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17 **UNITED STATES DISTRICT COURT**
18 **FOR THE EASTERN DISTRICT OF CALIFORNIA**
19 **FRESNO DIVISION**

1 JOHN JUDSON AND JO ANN HAMEL, on
2 behalf of themselves and others similarly
3 situated,

4 Plaintiffs,

5 v.

6 PRINSTON PHARMACEUTICAL INC. d/b/a
7 SOLCO HEALTHCARE LLC;

8 -and-

9 SOLCO HEALTHCARE U.S., LLC;

10 -and-

11 HUAHAI US INC.;

12 -and-

13 TEVA PHARMACEUTICAL INDUSTRIES,
14 LTD.;

15 -and-

16 TEVA PHARMACEUTICALS USA, INC., a
17 Delaware corporation,

18 Defendants.

Case No. _____

CLASS ACTION COMPLAINT

1. VIOLATIONS OF CAL. CIV. CODE §§ 1750, ET SEQ.
2. COMMON LAW FRAUD, INCLUDING FRAUDULENT INDUCEMENT, AND FRAUDULENT CONCEALMENT
3. VIOLATIONS OF CAL. CIV. CODE §§ 1709, 1710
4. VIOLATIONS OF CAL. CIV. CODE §§ 1792 & 1791.1(a), ET SEQ. (implied warranty of merchantability)
5. VIOLATIONS OF CAL. CIV. CODE §§ 1792.1 & 1791.1(b), ET SEQ. (implied warranty of fitness)
6. COMMON LAW IMPLIED WARRANTY OF MERCHANTABILITY
7. COMMON LAW IMPLIED WARRANTY OF FITNESS
8. VIOLATIONS OF CAL. BUS. & PROF. CODE §§ 17200, ET SEQ.(unfair and fraudulent prongs)
9. VIOLATIONS OF CAL. BUS. & PROF. CODE §§ 17200, ET SEQ.(unlawful prong)

JURY TRIAL DEMANDED

18 This is a putative class action on behalf of Plaintiffs John Judson and Jo Ann Hamel
19 (“Plaintiffs”) and a nationwide Class and California Subclass of all similarly situated individuals
20 against Defendants Prinston Pharmaceutical Inc. d/b/a Solco Healthcare LLC and Solco Healthcare
21 U.S., LLC (together “Solco”), Huahai US Inc. (“Huahai US”), and Teva Pharmaceutical Industries,
22 Ltd. (“Teva Pharmaceutical”) and Teva Pharmaceuticals USA, Inc. (“Teva USA”) (together
23 “Teva”). Upon the investigation of counsel and, where so alleged, upon information and belief,
24 Plaintiffs allege as follows:

25 **I. NATURE OF THE CASE**

26 1. Plaintiffs bring this nationwide and California class action individually and on
27 behalf of the Class and Subclass defined below of hundreds of thousands of consumers who paid
28

1 for Defendants' generic Valsartan ("Valsartan") that was adulterated through its contamination
2 with an IARC- and EPA-listed probable human carcinogen known as N-nitrosodimethylamine
3 ("NDMA").

4 2. At all times during the period alleged herein, Defendants represented and warranted
5 to consumers that their Valsartan products were therapeutically equivalent to and otherwise the
6 same as brand Diovan®, were otherwise fit for their ordinary uses, and were otherwise
7 manufactured and distributed in accordance with applicable laws and regulations.

8 3. However, for years, Defendants willfully ignored warnings signs regarding the
9 operating standards at the Zhejiang Huahai Pharmaceuticals ("ZHP") manufacturing plant in China,
10 and continued to allow ZHP to manufacture their Valsartan products for sale to consumers in the
11 United States even after Defendants knew or should have known that their Valsartan products
12 manufactured by ZHP contained or likely contained NDMA and/or other impurities.

13 4. These adulterated Valsartan drugs were introduced into the American market at least
14 as far back as 2015 by Defendants who profited from their sale to American consumers, such as
15 Plaintiffs and Class Members. However, evidence now suggests that the contamination dates back
16 at least as far as 2012. Plaintiffs and Class Members paid for all or part of their Valsartan
17 prescriptions that were illegally introduced into the market by Defendants and which were not fit
18 for their ordinary use. Defendants have been unjustly enriched through the sale of and profit from
19 these adulterated drugs since at least 2012. Defendants' conduct also constitutes actionable
20 common law fraud, consumer fraud, and other violations of state law.

21 **II. JURISDICTION AND VENUE**

22 5. This Court has original jurisdiction pursuant to the Class Action Fairness Act, 28
23 U.S.C. § 1332(d), because (a) at least one member of the proposed class is a citizen of a state
24 different from that of Defendants, (b) the amount in controversy exceeds \$5,000,000, exclusive of
25 interest and costs, (c) the proposed class consists of more than 100 class members, and (d) none of
26 the exceptions under the subsection apply to this action. In addition, this Court has original
27 jurisdiction pursuant to 28 U.S.C. § 1331.

28 6. This Court has personal jurisdiction over Defendants because Defendants have

1 sufficient minimum contacts in California, and otherwise intentionally avails itself of the markets
2 within California through its business activities, such that the exercise of jurisdiction by this Court
3 is proper and necessary.

4 7. Venue is proper in this Court pursuant to 28 U.S.C. § 1391, because a substantial
5 part of the events or omissions giving rise to Plaintiffs' claims occurred in this District, a
6 substantial part of the property that is the subject of this action is situated in this District, and the
7 Defendants are subject to personal jurisdiction in this District.

8 **III. PARTIES**

9 8. Plaintiff John Judson is a California resident. During the class period, Judson paid
10 money for one or more of Defendants' Valsartan products. Defendants expressly and impliedly
11 warranted to Plaintiff Judson that their respective generic Valsartan products were the same as
12 brand Diovan. Had Defendants' deception about the impurities within their products been made
13 known earlier, Plaintiff Judson would not have paid for Defendants' Valsartan products.

14 9. Plaintiff Jo Ann Hamel is a California resident. During the class period, Hamel paid
15 money for one or more of Defendants' Valsartan products. Defendants expressly and impliedly
16 warranted to Plaintiff Hamel that their respective generic Valsartan products were the same as
17 brand Diovan. Had Defendants' deception about the impurities within their products been made
18 known earlier, Plaintiff Hamel would not have paid for Defendants' Valsartan products.

19 10. Defendant Prinston Pharmaceutical Inc. d/b/a Solco Healthcare LLC ("Prinston") is
20 a Delaware limited liability company with its principal place of business located at 2002 Eastpark
21 Blvd., Cranbury, New Jersey 08512. Defendant Prinston is a subsidiary of Huahai Pharmaceutical.
22 At all times material to this case, Prinston has been engaged in the manufacturing, sale, and
23 distribution of adulterated generic Valsartan in the United States, including in the State of
24 California.

25 11. Defendant Solco Healthcare U.S., LLC ("Solco U.S.") is a Delaware limited liability
26 company with its principal place of business located at 2002 Eastpark Blvd., Cranbury, New Jersey
27 08512. Defendant Solco is a subsidiary of Huahai Pharmaceutical. At all times material to this case,
28 Solco U.S. has been engaged in the manufacturing, sale, and distribution of adulterated generic

1 Valsartan in the United States, including in the State of California.

2 12. Defendant Huahai US Inc. (“Huahai US”) is a New Jersey corporation, with its
3 principal place of business located at 2002 Eastpark Blvd., Cranbury, New Jersey 08512.
4 Defendant Huahai US is a subsidiary of Huahai Pharmaceutical. At all times material to this case,
5 Huahai has been engaged in the manufacture, sale, and distribution of adulterated generic Valsartan
6 in the United States, including in the State of California.

7 13. Defendant Teva Pharmaceutical Industries Ltd. (“Teva Pharmaceutical”) is a foreign
8 company incorporated and headquartered in Peta Tikvah, Israel. Teva on its own and/or through its
9 subsidiaries regularly conducts business throughout the United States of America and its territories
10 and possessions. At all times material to this case, Teva has been engaged in the manufacturing,
11 sale, and distribution of adulterated generic Valsartan in the United States including in California.

12 14. Defendant Teva Pharmaceuticals USA, Inc. (“Teva USA”) is a Delaware
13 corporation, with its principal place of business at 1090 Horsham Road, North Wales,
14 Pennsylvania, and is a wholly owned subsidiary of Teva Pharmaceutical. Teva USA on its own
15 and/or through its subsidiaries regularly conducts business throughout the United States of America
16 and its territories and possessions. At all times material to this case, Teva USA has been engaged
17 in the manufacturing, sale, and distribution of adulterated generic Valsartan in the United States
18 including in California. Collectively, Teva Pharmaceutical and Teva USA are referred to as “Teva”
19 herein.

20 IV. FACTUAL ALLEGATIONS

21 A. Valsartan Background

22 15. Valsartan is a potent, orally active nonpeptide tetrazole derivative which, when
23 injected, causes a reduction in blood pressure, and is used in the treatment of hypertension, heart
24 failure, and post-myocardial infarction.

25 16. Valsartan is the generic version of the registered listed drug (“RLD”) DIOVAN®
26 (“Diovan”), which was marketed in tablet form by Novartis AG (“Novartis”) beginning in July 2001
27 upon approval by the U.S. Food and Drug Administration (“FDA”).

28 17. Diovan® was an immensely popular drug. Globally, Diovan® generated \$5.6 billion

1 in sales in 2011 according to Novartis’s Form 20-F for that year, of which \$2.33 billion was from
2 the United States.

3 18. Diovan’s FDA-approved label specifies its active and inactive ingredients. NDMA
4 is not an FDA-approved ingredient of Diovan. Nor is NDMA an FDA-approved ingredient of any
5 generic Valsartan product.

6 19. Although Novartis’s Diovan® patents expired in September 2012, Novartis was
7 spared generic competition until approximately June 2014 because Ranbaxy Pharmaceuticals (the
8 generic exclusivity holder) was unable to achieve FDA approval for its generic Diovan, thus
9 effectively preventing other generic competition under the Hatch-Waxman Act, until Ranbaxy
10 achieved FDA approval and began to market its generic product.

11 **B. The Generic Drug Approval Framework**

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

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

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

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

1 24. In other words, generic drug manufacturers have an ongoing federal duty of
2 sameness in their products. Under 21 U.S.C. § 355(j), the generic manufacturer must show the
3 following things as relevant to this case: the active ingredient(s) are the same as the RLD,
4 § 355(j)(2)(A)(ii); and, that the generic drug is “bioequivalent” to the RLD and “can be expected to
5 have the same therapeutic effect,” *id.* at (A)(iv). A generic manufacturer (like a brand
6 manufacturer) must also make “a full statement of the composition of such drug” to the FDA. *Id.* at
7 (A)(vi); *see also* § 355(b)(1)(C).

8 25. And finally, a generic manufacturer must also submit information to show that the
9 “labeling proposed for the new drug is the same as the labeling approved for the [RLD][.]” 21
10 U.S.C. § 355(j)(2)(A)(v).

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

17 27. According to the FDA, there are fifteen Abbreviated New Drug Applications
18 (“ANDAs”) approved for generic Diovan, *i.e.*, Valsartan.

19 **C. Background on Current Good Manufacturing Practices (“cGMPs”)**

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

23 29. The FDA’s cGMP regulations are found in 21 C.F.R. Parts 210 and 211. These
24 detailed regulations set forth minimum standards regarding: organization and personnel (Subpart
25 B); buildings and facilities (Subpart C); equipment (Subpart D); control of components and drug
26 product containers and closures (Subpart E); production and process controls (Subpart F);
27 packaging and label controls (Subpart G); holding and distribution (Subpart H); laboratory controls
28 (Subpart I); records and reports (Subpart J); and returned and salvaged drug products (Subpart K).

1 The FDA has worldwide jurisdiction to enforce these regulations if the facility is making drugs
2 intended to be distributed in the United States.

3 30. Any drug not manufactured in accordance with cGMPs is deemed “adulterated” and
4 may not be distributed or sold in the United States. *See* 21 U.S.C. §§ 331(a), 351(a)(2)(B). Drugs
5 are deemed to be adulterated if the manufacturer fails to comply with cGMPs to assure the drugs’
6 safety, quality, purity, identity, and strength and/or if they are contaminated. *See* 21 U.S.C. §
7 351(a)(2)(A), (B). Federal law prohibits a manufacturer from directly or indirectly causing
8 adulterated drugs to be introduced or delivered for introduction into interstate commerce. *See id.* §
9 331(a). States have enacting laws adopting or mirroring these federal standards.

10 31. Per federal law, cGMPs include “the implementation of oversight and controls over
11 the manufacture of drugs to ensure quality, including managing the risk of and establishing the
12 safety of raw materials, materials used in the manufacturing of drugs, and finished drug products.”
13 21 U.S.C. § 351(j). Accordingly, it is a cGMP violation for a manufacturer to contract out
14 prescription drug manufacturing without sufficiently ensuring continuing quality of the
15 subcontractors’ operations.

16 32. Indeed FDA regulations require a “quality control unit” to independently test drug
17 products manufactured by another company on contract:

18 (a) There shall be a quality control unit that shall have the responsibility
19 and authority to approve or reject all components, drug product
20 containers, closures, in-process materials, packaging material, labeling,
21 and drug products, and the authority to review production records to
22 assure that no errors have occurred or, if errors have occurred, that they
23 have been fully investigated. The quality control unit shall be
24 responsible for approving or rejecting drug products manufactured,
25 processed, packed, or held under contract by another company.

26 21 C.F.R. § 211.22(a).

27 **D. The Zhejiang Huahai Pharmaceuticals (“ZHP”) Manufacturing Facilities**

28 33. Zhejiang Huahai Pharmaceuticals (“ZHP”) is a subsidiary of Huahai
Pharmaceutical, which is also the corporate parent of Defendants Prinston, Huahai US, and Solco.
ZHP has Active Pharmaceutical Ingredient (“API”) manufacturing facilities is located in Linhai
City, Zhejiang Province, China. According to ZHP’s website, ZHP was one of the first Chinese

1 companies approved to sell generic drugs in the United States, and it remains one of China's largest
2 exporters of pharmaceuticals to the United States and European Union.

3 34. ZHP serves as a contract manufacturer of Defendants' Valsartan products (including
4 Defendant Teva's Valsartan products), and Defendants thus have a quality assurance obligation
5 with respect to ZHP's processes and finished products as set forth above pursuant to federal law.

6 35. ZHP has a history of deviations from FDA's cGMP standards that began almost as
7 soon as ZHP was approved to export pharmaceuticals to the United States.

8 36. On or about March 27-30, 2007, the FDA inspected ZHP's Linhai City facilities.
9 That inspection revealed "deviations from current good manufacturing processes (CGMP)" at the
10 facility. Those deviations supposedly were later corrected by ZHP. The results of the inspection
11 and the steps purportedly taken subsequent to it were not made fully available to the public.

12 37. On May 15-19, 2017, FDA again inspected ZHP's Linhai City facilities. That
13 inspection resulted the FDA's finding that ZHP repeatedly re-tested out of specification ("OOS")
14 samples until obtaining a desirable result. This practice allegedly dated back to at least September
15 2016 per the FDA's letter at the time. The May 2017 inspection also resulted in FDA's finding that
16 "impurities occurring during analytical testing are not consistently documented/quantitated[.]"
17 These findings were not made fully available to the public.

18 38. Furthermore, for OOS sampling results, ZHP routinely invalidated these results
19 without conducting any kind of scientific investigation into the reasons behind the OOS sample
20 result. In fact, in one documented instance, the OOS result was attributed to "pollution" in the
21 environment surrounding the facility. These are disturbing signs of systematic data manipulation
22 designed to intentionally conceal and recklessly disregard the presence of harmful impurities such
23 as NDMA.

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

1 **E. Defendants Were Aware of Potential NDMA Contamination As Early As 2012**

2 40. Upon information and belief, ZHP changed its Valsartan manufacturing processes in
3 or about 2012, if not earlier.

4 41. According to the European Medicines Agency (“EMA”) – which has similar
5 jurisdiction to that of the FDA – “NDMA was an unexpected impurity believed to have formed as
6 a side product after Zhejiang Huahai introduced changes to its manufacturing process in 2012.”¹

7 42. NDMA is yellow, oily liquid with a faint, characteristic odor and a sweet taste, and
8 is often produced as a by-product of industrial manufacturing processes.

9 43. The World Health Organization’s (“WHO”) International Agency for Research on
10 Cancer (“IARC”) classifies NDMA as one of sixty-six (66) agents that are “probably carcinogenic
11 to humans” (Classification 2A).

12 44. The U.S. Environmental Protection Agency has likewise classified NDMA as a
13 probable human carcinogen by giving it a “B2” rating, meaning that it is “probably carcinogenic to
14 humans” with little or no human data.

15 45. Anecdotally, NDMA has also been used in intentional poisonings.²

16 46. Most assuredly, NDMA is not an FDA-approved ingredient for branded Diovan® or
17 generic Valsartan. None of Defendants’ Valsartan products (or any Valsartan product, for that
18 matter) identifies NDMA as an ingredient on the products’ labels or elsewhere.

19 47. If Defendants had not routinely disregarded the FDA’s cGMPs and deliberately
20 manipulated and disregarded sampling data suggestive of impurities, or had fulfilled their quality
21 assurance obligations, Defendants would have found the NDMA contamination almost
22 immediately.

23 48. 21 C.F.R. § 211.110 contains the cGMPs regarding the “Sampling and testing of in-
24 process materials and drug products[.]” Subsection (c) states the following:

25 _____
26 ¹ See European Medicines Agency, UPDATE ON REVIEW OF RECALLED VALSARTAN MEDICINES, at
27 http://www.ema.europa.eu/ema/index.jsp?curl=pages/news_and_events/news/2018/08/news_detail_003000.jsp&mid=WC0b01ac058004d5c1 (last accessed Aug. 31, 2018).

28 ² See Quartz, A COMMON BLOOD-PRESSURE MEDICINE IS BEING RECALLED BECAUSE OF A TOXIC INGREDIENT, <https://qz.com/1330936/the-fda-is-recalling-a-common-blood-pressure-drug-because-it-was-mixed-with-ndma/> (last accessed Aug. 31, 2018).

1 In-process materials shall be tested for identity, strength, quality, and
2 purity as appropriate, and approved or rejected by the quality control
unit, during the production process, e.g., at commencement or
3 completion of significant phases or after storage for long periods.

4 21 C.F.R. § 211.110(c).

5 49. And as reproduced above, Defendants' own quality control units are and were
6 responsible for approving or rejecting drug products manufactured, processed, packed, or held
under contract by ZHP.

7 50. If these sampling-related and quality-control-related cGMPs were properly observed
8 by Defendants and ZHP, the NDMA contamination in Defendants' Valsartan products would have
9 been discovered in 2012. Defendants were thus on (at minimum) constructive notice that their
10 Valsartan products were adulterated as early as 2012.

11 51. However, there are indications that Defendants and ZHP had actual knowledge of
12 Valsartan's contamination with NDMA, and made efforts to conceal or destroy the evidence.

13 52. As alleged above, FDA investigators visited ZHP's facilities in May 2017. In the
14 words of FDA inspectors, ZHP "invalidat[ed] [OOS] results [without] scientific justification" and
15 did not implement "appropriate controls ... to ensure the integrity of analytical testing" and
16 routinely disregarded sampling anomalies suggestive of impurities.

17 53. These discoveries by the FDA's investigators suggest that ZHP and Defendants
18 were specifically aware of impurities in the drugs being manufactured by ZHP, including
19 specifically contamination of Defendants' Valsartan with NDMA. The efforts to manipulate data
20 constituted an explicit effort to conceal and destroy evidence and to willfully and recklessly
21 introduce adulterated Valsartan into the U.S. market.

22 54. Defendants were also specifically aware of the manufacturing issues at ZHP based
23 on Defendants' awareness of cGMP violations as early as 2012 based on their own monitoring of
24 ZHP and of the Valsartan products being manufactured at ZHP, and based on the FDA's
25 inspections of ZHP's facilities in March 2007 and May 2017.

26 55. Indeed, Defendant Solco and ZHP (as well as Huahai US) are owned by the same
27 corporate parent, Huahai Pharmaceutical, and Solco was specifically aware, or should be imputed
28 with actual knowledge, of ZHP's willful deviations from cGMPs. Solco and Huahai US have

1 offices in the same office building in Cranbury, New Jersey.

2 56. And yet, Defendants knowingly, recklessly, and/or negligently introduced
3 adulterated Valsartan into the U.S. market that was contaminated with NDMA. Defendants failed to
4 recall their generic Valsartan products because they feared permanently ceding market share to
5 competitors. And, upon information and belief, Defendants issued the “voluntary” recall of their
6 Valsartan products only after the FDA had threatened an involuntary recall.

7 **F. FDA Announces Voluntary Recall of Defendants’ Adulterated Valsartan**

8 57. On or about July 13, 2018, the FDA announced voluntary recalls by Defendants and
9 other manufacturers for their Valsartan products manufactured by ZHP.³ The recall is for products
10 distributed as early as October 2015. However, as alleged above, it is likely that Defendants’
11 Valsartan manufactured 2012 and beyond was also contaminated with NDMA.

12 58. On or about July 27, 2018, the FDA announced expanded recalls of additional
13 Valsartan products manufactured by Defendants and non-parties, and re-packaged by third parties.⁴

14 59. As stated in the FDA’s July 13, 2018 statement:

15 The U.S. Food and Drug Administration is alerting health care
16 professionals and patients of a voluntary recall of several drug products
17 containing the active ingredient valsartan, used to treat high blood
18 pressure and heart failure. This recall is due to an impurity, N-
19 nitrosodimethylamine (NDMA), which was found in the recalled
20 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.

21 **G. Defendants’ Warranties and Fraudulent and Deceptive Statements to Consumers
22 Regarding Their Generic Valsartan Products**

23 60. Each Defendant made and breached express and implied warranties and also made
24 affirmative misrepresentations and omissions to consumers about their adulterated Valsartan
25 products.

26 ³ FDA News Release, FDA ANNOUNCES VOLUNTARY RECALL OF SEVERAL MEDICINES CONTAINING
27 VALSARTAN FOLLOWING DETECTION OF IMPURITY, *at*
<https://www.fda.gov/NewsEvents/Newsroom/PressAnnouncements/ucm613532.htm> (last accessed
28 Aug. 31, 2018).

⁴ FDA News Release, FDA UPDATES ON VALSARTAN RECALLS, *at*
<https://www.fda.gov/Drugs/DrugSafety/ucm613916.htm> (last accessed Aug. 31, 2018).

1 61. The FDA maintains a list of “Approved Drug Products with Therapeutic
2 Equivalence Evaluations” commonly referred to as the Orange Book.⁵ The Orange Book is a
3 public document; Defendants sought and received the inclusion of their products in the Orange
4 Book upon approval of their Valsartan ANDAs. In securing FDA approval to market generic
5 Valsartan in the United States as an Orange Book-listed therapeutic equivalent to Diovan,
6 Defendants were required to demonstrate that their generic Valsartan products were bioequivalent
7 to brand Diovan.

8 62. Therapeutic equivalence for purposes of generic substitution is a continuing
9 obligation on the part of the manufacturer. For example, according to the FDA’s Orange Book,
10 therapeutic equivalence depends in part on the manufacturer’s continued compliance with cGMPs.

11 63. By introducing their respective Valsartan products into the United States market
12 under the name “Valsartan” as a therapeutic equivalent to Diovan® and with the FDA-approved
13 label that is the same as that of Diovan, Defendants represent and warrant to end users that their
14 products are in fact the same as and are therapeutically interchangeable with Diovan.

15 64. Furthermore, Defendant Solco states on its “About Solco” page of its website that
16 “[b]y using the same active ingredients, [Solco] produce[s] products which are identical
17 (equivalent) to the branded medication.”⁶

18 65. On the “Drug Safety” page of Solco’s website, Solco states that “Solco Healthcare is
19 committed in providing ... its patients with high quality, FDA-approved generic medications.”⁷

20 66. Defendant Solco lists its Valsartan products on its website with the statement that
21 the “Reference Listed Drug” is “Diovan®” along with a link to download Solco’s Valsartan
22 Prescribing Information.⁸ Clicking the “Prescribing Information” link loads a .pdf of the
23 Prescribing Information with a Solco URL address

24 ⁵ FDA, APPROVED DRUG PRODUCTS WITH THERAPEUTIC EQUIVALENCE EVALUATIONS (ORANGE
25 BOOK) SHORT DESCRIPTION, at <https://www.fda.gov/drugs/informationondrugs/approveddrugs/approveddrugproductswiththerapeutic-equivalenceevaluationsorangebook/default.htm> (last accessed Aug. 31, 2018).

26 ⁶ Solco, OVERVIEW, at <http://solcohealthcare.com/about-solco.html> (last accessed Aug. 31, 2018).

27 ⁷ Solco, TRADE PARTNER INFORMATION, at <http://solcohealthcare.com/trade-partner-information.html#DrugSafety> (last accessed Aug. 31, 2018).

28 ⁸ Solco, VALSARTAN TABLETS, at <http://www.solcohealthcare.com/product/valsartan-tablets#NDC-43547-367-03> (last accessed Aug. 31, 2018).

1 (http://www.solcohealthcare.com/uploads/product/info/valsartan-pi-artwork_170524_141555.pdf).

2 67. Defendant Teva has a “Generics FAQs” on its website.⁹ In response to the question
3 “Are generic drugs safe?” Defendant Teva states the following:

4 A generic drug is bioequivalent to the original innovative drug and
5 meets the same quality standards. The active ingredient, the content, the
6 dosage form and the usage of a generic drug are similar to those of an
7 innovative drug. Generic drugs are essentially the same as the original
8 drug, but are offered at a lower price.

9 68. In response to the question “How do you ensure generic drug safety, having tried it
10 in only a limited number of patients?” Defendant Teva states the following:

11 The generic product's active pharmaceutical ingredient (API) is
12 identical to that of the innovative drug, its purity profile is similar and it
13 is found to be bioequivalent; therefore its safety and efficacy are also
14 comparable.

15 69. Similarly, under the webpage titled “Uncompromising Quality,” Teva states that it
16 knows that its products affect patient health. Teva further states that it “guarantee[s] the quality of
17 our products” through Teva’s “impeccable adherence to ... [cGMPs][.]”

18 70. Each Defendant’s Valsartan product is accompanied by an FDA-approved label. By
19 presenting consumers with an FDA-approved Valsartan label, Defendants, as generic
20 manufacturers of Valsartan, made representations and express or implied warranties to consumers
21 of the “sameness” of their products to Diovan, and that their products were consistent with the
22 safety, quality, purity, identity, and strength characteristics reflected in the FDA-approved labels
23 and/or were not adulterated.

24 71. In addition, on information and belief, each Defendant affirmatively misrepresented
25 and warranted to consumers through their websites, brochures, and other marketing or
26 informational materials that their Valsartan product complied with cGMPs and did not contain (or
27 were not likely to contain) any ingredients besides those identified on the products’ FDA-approved
28 labels.

72. 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

⁹ Teva, PRODUCTS, at http://www.tevapharm.com/our_products/generic_qa/ (last accessed Aug. 31, 2018).

1 interchangeable with Diovan, thus breaching Defendants' express warranties of sameness; (2) was
2 the result of gross deviations from cGMPs thus rendering Defendants' Valsartan products non-
3 therapeutically equivalent to Diovan®, and breaching Defendants' express warranties of sameness;
4 and (3) results in Defendants' Valsartan containing an ingredient that is not contained in Diovan®,
5 also breaching Defendants' express warranty of sameness (and express warranty that the products
6 contained the ingredients listed on each Defendant's FDA-approved label). Each Defendant
7 willfully, recklessly, and/or negligently failed to ensure their Valsartan products' labels and other
8 advertising or marketing statements accurately conveyed information about their products.

9 73. At all relevant times, Defendants have also impliedly warranted that their Valsartan
10 products were merchantable and/or fit for their ordinary purposes.

11 74. Naturally, due to its status as a probable human carcinogen as listed by both the
12 IARC and the U.S. EPA, NDMA is not an FDA-approved ingredient in Valsartan. The presence of
13 NDMA in Defendants' Valsartan means that Defendants have violated implied warranties to
14 Plaintiffs and Class Members. The presence of NDMA in Defendants' Valsartan results in
15 Defendants' Valsartan products being non-merchantable and not fit for its ordinary purposes (i.e.,
16 as a therapeutically interchangeable generic version of Diovan), breaching Defendants' implied
17 warranty of merchantability and/or fitness for ordinary purposes.

18 75. For these and other reasons, Defendants' Valsartan is therefore adulterated and it
19 was illegal for Defendants' to have introduced such Valsartan for sale and distribution in the United
20 States. *See* 21 U.S.C. §§ 331(a), 351(a)(2)(B).

21 76. Adulterated Valsartan is essentially worthless. No consumer would knowingly
22 purchase an adulterated Valsartan product. Indeed, the purchase of adulterated Valsartan product is
23 not allowed because it was illegally introduced into the United States. This is especially so given
24 that alternative, non-adulterated Valsartan products or competing medications with the same
25 approved indications were available from other manufacturers.

26 **H. New Revelations Continue to Unfold About Other Manufacturing Plants**

27 77. The recall of Defendants' Valsartan products is only the tip of the iceberg. Just two
28 weeks after the FDA's initial recall announcement, the FDA issued another announcement

1 expanding the recall to other Valsartan products manufactured at another plant in India, and by
2 other non-parties. *See supra* n.4. On August 20, 2018 the FDA announced that it was going to test
3 all Valsartan products for NDMA.¹⁰ Because of Defendants' and non-parties' ongoing fraud and
4 deception, the full scope of Defendants' and non-parties' unlawful conduct is not yet known.

5 **I. Fraudulent Concealment and Tolling**

6 78. Plaintiffs' and Class Members' causes of action accrued on the date the FDA
7 announced the recall of Defendants' generic Valsartan products.

8 79. Alternatively, any statute of limitation or prescriptive period is equitably tolled
9 Defendants' fraudulent concealment. Defendants each affirmatively concealed from Plaintiffs and
10 other Class Members their unlawful conduct. Each Defendant affirmatively strove to avoid
11 disclosing their knowledge of ZHP's cGMP violations with respect to Valsartan, and of the fact that
12 their Valsartan products were adulterated and contaminated with NDMA, and were not the same as
13 brand Diovan.

14 80. For instance, no Defendant revealed to the public that their Valsartan product
15 contained NDMA or was otherwise adulterated or non-therapeutically equivalent to Diovan® until
16 the FDA's recall announcement in July 2018. The inspection report which preceded the recall
17 announcement was heavily redacted (including the names of the drugs affected by ZHP's cGMP
18 violations), and prior inspection reports or warnings were not fully available to the public, if at all.

19 81. To the contrary, each Defendant continued to represent and warrant that their
20 generic Valsartan products were the same as and therapeutically interchangeable with Diovan.

21 82. For instance, Huahai US publicly announced on its website that, contrary to the
22 FDA's pronouncements, that no impurity was discovered until June 2018.¹¹

23 83. Because of this, Plaintiffs and other Class Members did not discover, nor would they
24 discover through reasonable and ordinarily diligence, each Defendant's deceptive, fraudulent, and
25 unlawful conduct alleged herein. Defendants' false and misleading explanations, or obfuscations,
26

27 ¹⁰ FDA Statement, STATEMENT FROM FDA COMMISSIONER, at
<http://freepdfhosting.com/1c7e5ed26e.pdf> (last accessed Aug. 31, 2018).

28 ¹¹ Huahai US, PRESS RELEASE – UPDATE ON VALSARTAN API – A STATEMENT FROM THE COMPANY, at
<https://www.huahaius.com/media.html> (last accessed Aug. 31, 2018).

1 lulled Plaintiffs and Class Members into believing that the prices paid for Valsartan were
2 appropriate for what they believed to be non-adulterated drugs despite their exercise of reasonable
3 and ordinary diligence.

4 84. As a result of each Defendant's affirmative and other acts of concealment, any
5 applicable statute of limitations affecting the rights of Plaintiffs and other Class Members has been
6 tolled. Plaintiffs and/or other Class Members exercised reasonable diligence by among other things
7 promptly investigating and bringing the allegations contained herein. Despite these or other efforts,
8 Plaintiffs were unable to discover, and could not have discovered, the unlawful conduct alleged
9 herein at the time it occurred or at an earlier time so as to enable this complaint to be filed sooner.

10 **J. Plaintiffs' Factual Allegations**

11 85. Plaintiff John Judson is a resident of Mountain House, California.

12 86. On or about May 14, 2018, Plaintiff Judson filled a 90-day prescription for
13 Valsartan manufactured by the Solco Defendants and paid a co-pay. Upon information and belief,
14 Plaintiff Judson filled additional Valsartan prescriptions during the Class Period manufactured by
15 one or both of the Solco and Teva Defendants.

16 87. The generic Valsartan purchased by Plaintiff Judson manufactured by the Solco
17 and/or Teva Defendants on May 14, 2018 and at other times during the Class Period was not
18 therapeutically equivalent to brand Diovan®, was manufactured out of compliance with cGMPs,
19 and was adulterated by its contamination with NDMA.

20 88. The Solco Defendants and/or Teva Defendants' generic Valsartan was sold illegally
21 to Plaintiff Judson.

22 89. Plaintiff Jo Ann Hamel is a resident of Merced, California.

23 90. On or about the following dates, Plaintiff Hamel purchased the Teva Defendants'
24 generic Valsartan products and paid the listed co-pay amounts:

- | | | |
|----|-------------------------------|-------------------------------|
| 25 | • March 17, 2014 (\$10.60) | • November 30, 2015 (\$25.20) |
| 26 | • June 17, 2014 (\$12.33) | • February 5, 2016 (\$22.26) |
| 27 | • February 7, 2015 (\$10.59) | • April 15, 2016 (\$22.26) |
| 28 | • March 13, 2015 (\$28.78) | • July 27, 2016 (\$22.32) |
| | • May 15, 2015 (\$28.78) | • October 26, 2016 (\$21.65) |
| | • September 2, 2015 (\$28.78) | • February 13, 2017 (\$22.04) |

- May 25, 2017 (\$26.61)
- August 22, 2017 (\$26.61)
- November 16, 2017 (\$21.40)
- February 12, 2018 (\$21.40)
- April 16, 2018 (\$7.88)
- May 21, 2018 (\$7.88)
- July 10, 2018 (\$21.40)

91. The generic Valsartan purchased by Plaintiff Hamel manufactured by the Solco and/or Teva Defendants during the Class Period was not therapeutically equivalent to brand Diovan®, was manufactured out of compliance with cGMPs, and was adulterated by its contamination with NDMA.

92. The Solco Defendants and/or Teva Defendants' generic Valsartan was sold illegally to Plaintiff Hamel.

V. CLASS ACTION ALLEGATIONS

93. Plaintiffs bring this action both individually and as a class action pursuant to Fed. R. Civ. P. 23(a), 23(b)(2) and 23(b)(3) against Defendants on their own behalf and on behalf of a Nationwide Class defined below:

All individuals in the United States of America and its territories and possessions who, since at least January 1, 2012, paid any amount of money out of pocket (for personal or household use) for Valsartan product manufactured by or for Defendants.

94. In the alternative, Plaintiffs allege Sub-Classes for all individuals in each State, territory, or possession including specifically the State of California who, since at least January 1, 2012, paid any amount of money out of pocket (for personal or household use) for Valsartan product manufactured by or for Defendants. Collectively, the foregoing Nationwide Class and alternative California Sub-Class and other state sub-classes are referred to as the "Class."

95. Excluded from the Class and Sub-Class[es] are: (a) any Judge or Magistrate presiding over this action, and members of their families; (b) Defendants and affiliated entities, and their employees, officers, directors, and agents; (c) Defendants' legal representatives, assigns and successors; and (d) all persons who properly execute and file a timely request for exclusion from any Court-approved class.

96. Plaintiffs reserve the right to narrow or expand the foregoing class definition, or to create further sub-classes as the Court deems necessary.

1 97. Plaintiffs meet the prerequisites of Rule 23(a) to bring this action on behalf of the
2 Class and Sub-Class[es].

3 98. **Numerosity:** While the exact number of Class Members cannot be determined
4 without discovery, they are believed to consist of potentially millions of Valsartan consumers
5 nationwide. The Class Members are therefore so numerous that joinder of all members is
6 impracticable.

7 99. **Commonality:** Common questions of law and fact exist as to all Class Members,
8 including but not limited to:

- 9 a. Whether each Defendant made express or implied warranties of “sameness” to
10 Plaintiffs and Class Members regarding Defendants’ Valsartan products;
- 11 b. Whether each Defendant’s Valsartan product was in fact the same as brand Diovan®
12 consistent with such express or implied warranties;
- 13 c. Whether each Defendant’s Valsartan product was contaminated with NDMA;
- 14 d. Whether each Defendant’s Valsartan product containing NMDA was adulterated;
- 15 e. Whether Defendants violated cGMPs regarding the manufacture of their Valsartan
16 products;
- 17 f. Whether each Defendant affirmatively misrepresented or omitted facts that its
18 Valsartan product was the same as brand Diovan® and thus therapeutically
19 interchangeable;
- 20 g. Whether each Defendant affirmatively misrepresented or omitted facts regarding its
21 compliance with cGMPs and/or was not adulterated;
- 22 h. Whether Plaintiffs and other Class Members have been injured as a result of each
23 Defendant’s unlawful conduct, and the amount of damages;
- 24 i. Whether a common damages model can calculate damages on a classwide basis;
- 25 j. When Plaintiffs’ and Class Members’ causes of action have accrued;
- 26 k. Whether Defendants fraudulently concealed Plaintiffs’ and Class Members’ causes
27 of action.

28 100. **Typicality:** Plaintiffs’ claims are typical of Class Members’ claims. Plaintiffs and

1 Class Members all suffered the same type of economic harm. Plaintiffs have substantially the same
2 interest in this matter as all other Class Members, and their claims arise out of the same set of facts
3 and conduct as all other Class Members.

4 101. **Adequacy of Representation:** Plaintiffs are committed to pursuing this action and
5 have retained competent counsel experienced in pharmaceutical litigation, consumer fraud
6 litigation, class action, and federal court litigation. Accordingly, Plaintiffs and their counsel will
7 fairly and adequately protect the interests of Class Members. Plaintiffs' claims are coincident with,
8 and not antagonistic to, those of the other Class Members they seek to represent. Plaintiffs have no
9 disabling conflicts with Class Members and will fairly and adequately represent the interests of
10 Class Members.

11 102. The elements of Rule 23(b)(2) are met. Defendants have acted on grounds that apply
12 generally to Class Members so that preliminary and/or final injunctive relief and corresponding
13 declaratory relief is appropriate as to the Class as a whole.

14 103. The elements of Rule 23(b)(3) are met. Here, the common questions of law and fact
15 enumerated above predominate over the questions affecting only individual Class Members, and a
16 class action is the superior method for fair and efficient adjudication of the controversy. Although
17 many other Class Members have claims against Defendants, the likelihood that individual Class
18 Members will prosecute separate actions is remote due to the time and expense necessary to
19 conduct such litigation. Serial adjudication in numerous venues is furthermore not efficient, timely
20 or proper. Judicial resources will be unnecessarily depleted by resolution of individual claims.
21 Joinder on an individual basis of thousands of claimants in one suit would be impractical or
22 impossible. In addition, individualized rulings and judgments could result in inconsistent relief for
23 similarly situated Plaintiffs. Plaintiffs' counsel, highly experienced in pharmaceutical litigation,
24 consumer fraud litigation, class actions, and federal court litigation, foresee little difficulty in the
25 management of this case as a class action.

1 (9) Advertising goods or services with intent not to sell them as
2 advertised;

3 (16) Representing that the subject of a transaction has been supplied in
4 accordance with a previous representation when it has not.

5 111. Defendants have violated and continue to violate the above-enumerated provisions
6 of Cal. Civ. Code. § 1770(a) by representing that their generic Valsartan products are the same as
7 brand Diovan®; and that their generic Valsartan products were distributed “as approved” by the
8 FDA. Defendants distributed their generic Valsartan products with the intent not to sell as
9 advertised (i.e., the same as brand Diovan).

10 112. Defendants have violated and continues to violate the above-enumerated provisions
11 of Cal. Civ. Code. § 1770(a) by making fraudulent omissions that were contrary to representations
12 actually made by Defendant; and, fraudulently omitting material facts Defendant was obliged to
13 disclose.

14 113. To the extent necessary, Plaintiffs and Class Members relied on such omissions.

15 114. Plaintiffs will file the declaration of venue required by Cal. Civ. C. § 1780(d).

16 115. Pursuant to Cal. Civ. Code § 1780(a), Plaintiffs currently seek restitution and an
17 order enjoining Defendants from engaging in the methods, acts, and practices alleged herein, and
18 any other relief deemed proper by the Court.

19 116. Either before or concurrent with filing the Complaint, Plaintiffs have sent or are
20 sending Defendants notice advising Defendants of their violations of Section 1770 of the CLRA
21 (the “Notice”). The Notice complied in all respects with Section 1782 of the CLRA. Plaintiffs sent
22 the Notice by Certified U.S. Mail, return-receipt requested to Defendants at Defendants’ principal
23 places of business. Plaintiffs’ Notice advised Defendants they must correct, repair, replace or
24 otherwise rectify its conduct alleged to be in violation of Section 1770. If Defendants fail to correct,
25 repair, replace or otherwise rectify the conduct alleged herein, Plaintiffs will amend this Complaint
26 to seek damages.

27 117. Pursuant to Cal. Civ. Code § 1780(e), Plaintiffs seek an award of restitution, costs
28 and attorney’s fees.

1
2 **COUNT II**
3 **COMMON LAW FRAUD, INCLUDING FRAUDULENT INDUCEMENT, AND**
4 **FRAUDULENT CONCEALMENT**
5 **(On Behalf of Plaintiffs and the Class(es))**

6 118. Plaintiffs re-allege and incorporate by reference the allegations contained in all
7 preceding paragraphs of this Complaint as though set forth fully herein.

8 119. Defendants made or caused to be made false and fraudulent representations of
9 material facts, and failed to disclose material facts, to Plaintiffs and all Class Members regarding
10 Defendants' Valsartan products.

11 120. Defendants affirmatively misrepresented material facts including, *inter alia*, that
12 their Valsartan products were therapeutically equivalent to brand Diovan® and/or complied with
13 cGMPs and/or were not adulterated.

14 121. Defendants failed to disclose material facts to render non-misleading its statements
15 about, *inter alia*, that their Valsartan products were not therapeutically equivalent to brand
16 Diovan® and/or did not comply with cGMPs and/or were adulterated.

17 122. Defendants' actions had the effect of fraudulently inducing customers to pay in
18 whole or in part for Defendants' Valsartan product – product which Defendants knew or should
19 have known was not therapeutically equivalent to brand Diovan® and/or did not comply with
20 GMPs and/or were adulterated. Plaintiffs and other Class Members would not have paid some or all
21 of the amounts they paid for Defendants' Valsartan product had they known the truth.

22 123. Defendants knew, or reasonably should have known, that their misrepresentations
23 were materially false or misleading, or that the omission of material facts rendered such
24 representations false or misleading.

25 124. Defendants also knew, or had reason to know, that their misrepresentations and
26 omissions would induce Class Members to pay for some or all of the cost of Defendants' Valsartan
27 products.

28 125. Defendants' misrepresentations and omissions were material.

126. To the extent applicable, Defendants intended their misrepresentations and
omissions to induce Plaintiffs and other Class Members to pay for Defendants' Valsartan product.

1 127. But for these misrepresentations and omissions, Plaintiffs and other Class Members
2 would not have paid for Defendants' Valsartan product.

3 128. To the extent applicable, Plaintiffs and other Class Members were justified in
4 relying on Defendants' misrepresentations and omissions. The same or substantively identical
5 misrepresentations and omissions were communicated, to each Class Member, including through
6 product labeling and other statements by Defendants. No reasonable consumer would have paid
7 what they did for Defendants' Valsartan product but-for Defendants' unlawful conduct. To the
8 extent applicable, reliance may be presumed in these circumstances.

9 129. Plaintiffs and other Class Members were damaged by reason of Defendants'
10 misrepresentations and omissions alleged herein.

11 **COUNT III**
12 **VIOLATION OF CAL. CIV. CODE §§ 1709, 1710**
13 **(Deceit by Concealment)**
14 ***(On Behalf of Plaintiffs and the Class(es))***

15 130. Plaintiffs re-allege and incorporate by reference the allegations contained in all
16 preceding paragraphs of this Complaint as though set forth fully herein.

17 131. Defendants engaged in deceit by suppressing facts that each was bound to disclose.
18 Namely, Defendants sold their generic Valsartan products to Plaintiffs and the Class and did not
19 disclose the fact that their generic Valsartan products were not the same as brand Diovan®, and
20 were in fact adulterated with NDMA and manufactured not in compliance with cGMPs.

21 132. Defendants' deceitful conduct was perpetrated with the intent to induce Plaintiffs
22 and Class Members to act in reliance thereon.

23 133. Plaintiffs and Class Members reasonably believed Defendants' representations that
24 their Valsartan products were therapeutically equivalent and interchangeable with brand Diovan®.

25 134. Plaintiffs and Class Members would not have purchased Defendants' Valsartan
26 products if the deceit had been disclosed.

27 135. As a direct and proximate result of the foregoing acts, omissions, Plaintiffs and
28 Class Members have suffered injury in fact and are entitled to restitution in an amount to be

1 determined at trial.

2
3 **COUNT IV**
4 **VIOLATION OF SONG-BEVERLY CONSUMER WARRANTY ACT FOR BREACH OF**
5 **IMPLIED WARRANTY OF MERCHANTABILITY, CAL. CIV. CODE §§ 1792 & 1791.1(a)**
6 ***(On Behalf of Plaintiffs and the Class(es))***

7 136. Plaintiffs re-allege and incorporate by reference the allegations contained in all
8 preceding paragraphs of this Complaint as though set forth fully herein.

9 137. Plaintiffs and Class Members are “retail buyers” within the meaning of §1791(b) of
10 the California Civil Code.

11 138. Defendants’ Valsartan products are “consumer goods” within the meaning of
12 §1791(a) of the California Civil Code.

13 139. Each Defendant is a “distributor”, “manufacturer”, and/or “retailer” of generic
14 Valsartan products within the meaning of §1791(e), (j), and (l) of the California Civil Code.

15 140. Defendants impliedly warranted to Plaintiffs and Class Members that their Valsartan
16 products were “merchantable” within the meaning of §§ 1791.1(a) and 1792 of the California Civil
17 Code.

18 141. Defendants breached the implied warranty of merchantability to Plaintiffs and Class
19 Members because Defendants’ Valsartan products were not manufactured in accordance with
20 Defendants’ approved ANDA, and were not the same as brand Diovan®, and because Defendants’
21 Valsartan products were adulterated with NDMA and manufactured not in compliance with
22 cGMPs. All of these failures resulted in Defendants’ Valsartan products being illegally distributed
23 in the United States, rendering them non-merchantable.

24 142. Defendants’ failure to warn Plaintiffs and Class Members of these risks was willful.

25 143. As a proximate result of Defendants’ breach of the implied warranty of
26 merchantability, Plaintiffs and Class Members sustained damages including but not limited to the
27 receipt of goods they would not have otherwise purchased and which are not fit for the ordinary
28 purpose for which they are used.

144. Pursuant to §§ 1791.1(d) and 1794 of the California Civil Code, Plaintiff Judson and

1 Hamel and Subclass Members seek and are entitled to restitution, civil penalties and other legal and
2 equitable relief including, a right of reimbursement, as well as costs, expenses and attorneys' fees.
3 Plaintiffs will amend this complaint to seek damages.

4
5 **COUNT V**
6 **VIOLATION OF SONG-BEVERLY CONSUMER WARRANTY ACT FOR BREACH OF**
7 **IMPLIED WARRANTY OF FITNESS, CAL. CIV. CODE §§ 1792.1 & 1791.1(b)**
8 ***(On Behalf of Plaintiffs and the Class(es))***

9 145. Plaintiffs re-alleges and incorporates by reference the allegations contained in all
10 preceding paragraphs of this Complaint as though set forth fully herein.

11 146. Plaintiffs and Class Members are “retail buyers” within the meaning of §1791(b) of
12 the California Civil Code.

13 147. Defendants' Valsartan products are “consumer goods” within the meaning of
14 §1791(a) of the California Civil Code.

15 148. Each Defendant is a “distributor”, “manufacturer”, and/or “retailer” of Valsartan
16 products within the meaning of §1791(e), (j), and (l) of the California Civil Code.

17 149. Defendants breached the implied warranty of merchantability to Plaintiffs and Class
18 Members because Defendants' Valsartan products were not manufactured in accordance with
19 Defendants' approved ANDA, and were not the same as brand Diovan®, and because Defendants'
20 Valsartan products were adulterated with NDMA and manufactured not in compliance with
21 cGMPs. All of these failures resulted in Defendants' Valsartan products being illegally distributed
22 in the United States, rendering them non-merchantable.

23 150. Plaintiffs and Class Members did in fact purchase Defendants' Valsartan products
24 for the particular purpose of consuming a generic version of the brand drug Diovan® as approved
25 by the FDA's ANDA process.

26 151. Plaintiffs and Class Members did in fact reasonably rely on Defendants' skill or
27 judgment to supply suitable pharmaceutical products for that purpose.

28 152. Defendants breached their implied warranty of fitness for a particular purpose and
are liable to Plaintiffs and Class Members.

153. Defendants' failure to warn Plaintiffs and Class Members was willful.

1 154. As a proximate result of Defendants’ breach of the implied warranty of fitness,
2 Plaintiffs and Class Members sustained damages including but not limited to the receipt of goods
3 they would not have otherwise purchased and which are not fit for the ordinary purpose for which
4 they are used.

5 155. Pursuant to §§ 1791.1(d) and 1794 of the California Civil Code, Plaintiffs and Class
6 Members are entitled to and hereby seek restitution, civil penalties and other legal and equitable
7 relief including, a right of reimbursement, as well as costs, expenses and attorneys’ fees. Plaintiffs
8 will amend this complaint to seek damages.

9 **COUNT VI**
10 **BREACH OF IMPLIED WARRANTY OF MERCHANTABILITY**
11 *(On Behalf of Plaintiffs and the Class(es))*

12 156. Plaintiffs re-allege and incorporate by reference the allegations contained in all
13 preceding paragraphs of this Complaint as though set forth fully herein.

14 157. Defendants are merchants within the meaning of Cal. Comm. Code § 2314.

15 158. Each Defendant’s Valsartan product constituted “goods” or the equivalent within the
16 meaning of the above statute and related provisions.

17 159. Each Defendant was obligated to provide Plaintiffs and other Class Members
18 reasonably fit Valsartan product for the purpose for which the product was sold, and to conform to
19 the standards of the trade in which Defendants are involved such that the product was of fit and
20 merchantable quality.

21 160. Each Defendant knew or should have known that its Valsartan product was being
22 manufactured and sold for the intended purpose of human consumption as a therapeutic equivalent
23 to brand Diovan®, and impliedly warranted that same was of merchantable quality and fit for that
24 purpose.

25 161. Each Defendant breached its implied warranty because each Defendant’s Valsartan
26 product was not of merchantable quality, nor fit for the product’s ordinary purpose, and did not
27 conform to the standards generally applicable to such goods.

28 162. As a direct and proximate result of each Defendant’s breach of implied warranty,
Plaintiffs and other Class Members have been injured and suffered damages, in that Defendants’

1 Valsartan product they purchased was so inherently flawed, unfit, or unmerchantable as to have
2 essentially zero, significantly diminished, or no intrinsic market value.

3 163. Plaintiffs are concurrently giving notice of Defendants' breach. Plaintiffs will amend
4 this complaint to seek damages in an amount to be determined at trial.

5 **COUNT VII**
6 **BREACH OF EXPRESS WARRANTIES**
7 ***(On Behalf of Plaintiffs and the Class(es))***

8 164. Plaintiffs re-allege and incorporate by reference the allegations contained in all
9 preceding paragraphs of this Complaint as though set forth fully herein.

10 165. Each Defendant expressly warranted that its Valsartan product was fit for its
11 ordinary use, i.e., as an FDA-approved generic pharmaceutical that is therapeutically to and
12 interchangeable with brand Diovan®. In other words, Defendants expressly warranted that their
13 products were the same as Diovan®.

14 166. Each Defendant sold Valsartan product that they expressly warranted were
15 compliant with cGMP and/or not adulterated.

16 167. Each Defendant's Valsartan product did not conform to each Defendant's express
17 representations and warranties because the product was not manufactured in compliance with
18 cGMP and/or was adulterated.

19 168. Each Defendant made express warranties regarding its Valsartan products as set
20 forth in Cal. Comm. Code § 2313.

21 169. At the time that each Defendant marketed and sold its Valsartan product, they
22 recognized the purposes for which the products would be used, and expressly warranted the
23 products were the same as brand Diovan, and cGMP compliant and/or not adulterated. These
24 affirmative representations became part of the basis of the bargain in every purchase by Plaintiffs
25 and other Class Members.

26 170. Each Defendant breached its express warranties with respect to its Valsartan product
27 as it was not of merchantable quality, was not fit for its ordinary purpose, and did not comply with
28 cGMP and/or was adulterated.

171. As a direct and proximate result of each Defendant's breach of implied warranty,

1 Plaintiffs and other Class Members have been injured and suffered damages, in that Defendants'
2 Valsartan product they purchased was so inherently flawed, unfit, or unmerchantable as to have
3 essentially zero, significantly diminished, or no intrinsic market value.

4 172. Plaintiffs are concurrently giving notice of Defendant's breach. If the violations are
5 not remedied or cured, Plaintiffs will amend this complaint to seek damages in an amount to be
6 determined at trial.

7 **COUNT VIII**
8 **VIOLATION OF CALIFORNIA UNFAIR COMPETITION LAW**
9 **CAL. BUS. & PROF. CODE § 17200, *et seq.***
10 **(“unfair” and “fraudulent” prongs)**
11 **(*On Behalf of Plaintiffs and the Class(es)*)**

12 173. Plaintiffs re-allege and incorporate by reference the allegations contained in all
13 preceding paragraphs of this Complaint as though set forth fully herein.

14 174. California Business & Professions Code section 17200 prohibits “unfair
15 competition” which includes “unfair” and “fraudulent” business practices.

16 175. Defendants engaged in unfair and fraudulent business practices by advertising,
17 marketing, and selling Valsartan products as therapeutically equivalent to and interchangeable with
18 brand Diovan® when that was not true.

19 176. Defendants engaged in unfair and fraudulent business practices by advertising,
20 marketing, and selling Valsartan products representing that their Valsartan was manufactured in
21 accordance with their respective ANDA approvals and in compliance with FDA's cGMPs.
22 However, this was factually untrue because Defendants' Valsartan products were contaminated
23 with NDMA and were not manufactured in accordance with cGMPs.

24 177. Defendants' business practices, as alleged herein, are unfair because: (1) the injury
25 to the consumer is substantial—they were charged significant sums for products that are
26 contaminated with a probable human carcinogen that was illegally distributed to them and which
27 they cannot use for their intended purpose; (2) the injury is not outweighed by any countervailing
28 benefits to consumers or competition, as there can be no benefit to consumers where they pay for a
product that is illegally manufactured and distributed to them and which is contaminated with a
probable human carcinogen; and (3) consumers could not reasonably have avoided the injury.

1 178. Defendants' business practices are also unfair because their materially false and
2 misleading advertising, marketing, promotion, and sale of their Valsartan products (namely,
3 representing they were the same as brand Diovan® and therapeutically interchangeable with brand
4 Diovan®) offends an established public policy and is immoral, unethical, oppressive, unscrupulous
5 or substantially injurious to consumers. Such public policy is tethered to a specific constitutional,
6 statutory provision, including California's consumer protection statutes, as alleged herein.

7 179. Defendants' business practices as alleged herein are fraudulent because Defendants
8 make and have made material misrepresentations and omissions in the marketing, promotion, and
9 sale of their Valsartan products. These misrepresentations and omissions by Defendants were
10 material, in that a reasonable consumer would attach importance to whether Defendants' generic
11 Valsartan products were therapeutically interchangeable with brand Diovan® and/or were free of
12 adulteration with carcinogenic substances.

13 180. Defendants' conduct is likely to deceive reasonable consumers. Indeed, reasonable
14 consumers would believe that the marketing, promotion, and sale of prescription drugs called
15 "Valsartan" carries an express assurance that Defendants' products are in fact manufactured as
16 approved by the FDA and are free of contamination and/or are therapeutically interchangeable with
17 brand Diovan®.

18 181. Plaintiffs and Class Members relied on Defendants' misrepresentations and
19 omissions of material facts. Had Defendants disclosed that their products were not manufactured in
20 accordance with the FDA approved label and/or were contaminated with NDMA and/or were not
21 therapeutically equivalent to brand Diovan, Plaintiffs and Class Members would not and could not
22 have paid for the products.

23 182. Defendants' acts and practices were false, misleading, deceptive, and unfair to
24 consumers, in violation of the California Unfair Competition Law.

25 183. As a direct and proximate result of Defendants' deceptive, fraudulent, and unfair
26 practices, Plaintiffs and members of the Class have lost money and suffered injury in fact in an
27 amount to be determined at trial.

28 184. Plaintiffs, on behalf of themselves and all others similarly situated, demand

1 judgment against the Defendant for restitution and injunctive relief.

2
3 **COUNT IX**
4 **VIOLATION OF CALIFORNIA UNFAIR COMPETITION LAW**
5 **CAL. BUS. & PROF. CODE § 17200, *et seq.***
6 **(“unlawful” prong)**
7 **(*On Behalf of Plaintiffs and the Class(es)*)**

8 185. Plaintiffs re-allege and incorporate by reference the allegations contained in all
9 preceding paragraphs of this Complaint as though set forth fully herein.

10 186. The actions of Defendant, as alleged herein, constitute illegal and unlawful practices
11 committed in violation of Cal. Bus. & Prof. Code § 17200, *et seq.*

12 187. Defendants have engaged in a scheme of introducing adulterated non-FDA approved
13 Valsartan products into the U.S. market manufactured out of compliance with cGMPs and which
14 are not therapeutically equivalent to brand Diovan. In undertaking these actions, Defendants are
15 violating the law, including the common law and violations of: (1) Cal. Civ. Code §§ 1770(a)(2),
16 1770(a)(5), and 1770(a)(9); (2) Cal. Civ. Code §§ 1709 & 1710; (3) Cal. Civ. Code §§ 1791 &
17 17922; and Cal. Bus. & Prof. Code § 17200 *et seq.*

18 188. Pursuant to Cal. Bus. & Prof. Code § 17203, Plaintiffs and Class Members seek an
19 order of this Court enjoining Defendants from engaging in the unfair competition alleged herein in
20 connection with advertising, marketing, promoting, and selling products based upon
21 misrepresentations and omissions of material facts, as alleged in greater detail above.

22 189. Additionally, Plaintiffs request an order awarding Plaintiffs and the Class restitution
23 of the money wrongfully acquired by Defendants by means of the unfair competition alleged
24 herein.

25 190. As a direct and proximate result of Defendants’ deceptive, fraudulent, and unfair
26 practices, Plaintiffs and members of the Class have lost money and suffered injury in fact in an
27 amount to be determined at trial.

28 191. Plaintiffs, on behalf of themselves and all others similarly situated, demand
judgment against the Defendant for restitution and injunctive relief.

1 **PRAYER FOR RELIEF**

2 WHEREFORE, Plaintiffs, on behalf of themselves and on behalf of the members of the
3 Class defined herein, pray for relief and judgment on all Counts of the Complaint and request the
4 following:

- 5 A. An order certifying the action may be maintained as a class action and appointing
6 Plaintiffs as the Class Representatives and their counsel as Class Counsel;
- 7 B. For restitution on behalf of Plaintiffs and all Class Members;
- 8 C. Imposition of a constructive trust upon all monies and assets Defendants have
9 acquired as a result of unfair practices;
- 10 D. For all appropriate declarative and injunctive relief, enjoining Defendant from
11 pursuing and/or continuing the unlawful conduct complained in herein;
- 12 E. For an order declaring and/or a judicial determination of the respective rights and
13 duties of Plaintiffs, the Class and Defendants with respect to whether Defendants
14 violated Cal Civ. C. §§ 1750, *et seq.*, Cal. Civ. Code §§ 1709, 1710, Cal. Civ. Code
15 §§ 1791, 1792, Cal. Bus. & Prof. C. §§ 17200, *et seq.*, and the common law;
- 16 F. For attorneys' fees and reimbursement of all costs for the prosecution of this action;
- 17 G. For pre-judgment and post-judgment interest; and,
- 18 H. For such other and further relief this Court deems just and appropriate.

19 **DEMAND FOR JURY TRIAL**

20 Plaintiffs respectfully demand a trial by jury on all issues within the instant action so triable.

21
22 Dated: October 11, 2018

23
24 /s/ Allan Kanner
25 **KANNER & WHITELEY, LLC**
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pro hac vice)

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Counsel for Plaintiffs and the Class

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

John Judson & Jo Ann Hamel

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

(c) Attorneys (Firm Name, Address, and Telephone Number) Allan Kanner; Conlee S. Whiteley; Layne Hilton; Michael L. Slack; John R. Davis; Ruben Honik; David Stanoch (see complaint for contact information)

DEFENDANTS

Prinston Pharmaceutical Inc. d/b/a Solco Healthcare LLC; Solco Healthcare U.S., LLC; Huahai US Inc.; Teva Pharmaceutical Industries

County of Residence of First Listed Defendant Middlesex Cnty, New Jersey (IN U.S. PLAINTIFF CASES ONLY)

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

Attorneys (If Known) n/a

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)

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

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

Click here for: Nature of Suit Code Descriptions.

Table with 5 columns: CONTRACT, REAL PROPERTY, TORTS, CIVIL RIGHTS, PRISONER PETITIONS, FORFEITURE/PENALTY, LABOR, IMMIGRATION, BANKRUPTCY, SOCIAL SECURITY, FEDERAL TAX SUITS, OTHER STATUTES. Includes various legal categories like Insurance, Real Estate, Personal Injury, etc.

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(d)

Brief description of cause: Proposed Class Action for breach of warranties and violation of consumer protection statutes

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: X Yes No

VIII. RELATED CASE(S) IF ANY

(See instructions): JUDGE DOCKET NUMBER

DATE 10/11/2018 SIGNATURE OF ATTORNEY OF RECORD /s/ Allan Kanner

FOR OFFICE USE ONLY

RECEIPT # AMOUNT APPLYING IFP JUDGE MAG. JUDGE

Case 1:18-cv-01405-DAD-EPG Document 1-1 Filed 10/11/18 Page 2 of 2
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 statute.
- 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.