (4) displayed a value of (b) (4) A production operator in Workshop (b) (4) stated (b) (4) equates to (b) (4) liters. The specification for (b) (4) at step (b) (4) in the batch manufacturing record for crude (b) (4) is (b) (4) +/- (b) (4) L.

SEE REVERSE OF THIS PAGE	EMPLOYEE(S) SIGNATURE	EMPLOYEE(S) NAME AND TITLE (*Print or Type*)	DATE ISSUED
	Cheryl Clausen	Cheryl Clausen, Investigator Joel Hustedt, Investigator	08/03/2018

JS 44 (Rev. 08/18)

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

LOREN LEWIS, individually and on behalf of a class of similarly situated individuals

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

(c) Attorneys *(Firm Name, Address, and Telephone Number)*
Robert A. Cox, Esq. and Edwin E. Wallis III, Esq.
Glassman, Wyatt, Tuttle & Cox, P.C.
26 N. 2nd Street, Memphis, TN 38103; (901) 527-4673

DEFENDANTS

ZHEJIANG HUAHAI PHARMACEUTICAL, CO., LTD., a Chinese corporation and HUAHAI US, INC., a New Jersey corporation

County of Residence of First Listed Defendant China
(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
- ❒ 110 Insurance
- ❒ 120 Marine
- ❒ 130 Miller Act
- ❒ 140 Negotiable Instrument
- ❒ 150 Recovery of Overpayment & Enforcement of Judgment
- ❒ 151 Medicare Act
- ❒ 152 Recovery of Defaulted Student Loans (Excludes Veterans)
- ❒ 153 Recovery of Overpayment of Veteran's Benefits
- ❒ 160 Stockholders' Suits
- ❒ 190 Other Contract
- ❒ 195 Contract Product Liability
- ❒ 196 Franchise

TORTS

PERSONAL INJURY
- ❒ 310 Airplane
- ❒ 315 Airplane Product Liability
- ❒ 320 Assault, Libel & Slander
- ❒ 330 Federal Employers' Liability
- ❒ 340 Marine
- ❒ 345 Marine Product Liability
- ❒ 350 Motor Vehicle
- ❒ 355 Motor Vehicle Product Liability
- ❒ 360 Other Personal Injury
- ❒ 362 Personal Injury - Medical Malpractice

PERSONAL INJURY
- ☒ 365 Personal Injury - Product Liability
- ❒ 367 Health Care/ Pharmaceutical Personal Injury Product Liability
- ❒ 368 Asbestos Personal Injury Product Liability

PERSONAL PROPERTY
- ❒ 370 Other Fraud
- ❒ 371 Truth in Lending
- ❒ 380 Other Personal Property Damage
- ❒ 385 Property Damage Product Liability

FORFEITURE/PENALTY
- ❒ 625 Drug Related Seizure of Property 21 USC 881
- ❒ 690 Other

BANKRUPTCY
- ❒ 422 Appeal 28 USC 158
- ❒ 423 Withdrawal 28 USC 157

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- ❒ 830 Patent
- ❒ 835 Patent - Abbreviated New Drug Application
- ❒ 840 Trademark

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- ❒ 376 Qui Tam (31 USC 3729(a))
- ❒ 400 State Reapportionment
- ❒ 410 Antitrust
- ❒ 430 Banks and Banking
- ❒ 450 Commerce
- ❒ 460 Deportation
- ❒ 470 Racketeer Influenced and Corrupt Organizations
- ❒ 480 Consumer Credit
- ❒ 485 Telephone Consumer Protection Act
- ❒ 490 Cable/Sat TV
- ❒ 850 Securities/Commodities/ Exchange
- ❒ 890 Other Statutory Actions
- ❒ 891 Agricultural Acts
- ❒ 893 Environmental Matters
- ❒ 895 Freedom of Information Act
- ❒ 896 Arbitration
- ❒ 899 Administrative Procedure Act/Review or Appeal of Agency Decision
- ❒ 950 Constitutionality of State Statutes

LABOR
- ❒ 710 Fair Labor Standards Act
- ❒ 720 Labor/Management Relations
- ❒ 740 Railway Labor Act
- ❒ 751 Family and Medical Leave Act
- ❒ 790 Other Labor Litigation
- ❒ 791 Employee Retirement Income Security Act

SOCIAL SECURITY
- ❒ 861 HIA (1395ff)
- ❒ 862 Black Lung (923)
- ❒ 863 DIWC/DIWW (405(g))
- ❒ 864 SSID Title XVI
- ❒ 865 RSI (405(g))

FEDERAL TAX SUITS
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- ❒ 871 IRS—Third Party 26 USC 7609

IMMIGRATION
- ❒ 462 Naturalization Application
- ❒ 465 Other Immigration Actions

REAL PROPERTY
- ❒ 210 Land Condemnation
- ❒ 220 Foreclosure
- ❒ 230 Rent Lease & Ejectment
- ❒ 240 Torts to Land
- ❒ 245 Tort Product Liability
- ❒ 290 All Other Real Property

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- ❒ 441 Voting
- ❒ 442 Employment
- ❒ 443 Housing/ Accommodations
- ❒ 445 Amer. w/Disabilities - Employment
- ❒ 446 Amer. w/Disabilities - Other
- ❒ 448 Education

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Habeas Corpus:
- ❒ 463 Alien Detainee
- ❒ 510 Motions to Vacate Sentence
- ❒ 530 General
- ❒ 535 Death Penalty

Other:
- ❒ 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 USC 1332

Brief description of cause:
Class Action for Multiple Causes of Action

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
10/16/2018

SIGNATURE OF ATTORNEY OF RECORD
/s/ Edwin E. Wallis, III

FOR OFFICE USE ONLY

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

UNITED STATES DISTRICT COURT

for the

Eastern District of Tennessee

LOREN LEWIS, individually and on behalf of a class of similarly situated individuals, *Plaintiff(s)* v. ZHEJIANG HUAHAI PHARMACEUTICAL CO., LTD., a Chinese corporation and HUAHAI US, INC., a New Jersey corporation, *Defendant(s)*	)	Civil Action No.

SUMMONS IN A CIVIL ACTION

To: *(Defendant's name and address)* HUAHAI US, INC.
c/o Jun Du, Registered Agent
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:

Robert A. Cox, Esq.
Edwin E. Wallis III, Esq.
Glassman, Wyatt, Tuttle & Cox, P.C.
26 N. 2nd Street
Memphis, TN 38103

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

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: