

1 **Kanner & Whiteley, L.L.C.**  
Allan Kanner (SBN 109152)  
2 [a.kanner@kanner-law.com](mailto:a.kanner@kanner-law.com)  
3 Kanner & Whiteley, L.L.C.  
701 Camp Street  
4 New Orleans, LA 70130  
5 (504) 524-5777

6 *Counsel for Plaintiff and the Proposed*  
7 *Class*

8  
9 **UNITED STATES DISTRICT COURT**  
10 **NORTHERN DISTRICT OF CALIFORNIA**

11  
12  
13  
14 MARI JONES, on behalf of herself and all  
others similarly situated,

15 Plaintiffs,

16 v.

17 RECKITT BENCKISER  
18 PHARMACEUTICALS, INC. and RECKITT  
19 BENCKISER LLC,

20 Defendants.

Case No.:

**CLASS ACTION COMPLAINT**

1. **BREACH OF EXPRESS WARRANTY;**
2. **BREACH OF IMPLIED WARRANTY;**
3. **VIOLATION OF THE MAGNUSON-MOSS WARRANTY ACT;**
4. **FRAUD (MISREPRESENTATION AND OMISSION);**
5. **VIOLATION OF STATE CONSUMER PROTECTION LAWS**
6. **UNJUST ENRICHMENT**
7. **NEGLIGENCE**
8. **NEGLIGENCE PER SE**

JURY TRIAL DEMANDED

1 Plaintiff Mari Jones (“Plaintiff”), by her undersigned counsel, on behalf of herself and  
2 all persons similarly situated, brings this Complaint against Defendants Reckitt Benckiser  
3 Pharmaceuticals Inc. and Reckitt Benckiser LLC (“Defendants” or “Reckitt”) and alleges as  
4 follows:

5 **NATURE OF THE ACTION**

6 1. This case arises from the putative class members' purchase of ineffective and  
7 worthless (or, certainly worth less) over-the-counter oral or liquid (not nasal) drugs that were  
8 designed, manufactured, marketed, distributed, packaged, and/or ultimately sold by Reckitt  
9 in the United States that contained phenylephrine (“PE”). Such products for Reckitt include  
10 but are not limited to: Mucinex Fast-Max Severe Congestion & Cough, and Mucinex Fast-  
11 Max Cold & Flu. All of Defendants’ PE-containing products are referred to as “PE Drugs”  
12 herein.

13 2. Defendants’ PE Drugs are marketed by them as effective for treating indications  
14 identified, most often nasal congestion.

15 3. On September 12, 2023, an FDA advisory panel unanimously voted 16-0 that  
16 PE is *not* effective for treating nasal congestion.<sup>1</sup> As stated by the panel, PE is “not effective  
17 as a nasal decongestant.” Thus, it recommends avoiding unnecessary costs or delays in care  
18 by “taking a drug that has no benefit.”<sup>2</sup>

19 4. At all relevant times, Defendants represented that their PE Drugs were properly  
20 branded and effective for treating the indications identified, including *inter alia* treating nasal  
21 congestion.

22 5. These represents were false and deceptive, as Defendants’ PE Drugs were not  
23 effective for treating all the indications identified and/or were misbranded.

24 6. Further, each Defendant willfully ignored scientific and industry knowledge  
25  
26

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27 <sup>1</sup> C. Jewett, A Decongestant in Cold Medicines Doesn’t Work at All, an F.D.A. Panel Says,  
28 NEW YORK TIMES, <https://www.nytimes.com/2023/09/12/health/cold-medicine-decongestantfda.html>?  
(last accessed Sept. 19, 2023).

<sup>2</sup> *Id.*

1 concerning the lack of effectiveness of PE Drugs for treating the indications identified, and  
2 performed inadequate testing and quality oversight of their respective PE Drugs to ascertain  
3 properly the true efficacy of their PE Drugs for treating the indications identified (principally,  
4 nasal decongestion).

5 7. Thus, Defendants' PE drugs are non-merchantable, not fit for ordinary purpose,  
6 and are not effective for treating the indications identified, and were misbranded as a result.

7 8. At all pertinent times for this action, each Defendant represented and warranted  
8 to consumers that its PE Drugs were effective for treating the indications identified and were  
9 properly branded. Specifically, each Defendant represented and warranted that its PE Drugs  
10 were merchantable and fit for their ordinary uses (e.g., effectively treating nasal congestion).

11 9. However, each Defendant willfully ignored scientific and industry knowledge  
12 concerning the lack of effectiveness of PE Drugs for treating the indications identified, and  
13 performed inadequate testing and quality oversight of their respective PE Drugs to ascertain  
14 properly the true efficacy of their PE Drugs for treating the indications identified (principally,  
15 nasal decongestion).

16 10. Accordingly, Plaintiff brings this action to recover for the economic and related  
17 equitable or injunctive relief for themselves and all other persons similarly situated who  
18 purchased Defendants' PE Drugs to redress the unlawful and deceptive practices employed  
19 by Defendants in connection with their labeling, marketing, and sale of PE Drugs.

20 11. Each putative class member paid for Defendants' PE Drugs, but those products  
21 were not effective for treating the indications identified and/or were misbranded, and they  
22 were not fit for ordinary purpose and were not merchantable. As a result of each Defendant's  
23 misconduct, each putative class member was damaged. Each Defendant's conduct as alleged  
24 herein constitutes breach of express and implied warranties and breach of warranty under the  
25 Magnuson Moss Warranty Act, fraud (affirmative and omission), negligent misrepresentation  
26 or omission, negligence and negligence per se, breach of consumer protection laws, and  
27 unjust enrichment.

1 **PARTIES**

2 **A. Plaintiff**

3 12. Plaintiff Mari Jones is a citizen and resident of Sonoma County, California.  
4 During the class period, Plaintiff Jones paid money for Defendants' PE Drugs. Plaintiff  
5 purchased at least one of Defendants' PE Drugs, specifically Mucinex Fast-Max Severe  
6 Congestion & Cough, within the applicable limitations periods. Each Defendant expressly  
7 and impliedly warranted to Plaintiff (either directly or indirectly by adopting warranties that  
8 were passed along to and incorporated further downstream) that their respective PE Drugs  
9 were effective at treating the indication identified and were not misbranded. Plaintiff was  
10 exposed to the product packaging and labeling at the time of each purchase, which  
11 represented and warranted the product was effective for treating the indications identified,  
12 principally nasal congestion. But in fact, Plaintiff bought PE Drugs made by each Defendant  
13 that were not effective at treating the indications identified. Had Plaintiff known this, Plaintiff  
14 would not have paid for Defendants' PE Drugs. Likewise, had each Defendant's deceptions  
15 been made known earlier, Plaintiff would not have paid for each Defendants' PE Drugs.

16 **B. Defendants**

17 13. Defendant Reckitt Benckiser Pharmaceuticals Inc. is a Delaware corporation  
18 with its principal place of business at 10710 Midlothian Turnpike, Suite 430, Richmond,  
19 Virginia, 23235. On information and belief, at all times material to this case, this Defendant  
20 has been engaged in the manufacturing, sale, and/or distribution of misbranded and  
21 ineffective PE Drugs in the United States.

22 14. Defendant Reckitt Benckiser LLC is a limited liability company with its  
23 principal place of business at 399 Interpace Parkway, Parsippany, NJ 07054. On information  
24 and belief, at all times material to this case, this Defendant has been engaged in the  
25 manufacturing, sale, and/or distribution of misbranded and ineffective PE Drugs in the United  
26 States.

**JURISDICTION AND VENUE**

1  
2 15. This Court has original jurisdiction under the Class Action Fairness Act, 28  
3 U.S.C. § 1332(d), because (a) at least one member of the proposed class is a citizen of a state  
4 different from that of each Defendant, (b) the amount in controversy exceeds \$5,000,000,  
5 exclusive of interest and costs, (c) the proposed class consists of more than 100 class  
6 members, and (d) none of the exceptions under the subsection apply to this action.

7 16. This Court has personal jurisdiction over Defendants because each Defendant  
8 has sufficient minimum contacts in this state, and because each Defendant has otherwise  
9 intentionally availed itself of the markets within this state through their business activities,  
10 such that the exercise of jurisdiction by this Court is proper and necessary.

11 17. Venue is proper in this District because the claims alleged in this action accrued  
12 in this District and each Defendant regularly transacts its affairs in this District.

13 18. Each Defendant is subject to the personal jurisdiction of this Court because the  
14 Defendants conduct business within this state, maintain and carry out continuous and  
15 systematic contacts within this state and this judicial District, regularly transact business  
16 within this state and this judicial District, and regularly avail themselves of the benefits of  
17 their presence in this state and this judicial District.

**FACTUAL ALLEGATIONS**

**A. History of PE Drugs**

19  
20 19. Phenylephrine (“PE”) is a specific alpha-1 adrenergic receptor agonist that  
21 works by temporarily constricting blood vessels. By contrast, pseudoephedrine (“PSE”) is a  
22 relatively less selective agonist that acts on both alpha and beta-adrenergic receptors. The  
23 literature reports that PSE is more lipophilic than PE and thus is more accessible to the central  
24 nervous system by crossing the blood-brain barrier (Gheorghiev et al. 2018). The  
25 vasoconstriction effect of PSE is likely contributed to by an indirect action via release of  
26 norepinephrine in synaptic nerve terminals (Gorodetsky 2014).

27 20. The final monograph (“FM”) for over-the-counter nasal decongestant drug  
28 products, issued in 1994, classified the PEH as a GRASE nasal decongestant when

1 administered orally (immediate-release [IR] formulations) or intranasally (M012.80,  
2 previously 21 CFR 341.80). The PEB, an IR effervescent tablet for oral administration, was  
3 added to the monograph in 2006, based on pharmacokinetic (PK) data demonstrating that it  
4 has similar bioavailability to PEH.

5 21. The liquid and oral (not nasal) PE drugs at issue in this case fall within two  
6 categories: (i) phenylephrine hydrochloride; and (ii) phenylephrine bitartrate.

7 22. The Federal Register, dated August 23, 1994 on page 433861 under section III,  
8 first allowed Phenylephrine hydrochloride to be sold: “Based on the available evidence, the  
9 agency is issuing a final monograph establishing conditions under which OTC nasal  
10 decongestant drug products are generally recognized as safe and effective and not  
11 misbranded. Specifically, the following ingredients are included in the final monograph as  
12 OTC oral nasal decongestants: Phenylephrine hydrochloride, pseudoephedrine  
13 hydrochloride, and pseudoephedrine sulfate.”<sup>3</sup>

14 23. Subsequently, Phenylephrine bitartrate was included in the Federal Register on  
15 August 1, 2006 on page 833582: “The Food and Drug Administration (FDA) is issuing a final  
16 rule to amend the final monograph (FM) for over-the-counter (OTC) nasal decongestant drug  
17 products (drug products used to relieve nasal congestion due to a cold, hay fever, or other  
18 upper respiratory allergies) to add phenylephrine bitartrate (PEB), both individually and in  
19 combination drug products in an effervescent dosage form, as generally recognized as safe  
20 and effective (GRASE).”<sup>4</sup>

21 24. As a result of the market withdrawal and restrictions on the sale of other  $\alpha$ -  
22 adrenergic agonists in the early and mid-2000s, Pfizer, Inc, introduced a replacement product  
23 (Sudafed-PE) that contained PE. Other manufacturers, including Defendants in this case,  
24 similarly followed suit by releasing products containing PE.

25 \_\_\_\_\_  
26 <sup>3</sup> Cold, Cough, Allergy, Bronchodilator, and Antiasthmatic Drug Products for Over-the-Counter Human  
27 Use; Final Monograph for OTC Nasal Decongestant Drug Products, 59 Fed. Reg. 43386-01 (Aug. 23,  
1994).

28 <sup>4</sup> Cold, Cough, Allergy, Bronchodilator, and Antiasthmatic Drug Products for Over-the-Counter Human  
Use; Amendment of Monograph for OTC Nasal Decongestant Drug Products, 71 Fed. Reg. 43358-01 (Aug.  
1, 2006).

1           **B. Questions Surrounding the Efficacy of PE Drugs**

2           25. Phenylephrine is an over-the-counter (OTC) ingredient marketed in both single  
3 ingredient and combination products. It has been available in the United States more than 75  
4 years and globally (e.g., Canada, Australia, UK).

5           26. PE has largely been approved for the temporary relief of nasal congestion due  
6 to the common cold, hay fever, or other respiratory allergies, or allergic rhinitis under the  
7 cough, cold, allergy, bronchodilator, and anti-asthmatic drug products monograph (“final  
8 monograph” or “CCABADP”).

9           27. On May 1, 2006, two professors at the University of Florida published a letter  
10 questioning the effectiveness of PE for nasal congestion based upon the results of multiple  
11 double blind, placebo-controlled studies, that show PE was no more effective than placebo in  
12 reducing nasal airway resistance.<sup>5</sup> Moreover, the letter notes that the studies relied on by the  
13 FDA to approve PE were unpublished, manufacturer-sponsored studies conducted by  
14 commercial testing laboratories.

15           28. On February 1, 2007, those professors filed a Citizens Petition with the FDA  
16 concerning PE Drugs.<sup>6</sup>

17           29. Specifically, the Petition requested the dosage of oral phenylephrine (PE) be re-  
18 evaluated and that approval for use in children under twelve years old be withdrawn.<sup>7</sup> The  
19 Petition further stated that there was no data on the safety of PE in children under twelve  
20 years old.<sup>8</sup>

21           30. As a result of the 2007 Citizens Petition, the FDA’s Nonprescription Drugs  
22 Advisory Committee met on December 14, 2007 and concluded that the products could  
23 continue to be sold, but 9 of 12 of the committee members voted that new studies on response  
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25 <sup>5</sup> L. Hendeles and R. Hatton, *Oral phenylephrine: An ineffective replacement for pseudoephedrine?*, 118 J.  
26 ALLERGY AND CLINICAL IMMUNOLOGY 279 (2006), [https://www.jacionline.org/article/S0091-6749\(06\)00633-6/fulltext](https://www.jacionline.org/article/S0091-6749(06)00633-6/fulltext).

27 <sup>6</sup> L. Hendeles, et al., Citizens Petition to U.S. Food and Drug Admin. (Feb. 1, 2007),  
[https://downloads.regulations.gov/FDA-2007-P-0108-0005/attachment\\_1.pdf](https://downloads.regulations.gov/FDA-2007-P-0108-0005/attachment_1.pdf).

28 <sup>7</sup> *Id.* at 1-2.

<sup>8</sup> *Id.* at 2-3.



1 to higher doses were required.<sup>9</sup> Further, a member of the Division of Nonprescription Drug  
2 Products expressed a preference for subjective symptom scores over objective measurement  
3 of nasal airway resistance to support the use of PE for temporary relief of nasal congestion.<sup>10</sup>

4 31. Schering-Plough Pharmaceuticals responded to the recommendations of the  
5 Committee and the Division by conducting a multicenter, phase 2, parallel trial among 539  
6 adults with seasonal allergic rhinitis. The results of the study revealed no significant  
7 differences between placebo and active treatment groups.<sup>11</sup>

8 32. Another manufacturer, McNeil Consumer Healthcare, conducted a  
9 pharmacokinetic, safety and cardiovascular tolerability study of PE. Similarly, this study  
10 revealed no difference in safety endpoints between placebo and 10, 20 and 30 mg of PE even  
11 though systemic exposure increased disproportionately with dose. According to the  
12 petitioners, “This is noteworthy since both the relief of congestion and systemic endpoints  
13 such as change in blood pressure and pulse are mediated by alpha adrenergic stimulation. The  
14 absence of a significant effect on the latter at the higher doses suggest that the concentrations  
15 reached are not sufficient to stimulate alpha adrenergic receptors.”<sup>12</sup>

16 33. On November 4, 2015, the authors of the 2007 Citizen Petition filed an  
17 additional Citizens Petition asking the FDA “to remove oral phenylephrine from the Final  
18 Monograph for OTC nasal decongestant products.” Specifically, the petition asked the FDA  
19 to remove Phenylephrine and to remove phenylephrine bitartrate (PEB), “both individually  
20 and in combination drug products in an effervescent dosage form[.]”<sup>13</sup>

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23 <sup>9</sup> U.S. Food and Drug Admin., Summary Minutes of the NDAC meeting (Dec. 14, 2007), avail. at  
24 [https://wayback.archive-](https://wayback.archive-it.org/7993/20170403222236/https://www.fda.gov/ohrms/dockets/ac/07/minutes/2007-4335m1-Final.pdf)  
25 [it.org/7993/20170403222236/https://www.fda.gov/ohrms/dockets/ac/07/minutes/2007-4335m1-Final.pdf](https://www.fda.gov/ohrms/dockets/ac/07/minutes/2007-4335m1-Final.pdf)  
(last accessed Sep. 19, 2023).

26 <sup>10</sup> L. Hendeles and R. Hatton, Citizens Petition to U.S. Food and Drug Admin. (Nov. 4, 2015), avail. at  
27 [https://truthinadvertising.org/wp-content/uploads/2023/02/Hatton-Hendeles-2015-Citizens-Petition-re-oral-](https://truthinadvertising.org/wp-content/uploads/2023/02/Hatton-Hendeles-2015-Citizens-Petition-re-oral-phenylephrine.pdf)  
[phenylephrine.pdf](https://truthinadvertising.org/wp-content/uploads/2023/02/Hatton-Hendeles-2015-Citizens-Petition-re-oral-phenylephrine.pdf), at 2.

<sup>11</sup> *Id.*

28 <sup>12</sup> *Id.* at 3.

<sup>13</sup> *Id.* at 1.



1           34. According to the 2015 Citizens Petition, “Two additional studies published in  
2 2009 provide further evidence of the absence of a decongestant effect from the FDA-  
3 approved nonprescription dose of 10 mg. Horak et al conducted a 3-way crossover, placebo-  
4 controlled study of the nasal decongestant effect of single doses of PE 12 mg,  
5 pseudoephedrine 60 mg or placebo among 39 grass-sensitive adults exposed to grass pollen  
6 in the Vienna Challenge Chamber. PE was not significantly different from placebo in the  
7 mean change in subjective nasal congestion scores whereas pseudoephedrine, a positive  
8 control in the study, decreased congestion significantly greater than placebo and PE.”<sup>14</sup>

9           35. The 2015 Citizens Petition was further supported by the American Academy of  
10 Allergy, Asthma & Immunology.<sup>15</sup>

11           36. On information and belief, at this time, each Defendant did not do additional  
12 testing and quality oversight of their respective PE Drugs to ascertain the true effectiveness  
13 for treating nasal congestion, or deliberately suppressed or avoid doing so. Had they done so  
14 and/or disclosed the results, the data would lead to the same inexorable conclusion reached  
15 on September 12, 2023 by an FDA Advisory Panel: PE is not effective for treating nasal  
16 congestion at all.

17           **C. The FDA Advisory Panel’s Unanimous Vote**

18           37. On September 12, 2023, the FDA Advisory Panel on the Division of  
19 Nonprescription Drugs recommended that PE Drugs not be sold due to lack of efficacy.<sup>16</sup>

20           38. In the FDA’s Briefing Document regarding the hearing that took place on  
21 September 11-12, 2023, the FDA notes that it has been reviewing the clinical studies on the  
22 efficacy of PE since the 2007 Citizens Petition.<sup>17</sup>

23           39. The Advisory Panel concluded,  
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25 <sup>14</sup> *Id.* at 4.

26 <sup>15</sup> Am. Academy of Allergy, Asthma & Immunology, Statement of Support of Citizens Petition (May 4,  
27 2022), avail. at <https://college.acaai.org/wp-content/uploads/2022/05/oral-phenylephrinefinal-statement-in-support-of-citizens-petition-05-4-22.pdf> (last accessed Sep. 19, 2023).

28 <sup>16</sup> U.S. Food and Drug Admin., Efficacy of Oral Phenylephrine as a Nasal Decongestant (Sep. 12, 2023),  
<https://www.fda.gov/media/171915/download>.

<sup>17</sup> *Id.*

1 In accordance with the effectiveness standard for determining that a category  
2 of over-the-counter (OTC) drugs is generally recognized as safe and effective  
3 that is set forth in 21 CFR § 330.10(a)(4)(ii), which defines effectiveness as:  
4 “a reasonable expectation that, in a significant proportion of the target  
5 population, the pharmacological effect of the drug, when used under adequate  
6 directions for use and warnings against unsafe use, will provide clinically  
7 significant relief of the type claimed”, we have now come to the initial  
8 conclusion that orally administered PE is not effective as a nasal decongestant  
9 at the monographed dosage (10 mg of PE hydrochloride every 4 hours) as well  
10 as at doses up to 40 mg (dosed every 4 hours).<sup>18</sup>

11 40. The Advisory Panel met for two days on September 11-12, 2023. During this  
12 meeting, FDA scientists presented the results of five studies conducted over the past two  
13 decades on the effectiveness of oral phenylephrine. All the studies concluded that the  
14 decongestant was no more effective than a placebo. The Advisory Panel further reevaluated  
15 the initial findings which supported PE Drugs’ use and found that the results were  
16 inconsistent, did not meet modern study design standards and further that these studies may  
17 have data integrity issues:<sup>19</sup>

18 “In conclusion, we do believe that the original studies were methodologically  
19 unsound and do not match today’s standard. By contrast, we believe the new  
20 data are credible and do not provide evidence that oral phenylephrine is  
21 effective as a nasal decongestant,” said Dr. Peter Starke, an FDA official who  
22 led the review of phenylephrine.<sup>20</sup>

23 41. At the conclusion of the meetings, members voted unanimously (16-0) that PE  
24 drugs were ineffective, paving the way for the drugs to be removed from the market.

25 42. Following this vote by the Advisory Panel, the FDA will now need to decide  
26 whether PE Drugs can still be sold and whether drugs should lose their designation as  
27 Generally Recognized as Safe and Effective (GRASE).

#### 28 **D. Misbranded Drugs Are Illegal to Sell**

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<sup>18</sup> *Id.*

<sup>19</sup> B. Lovelace, FDA panel says common over-the-counter decongestant doesn’t work, NBC NEWS (Sep. 12, 2023), <https://www.nbcnews.com/health/health-news/fda-panel-says-commoncounter-decongestant-phneylephrine-doesnt-work-rcna104424> (last accessed Sep. 19, 2023).

<sup>20</sup> *Id.*

1 43. Any drug not manufactured in accordance with cGMPs is deemed “adulterated”  
2 or “misbranded” and may not be distributed or sold in the United States. *See* 21 U.S.C. §§  
3 331(a), 351(a)(2)(B). States have enacted laws adopting or mirroring these federal standards.

4 44. A drug is misbranded:

- 5 a. “If its labeling is false or misleading in any particular”<sup>21</sup>;
- 6 b. “If any word, statement, or other information required ... to appear  
7 on the label or labeling is not prominently placed thereon...in such terms  
8 as to render it likely to be read and understood by the ordinary individual  
9 under customary conditions of purchase and use”<sup>22</sup>;
- 10 c. If the labeling does not contain, among other things, “the proportion  
11 of each active ingredient”<sup>23</sup>;
- 12 d. “Unless its labeling bears (1) adequate directions for use; and (2)  
13 such adequate warnings ... against unsafe dosage or methods or duration  
14 of administration or application, in such manner and form, as are  
15 necessary for the protection of users”<sup>24</sup>;
- 16 e. “If it purports to be a drug the name of which is recognized in  
17 an official compendium, unless it is packaged and labeled as prescribed  
18 therein”<sup>25</sup>
- 19 f. “if it is an imitation of another drug”<sup>26</sup>;
- 20 g. “if it is offered for sale under the name of another drug”<sup>27</sup>;
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25 <sup>21</sup> 21 U.S.C. § 352(a)(1).

26 <sup>22</sup> 21 U.S.C. § 352(c).

27 <sup>23</sup> 21 U.S.C. § 352(e)(1)(A)(ii).

28 <sup>24</sup> 21 U.S.C. § 352(f).

<sup>25</sup> 21 U.S.C. § 352(g).

<sup>26</sup> 21 U.S.C. § 352(i)(2).

<sup>27</sup> 21 U.S.C. § 352(i)(3).

1 h. “If it is dangerous to health when used in the dosage or manner, or  
2 with the frequency or duration prescribed, recommended, or suggested in  
3 the labeling thereof”<sup>28</sup>;

4 i. If the drug is advertised incorrectly in any manner<sup>29</sup>; and/or

5 j. If the drug’s “packaging or labeling is in violation of an applicable  
6 regulation.”<sup>30</sup>

7 45. The manufacture and sale of any misbranded drug is prohibited under federal  
8 law.<sup>31</sup>

9 46. The introduction into commerce of any misbranded drug is also prohibited.<sup>32</sup>

10 47. Similarly, the receipt in interstate commerce of any misbranded or misbranded  
11 drug is also unlawful.<sup>33</sup>

12 48. As articulated in this Complaint, Defendant’s sale of PE Drugs that were not  
13 effective for treating the indications identified were misbranded in violation of the above-  
14 cited reasons.

15 49. Plaintiff’s reference federal law in this Complaint not in any attempt to enforce  
16 it, but to demonstrate that their state-law tort claims do not impose any additional obligations  
17 on any Defendant, beyond what is already required of them under federal law.

18 ***i. Defendant Made False Statements in the Labeling***

19 50. A manufacturer must give adequate directions for the use of a pharmaceutical  
20 drug so that a “layman can use a drug safely and for the purposes for which it is intended,”<sup>34</sup>  
21 and conform to requirements governing the appearance of the label.<sup>35</sup>  
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25 <sup>28</sup> 21 U.S.C. § 352(j).

26 <sup>29</sup> 21 U.S.C. § 352(n).

27 <sup>30</sup> 21 U.S.C. § 352(p).

28 <sup>31</sup> 21 U.S.C. § 331(g).

<sup>32</sup> 21 U.S.C. § 331(a).

<sup>33</sup> 21 U.S.C. § 331(c).

<sup>34</sup> 21 C.F.R. § 201.5.

<sup>35</sup> 21 C.F.R. § 801.15.

1 51. “Labeling” encompasses all written, printed or graphic material accompanying  
2 the drug or device,<sup>36</sup> and therefore broadly includes nearly every form of promotional activity,  
3 including not only “package inserts” but also advertising.

4 52. “Most, if not all, labeling is advertising. The term ‘labeling’ is defined in the  
5 FDCA as including all printed matter accompanying any article. Congress did not, and we  
6 cannot, exclude from the definition printed matter which constitutes advertising.”<sup>37</sup>

7 53. Because the labels on Defendants’ PE drugs indicate that PE can be used to treat  
8 nasal congestion, the subject drugs were misbranded.

9 54. It is unlawful to introduce a misbranded drug into interstate commerce.<sup>38</sup> Thus,  
10 the PE Drugs ingested by Plaintiff were unlawfully distributed and sold.

11 ***ii. Each Defendant’s Warranties and Fraudulent and Deceptive Statements to***  
12 ***Consumers Regarding Their VCDs***

13 55. Each Defendant made and breached express and implied warranties and made  
14 affirmative misrepresentations and omissions to consumers about their PE Drugs.

15 56. Defendants, for instance, touted their PE Drugs as effective for treating nasal  
16 congestion. Their website states:

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<sup>36</sup> *Id.* 65 Fed. Reg. 14286 (March 16, 2000).

28 <sup>37</sup> *U.S. v. Research Labs.*, 126 F.2d 42, 45 (9th Cir. 1942).

<sup>38</sup> 21 U.S.C. § 331(a).

Mucinex

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Home / Maximum Strength Fast-Max® Cold & Flu (All-in-One) Liquid

NIGHT & DAY

# MAXIMUM STRENGTH FAST-MAX® COLD & FLU (ALL-IN-ONE) LIQUID



Maximum strength formula for relief of up to 9 symptoms. This all-in-one medicine relieves multiple cold & flu symptoms.

Also available in Liquid Gels

Also available in Orange & Pineapple Flavor

HSA/FSA eligible expense

3.0 (10) Write a review

Size: 6 FL OZ

Find A Retailer See More Mucinex Products

Mucinex

PRODUCTS ▾ SAVINGS OUR INGREDIENTS TIPS & RESOURCES



Home / Maximum Strength Fast-Max® Severe Congestion & Cough

NIGHT & DAY

# MAXIMUM STRENGTH FAST-MAX® SEVERE CONGESTION & COUGH



Temporarily relieves cough, nasal congestion and helps loosen mucus. When you're fighting a nasty cold, Maximum Strength Fast-Max Severe Congestion & Cough delivers multi-symptom relief.

Also available in caplets

HSA/FSA eligible expense

4.2 (20) Write a review

Size: 6 FL OZ

Find A Retailer See More Mucinex Products

57. They emphasized the PE Drugs' effectiveness for nasal congestion:

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The screenshot displays two product pages from the Mucinex website. The top page is for 'Mucinex FAST-MAX COLD & FLU'. It features a large image of the product bottle, a navigation menu with 'PRODUCTS', 'SAVINGS', 'OUR INGREDIENTS', and 'TIPS & RESOURCES', and a search bar. Below the product image, there are smaller images of other Mucinex products. The 'About' section states: 'Sometimes, when you're sick, you're really sick. 1 dose of this maximum strength formula provides relief from 9 symptoms so you can get on with your day.' It lists symptoms: 'Temporarily relieves these common cold & flu symptoms: Body Pain & Headache, Chest Congestion, Cough, Reduces Fever, Nasal Congestion, Sinus Congestion, Sinus Pressure, Sore Throat.' Product highlights include 'DAY TIME' and 'NIGHT TIME'. The bottom page is for 'Mucinex FAST-MAX SEVERE CONGESTION & COUGH'. It features a large image of the product bottle, a navigation menu, and a search bar. Below the product image, there are smaller images of other Mucinex products. The 'About' section states: 'Some colds come with bothersome symptoms. Nonstop coughing, severe congestion and menacing mucus.' It lists symptoms: 'Temporarily relieves the following symptoms: Chest Congestion, Cough, Nasal Congestion.' Product highlights include 'DAY TIME' and 'NIGHT TIME'.

58. Each of their PE Drugs contained PE as an advertised active ingredient supposedly effective at treating nasal congestion:

**Active Ingredients**

In each 20 mL dose:

Dextromethorphan HBr (20 mg)

Guaifenesin (400 mg)

Phenylephrine HCl (10 mg)



1  
2 59. Defendants' representations on their website, product packaging, product label,  
3 and other advertisements and promotions, were false and misleading. Contrary to  
4 Defendants' statements, and undisclosed by Defendants, PE was not effective at all for  
5 treating nasal congestion. Defendants knew, or should have known, this.

6 **iii. *Fraudulent Concealment and Tolling***

7  
8 60. Plaintiff's and Class Members' causes of action accrued on the date the FDA  
9 announced that PE was not effective at treating the indications identified in Defendants' PE  
10 Drug labeling and packaging, that is, September 12, 2023. This is the first date when Plaintiffs  
11 and Class Members could have reasonably discovered Defendants' unlawful methods, acts,  
12 and/or practices as described herein.

13  
14 61. Each Defendant affirmatively concealed from Plaintiff and other Class Members  
15 its unlawful conduct. Each Defendant affirmatively strove to avoid disclosing their knowledge  
16 of the ineffectiveness of their respective PE Drugs for treating the indications identified,  
17 and/or that such products were misbranded.

18  
19 62. For instance, no Defendant revealed to the public that their PE Drugs were *not*  
20 effective at treating the indications identified, or that in fact PE was not effective at all to treat  
21 same (principally, nasal decongestion), despite reasons to believe the contrary due to their  
22 superior knowledge and position and the manufacturer or seller of their respective PE Drugs.  
23

24  
25 63. To the contrary, each Defendant continued to represent and warrant that its  
26 respective PE Drugs were effective for treating the indications identified, principally nasal  
27 decongestion.  
28

1 64. Because of this, Plaintiff and other Class Members did not discover, nor could  
2 they have discovered through reasonable and ordinary diligence, each Defendant’s deceptive,  
3 fraudulent, and unlawful conduct alleged herein.  
4

5 65. As a result of each Defendant’s affirmative and other acts of concealment, any  
6 applicable statute of limitations affecting the rights of Plaintiff and other Class Members has  
7 been tolled. Plaintiff and/or other Class Members exercised reasonable diligence by among  
8 other things promptly investigating and bringing the allegations contained herein. Despite  
9 these or other efforts, Plaintiff was unable to discover, and could not have discovered, the  
10 unlawful conduct alleged herein at the time it occurred or at an earlier time so as to enable this  
11 complaint to be filed sooner.  
12  
13

14 **CLASS ACTION ALLEGATIONS**

15 66. Plaintiff seeks to represent a Nationwide Class pursuant to Fed. R. Civ. P. 23(a),  
16 23(b)(2) and 23(b)(3) as defined below:  
17

18 **National Class:** All individuals and entities in the United States and its  
19 territories and possessions who paid any amount of money for any  
20 Defendant’s PE Drugs (intended for personal or household use).

21 **California Subclass:** All individuals and entities California who paid any  
22 amount of money for any Defendant’s PE Drugs (intended for personal or  
23 household use).

24 67. Plaintiff alleges additional sub-classes for all Class Members in each State,  
25 territory, or possession – or combination(s) of States, territories, or possessions to the extent  
26 class members from these jurisdictions can be grouped together for purposes of class treatment  
27 – who, paid any amount of money for PE Drugs (intended for personal or household use) that  
28 was manufactured, distributed, or sold by any Defendant (collectively, the “Subclasses”).

1 68. Collectively, the foregoing Nationwide Class and the Subclasses are referred to  
2 as the “Class.”

3  
4 69. Excluded from the Class are: (a) any judge or magistrate presiding over this  
5 action, and members of their families; (b) Defendants and affiliated entities, and their  
6 employees, officers, directors, and agents; (c) Defendants’ legal representatives, assigns and  
7 successors; and (d) all persons who properly execute and file a timely request for exclusion  
8 from any Court-approved class.  
9

10 70. Plaintiff reserves the right to narrow or expand the foregoing class definition, or  
11 to create or modify subclasses as the Court deems necessary.  
12

13 71. Plaintiff meets the prerequisites of Rule 23(a) to bring this action on behalf of the  
14 Class.  
15

16 72. **Numerosity:** Membership in the Class is so numerous that separate joinder of  
17 each member is impracticable. The precise number of Class Members is unknown at this time  
18 but can be readily determined from Defendants’ records. Plaintiffs reasonably estimate that  
19 there are at least thousands of persons in the Class.  
20

21 73. **Existence and predominance of common questions of law and fact:** Common  
22 questions of law and fact exist as to all Class and Subclass Members and predominate over  
23 any questions affecting on individual Class and Subclass members. These common legal and  
24 factual questions include, but are not limited to, the following:  
25  
26  
27  
28

1 a. Whether each Defendant made express or implied warranties that their  
2 respective PE Drugs were effective for treating the indications identified (principally,  
3 nasal decongestion);  
4

5 b. Whether each Defendant's PE Drugs were not effective for treating the  
6 indications identified (principally, nasal decongestion);  
7

8 c. Whether each Defendant knew or should have known the truth about the  
9 effectiveness or lack thereof for their respective PE Drugs;

10 d. Whether Plaintiff and other Class Members have been injured as a result  
11 of each Defendant's unlawful conduct, and the amount of their damages;

12 e. Whether a common damages model can calculate damages on a class-wide  
13 basis;  
14

15 f. When Plaintiff's and Class Members' causes of action accrued; and

16 g. Whether each Defendant fraudulently concealed Plaintiff's and Class  
17 Members' causes of action.  
18

19  
20 74. **Typicality:** Plaintiff's claims are typical of Class Members' claims. Plaintiff and  
21 Class Members all suffered the same type of economic harm. Plaintiff has substantially the  
22 same interest in this matter as all other Class Members, and their claims arise out of the same  
23 set of facts and conduct as the claims of all other Class Members.  
24

25 75. **Adequacy of Representation:** Plaintiff is committed to pursuing this action and  
26 have retained competent counsel experienced in pharmaceutical litigation, consumer fraud  
27 litigation, class actions, and federal court litigation. Accordingly, Plaintiff and their counsel  
28

1 will fairly and adequately protect the interests of Class Members. Plaintiff's claims are  
2 coincident with, and not antagonistic to, those of the other Class Members they seek to  
3 represent. Plaintiff has no disabling conflicts with Class Members and will fairly and  
4 adequately represent the interests of Class Members.  
5

6 76. The elements of Rule 23(b)(2) are met. Defendant has acted on grounds that apply  
7 generally to Class Members so that preliminary and/or final injunctive relief and  
8 corresponding declaratory relief is appropriate respecting the Class as a whole.  
9

10 77. **Superiority:** A class action is superior to all other available means for the fair  
11 and efficient adjudication of this controversy. Although many other Class Members have  
12 claims against each Defendant, the likelihood that individual Class Members will prosecute  
13 separate actions is remote due to the time and expense necessary to conduct such litigation.  
14 Serial adjudication in numerous venues would not be efficient, timely or proper. Judicial  
15 resources would be unnecessarily depleted by resolution of individual claims. Joinder on an  
16 individual basis of thousands of claimants in one suit would be impractical or impossible. In  
17 addition, individualized rulings and judgments could result in inconsistent relief for similarly  
18 situated Plaintiff. Plaintiff's counsel, highly experienced in pharmaceutical litigation,  
19 consumer fraud litigation, class actions, and federal court litigation, foresee little difficulty in  
20 the management of this case as a class action.  
21  
22  
23  
24

25 **CAUSES OF ACTION**

26 **FIRST COUNT**

27 **BREACH OF EXPRESS WARRANTIES**

28 78. Plaintiff re-alleges and incorporates the preceding paragraphs as if fully set forth

1 herein.

2 79. Plaintiff, and each member of the Class, formed a contract with each Defendant  
3 at the time Plaintiff and the other Class Members purchased the PE Drugs. The terms of the  
4 contract include the promises and affirmations of fact made by Defendant on the PE Drugs'  
5 packaging and through marketing and advertising, including that the product would be  
6 effective for the indications provided. This labeling, marketing, and advertising constitute  
7 express warranties and became part of the basis of the bargain, and are part of the standardized  
8 contract between Plaintiff and the members of the Class and Defendants.  
9

10  
11 80. Each Defendant expressly warranted that its PE Drugs were fit for ordinary use  
12 and effective for the indications listed and were merchantable and not misbranded.  
13

14 81. Each Defendant sold PE Drugs that they expressly warranted to be effective at  
15 treating the indications identified and were not misbranded.  
16

17 82. At all times relevant all fifty States and the District of Columbia and Puerto Rico  
18 have codified and adopted the provisions of the Uniform Commercial Code: Ala. Code § 7-2-  
19 313; Alaska Stat. § 45.02.313; Ariz. Rev. Stat. Ann. § 47-2313; Ark. Code. Ann. § 4-2-313;  
20 Cal. Com. Code § 2313; Colo. Rev. Stat. § 4-2-313; Conn. Gen. Stat. Ann. § 42a-2-313; 6  
21 Del. Code. § 2-313; D.C. Code. § 28:2-313; Fla. Stat. Ann. § 672.313; Ga. Code. Ann. § 11-  
22 2-313; Haw. Rev. Stat. § 490:2- 313; Idaho Code § 28-2-313; 810 Ill. Comp. Stat. Ann. 5/2-  
23 313; Ind. Code Ann. § 26-1-2-313; Kan. Stat. Ann. § 84-2-313; Ky. Rev. Stat. Ann. § 355.2-  
24 313; La. Civ. Code Ann. Art. §§ 1943, 2520; 11 Me. Rev. Stat. Ann. § 2-313; Md. Code. Ann.  
25 § 2-313; Mass. Gen. Law Ch. 106 § 2-313; Mich. Comp. Laws Ann. § 440.2313; Minn. Stat.

1 Ann. § 336.2-313; Miss. Code Ann. § 75-2-313; Mo. Rev. Stat. § 400.2-313; Mont. Code Ann.  
2 § 30-2-313; Nev. Rev. Stat. U.C.C. § 104.2313; N.H. Rev. Ann. § 382-A:2-313; N.J. Stat.  
3 Ann. § 12A:2-313; N.M. Stat. Ann. § 55-2-313; N.Y. U.C.C. Law § 2-313; N.C. Gen. Stat.  
4 Ann. § 25-2-313; N.D. Stat. § 41-02-313; Ohio Rev. Code Ann. § 1302.26; Okla. Stat. tit. 12A  
5 § 2-313; Or. Rev. Stat. § 72.3130; 13 Pa. C.S. § 2313; P.R. Laws. Ann. Tit. 31, § 3841, et seq.;  
6 R.I. Gen. Laws § 6A-2-313; S.C. Code Ann. § 36-2-313; S.D. Stat. § 57A-2-313; Tenn. Code  
7 Ann. § 47-2-313; Tex. Bus. & Com. Code Ann. § 2-313; Utah Code Ann. § 70A-2-313; Va.  
8 Code § 8.2- 313; Vt. Stat. Ann. 9A § 2-313; W. Va. Code § 46-2-313; Wash. Rev. Code §  
9 62A 2-313; Wis. Stat. Ann. § 402.313; and Wyo. Stat. § 34.1-2-313.

10  
11  
12  
13 83. Each Defendant knew or should have known that its PE Drugs were being  
14 manufactured and sold for the intended purpose of human consumption for treating the  
15 indications identified (or is strictly liable in the event of lack of actual or constructive  
16 knowledge), and impliedly warranted that their PE Drugs were of merchantable quality and  
17 fit for that purpose.

18  
19  
20 84. Each Defendant breached its express warranty because each Defendant's PE  
21 Drugs were not of merchantable quality, nor fit for the product's ordinary purpose, and did  
22 not conform to the standards generally applicable to such goods.

23  
24 85. Each Defendant's express warranties were reflected in each PE Drug's product  
25 labeling (e.g., label, instructions, packaging) and promotion and marketing material, all of  
26 which uniformly identified PE as an active ingredient for effective treatment of the indications  
27 identified, principally nasal decongestion. Each Defendant's product labeling and other  
28



1 materials had to be truthful, accurate, and non-deceptive. But this was not the case, insofar as  
2 each Defendant's product labeling and other materials did not disclose that PE is not effective  
3 for the indications identified, principally nasal congestion.  
4

5 86. Each Defendant's PE Drugs did not fulfill their intended purpose. Plaintiff and  
6 other Class Members bargained for an adequately made, adequately labeled product, that  
7 performed as warranted. But each Defendant's PE Drugs were not adequately made, were not  
8 adequately labeled, and did not perform as warranted.  
9

10 87. Plaintiff and other Class Members purchased the PE Drugs in reliance upon  
11 Defendant's skill and judgment and the express warranties made.  
12

13 88. Plaintiff and other Class Members were reasonably expected purchasers who  
14 would use, consumer or be affected by (or whose insureds would use, consumer or be affected  
15 by) the misbranded, not effective PE Drugs marketed by each Defendant.  
16

17 89. The PE Drugs were not altered by Plaintiff or Class members.

18 90. As a direct and proximate result of each Defendant's breach of implied warranty,  
19 Plaintiff and other Class Members have been injured and suffered damages, in that  
20 Defendant's PE Drugs they purchased was so inherently flawed, unfit, or unmerchantable as  
21 to have significantly diminished or no intrinsic market value.  
22

23 91. To the extent applicable, pre-suit notice and/or a demand letter was sent to each  
24 Defendant prior to the filing of the Complaint.  
25  
26  
27  
28

**SECOND COUNT**

**BREACH OF IMPLIED WARRANTIES**

1  
2  
3 92.Plaintiff re-alleges and incorporates the preceding paragraphs as if full set forth  
4 herein.

5 93.Plaintiff, and each member of the Class, formed a contract with each Defendant at  
6 the time Plaintiff and the other Class Members purchased the PE Drugs. The terms of the  
7 contract include the promises and affirmations of fact made by Defendant on the PE Drugs’  
8 packaging and through marketing and advertising, including that the product would be  
9 effective for the indications provided. This labeling, marketing, and advertising constitute  
10 express warranties and became part of the basis of the bargain, and are part of the standardized  
11 contract between Plaintiff and the members of the Class and Defendants.  
12  
13

14 94.At all times relevant all fifty States and the District of Columbia and Puerto Rico  
15 have codified and adopted the provisions of the Uniform Commercial Code governing the  
16 implied warranty of merchantability and fitness for ordinary purpose: Ala. Code § 7-2-314;  
17 Alaska Stat. § 45.02.314; Ariz. Rev. Stat. Ann. § 47-2314; Ark. Code. Ann. § 4-2-314; Cal.  
18 Com. Code § 2314; Colo. Rev. Stat. § 4-2-314; Conn. Gen. Stat. Ann. § 42a-2-314; 6 Del.  
19 Code. § 2-314; D.C. Code. § 28:2-314; Fla. Stat. Ann. § 672.314; Ga. Code. Ann. § 11-2-314;  
20 Haw. Rev. Stat. § 490:2- 314; Idaho Code § 28-2-314; 810 Ill. Comp. Stat. Ann. 5/2-314; Kan.  
21 Stat. Ann. § 84-2-314; Ky. Rev. Stat. Ann. § 355.2-314; ; La. Civ. Code Ann. Art. § 2520; 11  
22 Me. Rev. Stat. Ann. § 2-314; Md. Code. Ann. § 2-314; Mass. Gen. Law Ch. 106 § 2-314;  
23 Mich. Comp. Laws Ann. § 440.2314; Minn. Stat. Ann. § 336.2-314; Miss. Code Ann. § 75-2-  
24 314; Mo. Rev. Stat. § 400.2-314; Mont. Code Ann. § 30-2-314; Nev. Rev. Stat. U.C.C. §  
25  
26  
27  
28

1 104.2314; N.H. Rev. Ann. § 382-A:2-314; N.J. Stat. Ann. § 12A:2-314; N.M. Stat. Ann. § 55-  
2 2-314; N.Y. U.C.C. Law § 2-314; N.C. Gen. Stat. Ann. § 25-2-314; N.D. Stat. § 41-02-314;  
3  
4 Ohio Rev. Code Ann. § 1302.27; Okla. Stat. tit. 12A § 2-314; Or. Rev. Stat. § 72.3140; 13 Pa.  
5 C.S. § 2314; P.R. Laws. Ann. Tit. 31, § 3841, et seq.; R.I. Gen. Laws § 6A-2-314; S.C. Code  
6 Ann. § 36-2-314; S.D. Stat. § 57A-2-314; Tenn. Code Ann. § 47-2-314; Tex. Bus. & Com.  
7 Code Ann. § 2-314; Utah Code Ann. § 70A-2-314; Va. Code § 8.2-314; Vt. Stat. Ann. 9A §  
8 2-314; W. Va. Code § 46-2-314; Wash. Rev. Code § 62A 2-314; Wis. Stat. Ann. § 402.314;  
9  
10 and Wyo. Stat. § 34.1-2-314.

11  
12 95. Each Defendant was a merchant within the meaning of the above statutes.

13 96. Each Defendant's PE Drugs constituted "goods" or the equivalent within the  
14 meaning of the above statutes. Each Defendant placed their PE Drugs in sealed packaging or  
15 other closed containers and placed them on the market.  
16

17 97. Each Defendant impliedly warranted that its PE Drugs were fit for ordinary use and  
18 effective for the indications listed and were merchantable and not misbranded.

19  
20 98. Each Defendant sold PE Drugs that they impliedly warranted to be effective at  
21 treating the indications identified and were not misbranded.

22 99. Each Defendant knew or should have known that its PE Drugs were being  
23 manufactured and sold for the intended purpose of human consumption for treating the  
24 indications identified (or is strictly liable in the event of lack of actual or constructive  
25 knowledge), and impliedly warranted that their PE Drugs were of merchantable quality and  
26 fit for that purpose.  
27  
28

1 100. Each Defendant breached its implied warranty because each Defendant's PE  
2 Drugs were not of merchantable quality, nor fit for the product's ordinary purpose, and did  
3 not conform to the standards generally applicable to such goods.  
4

5 101. Plaintiff and other Class Members purchased the PE Drugs in reliance upon  
6 Defendant's skill and judgment and the implied warranties of fitness for the purpose.  
7

8 102. Each Defendant's PE Drugs did not fulfill their intended purpose. Plaintiff and  
9 other Class Members bargained for an adequately made, adequately labeled product, that  
10 performed as warranted. But each Defendant's PE Drugs were not adequately made, were not  
11 adequately labeled, and did not perform as warranted.  
12

13 103. Each Defendant's implied warranties were reflected in each PE Drug's product  
14 labeling (e.g., label, instructions, packaging) and promotion and marketing material, all of  
15 which uniformly identified PE as an active ingredient for effective treatment of the indications  
16 identified, principally nasal decongestion. Each Defendant's product labeling and other  
17 materials had to be truthful, accurate, and non-deceptive. But this was not the case, insofar as  
18 each Defendant's product labeling and other materials did not disclose that PE is not effective  
19 for the indications identified, principally nasal congestion.  
20  
21

22 104. Each Defendant's PE Drugs did not fulfill their intended purpose. Plaintiff and  
23 other Class Members bargained for an adequately made, adequately labeled product, that  
24 performed as warranted. But each Defendant's PE Drugs were not adequately made, were not  
25 adequately labeled, and did not perform as warranted.  
26

27 105. Plaintiff and other Class Members purchased the PE Drugs in reliance upon  
28

1 Defendant's skill and judgment and the express warranties made.

2 106. Plaintiff and other Class Members were reasonably expected purchasers who  
3 would use, consumer or be affected by (or whose insureds would use, consumer or be affected  
4 by) the misbranded, not effective PE Drugs marketed by each Defendant.  
5

6 107. Plaintiff and other Class Members were the intended third-party beneficiary  
7 recipients of all arrangements Defendant had with downstream resellers of Defendant's PE  
8 Drugs. Plaintiffs and other Class Members were those whose benefit any promises,  
9 affirmations, or warranties were made by Defendant concerning the PE Drugs, as they were  
10 the intended end purchasers and end users (or, in the case of entities, their insureds were the  
11 intended end users) of Defendant's PE Drugs, which Defendant knew by virtue of its position  
12 as manufacturer and seller of the PE Drugs.  
13  
14

15 108. The PE Drugs were not altered by Plaintiff or Class members.  
16

17 109. As a direct and proximate result of each Defendant's breach of implied warranty,  
18 Plaintiff and other Class Members have been injured and suffered damages, in that  
19 Defendant's PE Drugs they purchased were so inherently flawed, unfit, or unmerchantable as  
20 to have significantly diminished or no intrinsic market value.  
21

22 110. To the extent applicable, pre-suit notice and/or a demand letter was sent to each  
23 Defendant prior to the filing of the Complaint.  
24

25  
26 **THIRD COUNT**

27 **MAGNUSON-MOSS WARRANTY ACT, 15 U.S.C. § 2301, ET SEQ.**  
28

1 111. Plaintiff re-alleges and incorporates the preceding paragraphs as if fully set forth  
2 herein.

3  
4 112. Each Defendant is a “warrantor” within the meaning of the Magnuson-Moss  
5 Warranty Act.

6 113. Plaintiff and other Class Members are “consumers” within the meaning of the  
7 Magnuson-Moss Warranty Act.  
8

9 114. Each Defendant expressly or impliedly warranted their PE Drugs as alleged in  
10 the First and Second Causes of Action.  
11

12 115. Under 15 U.S.C. § 2310(d)(1), Plaintiff and other Class Members were “damaged  
13 by the failure of a supplier, warrantor, or service contractor to comply with any obligation  
14 under this chapter, or under a written warranty, implied warranty, or service contract, may  
15 bring suit for damages and other legal and equitable relief.” 15 U.S.C. § 2310(d)(1). Plaintiff  
16 sues pursuant to this section to recover money damages and for legal and equitable relief on  
17 behalf of itself and the Class Members.  
18

19  
20 116. Each Defendant has not acted on the opportunity to cure its failure with respect  
21 to its warranted PE Drugs.

22 117. Likewise, pursuant to 15 U.S.C. § 2310(d)(2), upon prevailing in this action,  
23 Plaintiffs are entitled to receive an award of attorneys’ fees and expenses and pray for the  
24 same.  
25

26 **FOURTH COUNT**  
27  
28

**FRAUD (AFFIRMATIVE MISREPRESENTATION AND OMISSION)**

1  
2 118. Plaintiff re-alleges and incorporates the preceding paragraphs as if fully set forth  
3 herein.

4 119. Each Defendant affirmatively misrepresented material facts including, inter alia,  
5 that their PE Drugs were effective at treating the indications identified and/or were not  
6 misbranded.

7  
8 120. Each Defendant omitted material facts including, inter alia, that their PE Drugs  
9 were not effective at treating the indications identifies and/or were misbranded.

10  
11 121. Each Defendant's actions had the effect of fraudulently inducing customers to  
12 pay in whole or in part for each Defendant's PE Drugs – products which each Defendant knew  
13 or should have known were not effective at treating the indications identified and/or were  
14 misbranded. Plaintiff and other Class Members would not have purchased Defendants' PE  
15 Drugs had they known the truth. Indeed, Plaintiff and other Class Members could not have  
16 paid for Defendants' PE Drugs had they known the truth because Defendants' PE Drugs were  
17 illegally manufactured, illegally imported, illegally distributed, and illegally sold to Plaintiffs  
18 and Class Members based on each Defendants' fraudulent misrepresentations and omissions.

19  
20  
21 122. Each Defendant knew or should have known about the effectiveness and  
22 branding status of its PE Drugs as a result of industry and regulatory guidance dating back  
23 years.

24  
25 123. Each Defendant knowingly, or at least recklessly, represented that its PE Drugs  
26 were effective in treating the indications identified and not misbranded, when that was not the  
27 case. Rather, each Defendant knew or recklessly disregarded industry and regulatory guidance  
28



1 that was available to each Defendant.

2 124. Each Defendant knew, or reasonably should have known, that their  
3 misrepresentations were materially false or misleading, or that the omission of material facts  
4 rendered such representations false or misleading.  
5

6 125. Each Defendant also knew, or had reason to know, that their misrepresentations  
7 and omissions would induce Class Members to pay for some or all of the cost of Defendant's  
8 PE Drugs.  
9

10 126. Each Defendant's misrepresentations and omissions were material.

11 127. Each Defendant's actively concealed their misrepresentations and omissions  
12 from the Class, government regulators, and the public.  
13

14 128. To the extent applicable, each Defendant intended their misrepresentations and  
15 omissions to induce Plaintiffs and other Class Members to pay for each Defendant's PE Drugs.  
16

17 129. But for these misrepresentations and omissions, Plaintiff and other Class  
18 Members would not have paid for each Defendant's PE Drugs.  
19

20 130. To the extent applicable, Plaintiff and other Class Members were justified in  
21 relying on each Defendant's misrepresentations and omissions. The same or substantively  
22 identical misrepresentations and omissions were communicated, to each Class Member,  
23 including through product labeling and other statements by each Defendant. No reasonable  
24 consumer would have paid what they did for Defendants' PE Drugs but for Defendants'  
25 unlawful conduct. To the extent applicable, reliance may be presumed in these circumstances.  
26  
27

28 131. Plaintiff and other Class Members were damaged by reason of Defendants'

1 misrepresentations and omissions alleged herein.

2 **FIFTH COUNT**

3 **NEGLIGENT MISREPRESENTATION AND OMISSION**

4 132. Plaintiff re-alleges and incorporates the preceding paragraphs as if fully set forth  
5 herein.

6  
7 133. Each Defendant had or undertook a duty to represent the effectiveness of its PE  
8 Drugs accurately and truthfully.

9  
10 134. Each Defendant failed to exercise ordinary care in making representations (or in  
11 failing to disclose facts) concerning the effectiveness of its PE Drugs.

12 135. Each Defendant negligently misrepresented or omitted facts regarding the  
13 effectiveness of its PE Drugs.

14  
15 136. Defendant's statements were false at the time the misrepresentations were made  
16 (or at the time omissions were not made).

17  
18 137. Each Defendant knew, or reasonably should have known, that its representations  
19 alleged herein were materially false or misleading, or that omission of material facts rendered  
20 such representations false or misleading. Each Defendant also knew, or had reason to know,  
21 that its misrepresentations and omissions would induce Class Members to make purchases of  
22 each Defendant's PE Drugs.

23  
24 138. Each Defendant had a duty to exercise reasonable care in the manufacture, quality  
25 control, and distribution of PE Drugs. Each Defendant's failure to exercise this duty, in spite  
26 of knowing or recklessly disregarding the effectiveness of its PE Drugs, meant Defendants  
27 could not assure that their PE Drugs were of as represented effectiveness.  
28

1 139. As a direct and proximate result of Defendants' acts and omissions described  
2 herein, Plaintiffs and other Class Members have suffered harm, and will continue to do so.

3  
4 140. Each Defendant's misrepresentations or omissions were material and a  
5 substantial factor in Plaintiffs' and other Class Members' paying for PE Drugs.

6 141. Each Defendant intended its misrepresentations or omissions to induce Plaintiff  
7 and Class Members to make purchases of PE Drugs, or had reckless disregard for same.

8  
9 142. But for these misrepresentations (or omissions), Plaintiff and other Class  
10 Members would not have made purchases of Defendants' PE Drugs.

11  
12 143. Plaintiff and other Class Members were justified in relying on Defendants'  
13 misrepresentations or omissions. The same or substantively identical misrepresentations were  
14 communicated, and/or the same or substantively identical omissions were not communicated,  
15 to each Class Member.

16  
17 144. Plaintiff and other Class Members were damaged by reason of each Defendant's  
18 misrepresentations or omissions alleged herein.

19  
20 **SIXTH COUNT**

21 **VIOLATION OF STATE CONSUMER PROTECTION LAWS**

22 145. Plaintiff re-alleges and incorporates the preceding paragraphs as if fully set forth  
23 herein.

24 146. Each Defendant has violated the consumer protection statutes as follows:

- 25  
26 a. Defendants have engaged in unfair competition or unfair or deceptive acts  
27 or practices in violation of Ala. Code § 8-19-1, *et seq.*;
- 28 b. Defendants have engaged in unfair competition or unfair or deceptive acts

1 or practices in violation of Alaska Stat. § 45.50.471, *et seq.*;

2 c. Defendants have engaged in unfair competition or unfair or deceptive acts  
3 or practices in violation of Arizona Rev. Stat. § 44-1522, *et seq.*;

4 d. Defendants have engaged in unfair competition or unfair or deceptive acts  
5 or practices in violation of Ark. Code § 4-88-101, *et seq.*;

6 e. Defendants have violated the California Unfair Competition Law by  
7 engaging in unfair or deceptive acts or practices in violation of Cal. Bus.  
8 Prof. Code § 17200, *et seq.*;

9 f. Defendants have violated the California Consumers Legal Remedies Act,  
10 Cal. Civ. Code §§ 1750, *et seq.*;

11 g. Defendants have violated the California False Advertising Law, Cal. Bus.  
12 & Prof. Code §§ 17500, *et seq.*

13 h. Defendants have engaged in unfair competition or unfair or deceptive acts  
14 or practices in violation of Colo. Rev. Stat. § 6-1-105, *et seq.*;

15 i. Defendants have engaged in unfair competition or unfair or deceptive acts  
16 or practices in violation of Conn. Gen. Stat. § 42-110b, *et seq.*;

17 j. Defendants have engaged in unfair competition or unfair or deceptive acts  
18 or practices in violation of 6 Del. Code § 2511, *et seq.*;

19 k. Defendants have engaged in unfair competition or unfair or deceptive acts  
20 or practices in violation of D.C. Code § 28-3901, *et seq.*;

21 l. Defendant have engaged in unfair competition or unfair or deceptive acts  
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1 or practices in violation of Fla. Stat. § 501.201, *et seq.*;

2 m. Defendants have engaged in unfair competition or unfair or deceptive acts  
3 or practices in violation of Ga. State 10-1-392, *et seq.*;

4 n. Defendants have engaged in unfair competition or unfair or deceptive acts  
5 or practices in violation of Haw. Rev. Stat. § 480, *et seq.*;

6 o. Defendants have engaged in unfair competition or unfair or deceptive acts  
7 or practices in violation of Idaho Code § 48-601, *et seq.*;

8 p. Defendants have engaged in unfair competition or unfair or deceptive acts  
9 or practices in violation 815 ILCS 505/1, *et seq.*;

10 q. Defendants have engaged in unfair competition or unfair or deceptive acts  
11 or practices in violation of Ind. Code Ann. § 24-5-0.5.1, *et seq.*;

12 r. Defendants have engaged in unfair competition or unfair or deceptive acts  
13 or practices in violation of Iowa Code Ann. § 714H, *et seq.*;

14 s. Defendants have engaged in unfair competition or unfair or deceptive acts  
15 or practices in violation of Kan. Stat. § 50-623, *et seq.*;

16 t. Defendants have engaged in unfair competition or unfair or deceptive acts  
17 or practices in violation of Ky. Rev. Stat. § 367.110, *et seq.*;

18 u. Defendants have engaged in unfair competition or unfair or deceptive acts  
19 or practices in violation of La. Rev. Stat. § 51:1401, *et seq.* and  
20 alternatively La. Rev. Stat. Ann. § 9:2800.51, *et seq.*;

21 v. Defendants have engaged in unfair competition or unfair or deceptive acts  
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1 or practices in violation of 5 Me. Rev. Stat. § 207, *et seq.*;

2 w. Defendant have engaged in unfair competition or unfair or deceptive acts  
3 or practices in violation of Md. Com. Law Code § 13-101, *et seq.*;

4 x. Defendants have engaged in unfair competition or unfair or deceptive acts  
5 or practices in violation of Mass. Gen. L. Ch. 93A, *et seq.*;

6 y. Defendants have engaged in unfair competition or unfair or deceptive acts  
7 or practices in violation of Mich. Stat. § 445.901, *et seq.*;

8 z. Defendants have engaged in unfair competition or unfair or deceptive acts  
9 or practices in violation of Minn. Stat. § 325F.67, *et seq.*;

10 aa. Defendants have engaged in unfair competition or unfair or deceptive acts  
11 or practices in violation of Miss. Code Ann. § 75-24-1, *et seq.*;

12 bb. Defendants have engaged in unfair competition or unfair or deceptive acts  
13 or practices in violation of Mo. Rev. Stat. § 407.0 10, *et seq.*;

14 cc. Defendants have engaged in unfair competition or unfair or deceptive acts  
15 or practices in violation of Mont. Code § 30-14-101, *et seq.*;

16 dd. Defendants have engaged in unfair competition or unfair or deceptive acts  
17 or practices in violation of Neb. Rev. Stat. § 59-1601, *et seq.*;

18 ee. Defendants have engaged in unfair competition or unfair or deceptive acts  
19 or practices in violation of Nev. Rev. Stat. § 598.0903, *et seq.*;

20 ff. Defendants have engaged in unfair competition or unfair or deceptive acts  
21 or practices in violation of N.H. Rev. Stat. § 358-A:1, *et seq.*;

- 1 gg. Defendants have engaged in unfair competition or unfair or deceptive acts  
2 or practices in violation of N.J. Stat. Ann. § 56:8-1, *et seq.*;
- 3  
4 hh. Defendants have engaged in unfair competition or unfair or deceptive acts  
5 or practices in violation of N.M. Stat. Ann. § 57-12-1, *et seq.*;
- 6  
7 ii. Defendants have engaged in unfair competition or unfair or deceptive acts  
8 or practices in violation of N.Y. Gen. Bus. Law § 349, *et seq.*;
- 9  
10 jj. Defendants have engaged in unfair competition or unfair or deceptive acts  
11 or practices in violation of N.C. Gen. Stat. § 75-1.1, *et seq.*;
- 12  
13 kk. Defendants have engaged in unfair competition or unfair or deceptive acts  
14 or practices in violation of N.D. Cent. Code § 51-15-01, *et seq.*;
- 15  
16 ll. Defendants have engaged in unfair competition or unfair or deceptive acts  
17 or practices in violation of Ohio Rev. Stat. § 1345.01, *et seq.*
- 18  
19 mm. Defendants have engaged in unfair competition or unfair or deceptive acts  
20 or practices in violation of Okla. Stat. tit. 15 § 751, *et seq.*;
- 21  
22 nn. Defendants have engaged in unfair competition or unfair or deceptive acts  
23 or practices in violation of Or. Rev. Stat. § 646.605, *et seq.*;
- 24  
25 oo. Defendants have engaged in unfair competition or unfair or deceptive acts  
26 or practices in violation of 73 Pa. Stat. § 201-1, *et seq.*;
- 27  
28 pp. Defendants have engaged in unfair competition or unfair or deceptive acts  
or practices in violation of R.I. Gen. Laws § 6-13.1-1, *et seq.*;
- qq. Defendants have engaged in unfair competition or unfair or deceptive acts

1 or practices in violation of S.C. Code Laws § 39-5-10, *et seq.*;

2 rr. Defendants have engaged in unfair competition or unfair or deceptive acts  
3 or practices in violation of S.D. Code Laws § 37-24-1, *et seq.*;

4 ss. Defendants have engaged in unfair competition or unfair or deceptive acts  
5 or practices in violation of Tenn. Code § 47-18-101, *et seq.*;

6 tt. Defendants have engaged in unfair competition or unfair or deceptive acts  
7 or practices in violation of Tex. Bus. & Com. Code § 17.41, *et seq.*;

8 uu. Defendant have engaged in unfair competition or unfair or deceptive acts  
9 or practices in violation of Utah Code Ann. § 13-11-1, *et seq.*;

10 vv. Defendant have engaged in unfair competition or unfair or deceptive acts  
11 or practices in violation of Vt. Stat. Ann. Tit. 9, § 2451, *et seq.*;

12 ww. Defendants have engaged in unfair competition or unfair or deceptive acts  
13 or practices in violation of Va. Code § 59.1-196, *et seq.*;

14 xx. Defendants have engaged in unfair competition or unfair or deceptive acts  
15 or practices in violation of Wash. Rev. Code § 19.86.010, *et seq.*;

16 Defendants have engaged in unfair competition or unfair or deceptive acts  
17 or practices in violation of W. Va. Code § 46A-6-101, *et seq.*;

18 yy. Defendants have engaged in unfair competition or unfair or deceptive acts  
19 or practices in violation of Wis. Stat. § 100.20, *et seq.*;

20 zz. Defendants have engaged in unfair competition or unfair or deceptive acts  
21 or practices in violation of Wyo. Stat. § 40-12-100, *et seq.*; and  
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1 States for human consumption. On top of that, because each Defendant's PE Drugs were  
2 misbranded, their distribution and sale in the United States was illegal.

3  
4 155. Plaintiff and other Class Members were unjustly deprived of money obtained by  
5 each Defendant as a result of the improper amounts paid for Defendant's PE Drugs. It would  
6 be inequitable and unconscionable for each Defendant to retain the profit, benefit, and other  
7 compensation obtained from Plaintiff and other Class Members as a result of their wrongful  
8 conduct alleged in this Complaint. There is no adequate remedy at law for Plaintiff and other  
9 Class Members.  
10

11  
12 156. Plaintiff and other Class Members are entitled to seek and do seek restitution  
13 from each Defendant as well as an order from this Court requiring disgorgement of all profits,  
14 benefits, and other compensation obtained by each Defendant by virtue of its wrongful  
15 conduct.  
16

17 **EIGHTH COUNT**

18 **NEGLIGENCE**

19 157. Plaintiff re-alleges and incorporates the preceding paragraphs as if fully set forth  
20 herein.  
21

22 158. Each Defendant owed a duty to Plaintiff and the Class to use and exercise  
23 reasonable and due care in the manufacturing and sale of its PE Drugs.

24 159. Each Defendant owed a duty to Plaintiff and the Class to ensure that the PE Drugs  
25 it sold in the United States were effective for the indications identified and not misbranded.  
26

27 160. Each Defendant owed a duty of care to Plaintiff and the Class because they were  
28 the foreseeable, reasonable, and probable user of PE Drugs and victim of Defendant's

1 fraudulent and deceptive activities. Each Defendant knew, or should have known, that its PE  
2 Drugs were not effective for treating the indications identified and were misbranded, and each  
3 was in the best position to uncover and remedy these shortcomings.  
4

5 161. Each Defendant failed to do this. Defendant inadequately oversaw the research,  
6 development, testing and sale of its own PE Drugs. Each Defendant knew that ignoring the  
7 research, development and testing issues surrounding its PE Drugs would damage Plaintiffs  
8 and the Class and increase its own profits.  
9

10 162. Each Defendant maintained or should have maintained a special relationship with  
11 Plaintiffs and the Class, as they were obligated to ensure that its PE Drugs were effective to  
12 treat the indications identified and not misbranded.  
13

14 163. Each Defendant's own actions and inactions created a foreseeable risk of harm  
15 to Plaintiff and the Class. Each Defendant's misconduct included, but was not limited to,  
16 failing to oversee actions taken in the manufacture and sale of its PE Drugs.  
17

18 164. Each Defendant breached duties owed to Plaintiff and the Class by failing to  
19 exercise reasonable care sufficient to protect the interests and meet the needs of Plaintiff and  
20 the Class.  
21

22 165. As a direct and proximate result of each Defendant's negligent conduct, Plaintiff  
23 and the Class has suffered injury and are entitled to damages in an amount to be proven at  
24 trial.  
25

26 **NINTH COUNT**  
27 **NEGLIGENCE PER SE**  
28

166. Plaintiff re-alleges and incorporates the preceding paragraphs as if fully set forth

1 herein.

2 167. Each Defendant owed a duty to Plaintiff and the Class to use and exercise  
3 reasonable and due care in the manufacturing and sale of its PE Drugs.  
4

5 168. Each Defendant owed a duty to Plaintiff and the Class to ensure that the PE Drugs  
6 it sold in the United States were effective at treating the indications identified and were not  
7 misbranded.  
8

9 169. Each Defendant owed a duty to Plaintiff and the Class because each state,  
10 territory, and possession has adopted/or adheres to federal standards, including but not limited  
11 to the following parallel state statutes:  
12

- 13 • Alabama Code §§ 20-1-24 and -27(1);
- 14 • Alaska Statutes § 17.20.290(a)(1);
- 15 • Arizona Statutes §§ 32-1965(1), (2) and -1966(3);
- 16 • Arkansas Code § 20-56-215(1);
- 17 • California Health and Safety Code §§ 111295 and 111400;
- 18 • Colorado Statutes §§ 25-5-403(1)(a),(b) and -414(1)(c);
- 19 • Title 16, Delaware Code §§ 3302 and 3303(2);
- 20 • District of Columbia Code § 48-702(2);
- 21 • Florida Statutes §§ 499.005(1) and .006(3);
- 22 • Georgia Code § 26-3-3(1);
- 23 • Hawaii Revised Statutes §§ 328-6(1) and -14(1)(B)(ii);
- 24 • Idaho Code § 37-115(a);
- 25 • Chapter 410, Illinois Statutes §§ 620/3.1 and /14(a)(2)(B);
- 26 • Iowa Code §§ 126.3(1) and .9(1)(c);
- 27 • Kentucky Statutes § 217.175(1);
- 28

- 1 • La. Rev. Stat. § 40:601, *et seq.*;
- 2 • Maryland Code, Health–General §§ 21-216(c)(5)(2) and -256(1);
- 3 • Massachusetts General Laws chapter 94 §§ 186 and 190;
- 4 • Minnesota Statutes §§ 151.34(1) and .35(1);
- 5 • Missouri Statutes § 196.015(1);
- 6 • Montana Code §§ § 50-31-305(3) and -501(1);
- 7 • Nebraska Revised Statutes §§ 71-2461(2) and -2481;
- 8 • Nevada Statutes § 585.520(1);
- 9 • New Hampshire Revised Statutes §§ 146:1(I) and :4(V);
- 10 • New Mexico Statutes §§ 26-1-3(A) and -10(A);
- 11 • New York Education Law § 6811;
- 12 • North Dakota Century Code §§ 19-02.1-02(1) and .1-13(3);
- 13 • Ohio Code § 3715.52(A)(1);
- 14 • Oklahoma Statutes title 63 § 1-1402(a);
- 15 • Title 35, Pennsylvania Statutes § 780-113(a)(1);
- 16 • Title 21, Rhode Island General Laws § 21-3-3(1);
- 17 • South Carolina Code §§ 39-23-30(a)(2)(B) and -80(A)(1);
- 18 • South Dakota Code §§ 39-15-3 and -10;
- 19 • Title 18, Vermont Statutes § 4052(1);
- 20 • Virginia Code § 54.1-3457(1);
- 21 • West Virginia Code §§ 16-7-1 and -2(a)(3); and
- 22 • Wyoming Statutes §§ 35-7-111(a)(i)–(iv), (vi) and -116.

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24  
25 170. Each Defendant failed to comply with federal standards, including branding  
26 standards.

27 171. As a result of each Defendant’s failures to do so, each Defendant’s own actions  
28

1 and inactions created a foreseeable risk of harm to Plaintiff and the Class.

2 172. As a direct and proximate result of each Defendant's negligent conduct, Plaintiff  
3 and the Class have suffered injury and are entitled to damages in an amount to be proven at  
4 trial.  
5

6  
7 **PRAYER FOR RELIEF**

8 For these reasons, Plaintiff prays for the following judgment:

- 9
- 10 A. An order certifying this action as a class action;
  - 11 B. An order appointing Plaintiff as Class Representative, and appointing  
12 undersigned counsel as Class Counsel to represent the Class;
  - 13 C. A declaration that each Defendant is liable under each and every one of the  
14 above-enumerated causes of action;
  - 15 D. An order awarding appropriate preliminary and/or final injunctive relief  
16 against the conduct of each Defendant described above;
  - 17 E. Payment to Plaintiff and Class Members of all damages, exemplary or  
18 punitive damages, and/or restitution associated with the conduct for all causes of action  
19 in an amount to be proven at trial, including but not limited to the full amounts paid for  
20 the PE Drugs; the costs to replace or return PE Drugs; and/or the increases in the  
21 amounts paid for non-misbranded substitute products;
  - 22 F. An award of attorneys' fees, expert witness fees, and costs, as provided by  
23 applicable law and/or as would be reasonable from any recovery of monies recovered  
24 for or benefits bestowed on the Class Members;
  - 25  
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1 G. An award of statutory penalties to the extent available;

2 H. Interest as provided by law, including but not limited to pre-judgment and  
3 post-judgment interest as provided by rule or statute; and  
4

5 I. Such other and further relief as this Court may deem just, equitable, or  
6 proper.  
7

8 **DEMAND FOR JURY TRIAL**

9 Plaintiffs demand a trial by jury of all issues in this action so triable.  
10

11  
12 Dated: September 19, 2023

By: /s/ Allan Kanner

13 **Kanner & Whiteley, L.L.C.**  
14 Allan Kanner (SBN 109152)  
[a.kanner@kanner-law.com](mailto:a.kanner@kanner-law.com)  
15 Kanner & Whiteley, L.L.C.  
16 701 Camp Street  
17 New Orleans, LA 70130  
18 (504) 524-5777  
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CIVIL COVER SHEET

The JS-CAND 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 in its original form by the Judicial Conference of the United States in September 1974, is required for the Clerk of Court to initiate the civil docket sheet. (SEE INSTRUCTIONS ON NEXT PAGE OF THIS FORM.)

I. (a) PLAINTIFFS

Mari Jones

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

(c) Attorneys (Firm Name, Address, and Telephone Number)

Kanner & Whiteley LLC, 701 Camp St. New Orleans, LA 70130, 504-524-5777

DEFENDANTS

Reckett Benckiser Pharmaceuticals, Inc. et al.

County of Residence of First Listed Defendant Henrico County, VA (IN U.S. PLAINTIFF CASES ONLY)

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

Attorneys (If Known)

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

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

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

Table with columns for Plaintiff (PTF) and Defendant (DEF) citizenship: Citizen of This State, Citizen of Another State, Citizen or Subject of a Foreign Country, Incorporated or Principal Place of Business In This State, Incorporated and Principal Place of Business In Another State, Foreign Nation.

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

Large table with categories: CONTRACT, REAL PROPERTY, TORTS, CIVIL RIGHTS, PRISONER PETITIONS, HABEAS CORPUS, OTHER, FORFEITURE/PENALTY, LABOR, IMMIGRATION, BANKRUPTCY, SOCIAL SECURITY, FEDERAL TAX SUITS, OTHER STATUTES.

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): Class Action Fairness Act, 28 U.S.C. § 1332(d) Brief description of cause: This is a suit regarding phenylephrine-containing cold products in reaction to the FDA voting phenylephrine is "Not effective as a nasal decongestant."

VII. REQUESTED IN COMPLAINT:

CHECK IF THIS IS A CLASS ACTION UNDER RULE 23, Fed. R. Civ. P. DEMAND \$ 5,000,001.00 CHECK YES only if demanded in complaint: JURY DEMAND: X Yes No

VIII. RELATED CASE(S), IF ANY (See instructions):

JUDGE DOCKET NUMBER

IX. DIVISIONAL ASSIGNMENT (Civil Local Rule 3-2)

(Place an "X" in One Box Only) X SAN FRANCISCO/OAKLAND SAN JOSE EUREKA-MCKINLEYVILLE

DATE 09/19/2023

SIGNATURE OF ATTORNEY OF RECORD

Allan Kanner



## INSTRUCTIONS FOR ATTORNEYS COMPLETING CIVIL COVER SHEET FORM JS-CAND 44

**Authority For Civil Cover Sheet.** The JS-CAND 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 in its original form by the Judicial Conference of the United States in September 1974, is required for the Clerk of Court to initiate 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 Federal Rule of Civil Procedure 8(a), 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.
- (1) United States plaintiff. Jurisdiction based on 28 USC §§ 1345 and 1348. Suits by agencies and officers of the United States are included here.
  - (2) United States defendant. When the plaintiff is suing the United States, its officers or agencies, place an “X” in this box.
  - (3) Federal question. This refers to suits under 28 USC § 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.
  - (4) Diversity of citizenship. This refers to suits under 28 USC § 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-CAND 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 the nature of suit cannot be determined, be sure the cause of action, in Section VI below, is sufficient to enable the deputy clerk or the statistical clerk(s) in the Administrative Office to determine the nature of suit. If the cause fits more than one nature of suit, select the most definitive.
- V. Origin.** Place an “X” in one of the six boxes.
- (1) Original Proceedings. Cases originating in the United States district courts.
  - (2) Removed from State Court. Proceedings initiated in state courts may be removed to the district courts under Title 28 USC § 1441. When the petition for removal is granted, check this box.
  - (3) Remanded from Appellate Court. Check this box for cases remanded to the district court for further action. Use the date of remand as the filing date.
  - (4) Reinstated or Reopened. Check this box for cases reinstated or reopened in the district court. Use the reopening date as the filing date.
  - (5) Transferred from Another District. For cases transferred under Title 28 USC § 1404(a). Do not use this for within district transfers or multidistrict litigation transfers.
  - (6) Multidistrict Litigation Transfer. Check this box when a multidistrict case is transferred into the district under authority of Title 28 USC § 1407. When this box is checked, do not check (5) above.
  - (8) Multidistrict Litigation Direct File. Check this box when a multidistrict litigation case is filed in the same district as the Master MDL docket. Please note that there is no 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 Federal Rule of Civil Procedure 23. 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-CAND 44 is used to identify related pending cases, if any. If there are related pending cases, insert the docket numbers and the corresponding judge names for such cases.
- IX. Divisional Assignment.** If the Nature of Suit is under Property Rights or Prisoner Petitions or the matter is a Securities Class Action, leave this section blank. For all other cases, identify the divisional venue according to Civil Local Rule 3-2: “the county in which a substantial part of the events or omissions which give rise to the claim occurred or in which a substantial part of the property that is the subject of the action is situated.”
- Date and Attorney Signature.** Date and sign the civil cover sheet.