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UNITED STATES DISTRICT COURT
CENTRAL DISTRICT OF CALIFORNIA
WESTERN DIVISION

KIM ALLEN, DANIELE XENOS, ROGER HUTCHINSON, MELISSA NIGH, SHERRELL SMITH, YUANKE XU, DIANA SISTI, and NANCY RODRIGUEZ on behalf of themselves, all others similarly situated, and the general public,

Plaintiffs,

v.

HYLAND'S, INC., a California Corporation; and STANDARD HOMEOPATHIC COMPANY,

Defendants.

Case No. 3:12-cv-1150-DMG (MAN)
CLASS ACTION
Filed: February 9, 2012

THIRD AMENDED COMPLAINT FOR:

1) **VIOLATION OF THE CONSUMERS LEGAL REMEDIES ACT, CAL. CIV. CODE §§ 1750, *et seq.*;**

2) **VIOLATION OF THE UNFAIR COMPETITION LAW, CAL. BUS. & PROF. CODE §§ 17200, *et seq.*;**

3) **VIOLATION OF THE FALSE ADVERTISING LAW, CAL. BUS. &**

PROF. CODE §§ 17500, *et seq.*;

4) BREACH OF EXPRESS WARRANTY;

5) BREACH OF IMPLIED WARRANTY OF MERCHANTABILITY;

6) VIOLATION OF MAGNUSON-MOSS ACT, 15 U.S.C. §§ 2301, *et. seq.*;

7) VIOLATION OF FLORIDA DECEPTIVE AND UNFAIR TRADE PRACTICES ACT, Fla. Stat. Ann. §§ 501 201, *et seq.;*

8) VIOLATION OF GEORGIA UNIFORM DECEPTIVE TRADE PRACTICE ACT, Ga. Code Ann. §§ 10-1-391(a), *et seq.*

DEMAND FOR JURY TRIAL

INTRODUCTION

1. Plaintiffs Kim Allen, Daniele Xenos, Melissa Nigh, Sherrell Smith, Yuanke Xu, Diana Sisti and Nancy Rodriguez on behalf of themselves, all others similarly situated, and the general public ("Plaintiffs"), allege against defendants Hyland's, Inc., and Standard Homeopathic Corporation (collectively, "Defendants") as follows:

2. Defendants are the manufacturers and sellers of homeopathic products that are falsely and deceptively advertised, as set forth herein. This complaint concerns twelve of Defendants' homeopathic products, known as Calms Forté, Teething Tablets, Migraine Headache Relief, ClearAc, Poison Ivy/Oak Tablets, Colic Tablets, Leg Cramps with Quinine, Leg Cramps, Defend Cold & Cough, Defend Cold & Cough Night, Hyland's Cough, and Seasonal Allergy Relief (collectively referred to herein as the "Products"). Ex. 1 (photos of Products' packaging).

JURISDICTION AND VENUE

3. This Court has original jurisdiction pursuant to 28 U.S.C. §1332(d)(2), as amended by the Class Action Fairness Act of 2005, because the matter in controversy, exclusive of interest and costs, exceeds the sum or value of $5,000,000 and is a class action in which some members of the class are citizens of states different than Defendants. This Court also has original jurisdiction over the federal claims under the Magnuson-Moss Warranty Act pursuant to 28 U.S.C. § 1331. This Court has supplemental jurisdiction over the state law claims pursuant to 28 U.S.C. § 1367. Further, greater than two-thirds of the class members reside in states other than the states in which Defendants are citizens.

4. Venue is proper in this Court pursuant to 28 U.S.C. § 1391(b)(2) because many of the acts and transactions, including the purchases and sales giving rise to this action, occurred in this district and because Defendants (i) are authorized to conduct business in this district and have intentionally availed themselves of the laws and

markets within this district through the promotion, marketing, distribution and sale of its Products in this district; (ii) do substantial business in this district; (iii) advertise to consumers residing in this district, and (iv) are subject to personal jurisdiction in this district.

THE PARTIES

5. Plaintiff Kim Allen is a resident of Sarasota, Florida.

6. Plaintiff Daniele Xenos is a resident of Decatur, Georgia.

7. Plaintiff Melissa Nigh is a resident of Morgan Hill, California.

8. Plaintiff Sherrell Smith is a resident of Vista, California.

9. Plaintiff Yuanke Xu is a resident of Oceanside, California.

10. Plaintiff Diana Sisti is a resident of San Diego, California.

11. Plaintiff Nancy Rodriguez is a resident of Ormond Beach, Florida.

12. Defendant Hyland's, Inc. is a California corporation that maintains its principal place of business in the County of Los Angeles, California.

13. Defendant Standard Homeopathic Company is a Nevada corporation and the parent corporation of Hyland's, Inc. that maintains its principal place of business in the County of Los Angeles, California.

14. Plaintiffs are informed and believe and thereon allege that, at all times herein mentioned, the Defendants and Defendants' employees were the agents, servants and employees of the Defendants, acting within the purpose and scope of that agency and employment.

15. Defendants produce, market, and sell homeopathic Products throughout the United States. Defendants have long maintained substantial manufacturing, distribution, marketing and warehousing operations in Los Angeles, California. Defendants' formulation, labeling and marketing decisions regarding the Products occurred in Los Angeles, California.

FACTUAL BACKGROUND

16. Homeopathy seeks to stimulate the body's ability to heal itself by giving very small doses of highly diluted substances. However, there is "little evidence" that homeopathy is effective, much less that people understand homeopathic dilution principles. *See* nccam.nih.gov/sites/nccam.nih.gov/files/ homeopathy.pdf.

17. Homeopathy is premised on two main principles; the principle of similars and the principle of dilutions. Under the "principle of similars" a disease can be cured by a substance that produces similar symptoms in healthy people. Thus, homeopathic drugs are intended to work by causing "aggravation," or a temporary worsening of symptoms initially, a fact that is not communicated to consumers. *See id.*

18. Under the "principle of dilutions" the *lower* the dose of the medication, the *greater* its effectiveness. However, it is paradoxical that through dilution an ingredient would reach higher potency. Further, in highly diluted remedies, there is a very low probability that even a single molecule of the original substance is present in the Product. For example, a level of 12C dilution is the equivalent to a pinch of salt in both the North and South Atlantic Oceans.[1]

19. Homeopathic remedies are not marketed and sold in the United States in the same manner as when they first originated, approximately 200 years ago. When homeopathic drugs first originated, people would typically consult with a licensed homeopathic practitioner, who would compound his or her own homeopathic remedy, or provide a prescription to the patient. Food and Drug Administration Compliance Policy Guide ("CPG") § 400.400.

20. Historically, homeopathic drugs were also not labeled and there was no direct-to-consumer advertising. Instead, homeopathic remedies were primarily marketed to licensed homeopathic practitioners. CPG § 400.400.

[1] *See* http://www.healthguidance.org/entry/12178/1/An-Introduction-to-Homeopathic-Remedies.html, last visited on May 9, 2012.

21. There was good reason for this historical practice: Homeopathic drugs are intended to be "'individualized' or tailored to each person-it is not uncommon for different people with the same condition to receive different treatments." nccam.nih.gov/sites/nccam.nih.gov/files/homeopathy.pdf. Defendants do not communicate this important fact to consumers regarding the Products.

22. Instead, Defendants market and sell one-size-fits-all, combination homeopathic remedies directly to consumers in the over-the-counter ("OTC") aisles of major retail stores. CPG § 400.400.

23. Most consumers who purchase homeopathic drugs in the OTC aisles of retail stores are unaware of homeopathic dilution principles, and are merely seeking a natural alternative to prescription or other OTC non-homeopathic (i.e., allopathic) drugs; and Defendants are aware of this reality. Ex. 2 (Oct. 1, 2007 Chain Drug Rev. article, stating: "Customers looking for homeopathic remedies in chain drug stores tend to be much different than the people who rely on natural food stores for these products, those in the industry note. 'Consequently,' points out Hyland's Inc. president Dale Nepsa, 'there's a vast difference between the way homeopathy is merchandised.' In the natural food store, he notes, shoppers tend to be better educated and have a rudimentary knowledge of homeopathy. . . . 'In a chain drug store,' Nepsa says, 'you don't have the same type of shopper or the same personnel. It's more of a self-service environment.'").

24. Indeed, Defendants take credit for being the first homeopathic drug company to break into the over-the-counter drug market in retail stores. Ex. 2 (June 21, 2004 Chain Drug Review article; and ALLEN0007121-7122 ["The trend of integrating 'natural' remedies with mainstream drugs on store shelves started in the early 1990s. A homeopathic brand called Hyland's, previously only sold in natural food stores, gets credit. It started by accident, said Hyland's CEO J.P. Borneman. A drugstore chain shelved Hyland's remedy for babies' teething pain with the rest of its

teething products. The product was selling well. 'We began to get the suspicion that a few products could hop the fence,' Borneman said. 'By 2000, we had a half-dozen products solidly in that class.'").

25. Defendants also strive to market the Products as natural, safe, and effective alternatives to prescription and non-homeopathic OTC drugs, and have taken steps to ensure that retailers will place them next to OTC allopathic remedies on store shelves. *See id.* But the latter category of drugs have undergone rigorous scrutiny by the FDA and its appointed scientific committees. *See, e.g.,* 21 C.F.R. § 330.10 (which only applies to OTC monographed drugs, and not Defendants' Products). In contrast, homeopathic drugs undergo no FDA review or approval of efficacy or labeling claims, an important fact to the purchasing decision that Defendants do not communicate to consumers, despite seeking to mimic OTC allopathic remedies in terms of package size, splashy graphics, and placement next to OTC allopathic drugs on store shelves.

26. Accordingly, a reasonable consumer is likely to believe that Defendants' Products are subject to review and approval just like the OTC allopathic products next to which they are shelved, which is untrue, and Defendants do not disclose anything to consumers to remedy this likely confusion. *See* labels.fda.gov/.

27. Indeed, the FDA, itself, has stated that it is aware of no scientific evidence that homeopathy is effective, another important fact that Defendants do not communicate to consumers. *See id.*

28. Defendant SHC uses its wholly owned subsidiary, Hyland's, exclusively for mass market, retail chain store homeopathic drug sales, aggressively striving to place Hyland's Products next to other manufacturers' OTC allopathic remedies, where Defendants can achieve far more lucrative profits. *See* Ex. 2 (June 21, 2004 Chain Drug Review article, confirming that "Hyland's Inc. has established itself as the brand most often found in chain drug stores across North America;" and "[o]ver the years, [Chief Executive Officer Jay Borneman] says, Hyland's has reinforced its position in

chain drug stores by increasing the number of SKUs it offers the trade class and by growing its market share in the channel. In fact, the company has a long heritage of doing business with drug chains. 'Hyland's Teething Tablets have been merchandised in chain drug stores since World War II,' he notes. '*We have aggressively marketed our products in chain drug stores for the past 12 years.*'"); *id.* ("The [Hyland's] line of approximately 200 medicines is tailored specifically for drug store customers, says Borneman. Hyland's corporate parent, Standard Homeopathic Co., manufactures more than 2,500 homeopathic medicines, but not all of them are applicable to mass market outlets.").

29. But Defendants know, and have known for many years, that consumers purchasing in these retail channels do not understand what homeopathy is, how it supposedly works, or the nature of the Products. *See, e.g.,* Ex. 2 (March 4, 2002 article in Chain Drug Review, quoting Dale Nepsa, Hyland's Vice President as stating, "'Young mothers and other consumers in chain drug outlets are different than shoppers in natural food stores,' . . . 'The chain drug channel is basically a self-sevice environment,' he observes, 'and consumers are generally not as conversant in the category.'"); Ex. 2 (June 21, 2004 Chain Drug Review article, quoting CEO Jay Borneman as stating, "'You don't need to know anything technical about homeopathy to use Hyland's products, . . .'"); Ex. 2 (Oct. 1, 2007 Chain Drug Review article, stating, "not all consumers know what they are buying when they purchase a homeopathic item. In most cases, they say, shoppers are attracted to an item's all-natural qualities before they are drawn to its homeopathic heritage. In many cases homeopathy is not even a factor in their decision to buy a product. 'A lot of people who are buying homeopathy in food, drug and mass don't know the products are homeopathic,' Hylands' Nepsa says.").

30. Defendants have also capitalized on the public's desire to purchase "natural" medicines, heavily branding every one of its Products with the words

"natural," "all natural," and/or "100% natural." Ex. 1; *see also* Ex. 2 (June 25, 2007 Chain Drug Rev. article, stating "Hyland's Inc., the nation's oldest manufacturer of homeopathic medicine, has seen tremendous growth in recent years, as more consumers look to natural medicines;" and "the company's success is grounded in providing consumers with unprecedented over-the-counter access to the natural alternatives they are seeking.").

31. Defendants have also emphasized the supposed natural characteristics of their Products by placing the words, "natural," "all natural," and/or "100% natural" on all of the Products in a green bar, banner, pull down, or leaf. *See* Ex. 1; *see also* Ex. 2 (July 21, 2004 Chain Drug Reg. article, quoting CEO Jay Borneman as stating, "We focus on consumers' need for natural medicines . . ."). But, as detailed further herein, not all of Defendants' Products are natural, and Defendants know or should know those Products are not natural and should not be advertised as such.

32. Defendants have pursued their false and deceptive marketing campaign with the fore knowledge that consumers are confused about the true nature of their Products. *See* Ex. 2 (Oct. 1, 2007 Chain Drug Review article, stating "not all consumers know what they are buying when they purchase a homeopathic item. . . . In many cases homeopathy is not even a factor in their decision to buy a product. 'A lot of people who are buying homeopathy in food, drug and mass don't know the products are homeopathic,' Hylands' Nepsa says.").

33. Defendants have also taken advantage of highly publicized problems with OTC and prescription allopathic medicines, such as harmful side effects of acetaminophen in cough/cold remedies and reports of addiction to sleep aid products. Ex. 2 (June 25, 2007 Chain Drug Rev., stating "In the wake of highly publicized side effects often caused by expensive prescription sleep aids, a growing number of families are turning to Hyland's Calms Forte, which promises 100%-natural relief of nervous tension and insomnia without side effects or the danger of addiction.").

34. "Today the homeopathic drug market has grown to become a multimillion dollar industry in the United States, with a significant increase shown in the importation and domestic marketing of homeopathic drug products." CPG § 400.400. "The homeopathic cough/cold/ flu medicine category, [homeopathic drug manufacturers] say, generates over $100 million a year in sales." Ex. 2 (Sept. 6, 2011 Chain Drug Review article).

35. Health care costs in the United States reached almost $2.6 trillion in 2010, with 10% of that amount spent on retail and prescription drugs. www.kaiseredu.org/issue-modules/us-health-care-costs/background-brief.aspx. But unless drug manufacturers disclose the complete truth to consumers, consumers are unable to make informed decisions about where to spend their limited healthcare dollars. *See id.*

36. Homeopathic drugs must comply with the minimal requirements set forth in the CPG. But, the FDA has cautioned that compliance with the CPG, "the HPUS, USP, or NF does not establish that [a homeopathic drug] has been shown by appropriate means to be safe, effective, and not misbranded for its intended use." CPG § 400.400.

37. On August 26, 2011, the non-profit group, Center for Public Inquiry, petitioned the FDA to require homeopathic drug manufacturers to undergo the same efficacy requirements as other OTC products, and to label their drugs with a disclaimer that states: "The FDA has not determined that this product is safe, effective, and not misbranded for its intended use." See *Gallucci v. Boiron, Inc.*, Case No. 3:11-CV-2039 JAH (S.D. Cal.), Dkt. No. 93-1 at p. 18.

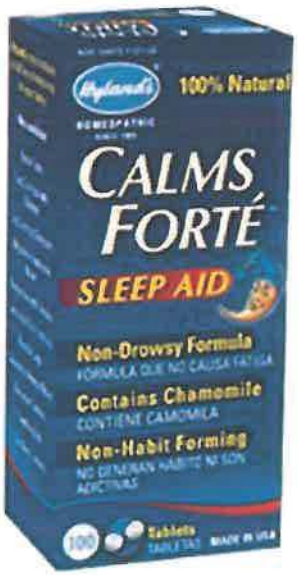
38. As a result of other class action litigation, such as *Gallucci*, *supra*, other homeopathic drug manufacturers have voluntarily agreed to implement a FDA disclaimer similar to the one noted above, along with additional injunctive relief, such as a dilution disclaimer and explanation of homeopathic dilution for consumers. *See,*

e.g., *Gallucci*, Dkt. No. 105 at pp. 13-15; Dkt. No. 125 at pp. 9-10. Thus, even those in the industry recognize a need to more truthfully label homeopathic drugs for the average consumer. *See id.*

39. At some point during the Class Period, and as a result of *Gallucci*, Defendants initiated a packaging change to its homeopathic products, labeling them with the vague and ambiguous phrase, "The [FDA] does not evaluate homeopathic products." This disclaimer does not achieve the same result as the *Gallucci* injunctive relief because it is not linked to any efficacy statements on the Products' packaging, and does not discuss dilution at all. Further, Defendants continue to market its Products with false or deceptive advertising claims that are not addressed by the disclaimer, as more fully described herein.

FACTS

A. Hyland's Calms Forté ("Calms Forté")[2]



[2] *See* Exhibit 1 ("Ex. 1") attached hereto for larger images of Calms Forté and other Products.

40. During the Class Period defined herein, in 2009 and 2011, Plaintiff Allen purchased Calms Forté 32-caplet packages from various stores in Sarasota, Florida, including Walgreen's and Publix Supermarket. Ms. Allen's individual purchases ranged from approximately $6.50 to $8.

41. Sometime during 2008 or 2009, and during the Class Period defined herein, Plaintiff Xenos purchased Calms Forté on at least one occasion from a Walgreens or Walmart located in Decatur Georgia, or online from her home in Georgia. Ms. Xenos' individual purchases were approximately $10.00.

42. During the Class Period defined herein, in 2009, Plaintiff Nigh purchased Calms Forté on at least one occasion from a RiteAid or Target located in Morgan Hill, California. Ms. Nigh's individual purchases were approximately $10.00.

43. During 2005 to 2007, Plaintiff Rodriguez purchased Calms Forté on at least one occasion online from her home located in Florida. Her individual purchases were approximately $10.00. Plaintiff first discovered Defendants' unlawful acts described herein in 2012-2013, when she learned that the Defendants' Product violates the Federal Food, Drug and Cosmetic Act ("FDCA") and its implementing regulations, and that the labels were untrue and/or misleading. Plaintiff, in the exercise of reasonable diligence, could not have discovered earlier Defendants' unlawful acts described herein because the violations were known to Defendants, and not to her, throughout the Class Period defined herein. Plaintiff is not a nutritionist, drug expert, or scientist, but rather a lay consumer who did not have the specialized knowledge that Defendants had.

44. Defendants advertise Calms Forté as a treatment and cure for "simple nervous tension and occasional sleeplessness." Defendants claim Calms Forté is a "Sleep Aid," "For Restless or Wakeful Sleep from Exhaustion," "100% Natural," "All Natural," "For Stress, Nervousness or Nervous Headache," "For Drowsiness with Incomplete Sleep," "For Nervous Irritability," has "Biochemic Phosphates for

Enhancing Cellular Function," helps consumers "Wake up Rested & Refreshed," and "Relieves Stress to Help you Sleep." These messages are reinforced through the use of a graphic depicting a smiling yellow moon wearing a blue night cap.

45. Calms Forté is composed of nothing more than sugar pellets or tablets onto which minute quantities of water have been absorbed. The purported active ingredients in Calms Forté are: *Avena Sativa 1X Double Strength*, *Humulus Lupulus 1X Double Strength*, *Chamomilla 2X (Chamomile)*, *Passiflora 1X Triple Strength*, *Calcarea Phosphorica (purported cellular function enhancer)*, *Ferrum Phosphoricum*, *Kali Phosphoricum*, *Natrum Phosphoricum*, and *Magnesia Phosphoricum*. Calms Forté, at best, contains only trace amount of "active ingredients" and has no effect on sleeplessness.

46. In purchasing Calms Forté, Plaintiff Allen relied upon various representations, taken together and in context, Defendants made on the Product's label, taken together and in context, such as the name of the Product itself, that it is "100% natural" and/or "natural," and the statements that Calms Forté will relieve her and her minor daughter's sleeplessness due to stress.

47. Plaintiffs Xenos, Nigh, and Rodriguez purchased Calms Forté because they wanted a more natural alternative to traditional over-the-counter remedies for anxiety/stress. Plaintiffs relied upon various representations, taken together and in context, Defendants made on the Product's label, taken together and in context, such as the name of the Product itself, that it is "100% natural" and/or "natural," and that Calms Forté is effective in relieving symptoms related to sleeplessness or feelings of stress.

48. Calms Forte is, however, not "100% natural" because it contains magnesium stearate, a synthetic chemical, that is often used as a flow aid or tablet lubricant. In addition, Calms Forte contains biochemical phosphates that are synthetically derived or chemically reduced, such as Calcarea phosphorica, for which

the HPUS states "is contained in bones (80%), and extracted from them by dissolving in hydrochloric acid and precipitating with ammonium hydroxide." *See* Ex. 5.

49. Calms Forté did not work for Plaintiffs as advertised.

50. Absent the misstatements described herein, Plaintiffs would not have purchased Calms Forté.

51. To the detriment of Plaintiffs and similarly situated consumers, the substances listed as the "active ingredients" in Calms Forté, are not active in combating sleeplessness. Moreover, because of enormous dilutions used in its preparation, the "active ingredients" are not actually present in the Calms Forté preparations sold to the Plaintiffs and other consumers. *See* the Ingredient List, Dilution Chart, and Advertising Claims Charts attached hereto as Exhibit 3.

52. The ingredients used in Calms Forté provide no health benefit. Moreover, at the stupendously high dilutions used to prepare the product, they can have no effect of any kind in humans because the odds are astronomically high that even a single molecule derived from the original "extract" of the "active ingredients" could be present in the solution used to soak the tiny balls of lactose which constitute the product sold to consumers.[3]

53. Defendants know that there are, at best, traceable amounts of active ingredients present in Calms Forté and therefore must be aware that Calms Forté cannot relieve any symptoms for which Defendants advertise the Product.

54. Further, Calms Forte contains magnesium stearate, which is not natural.

[3] The final stage in the preparation of Calms Forté, as is the case for all homeopathic "medicines," is the infusion of what is essentially water onto the surface of tiny balls of sugar. This effectuates an additional "dilution" of the water, imposing another layer of uncertainty upon the indeterminate but undeniably vast dilution in Defendants' Products.

55. Calms Forté comes in 32, 50 and 100 caplet bottle sizes and the price depends on the package size, starting at approximately $7.50 per 32-caplet package. Hence, Defendants' unfair and deceptive practices have enriched them by tens of millions of dollars, at the expense of tens of thousands of Americans.

56. Plaintiffs seek justice for themselves and for similarly-situated consumers of Calms Forté by means of this action, among other things, to enjoin the ongoing deceptive practices described herein.

B. Hyland's Teething Tablets ("Teething Tablets")

57. During 2003-2004 and 2006-2007, Plaintiff Xenos purchased Teething Tablets on several occasions, from a co-op in Georgia, or online from her home in Georgia. Ms. Xenos' individual purchases were approximately $10.00.

58. During the Class Period defined herein, in 2009, Plaintiff Nigh purchased Teething Tablets from Target and Rite Aid stores in Morgan Hill, California.

59. In 1993, Plaintiff Allen purchased Teething Tablets from Walgreens and Publix Supermarket in Sarasota, Florida.

60. Plaintiffs Xenos and Allen first discovered Defendants' unlawful acts described herein in 2012-2013, when they learned that the Defendants' Product

violates the Federal Food, Drug and Cosmetic Act ("FDCA") and its implementing regulations, and that the labels were untrue and/or misleading.

61. Plaintiffs Xenos and Allen, in the exercise of reasonable diligence, could not have discovered earlier Defendants' unlawful acts described herein because the violations were known to Defendants, and not to them, throughout the Class Period defined herein. Plaintiffs are not nutritionists, drug experts, or scientists, but rather lay consumers who did not have the specialized knowledge that Defendants had.

62. Defendants advertise Teething Tablets for the relief of symptoms associated with baby teething, such as "Relieve Pain and Irritability from Teething," "Simple Restlessness and Wakeful Irritability Due to the Cutting of Teeth," "Soft Tablets Dissolve Instantly," "100% Natural" and "Helps Reduce Redness and Inflammation of Gums."

63. The purportedly active ingredients Teething Tablets include *Calcarea Phosphorica* (6X HPUS), *Chamomilla Recutita* (Chamomile) (6X HPUS), *Coffee Cruda* (6X HPUS) and *Belladonna* (12X HPUS). However, as with Calms Forté, the active ingredients, even if they were otherwise effective, are so greatly diluted as to be effectively non-existent in the Product, such that the Product is ineffective for its intended uses.

64. Plaintiffs Xenos, Nigh and Allen purchased Teething Tablets, because she wanted a more natural alternative to traditional over-the-counter remedies. In purchasing Teething Tablets, Plaintiffs relied upon various representations, taken together and in context, Defendants made on the Product's label, taken together and in context, such as the Product's name itself, and that Teething Tablets are effective in relieving symptoms associated with baby teething, such as, "Relieve Pain and Irritability from Teething," "100% natural," among other representations.

65. Teething Tablets are not, however, "100% natural," because they contain biochemical phosphates that are synthetically derived or chemically reduced. For

example, the Product contains Calcarea phosphorica, for which the HPUS states "is contained in bones (80%), and extracted from them by dissolving in hydrochloric acid and precipitating with ammonium hydroxide." *See* Ex. 5. Further, the children's products (Colic Tablets and Teething Tablets) contain an acacia gum made with isopropyl alcohol but isopropyl alcohol is not listed as an ingredient in these Products. SHCALLEN011730.

66. Teething Tablets did not work for Plaintiffs as advertised.

67. Absent the misstatements described herein, Plaintiffs would not have purchased Teething Tablets.

68. Plaintiffs seek justice for themselves and for similarly-situated consumers of Teething Tablets by means of this action, among other reasons, to enjoin the ongoing deceptive practices described herein.

C. Hyland's Migraine Headache Relief ("Migraine Headache Relief")

69. During the Class Period defined herein, in 2009, Plaintiff Xenos purchased Migraine Headache Relief on at least one occasion, from a co—op located in North Carolina, or online from her home in Georgia. Ms. Xenos' individual purchases were approximately $10.00.

70. During the Class Period defined herein, in 2009, Plaintiff Allen purchased Migraine Headache Relief on at least one occasion, from Walgreens and Publix Supermarket located in Sarasota, Florida. Ms. Allen's individual purchases were approximately $10.00.

71. During the Class Period defined herein, in 2011, Plaintiff Sisti purchased Migraine Headache Relief on at least one occasion, from a CVS store located in San Diego, California. Ms. Sisti's individual purchases were approximately $10.00.

72. During the Class Period defined herein, in 2009-2010, Plaintiff Rodriguez purchased Migraine Headache Relief on at least one occasion, from a Love's Whole Foods located in Florida. Ms. Rodriguez' individual purchases were approximately $10.00.

73. Defendants advertise Migraine Headache Relief as a natural remedy for migraines, that "works fast to relieve migraine headache pain without aspirin, caffeine or sedatives" and that the Product is "100% Natural," "Aspirin Free," "Quick Dissolving Tablets," "Relieves Pressure, Throbbing, Light + Noise Sensitivity" and "Temporarily Relieves the Symptoms of Migraine Pain." One of the Migraine Headache Relief's packaging depicts a happy, smiling woman.

74. Plaintiffs purchased Migraine Headache Relief, because they wanted a more natural alternative to traditional over-the-counter remedies. In purchasing Migraine Headache Relief, Plaintiffs relied upon various representations, taken together and in context, Defendants made on the label of the Products, such as the Product's name itself, "works fast to relieve migraine headache pain without aspirin, caffeine or sedatives," "temporarily relieves the symptoms of migraine pain," "relieves pressure, throbbing, light and noise sensitivity, "Migraine Headache Relief," and "100% Natural."

75. The purported active ingredients in this Product are: *Glonoinum* (12X HPUS), *Belladonna* (6X HPUS), *Gelsemium* (6X HPUS), *Nux Vomica* (6X HPUS),

Iris Versicolor (6X HPUS) and *Sanguinaria Canadensis* (6X HPUS). However, as with Calms Forté and Teething Tablets, the active ingredients, even if they were otherwise effective, are so greatly diluted as to be effectively non-existent in the Product, such that the Product is ineffective for its intended uses.

76. A reasonable consumer is not likely to be aware that Glonoinum is another name for Nitroglyceride, and Plaintiffs were not aware of this fact at the time of purchase.

77. Nitroglyceride is not natural because it is a synthetic derived through chemical processing (generally, by mixing sulfuric acid with nitric acid, or through mixing similar, cheaper sulfur and nitrous ingredients).

78. Migraine Headache Relief did not work for Plaintiffs as advertised.

79. Absent the misstatements described herein, Plaintiffs would not have purchased Migraine Headache Relief.

80. Plaintiffs seeks justice for themselves and for similarly-situated consumers of Migraine Headache Relief by means of this action, among other reasons, to enjoin the ongoing deceptive practices described herein.

D. Hyland's ClearAc ("ClearAc")

81. In 2005, Plaintiff Xenos purchased ClearAc on at least one occasion, from a co-op located in North Carolina, or online from her home in Georgia. Ms. Xenos' individual purchases were approximately $10.00.

82. Plaintiff first discovered Defendants' unlawful acts described herein in 2012-2013, when she learned that the Defendants' Product violates the Federal Food, Drug and Cosmetic Act ("FDCA") and its implementing regulations, and that the labels were untrue and/or misleading.

83. Plaintiff, in the exercise of reasonable diligence, could not have discovered earlier Defendants' unlawful acts described herein because the violations were known to Defendants, and not to her, throughout the Class Period defined herein. Plaintiff is not a nutritionist, drug expert, or scientist, but rather a lay consumer who did not have the specialized knowledge that Defendants had.

84. Defendants advertise ClearAc as an "All Natural" remedy for the management and symptomatic relief of symptoms of pimples, blackheads and blemishes associated with common acne (acne vulgaris).

85. Plaintiff Xenos purchased ClearAc, because she wanted a more natural alternative to traditional over-the-counter remedies. In purchasing ClearAc, Plaintiff Xenos relied upon various representations, taken together and in context, Defendants made on the Product's label, such as the Product's name itself, and: "Natural Treatment for Pimples, Acne, Blackheads, and Oily Skin," "Medicated Skin Cleanser," "Gentle on Skin No Harsh Chemicals," "Hyland's 100% Natural ClearAc Acne Tablets," and "No Messy Makeup," among other representations.

86. The purported active ingredients in this Product include *Echinacea Ang.* (6X HPUS), *Berberis Vulg.* (6X HPUS), *Sulphur Iod* (6X HPUS) and *Hepar Sulph* (6X HPUS). However, as with Calms Forté, Teething Tablets and Migraine Headache Relief, the active ingredients, even if they were otherwise effective, are so greatly

diluted as to be effectively non-existent in the Product, such that the Product is ineffective for its intended uses.

87. ClearAc did not work for Plaintiff Xenos as advertised.

88. Absent the misstatements described herein, Plaintiff would not have purchased Hyland's ClearAc.

89. Plaintiff seeks justice for herself and for similarly-situated consumers of ClearAc by means of this action, among other reasons, to enjoin the ongoing deceptive practices described herein.

E. Hyland's Poison Ivy/Oak Tablets ("Poison Ivy/Oak Tablets")

90. In 2005, Plaintiff Xenos purchased Poison Ivy/Oak Tablets on at least one occasion, from a co-op located in North Carolina, or online from her home is Georgia. Ms. Xenos' individual purchases were approximately $10.00.

91. Plaintiff first discovered Defendants' unlawful acts described herein in 2012-2013, when she learned that the Defendants' Product violates the Federal Food, Drug and Cosmetic Act ("FDCA") and its implementing regulations, and that the labels were untrue and/or misleading.

92. Plaintiff, in the exercise of reasonable diligence, could not have discovered earlier Defendants' unlawful acts described herein because the violations were known to Defendants, and not to her, throughout the Class Period defined herein. Plaintiff is not a nutritionist, drug expert, or scientist, but rather a lay consumer who did not have the specialized knowledge that Defendants had.

93. Defendants advertise Poison Ivy/Oak Tablets as "Natural Relief" for "Symptomatic Treatment after Contact with Poison Ivy or Oak," "100% Natural," and to relieve the symptoms such as skin break outs, itching, burning and blisters.

94. Plaintiff Xenos purchased Poison Ivy/Oak Tablets, because she wanted a more natural alternative to traditional over-the-counter remedies. In purchasing Poison Ivy/Oak Tablets, Plaintiff Xenos relied upon various representations, taken together and in context, Defendants made on the label and elsewhere, such as the Product's name itself, that the Product provides a "Natural Relief for Itching, Burning and Crusting Skin Due to Exposure to Poison Ivy or Oak".

95. The purported active ingredients in this Product include *Rhus Toxicodendron* (6X HPUS), *Croton Tiglium* (6X HPUS) and *Xerophyllum* (6X HPUS). However, as with Calms Forté, Teething Tablets, Migraine Headache Relief and ClearAc, the active ingredients, even if they were otherwise effective, are so greatly diluted as to be effectively non-existent in the Product, such that the Product is ineffective for its intended uses.

96. Poison Ivy/Oak Tablets did not work for Plaintiff Xenos as advertised.

97. Absent the misstatements described herein, Plaintiff Xenos would not have purchased Poison Ivy/Oak Tablet.

98. Plaintiff seeks justice for herself and for similarly-situated consumers of Poison Ivy/Oak Tablets by means of this action, among other reasons, to enjoin the ongoing deceptive practices described herein.

F. Hyland's Colic Tablets ("Colic Tablets")

99. In 1993, Plaintiff Allen purchased Colic Tablets on at least one occasion, from Walgreens and Publix Supermarket located in Sarasota, Florida. Ms. Allen's individual purchases were approximately $10.00.

100. Plaintiff first discovered Defendants' unlawful acts described herein in 2012-2013, when she learned that the Defendants' Product violates the Federal Food, Drug and Cosmetic Act ("FDCA") and its implementing regulations, and that the labels were untrue and/or misleading.

101. Plaintiff, in the exercise of reasonable diligence, could not have discovered earlier Defendants' unlawful acts described herein because the violations were known to Defendants, and not to her, throughout the Class Period defined herein. Plaintiff is not a nutritionist, drug expert, or scientist, but rather a lay consumer who did not have the specialized knowledge that Defendants had.

102. Defendants represent that Colic Tablets are "100% Natural," "Soft Tablets [that] Dissolve Instantly," "[without] Side Effects," that provide "Symptomatic Relief from Colic in Children;" and is "Effective" for Gas Pain and Irritability."

103. Plaintiff Allen purchased Colic Tablets, because she wanted a more natural alternative to traditional over-the-counter remedies. In purchasing the Product, Plaintiff Allen relied upon various representations Defendants made on the Product's label, taken together and in context, such as the Product's name itself, "Symptomatic Relief for Colic in Children," and "100% Natural."

104. The purported active ingredients in this Product include *Dioscorea* (3X HPUS), *Chamomilla* (3X HPUS) and *Colocynth* (3X HPUS). However, as with Calms Forté, Teething Tablets, Migraine Headache Relief, ClearAc and Poison Ivy/Oak Tablets, the active ingredients, even if they were otherwise effective, are so greatly diluted as to be effectively non-existent in the Product, such that the Product is ineffective for its intended uses. Further, the children's products (Colic Tablets and Teething Tablets) contain an acacia gum made with isopropyl alcohol but isopropyl alcohol is not listed as an ingredient in these Products. SHCALLEN011730.

105. Colic Tablets did not work for Plaintiff as advertised.

106. Absent the misstatements described herein, Plaintiff would not have purchased Colic Tablets.

107. Plaintiff seeks justice for herself and for similarly-situated consumers of Colic Tablets by means of this action, among other reasons, to enjoin the ongoing deceptive practices described herein.

G. Hyland's Leg Cramps with Quinine

108. During the Class Period defined herein, in 2009, Plaintiff Allen purchased Leg Cramps with Quinine on at least one occasion, from a Walgreens and Publix Supermarket located in Sarasota, Florida. Ms. Allen's individual purchases were approximately $10.00.

109. Defendants represent that Leg Cramps with Quinine is a "non-habit forming" "100% natural," product to "relax calf & foot cramps," to "stop the pain!"

110. Plaintiff Allen purchased Leg Cramps with Quinine because she wanted a more natural alternative to traditional over-the-counter remedies and because she

believed that quinine was helpful for leg cramps. Allen Dep. Tr. At 57 (condensed version). In purchasing Leg Cramps with Quinine, Plaintiff Allen relied upon various representations, taken together and in context, Defendants made on the Product's label, such as the Product's name itself, "100% Natural," that it could be taken any time of day or night to alleviate lower leg cramps, had quinine in it, and "Temporarily relieves the symptoms of pain and cramps in lower body, legs, feet and toes," among other representations.

111. The purported active ingredients in this Product include *Calcarea Carbonica* (12X HPUS), *Causticum* (12X HPUS), *Chamomilla* (6X HPUS), *Cinchona Officinalis* (3X HPUS), *Cuprum Metallicum* (12X HPUS), *Lycopodium* (12X HPUS), *Magnesia Phosphorica* (6X HPUS), *Rhus Toxicodendron* (6X HPUS), *Silicea* (12X HPUS) and *Sulphur* (6X HPUS). However, as with Calms Forté, Teething Tablets, Migraine Headache Relief, ClearAc, Poison Ivy/Oak Tablets and Colic Tablets, the active ingredients, even if they were otherwise effective, are so greatly diluted as to be effectively non-existent in the Product, such that the Product is ineffective for its intended uses.

112. Defendants also sell an identical Product called Leg Cramps with Quinine PM. The sole difference between Leg Cramps with Quinine and Leg Cramps with Quinine PM are the inclusion of the letters "PM" on the front of the package of the latter Product. Otherwise, the advertising claims and ingredients are identical. *See* Ex. 1.

113. Leg Cramps with Quinine does not state "not for nighttime use" or similar language to convey to consumers that the Product is not intended to be used for nighttime leg cramp relief. *See* Ex. 1.

114. The purported ingredient that adds quinine to Defendants' Leg Cramps products is cinchona bark. *See* Ex. 4 (FDA's warning letter to Defendants dated April 29, 2011).

115. But, the FDA has stated that "*Quinine . . . is not considered safe and effective for the treatment or prevention of leg cramps -- an 'off-label' (non-FDA-approved) use.*" fda.gov/ForHealthProfessionals/ArticlesofInterest/ucm317811.htm. Therefore, Defendants' Leg Cramps Products are all unlawfully labeled, are unapproved new drugs, and accordingly misbranded under the California Sherman Law. Cal. Health & Safety Code §§ 110100, 110105, 110110, 110111 (incorporating all food, drug, OTC drug, and good manufacturing practices of the federal Food, Drug and Cosmetic Act as the laws of this state).

116. Further, 21 C.F.R. § 310.546(a) states: "There is a lack of adequate data to establish general recognition of the safety and effectiveness of quinine sulfate, vitamin E, *or any other ingredients* for OTC use in the treatment and/or prevention of nocturnal leg muscle cramps." Accordingly, Defendants' Leg Cramps Products are unlawfully labeled, are unapproved new drugs, and accordingly misbranded under the California Sherman Law. *See id.*; *id.* § 310.546(b); Cal. Health & Safety Code §§ 110100, 110105, 110110, 110111.

117. In addition, on April 29, 2011, the FDA warned Defendants that their Leg Cramps Products were falsely and misleadingly labeled. *See* Ex. 4 ("The labeling of 'Leg Cramps with Quinine' and 'Leg Cramps PM with Quinine' prominently displays the ingredient 'Quinine'" on the front of the package and in the name of the product. The labeling is false and misleading because it suggests that quinine is the active ingredient when in fact the active ingredient is 'Cinchona Officinalis.' Further, the label identifies this active ingredient as 'Cinchona Officinalis 3X HPUS (Quinine).' According to the HPUS, although Cinchona bark contains quinine, it also contains other related alkaloids. Your selective identification of only one of the alkaloids in Cinchona bark is false and misleading because it incorrectly suggests that there is only one alkaloid in Cinchona bark.")

118. Further, Leg Cramps with Quinine contains causticum, also known as lime. The HPUS directs that "recently burnt lime" be used. Burning lime is a chemical alteration (calcination) and converts it into the highly caustic material known as quicklime (calcium oxide, CaO). The addition of water to quicklime converts it further to slaked lime (calcium hydroxide). Slaked lime is considered toxic by the National Institutes of Health. www.nlm.nih.gov/medlineplus/ency/article/002910.htm

119. The Product also contains potassium bisulfate, because the HPUS directs that the slaked lime be added, equal parts, to potassium bisulfate (the potassium salt of sulfuric acid), a food additive. *See* 21 C.F.R. § 182.3616 (designating potassium bisulfate as a "Chemical Preservative[]"). Potassium bisulfate—which makes us 50% of Causticum—is also artificially produced, typically by heating potassium sulfate with sulfuric acid.

120. This product contains Cuprum metallicum (i.e., copper). Too much copper can be toxic, www.nlm.nih.gov/medlineplus/ency/article/002419.htm, so even if this ingredient were natural, it is deceptive because consumers perceive the benefits of natural products as being wholesome and better for their health than synthetic, manmade or artificial products.

121. Leg Cramps with Quinine did not work for Plaintiff as advertised.

122. Absent the misstatements described herein, Plaintiff would not have purchased Leg Cramps with Quinine.

123. Plaintiff seeks justice for herself and for similarly-situated consumers of Hyland's Leg Cramps with Quinine, by means of this action, among other reasons, to enjoin the ongoing deceptive practices described herein.

H. Hyland's Leg Cramps ("Leg Cramps")

124. During the Class Period defined herein, in 2011, Plaintiff Smith purchased Leg Cramps on more than one occasion from a Henry's/Sprouts store located in Vista and Oceanside, California. Her purchases cost approximately $10 each.

125. During the Class Period defined herein, in 2008-2009, Plaintiff Xenos purchased Leg Cramps at least once from a Walmart or Walgreens located in Decatur, Georgia, or online. Her purchases cost approximately $10 each.

126. Even if the foregoing were not true, Plaintiff Xenos first discovered Defendants' unlawful acts described herein in 2012-2013, when she learned that the Defendants' Product violates the Federal Food, Drug and Cosmetic Act ("FDCA") and its implementing regulations, and that the labels were untrue and/or misleading.

127. Plaintiff, in the exercise of reasonable diligence, could not have discovered earlier Defendants' unlawful acts described herein because the violations were known to Defendants, and not to her, throughout the Class Period defined herein.

Plaintiff is not a nutritionist, drug expert, or scientist, but rather a lay consumer who did not have the specialized knowledge that Defendants had.

128. Defendants represent, among other representations, that Leg Cramps "temporarily relieves the symptoms of cramps and pains in lower back and legs," is "100% natural," that it contains quinine, "relax[es] calf and foot cramps," and "stop[s] the pain!"

129. In purchasing Leg Cramps, Plaintiffs relied upon various representations, taken together and in context, Defendants made on the Product's label, such as the Product's name itself, that it is "100% natural," can be taken any time of day or night to alleviate lower leg cramps, has quinine, and is effective at relaxing calf and foot cramps.

130. The purported active ingredients in this Product include *Cinchona Officinalis* (3X HPUS), *Viscum Album* (3X HPUS), *Gnaphalium Polycephalum* (3X HPUS), *Rhus Toxicodendron* (6X HPUS), *Aconitum Napellus* (6X HPUS), *Ledum Pal* (6X HPUS) and *Magnesia Phosphorica* (6X HPUS).

131. However, as with Calms Forté, Teething Tablets, Migraine Headache Relief, ClearAc, Poison Ivy/Oak Tablets, Colic Tablets and Leg Cramps with Quinine, the active ingredients, even if they were otherwise effective, are so greatly diluted as to be effectively non-existent in the Product, such that the Product is ineffective for its intended uses.

132. Defendants also sell identical Products called Leg Cramps with Quinine and Leg Cramps with Quinine PM. The sole difference between these Products are the words "with Quinine" on the front of the Leg Cramps with Quinine and "with Quinine PM" on Leg Cramps with Quinine PM packages. Otherwise, the advertising claims and ingredients are identical. *See* Ex. 1.