

**THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF NEW JERSEY
CAMDEN VICINAGE**

IRA SANDERS, JOSEPH GLENN
CUMMINGS, SOLOMON ZELLER, ROSA
BURTON and DAMITA OWENS, on behalf
of themselves and all others similarly situated,

Plaintiffs,

v.

TORRENT PHARMA, INC.,

Defendant.

COMPLAINT AND JURY DEMAND

CLASS ACTION

Civil Action No.

Plaintiffs Ira Sanders (“Plaintiff”), residing at 16730 Hampton Crossing Drive, Huntersville, North Carolina 28078, Joseph Glenn Cummings, residing at 1737 Old Pearl Road, Florence, Mississippi 39073, Solomon Zeller, residing at 19637 Back Nine Drive, Boca Raton, Florida 33498, Rosa Burton, residing in Zellwood, Florida 32798, and Damita Owens, residing at 775 Lafayette Avenue, Brooklyn, New York 11221, bring this action on behalf of themselves and all others similarly situated against Defendant Torrent Pharma, Inc. (“Torrent” or “Defendant”), having its principal place of business at 150 Allen Road, Basking Ridge, New Jersey 07920. Plaintiffs make the following allegations pursuant to the investigation of their counsel and based upon information and belief, except as to the allegations specifically pertaining to themselves, which are based on personal knowledge.

NATURE OF THE ACTION AND FACTS COMMON TO ALL CLAIMS

1. This is a class action lawsuit regarding Defendant Torrent’s manufacturing, distribution, and sale of losartan-containing generic prescription medications contaminated with

N-Nitrosodiethylamine (“NDEA”) and N-Methylnitrosobutyric acid (NMBA), carcinogenic and liver-damaging impurities.

2. Originally marketed under the brand names Cozaar (Losartan Potassium), Tozaar (Hydrochlorothiazide and Losartan), and Tozam (Amlodipine and Losartan), losartan is a prescription medication mainly used for the treatment of high blood pressure, diabetic kidney disease, congestive heart failure, and left ventricular enlargement, among other issues. However, due to manufacturing defects originating from overseas laboratories in India, certain generic formulations have become contaminated with NDEA and/or NMBA.

3. NDEA is an organic chemical. The U.S. Food and Drug Administration (“FDA”) reports that NDEA is found in “air pollution, and industrial processes, and has been classified as a probable human carcinogen as per international Agency for Research on Cancer (IARC) classification.” NDEA is also classified as a Group 2A carcinogen (probable human carcinogen) by the World Health Organization. NDEA is acutely toxic when consumed orally. NMBA, like NDEA, is a nitrosamine contaminant. NMBA is a possible human carcinogen.

A. Torrent recalls its losartan-containing medications due to the presence of nitrosamine impurities NDEA and NMBA, resulting from manufacturing defects from an overseas supplier in India

4. On December 20, 2018, Defendant Torrent “voluntarily recall[ed] 2 lots of Losartan potassium tablets, USP to the consumer level due to the detection of trace amounts of an unexpected impurity found in an active pharmaceutical ingredient (‘API’),” resulting from Torrent’s overseas API supplier in India. Further, “[t]he impurity detected in the API [was] N-nitrosodiethylamine (NDEA).”

5. The December 20, 2018 recall concerned the following prescriptions:

NDC	Manufacturer	Product Description	Lot/Batch	Expiration Date
13668-115-30	Torrent Pharmaceuticals LTD	LOSARTAN POTASSIUM TAB, USP 100mg,30count bottles	BO31C016	04/2019
13668-115-90	Torrent Pharmaceuticals LTD	LOSARTAN POTASSIUM TAB, USP 100mg,90count bottles	BO31C016	04/2019
13668-115-10	Torrent Pharmaceuticals LTD	LOSARTAN POTASSIUM TAB, USP 100mg,1000-count bottles	4DK3C005	04/2019

6. The recall further warns that “[c]onsumers should also contact their physician or healthcare provider if they have experienced any problems that may be related to taking or using this drug product,” and that “[p]atients should contact their pharmacist or physician who can advise them about an alternative treatment.”

7. On January 22, 2019, Defendant Torrent expanded its recall to the following lots:

NDC	Manufacturer	Product Description	Lot/Batch	Expiration Date
13668-115-30	Torrent Pharmaceuticals LTD	LOSARTAN POTASSIUM TAB, USP 100mg,30count bottles	BO31C016	04/2019
13668-115-90	Torrent Pharmaceuticals LTD	LOSARTAN POTASSIUM TAB, USP 100mg,90count bottles	BO31C016	04/2019
13668-115-10	Torrent Pharmaceuticals LTD	LOSARTAN POTASSIUM TAB, USP 100mg,1000-count bottles	4DK3C005	04/2019
13668-115-10	Torrent Pharmaceuticals LTD	LOSARTAN POTASSIUM TAB, USP 100mg,1000-count bottles	4DK3C004	04/2019
13668-115-10	Torrent Pharmaceuticals LTD	LOSARTAN POTASSIUM TAB, USP 100mg,1000-count bottles	4DU3C040	10/2019
13668-115-10	Torrent Pharmaceuticals LTD	LOSARTAN POTASSIUM TAB, USP 100mg,1000-count bottles	4DU3E049	05/2021

NDC	Manufacturer	Product Description	Lot/Batch	Expiration Date
13668-115-10	Torrent Pharmaceuticals LTD	LOSARTAN POTASSIUM TAB, USP 100mg,1000-count bottles	4DU3E050	05/2021
13668-409-30	Torrent Pharmaceuticals LTD	LOSARTAN POTASSIUM TAB, USP 50mg,30count bottles	4L67C035	10/2019
13668-409-90	Torrent Pharmaceuticals LTD	LOSARTAN POTASSIUM TAB, USP 50mg,90count bottles	4L67C035	10/2019
13668-409-90	Torrent Pharmaceuticals LTD	LOSARTAN POTASSIUM TAB, USP 50mg,90count bottles	4L67C036	10/2019
13668-409-10	Torrent Pharmaceuticals LTD	LOSARTAN POTASSIUM TAB, USP 50mg,1000-count bottles	4O50C005	11/2019
13668-113-90	Torrent Pharmaceuticals LTD	LOSARTAN POTASSIUM TAB, USP 25mg,90count bottles	4O49C013	09/2019
13668-116-90	Torrent Pharmaceuticals LTD	LOSARTAN POTASSIUM and HYDROCHOLOROTHIAZIDE TABLETS, USP 50mg/12.5 mg, 90 count bottles.	BP02C008	03/2019
13668-116-10	Torrent Pharmaceuticals LTD	LOSARTAN POTASSIUM and HYDROCHOLOROTHIAZIDE TABLETS, USP 50mg/12.5 mg, 1000 count bottles.	BEF7D006	03/2020
13668-117-90	Torrent Pharmaceuticals LTD	LOSARTAN POTASSIUM and HYDROCHOLOROTHIAZIDE TABLETS, USP 100 mg/12.5 mg, 90 count bottles.	BX35C020	05/2019
13668-117-90	Torrent Pharmaceuticals LTD	LOSARTAN POTASSIUM and HYDROCHOLOROTHIAZIDE TABLETS, USP 100 mg/12.5 mg, 90 count bottles.	BX35C049	08/2019
13668-117-10	Torrent Pharmaceuticals LTD	LOSARTAN POTASSIUM and HYDROCHOLOROTHIAZIDE TABLETS, USP 100 mg/12.5 mg, 1000 count bottles.	BX35C022	05/2019

NDC	Manufacturer	Product Description	Lot/Batch	Expiration Date
13668-117-10	Torrent Pharmaceuticals LTD	LOSARTAN POTASSIUM and HYDROCHLOROTHIAZIDE TABLETS, USP 100 mg/12.5 mg, 1000 count bottles.	BX35C023	05/2019

8. On April 18, 2019, approximately four months after the initial recall stemming from the same overseas API supplier, Torrent expanded its recall to add over a million¹ additional bottles of losartan-containing medication to the recall due to the presence of NMBA.²

B. Defendant’s losartan generic medications are not of equal quality and safety to brand-name drugs

9. Generic drugs reach the market when the brand-name version of the drug comes off patent, and other competitors are able to seek approval for, market, and sell bioequivalent versions of the brand-name drug. These generic equivalents are supposed to be of equal quality and equal safety. According to the FDA, “[a]ll generic drugs approved by [the] FDA have the same high quality, strength, purity, and stability as brand-name drugs.”

10. Here, the losartan-containing drugs manufactured by Torrent are supposed to be equivalent to the brand-name drugs. However, they are not because they suffer from a manufacturing defect which caused their generic losartan to become contaminated with NDEA and/or NMBA.

11. As such, Torrent’s losartan-containing medications are neither safe nor of equal quality to the brand-name version of the medication.

¹ <https://www.fiercepharma.com/manufacturing/torrent-recalls-more-than-1m-bottles-tainted-blood-pressure-med> (last visited 5/7/19).

² <https://www.fda.gov/safety/recalls-market-withdrawals-safety-alerts/updated-torrent-pharmaceuticals-limited-expands-voluntary-nationwide-recall-losartan-potassium> (last visited 5/7/19).

C. Plaintiffs and Class Members were harmed by purchasing and consuming contaminated losartan-containing medications manufactured, distributed, and sold by Defendant

12. Plaintiffs and the Class were injured by the full purchase price of their losartan-containing medications. These medications are worthless, as they are contaminated with carcinogenic and harmful NDEA and/or NMBA, and therefore are not fit for human consumption. Indeed, Plaintiffs have been instructed to consult with their doctors immediately and were warned that consumption of their losartan medication may result in a “potential health hazard or safety risk.” Plaintiffs and the Class are further entitled to statutory damages, damages for the injury sustained in consuming high levels of acutely-toxic NDEA and NMBA, and for damages related to Defendant’s conduct.

13. Plaintiffs bring this action on behalf of themselves and Class Members for equitable relief and to recover damages and restitution for: (i) breach of express warranty, (ii) breach of the implied warranty of merchantability, (iii) violation of North Carolina’s Unfair or Deceptive Trade Practices Act, N.C. Gen. Stat. §§ 75-1.1, *et seq.*, (iv) violation of Florida’s Deceptive and Unfair Trade Practices Act (“FDUTPA”), Fla. Stat. Ann. §§ 501.201, *et seq.*, (v) violation of New York’s General Business Law § 349, (vi) violation of New York’s General Business Law § 350, (vii) unjust enrichment, (viii) fraudulent concealment, (ix) fraud, and (x) conversion.

PARTIES

14. Plaintiff Ira Sanders is a citizen of North Carolina who resides in Huntersville, North Carolina. During all relevant time periods, Plaintiff Sanders was prescribed losartan containing medication manufactured and distributed by Defendant Torrent, and sold by Harris Teeter. On several occasions, Plaintiff Sanders was prescribed and purchased losartan

medication bearing the NDC numbers 13668-0115-10 and 13668-0115-30, a 100 mg dose.

Plaintiff Sanders originally learned about the recall by receiving notices from Aetna and Harris Teeter. The Aetna letter, dated January 3, 2019, warned Plaintiff Sanders that “[t]here’s a recall for a drug you may use,” due to **“an unexpected impurity [that] was found in these products that may cause health risks”** (bold in original). The Aetna letter further warned that **“[t]here’s a potential health hazard or safety risk if you’re using this product”** (bold in original). The Aetna letter further urged Plaintiff Sanders to **“[p]lease call your doctor right away for advice if you may be using affected product”** (bold in original). Plaintiff Sanders reviewed the recall letter, cross referenced the affected NDC numbers with the NDC numbers of the medications he received, and determined that he had been consuming the contaminated losartan medication manufactured by Torrent, and sold by Harris Teeter. When purchasing his losartan-containing medications from Torrent and Harris Teeter, Plaintiff Sanders reviewed the accompanying labels and disclosures, and understood them as representations and warranties by Torrent that the medications were the bioequivalent of the name-brand medication, and were properly manufactured and free from contaminants and defects. Plaintiff Sanders relied on these representations and warranties in deciding to purchase his losartan-containing medications from Torrent and Harris Teeter, and these representations and warranties were part of the basis of the bargain, in that he would not have purchased his losartan-containing medications from Torrent and Harris Teeter if he had known that they were not, in fact, properly manufactured and free from contaminants and defects. Plaintiff Sanders also understood that each purchase involved a direct transaction between himself and Torrent, because his medication came with packaging and other materials prepared by Torrent, including representations and warranties that his medications were bioequivalent to the name-brand medication, and were properly manufactured

and free from contaminants and defects.

15. Plaintiff Joseph Glenn Cummings is a citizen of Mississippi who resides in Florence, Mississippi. During all relevant time periods, Plaintiff Cummings was prescribed losartan-containing medication manufactured and distributed by Defendant Torrent, which he purchased from Kroger in Richland, Mississippi. Plaintiff Cummings was prescribed and purchased losartan medication bearing NDC number 13668-409-10, a 50 mg dose. Each time, Plaintiff Cummings paid a co-pay of \$12.92 for the contaminated medication. After learning of the recall, Plaintiff Cummings called Kroger, who identified his medication as subject to the recall. When purchasing his losartan-containing medications from Torrent and Kroger, Plaintiff Cummings reviewed the accompanying labels and disclosures, and understood them as representations and warranties by Torrent that the medications were the bioequivalent of the name-brand medication, and were properly manufactured and free from contaminants and defects. Plaintiff Cummings relied on these representations and warranties in deciding to purchase his losartan-containing medications from Torrent and Kroger, and these representations and warranties were part of the basis of the bargain, in that he would not have purchased his losartan-containing medications from Torrent and Kroger if he had known that they were not, in fact, properly manufactured and free from contaminants and defects. Plaintiff Cummings also understood that each purchase involved a direct transaction between himself and Torrent, because his medication came with packaging and other materials prepared by Torrent, including representations and warranties that his medications were bioequivalent to the name-brand medication, and were properly manufactured and free from contaminants and defects.

16. Plaintiff Solomon Zeller is a citizen of Florida who resides in Boca Raton, Florida. During all relevant time periods, Plaintiff Zeller was prescribed losartan-containing

medication manufactured and distributed by Defendant Torrent, which he purchased from CVS in Boca Raton, Florida. On October 17, 2018, Plaintiff Zeller received losartan medication bearing the NDC number 13668-0409-90, at a 50 mg dose. Plaintiff Zeller paid a co-pay of \$3.35. Plaintiff Zeller originally learned about the recall by receiving notices from United Healthcare and CVS. The CVS letter, dated January 7, 2019, provided Plaintiff Zeller with the NDC numbers and lots affected by the recall. Plaintiff Zeller reviewed the recall letters, cross referenced the affected NDC numbers with the NDC number of the medication he purchased, and determined that he was prescribed, purchased, and had been consuming one of the contaminated medications manufactured by Torrent, and sold by CVS. When purchasing his losartan-containing medications from Torrent and CVS, Plaintiff Zeller reviewed the accompanying labels and disclosures, and understood them as representations and warranties by Torrent that the medications were properly manufactured and free from contaminants and defects. Plaintiff Zeller relied on these representations and warranties in deciding to purchase his losartan-containing medications from Torrent and CVS, and these representations and warranties were part of the basis of the bargain, in that he would not have purchased his losartan-containing medications from Torrent and CVS if he had known that they were not, in fact, properly manufactured and free from contaminants and defects. Plaintiff Zeller also understood that each purchase involved a direct transaction between himself and Torrent, because his medication came with packaging and other materials prepared by Torrent, including representations and warranties that his medications were bioequivalent to the name-brand medication, and were properly manufactured and free from contaminants and defects.

17. Plaintiff Rosa Burton is a citizen of Florida who resides in Zellwood, Florida. During all relevant time periods, Plaintiff Burton was prescribed losartan-containing medication

manufactured and distributed by Defendant Torrent, which she purchased from The Pharmacy Store in Apopka, Florida. On several occasions in 2018, but specifically on October 22, 2018, Plaintiff Burton received losartan-containing medication bearing NDC number 13668-0118-10, a 100 mg dose. Plaintiff Burton paid a co-pay for the medications, including a \$4.58 co-pay on October 22, 2018. After hearing about the recall, Plaintiff Burton cross-referenced the affected NDC numbers with the NDC number of the medication she purchased, and determined that she was prescribed, purchased, and had been consuming one of the contaminated medications manufactured by Torrent, and sold by The Pharmacy Store. When purchasing her losartan-containing medications from Torrent and Duane Reade, Plaintiff Burton reviewed the accompanying labels and disclosures, and understood them as representations and warranties by Torrent that the medications were properly manufactured and free from contaminants and defects. Plaintiff Burton relied on these representations and warranties in deciding to purchase her losartan-containing medications from Torrent and The Pharmacy Store, and these representations and warranties were part of the basis of the bargain, in that she would not have purchased her losartan-containing medications from Torrent and The Pharmacy Store if she had known that they were not, in fact, properly manufactured and free from contaminants and defects. Plaintiff Owens also understood that each purchase involved a direct transaction between herself and Torrent, because her medication came with packaging and other materials prepared by Torrent, including representations and warranties that her medications were bioequivalent to the name-brand medication, and were properly manufactured and free from contaminants and defects.

18. Plaintiff Damita Owens is a citizen of New York who resides in Brooklyn, New York. During all relevant time periods, Plaintiff Owens was prescribed losartan-containing

medication manufactured and distributed by Defendant Torrent, which she purchased from Duane Reade in Brooklyn, New York. On several occasions in 2018 and 2019, Plaintiff Owens received losartan-containing medication bearing the NDC number 13668-0116-90, at a 50 mg dose. Plaintiff Owens paid a co-pay for each fill of the medication. Plaintiff Owens originally learned about the recall by receiving a notice from Walgreens. The Walgreens letter, dated March 2019, warned Plaintiff Owens that she may have “received one or more prescriptions for Losartan products manufactured by Torrent Pharmaceuticals from a Walgreens pharmacy.” The letter continued that Torrent “is voluntarily recalling these items due to the detection of a trace amount of N-Nitrosodimethylamine (NDEA),” which is a substance that “has been classified as a probable human carcinogen.” The Walgreens letter also provided Plaintiff Owens with the NDC numbers and lots affected by the recall. Plaintiff Owens reviewed the recall letter, cross referenced the affected NDC numbers with the NDC number of the medication she purchased, and determined that she was prescribed, purchased, and had been consuming one of the contaminated medications manufactured by Torrent, and sold by Duane Reade. When purchasing her losartan-containing medications from Torrent and Duane Reade, Plaintiff Owens reviewed the accompanying labels and disclosures, and understood them as representations and warranties by Torrent that the medications were properly manufactured and free from contaminants and defects. Plaintiff Owens relied on these representations and warranties in deciding to purchase her losartan-containing medications from Torrent and Duane Reade, and these representations and warranties were part of the basis of the bargain, in that she would not have purchased her losartan-containing medications from Torrent and CVS if she had known that they were not, in fact, properly manufactured and free from contaminants and defects. Plaintiff Owens also understood that each purchase involved a direct transaction between herself and

Torrent, because her medication came with packaging and other materials prepared by Torrent, including representations and warranties that her medications were bioequivalent to the name-brand medication, and were properly manufactured and free from contaminants and defects.

19. Defendant Torrent Pharma, Inc. is a corporation organized under the laws of the State of Delaware and maintains its principal place of business at 150 Allen Road, Basking Ridge, New Jersey 07920. Defendant Torrent conducts substantial business in the United States, and specifically in the state of New Jersey. Torrent has been engaged in the manufacturing, sale, and distribution of contaminated generic losartan in the United States.

JURISDICTION AND VENUE

20. This Court has jurisdiction over this action pursuant to 28 U.S.C. § 1332(d)(2)(A), as modified by the Class Action Fairness Act of 2005, because at least one member of the Class, as defined below, is a citizen of a different state than Defendant, there are more than 100 members of the Class, and the aggregate amount in controversy exceeds \$5,000,000 exclusive of interest and costs.

21. Venue is proper in this Court pursuant to 28 U.S.C. § 1391 because many of the acts and transactions giving rise to this action occurred in this District, and because Defendant (a) is authorized to conduct business in this District and has intentionally availed itself of the laws and markets within this District through the promotion, marketing, distribution, and sale of contaminated losartan-containing medications in this District; (b) conducts substantial business in this District; and (c) is subject to personal jurisdiction in this District.

CLASS ALLEGATIONS

22. Plaintiffs seek to represent a class defined as all persons in the United States who purchased losartan-containing medications that are contaminated with NDEA and/or NMBA (the

“Nationwide Class”). Specifically excluded from the Class are persons who made such purchase for the purpose of resale, Defendant, Defendant’s officers, directors, agents, trustees, parents, children, corporations, trusts, representatives, employees, principals, servants, partners, joint venturers, or entities controlled by Defendant, and their heirs, successors, assigns, or other persons or entities related to or affiliated with Defendant and/or Defendant’s officers and/or directors, the judge assigned to this action, and any member of the judge’s immediate family.

23. Plaintiff Sanders also seeks to represent a subclass of all Class members who purchased losartan-containing medications in North Carolina (the “North Carolina Subclass”).

24. Plaintiff Cummings also seeks to represent a subclass of all Class members who purchased losartan-containing medications in Mississippi (the “Mississippi Subclass”).

25. Plaintiffs Zeller and Burton also seek to represent a subclass of all Class members who purchased losartan-containing medications in Florida (the “Florida Subclass”).

26. Plaintiff Owens also seeks to represent a subclass of all Class members who purchased losartan-containing medications in New York (the “New York Subclass”). The Nationwide Class and Subclasses are collectively referred to as the “Class.”

27. Subject to additional information obtained through further investigation and discovery, the foregoing definition of the Class may be expanded or narrowed by amendment or amended complaint.

28. **Numerosity.** The members of the Class are geographically dispersed throughout the United States and are so numerous that individual joinder is impracticable. Upon information and belief, Plaintiffs reasonably estimate that there are hundreds of thousands of members in the Class. Although the precise number of Class members is unknown to Plaintiffs, the true number of Class members is known by Defendant. More specifically, Defendant

maintains databases that contain the following information: (i) the name of each Class member who was prescribed the contaminated medication; (ii) the address of each Class member; and (iii) each Class member's payment information related to the contaminated medication. Thus, Class members may be identified and notified of the pendency of this action by U.S. Mail, electronic mail, and/or published notice, as is customarily done in consumer class actions.

29. **Existence and predominance of common questions of law and fact.** Common questions of law and fact exist as to all members of the Class and predominate over any questions affecting only individual Class members. These common legal and factual questions include, but are not limited to, the following:

(a) whether the losartan-containing medications manufactured, distributed, and sold by Defendant were in fact contaminated with NDEA and/or NMBA, thereby breaching the express and implied warranties made by Defendant and making the medication unfit for human consumption and therefore unfit for its intended purpose;

(b) whether Defendant knew or should have known that the losartan-containing medications were in fact contaminated with NDEA and/or NMBA prior to the recall, thereby constituting fraud and/or fraudulent concealment, and negligence or gross negligence;

(c) whether Defendant has unlawfully converted money from Plaintiffs and the Class;

(d) whether Defendant is liable to Plaintiffs and the Class for unjust enrichment;

(e) whether Defendant is liable to Plaintiffs and the Class for fraudulent concealment;

(f) whether Defendant is liable to Plaintiffs and the Class for violation of North Carolina's Unfair or Deceptive Trade Practices Act, N.C. Gen. Stat. §§ 75-1.1, *et seq.*,

(g) whether Defendant is liable to Plaintiffs and the Class for violation of Florida's Deceptive and Unfair Trade Practices Act, Fla. Stat. Ann. §§ 501.201, *et seq.*;

- (h) whether Defendant is liable to Plaintiffs and the Class for violation of New York's General Business Law §§ 349-350;
- (i) whether Defendant is liable to Plaintiffs for breaches of express and implied warranties;
- (j) whether Plaintiffs and the Class have sustained monetary loss and the proper measure of that loss;
- (k) whether Plaintiffs and the Class are entitled to declaratory and injunctive relief;
- (l) whether Plaintiffs and the Class are entitled to restitution and disgorgement from Defendant; and
- (m) Whether the marketing, advertising, packaging, labeling, and other promotional materials for Defendant's losartan medications are deceptive.

30. **Typicality.** Plaintiffs' claims are typical of the claims of the other members of the Class in that Defendant mass marketed and sold contaminated medications to consumers throughout the United States. This contamination was present in all of the recalled medications manufactured, distributed, and sold by Defendant. Therefore, Defendant breached its express and implied warranties to Plaintiffs and Class members by manufacturing, distributing, and selling the contaminated losartan medication. Plaintiffs' claims are typical in that they were uniformly harmed in purchasing and consuming the contaminated medications. Plaintiffs' claims are further typical in that Defendant deceived Plaintiffs in the very same manner as it deceived each member of the Class. Further, there are no defenses available to Defendant that are unique to Plaintiff.

31. **Adequacy of Representation.** Plaintiffs will fairly and adequately protect the interests of the Class. Plaintiffs have retained counsel that is highly experienced in complex

consumer class action litigation, and Plaintiffs intend to vigorously prosecute this action on behalf of the Class. Furthermore, Plaintiffs have no interests that are antagonistic to those of the Class.

32. **Superiority.** A class action is superior to all other available means for the fair and efficient adjudication of this controversy. The damages or other financial detriment suffered by individual Class members is relatively small compared to the burden and expense of individual litigation of their claims against Defendant. It would, thus, be virtually impossible for the Class, on an individual basis, to obtain effective redress for the wrongs committed against them. Furthermore, even if Class members could afford such individualized litigation, the court system could not. Individualized litigation would create the danger of inconsistent or contradictory judgments arising from the same set of facts. Individualized litigation would also increase the delay and expense to all parties and the court system from the issues raised by this action. By contrast, the class action device provides the benefits of adjudication of these issues in a single proceeding, economies of scale, and comprehensive supervision by a single court, and presents no unusual management difficulties under the circumstances.

33. In the alternative, the Class may also be certified because:

(a) the prosecution of separate actions by individual Class members would create a risk of inconsistent or varying adjudication with respect to individual Class members that would establish incompatible standards of conduct for the Defendant;

(b) the prosecution of separate actions by individual Class members would create a risk of adjudications with respect to them that would, as a practical matter, be dispositive of the interests of other Class members not parties to the adjudications, or substantially impair or impede their ability to protect their interests; and/or

(c) Defendant has acted or refused to act on grounds generally applicable to the Class as a whole, thereby making appropriate final declaratory and/or injunctive relief with respect to the members of the Class as a whole.

COUNT I
Breach Of Express Warranty
(On Behalf Of The Nationwide Class)

34. Plaintiffs hereby incorporate by reference the allegations contained in all preceding paragraphs of this complaint.

35. Plaintiffs bring this claim individually and on behalf of the members of the proposed Class and the Subclasses against Defendant.

36. Plaintiffs, and each member of the Nationwide Class and Subclasses, formed a contract with Defendant at the time Plaintiffs and the other Class members purchased the contaminated losartan medications. The terms of the contract include the promises and affirmations of fact made by Defendant on the contaminated medication's packaging and through marketing and advertising. This labeling, marketing, and advertising constitute express warranties and became part of the basis of the bargain, and are part of the standardized contract between Plaintiffs and the members of the Class and Defendant.

37. Defendant expressly warranted that the losartan-containing medications would be the bioequivalent of the name-brand medication, would contain only what was stated on the label, and would not contain harmful and carcinogenic defects and impurities such as NDEA and/or NMBA. Plaintiffs relied on the express warranty that their medications would contain only what was stated on the label, and that they would not be contaminated with impurities. These express warranties further formed the basis of the bargain, and are part of the standardized contract between Plaintiffs and the members of the Class and Defendant.

38. Plaintiffs and the Class performed all conditions precedent to Defendant's liability

under this contract when they purchased the contaminated medication.

39. Defendant breached express warranties about the contaminated medication and their qualities because Defendant's statements about the contaminated medications were false and the contaminated medications do not conform to Defendant's affirmations and promises described above.

40. Plaintiffs and each of the members of the Class would not have purchased the contaminated medications had they known the true nature of the contaminated medications' ingredients and what the contaminated medications contained (*i.e.*, NDEA and/or NMBA).

41. As a result of Defendant's breaches of express warranty, Plaintiffs and each of the members of the Class have been damaged in the amount of the purchase price of the product and any consequential damages resulting from the purchases.

42. On May 7, 2019, prior to filing this action, Defendant was served with a pre-suit notice letter that complied in all respects with U.C.C. §§ 2-313, 2-607. Plaintiffs' counsel sent Defendant a letter advising that it breached an express warranty and demanded that it cease and desist from such breaches and make full restitution by refunding the monies received therefrom. A true and correct copy of Plaintiffs' counsel's letter is attached hereto as Exhibit A.

COUNT II
Breach Of The Implied Warranty Of Merchantability
(On Behalf Of The Nationwide Class)

43. Plaintiffs hereby incorporate by reference the allegations contained in all preceding paragraphs of this complaint.

44. Plaintiffs bring this claim individually and on behalf of the members of the proposed Class and Subclasses against Defendant.

45. Defendant, as the designer, manufacturer, marketer, distributor, and/or seller,

impliedly warranted that the losartan-containing medications (i) contained no NDEA and/or NMBA and (ii) are generally recognized as safe for human consumption.

46. Defendant breached the warranty implied in the contract for the sale of the contaminated losartan-containing medications because they could not pass without objection in the trade under the contract description, the goods were not of fair average quality within the description, and the goods were unfit for their intended and ordinary purpose because the losartan-containing medications manufactured, distributed, and sold by Defendant were contaminated with carcinogenic and liver toxic NDEA and/o NMBA, and as such are not generally recognized as safe for human consumption. As a result, Plaintiffs and Class members did not receive the goods as impliedly warranted by Defendant to be merchantable.

47. Plaintiffs and Class members purchased the losartan-containing medications in reliance upon Defendant's skill and judgment and the implied warranties of fitness for the purpose.

48. The losartan-containing medications were not altered by Plaintiffs or Class members.

49. The losartan-containing medications were defective when they left the exclusive control of Defendant.

50. Defendant knew that the losartan-containing medications would be purchased and used without additional testing by Plaintiffs and Class members.

51. The contaminated losartan medications were defectively manufactured and unfit for its intended purpose, and Plaintiffs and Class members did not receive the goods as warranted.

52. As a direct and proximate cause of Defendant's breach of the implied warranty of

merchantability, Plaintiffs and Class members have been injured and harmed because: (a) they would not have purchased the losartan-containing medications on the same terms if they knew that the products contained NDEA and/or NMBA, and are not generally recognized as safe for human consumption; and (b) the losartan-containing medications do not have the characteristics, ingredients, uses, or benefits as promised by Defendant.

COUNT III
Violation Of North Carolina's Unfair or Deceptive Trade Practices Act,
N.C. Gen. Stat. §§ 75-1.1, *et seq.*
(On Behalf Of The North Carolina Subclass)

53. Plaintiffs hereby incorporate by reference the allegations contained in all preceding paragraphs of this complaint.

54. Plaintiff Sanders brings this claim individually and on behalf of the members of the proposed North Carolina Subclass against Defendant.

55. Defendant's advertising, marketing, and sale of the losartan-containing medications constitutes activities in and affecting commerce.

56. Defendant had superior knowledge that its losartan-containing medications were contaminated with NDEA and/or NMBA. As the manufacturer and seller of prescription pharmaceuticals, Defendant had conducted quality testing of its medications.

57. Further, despite the initial wave of recalls on December 20, 2018, Defendant continued to sell losartan-containing medications from overseas API manufacturers contaminated with NDEA and/or NMBA. Defendant continued to manufacture and sell contaminated losartan medications after the initial recalls, which led to a subsequent recall on April 18, 2019 of over a million additional bottles of losartan medication.

58. Defendant's conduct, including its concealment, constitutes unfair and deceptive trade practices, in violation of the North Carolina Unfair and Deceptive Trade Practices Act,

N.C. Gen. Stat. §§ 75-1.1, *et seq.*

59. Defendant misrepresented its losartan-containing medications as (i) containing no NDEA and/or NMBA and (ii) being generally recognized as safe for human consumption.

60. As a proximate and direct cause of Defendant's violations of the North Carolina Unfair and Deceptive Trade Practices Act, Plaintiff Sanders and North Carolina Subclass members have been injured and harmed because: (a) they would not have purchased the losartan-containing medications on the same terms if they knew that the products contained NDEA and/or NMBA, and are not generally recognized as safe for human consumption; and (b) the losartan-containing medications do not have the characteristics, ingredients, uses, or benefits as promised by Defendant.

COUNT IV
Violation Of Florida's Deceptive And Unfair Trade Practices Act,
Fla. Stat. Ann. §§ 501.201, *et seq.*
(On Behalf Of The Florida Subclass)

61. Plaintiffs hereby incorporate by reference the allegations contained in all preceding paragraphs of this complaint.

62. Plaintiff Zeller brings this claim individually and on behalf of the members of the proposed Florida Subclass against Defendant.

63. Defendant's advertising, marketing, and sale of the losartan-containing medications constitute activities in and affecting trade and commerce.

64. Defendant had superior knowledge that its losartan-containing medications were contaminated with NDEA and/or NMBA. As manufacturers and retailers of prescription pharmaceuticals, Defendant had conducted quality testing of its medications.

65. Further, despite the initial wave of recalls on December 20, 2018, Defendant continued to sell losartan-containing medications from overseas API manufacturers

contaminated with NDEA and/or NMBA. Defendant continued to manufacture and sell contaminated losartan medications after the initial recalls, which led to a subsequent recall on April 18, 2019 of over a million additional bottles of losartan medication.

66. Defendant's conduct, including its concealment, constitutes unfair and deceptive trade practices, in violation of the Florida's Deceptive and Unfair Trade Practices Act, Fla Stat. Ann. §§ 501-201, *et seq.*

67. Defendant misrepresented its losartan-containing medications as (i) containing no NDEA and/or NMBA and (ii) being generally recognized as safe for human consumption.

68. Plaintiff Zeller and Florida Subclass members were reasonable consumers acting reasonably under the circumstances when they relied on – and were misled by – Defendant's representations that the losartan-containing medications were safe and beneficial.

69. As a proximate and direct cause of Defendant's violations of FDUTPA, Plaintiff Zeller and Florida Subclass members have been injured and harmed because: (a) they would not have purchased the losartan-containing medications on the same terms if they knew that the products contained NDEA and/or NMBA, and are not generally recognized as safe for human consumption; and (b) the losartan-containing medications do not have the characteristics, ingredients, uses, or benefits as promised by Defendant.

70. Accordingly, Defendant is liable to Plaintiff Zeller and the Florida Subclass for damages in amounts to be proven at trial, including attorneys' fees and costs.

COUNT V
Violation Of New York's General Business Law § 349
(On Behalf Of The New York Subclass)

71. Plaintiffs hereby incorporate by reference the allegations contained in all preceding paragraphs of this complaint.

72. Plaintiff Owens brings this claim individually and on behalf of the members of

the New York Subclass against Defendant.

73. New York's General Business Law § 349 prohibits deceptive acts or practices in the conduct of any business, trade, or commerce.

74. In its sale of goods throughout the State of New York, Defendant conducts business and trade within the meaning and intendment of New York's General Business Law § 349.

75. Plaintiff Owens and members of the New York Subclass are consumers who purchased products from Defendant for their personal use.

76. By the acts and conduct alleged herein, Defendant has engaged in deceptive, unfair, and misleading acts and practices, which include, without limitation, misrepresenting that the losartan-containing medications (i) contained no NDEA, NMBA or other harmful impurities; and (ii) are generally recognized as safe for human consumption.

77. The foregoing deceptive acts and practices were directed at consumers.

78. The foregoing deceptive acts and practices are misleading in a material way because they fundamentally misrepresent the characteristics and quality of the losartan-containing medications manufactured, distributed, and sold by Defendant to induce consumers to purchase the same.

79. By reason of this conduct, Defendant engaged in deceptive conduct in violation of New York's General Business Law.

80. Defendant's actions are the direct, foreseeable, and proximate cause of the damages that Plaintiff Owens and members of the New York Subclass have sustained from having paid for and consumed Defendant's products.

81. As a result of Defendant's violations, Plaintiff Owens and members of the New

York Subclass have suffered damages because: (a) they would not have purchased Defendant's losartan-containing medications on the same terms if they knew that the products contained NDEA and/or NMBA, and are not generally recognized as safe for human consumption; and (b) Defendant's losartan-containing products do not have the characteristics, ingredients, uses, or benefits promised.

82. On behalf of herself and other members of the New York Subclass, Plaintiff Owens seeks to recover her actual damages or fifty dollars, whichever is greater, three times actual damages, and reasonable attorneys' fees.

COUNT VI
Violation Of New York's General Business Law § 350
(On Behalf Of The New York Subclass)

83. Plaintiffs hereby incorporate by reference the allegations contained in all preceding paragraphs of this complaint.

84. Plaintiff Owens brings this claim individually and on behalf of the members of the proposed New York Subclass against Defendant.

85. Based on the foregoing, Defendant engaged in consumer-oriented conduct that is deceptive or misleading in a material way which constitutes false advertising in violation of Section 350 of the New York GBL.

86. Defendant's false, misleading, and deceptive statements and representations of fact, including but not limited to, that the medication was safe and was not tainted with harmful impurities such as NDEA and/or NMBA ("the Misrepresentations"), were and are directed to consumers.

87. Defendant's false, misleading, and deceptive statements and representations of fact, including but not limited to the Misrepresentations, were and are likely to mislead a reasonable consumer acting reasonably under the circumstances.

88. Defendant's false, misleading, and deceptive statements and representations of fact, including but not limited to the Misrepresentations, have resulted in consumer injury or harm to the public interest.

89. Plaintiff Owens and members of the New York Subclass have been injured because: (a) they would not have purchased the contaminated losartan-containing medication if they had known that the medications contained liver-toxic and carcinogenic NDEA and/or NMBA; and (b) the medications do not have the characteristics, uses, or benefits as promised, namely that the medications were contaminated with NDEA and/or NMBA. As a result, Plaintiff Owens and members of the New York Subclass have been damaged in the full amount of the purchase price of the medications.

90. As a result of Defendant's false, misleading, and deceptive statements and representations of fact, including but not limited to the misrepresentations discussed above, Plaintiff Owens and members of the New York Subclass have suffered and will continue to suffer economic injury.

91. Plaintiff Owens and members of the New York Subclass suffered an ascertainable loss caused by Defendant's misrepresentations because they paid more for the medications than they would have had they known the truth about the products.

92. On behalf of herself and the other members of the New York Subclass, Plaintiff Owens seeks to enjoin the unlawful acts and practices described herein, to recover her actual damages or five hundred dollars, whichever is greater, three times actual damages, and reasonable attorneys' fees.

COUNT VII
Unjust Enrichment
(On Behalf Of The Nationwide Class)

93. Plaintiffs hereby incorporate by reference the allegations contained in all preceding paragraphs of this complaint.

94. Plaintiffs bring this claim individually and on behalf of the members of the Nationwide Class and Subclasses against Defendant.

95. Plaintiffs and the Class conferred a benefit on Defendant in the form of monies paid to purchase Defendant's contaminated losartan medications.

96. Defendant voluntarily accepted and retained this benefit.

97. Because this benefit was obtained unlawfully, namely by selling and accepting compensation for contaminated medications unfit for human use, it would be unjust and inequitable for the Defendant to retain it without paying the value thereof.

COUNT VIII
Fraudulent Concealment
(On Behalf Of The Nationwide Class)

98. Plaintiffs hereby incorporate by reference the allegations contained in all preceding paragraphs of this complaint.

99. Plaintiffs bring this claim individually and on behalf of the members of the Nationwide Class and Subclasses against Defendant.

100. Defendant had a duty to disclose material facts to Plaintiffs and the Class given their relationship as contracting parties and intended users of the medication. Defendant also had a duty to disclose material facts to Plaintiffs and the Class, namely that they were in fact manufacturing, distributing, and selling harmful and contaminated medications unfit for human consumption, because Defendant had superior knowledge such that the transactions without the

disclosure were rendered inherently unfair.

101. Defendant possessed knowledge of these material facts. As the manufacturer and seller of prescription pharmaceuticals, Defendant had conducted quality testing of its medications.

102. Further, despite the initial wave of recalls on December 20, 2018, Defendant continued to sell losartan-containing medications from overseas API manufacturers contaminated with NDEA and/or NMBA. Defendant continued to manufacture and sell contaminated losartan medications after the initial recalls.

103. Defendant failed to discharge its duty to disclose these materials facts.

104. In so failing to disclose these material facts to Plaintiffs and the Class, Defendant intended to hide from Plaintiffs and the Class that they were purchasing and consuming medications with harmful impurities that were unfit for human use, and thus acted with scienter and/or an intent to defraud.

105. Plaintiffs and the Class reasonably relied on Defendant's failure to disclose insofar as they would not have purchased the contaminated losartan medications manufactured, distributed, and sold by Defendant had they known it was contaminated with NDEA and/or NMBA.

106. As a direct and proximate cause of Defendant's fraudulent concealment, Plaintiffs and the Class suffered damages in the amount of monies paid for the defective medication.

107. As a result of Defendant's willful and malicious conduct, punitive damages are warranted.

COUNT IX
Fraud
(On Behalf Of The Nationwide Class)

108. Plaintiffs hereby incorporate by reference the allegations contained in all preceding paragraphs of this complaint.

109. Plaintiffs bring this claim individually and on behalf of the members of the proposed Class and Subclasses against Defendant.

110. As discussed above, Defendant provided Plaintiffs and Class members with false or misleading material information about the losartan medications manufactured, distributed, and sold by Defendant on the medication's packaging, labels, and accompanying documentation.

111. The misrepresentations and omissions of material fact made by Defendant, upon which Plaintiffs and Class members reasonably and justifiably relied, were intended to induce and actually induced Plaintiffs and Class members to purchase these contaminated losartan-containing medications.

112. Defendant knew that the medications contained these harmful impurities. As manufacturers and retailers of prescription pharmaceuticals, Defendant had conducted quality testing of its medications.

113. Further, despite the initial wave of recalls on December 20, 2018, Defendant continued to sell losartan-containing medications from overseas API manufacturers contaminated with NDEA and/or NMBA. Defendant continued to manufacture and sell contaminated losartan medications after the initial recalls, which led to a subsequent recall on April 18, 2019 of over a million additional bottles of losartan medication.

114. The fraudulent actions of Defendant caused damage to Plaintiffs and Class members, who are entitled to damages and other legal and equitable relief as a result.

115. As a result of Defendant's willful and malicious conduct, punitive damages are warranted.

COUNT X
Conversion
(On Behalf Of The Nationwide Class)

116. Plaintiffs hereby incorporate by reference the allegations contained in all preceding paragraphs of this complaint.

117. Plaintiffs bring this claim individually and on behalf of the members of the proposed Class and Subclasses against Defendant.

118. Plaintiffs and the Class have an ownership right to the monies paid for the contaminated medications manufactured, distributed, and sold by Defendant.

119. Defendant has wrongly asserted dominion over the payments illegally diverted to them for the contaminated medications. Defendant has done so every time that Plaintiffs and the Class have paid to have their prescriptions filled.

120. As a direct and proximate cause of Defendant's conversion, Plaintiffs and the Class suffered damages in the amount of the payments made for each time they filled their prescriptions.

PRAYER FOR RELIEF

WHEREFORE, Plaintiffs, individually and on behalf of all others similarly situated, seeks judgment against Defendant, as follows:

- A. For an order certifying the nationwide Class and the Subclasses under Rule 23 of the Federal Rules of Civil Procedure and naming Plaintiffs as the representatives of the Class and Subclasses and Plaintiffs' attorneys as Class Counsel to represent the Class and Subclass members;
- B. For an order declaring that the Defendant's conduct violates the statutes referenced herein;

- C. For an order finding in favor of Plaintiffs, the nationwide Class, and the Subclasses on all counts asserted herein;
- D. For compensatory, statutory, treble, and punitive damages in amounts to be determined by the Court and/or jury;
- E. For prejudgment interest on all amounts awarded;
- F. For an order of restitution and all other forms of equitable monetary relief;
- G. For injunctive relief as pleaded or as the Court may deem proper; and
- H. For an order awarding Plaintiffs and the Class and Subclasses their reasonable attorneys' fees and expenses and costs of suit.

DEMAND FOR TRIAL BY JURY

Pursuant to Federal Rule of Civil Procedure 38(b), Plaintiffs demand a trial by jury of any and all issues in this action so triable of right.

Dated: May 21, 2019

Respectfully submitted,

BURSOR & FISHER, P.A.

By: /s/ Andrew J. Oberfell
Andrew J. Oberfell

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EXHIBIT A



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May 7, 2019

Via Certified Mail – Return Receipt Requested

Torrent Pharma, Inc.
150 Allen Road
Basking Ridge, NJ 07920

Re: Notice and Demand Letter

To Whom It May Concern:

This letter serves as a preliminary notice and demand for corrective action by Torrent Pharma, Inc. (“Torrent”) pursuant to U.C.C. § 2-607(3)(a) concerning breaches of express and implied warranties related to our clients, Ira Sanders, Joseph Glenn Cummings, Solomon Zeller, Rosa Burton, Damita Owens, and a class of all similarly situated purchasers (the “Class”) of contaminated losartan-containing medication manufactured, distributed, and sold by Torrent. This letter also serves as notice of violation of North Carolina’s Unfair or Deceptive Trade Practices Act, N.C. Gen. Stat. §§ 75-1.1, *et seq.*, Florida’s Deceptive and Unfair Trade Practices Act, Fla Stat. Ann. §§ 501-201, *et seq.*, and New York’s General Business Law §§ 349-350.

Our clients were prescribed and purchased losartan-containing medications manufactured and distributed by Torrent. Our clients’ losartan-containing medications were contaminated with N-nitrosodiethylamine (“NDEA”) and/or N-Methylnitrosobutyric acid (NMBA), carcinogenic impurities. On December 20, 2018, the U.S. Food & Drug Administration announced a voluntary recall of certain lots of losartan-containing generic medications manufactured and distributed by Torrent. The recall was due to the presence of NDEA in the recalled products, which later expanded to additional lots on January 22, 2019. The recall expanded again on April 18, 2019 due to the detection of another related impurity, NMBA. These defects rendered the products unusable and unfit for human consumption. In short, the losartan-containing medications that our clients and the Class were purchasing are worthless, as they contained one or more toxic impurities rendering them unfit for human use. Torrent violated express and implied warranties made to our clients and the Class regarding the quality and safety of the losartan-containing medications they purchased, and violated the state consumer protection statutes reference above. *See* U.C.C. §§ 2-313, 2-314.

On behalf of our clients and the Class, we hereby demand that Torrent immediately

- (1) cease and desist from continuing to sell contaminated losartan-containing medications and
- (2) make full restitution to all purchasers of the contaminated losartan-containing medications of all purchase money obtained from sales thereof.

We also demand that Torrent preserve all documents and other evidence which refer or relate to any of the above-described practices including, but not limited to, the following:

1. All documents concerning the packaging, labeling, and manufacturing process for Torrent's losartan-containing medications;
2. All documents concerning the design, development, supply, production, extraction, and/or testing of losartan-containing medications manufactured and distributed by Torrent;
3. All laboratory tests of the losartan-containing medications manufactured and distributed by Torrent;
4. All documents concerning the pricing, advertising, marketing, and/or sale of losartan-containing medications manufactured and distributed by Torrent;
5. All communications with customers involving complaints or comments concerning the losartan-containing medications manufactured and distributed by Torrent;
6. All documents concerning communications with any retailer involved in the marketing or sale of losartan-containing medications manufactured and distributed by Torrent;
7. All documents concerning communications with federal or state regulators; and
8. All documents concerning the total revenue derived from sales of losartan-containing medication.

If you contend that any statement in this letter is inaccurate in any respect, please provide us with your contentions and supporting documents immediately upon receipt of this letter.

Please contact me right away if you wish to discuss an appropriate way to remedy this matter. If I do not hear from you promptly, I will take that as an indication that you are not interested in doing so.

Very truly yours,



Neal J. Deckant