

1 Michael Connett (Cal. Bar No. 300314)  
2 **SIRI & GLIMSTAD LLP**  
3 700 S. Flower St., Suite 1000  
4 Los Angeles, CA 90017  
5 [mconnett@sirillp.com](mailto:mconnett@sirillp.com)  
6 Tel: (888) 747-4529

7 Aaron Siri (*pro hac vice* to be sought)  
8 Elizabeth A. Brehm (*pro hac vice* to be sought)  
9 **SIRI & GLIMSTAD LLP**  
10 745 Fifth Avenue, Suite 500  
11 New York, NY 10151  
12 [aaron@sirillp.com](mailto:aaron@sirillp.com)  
13 [ebrehm@sirillp.com](mailto:ebrehm@sirillp.com)  
14 Tel: (888) 747-4529

15 *Attorney for Plaintiffs and Putative Class*

16 **UNITED STATES DISTRICT COURT**  
17 **SOUTHERN DISTRICT OF CALIFORNIA**

18 AMBER MILLER, JOSH COOK, &  
19 MARINA VASILYEVA, individually and  
20 on behalf of those similarly situated,

21 Plaintiffs,

22 v.

23 HELLO PRODUCTS LLC,

24 Defendant.

25 Case No. 3:25-cv-00071

26 **AMENDED CLASS ACTION COMPLAINT**

27 **JURY TRIAL DEMANDED**

28 Plaintiffs Amber Miller, Josh Cook, and Marina Vasilyeva (“**Plaintiffs**”), by their undersigned counsel, on behalf of themselves and all persons similarly situated who purchased Hello “Kids Fluoride Rinse” for their preschool children, bring this class action lawsuit against defendant Hello Products LLC. (“**Defendant**”). Plaintiffs allege the following upon information and belief, except for those allegations that pertain to Plaintiffs, which are based on Plaintiffs’ personal knowledge.

29 **INTRODUCTION**

30 1. Defendant manufactures and sells a “naturally friendly” fluoride mouthrinse that it

1 specifically markets for use by kids called Hello Kids Fluoride Rinse (“**Hello Rinse**” or “**Rinse**”).  
2 The Rinse comes in two kid-enticing flavors: “Wild Strawberry” and “Unicorn Splash.”

3 2. The label of Defendant’s Wild Strawberry Rinse states it is “thoughtfully formulated  
4 with wild strawberry natural flavor and xylitol” and “tastes so delicious they’ll rush to rinse.”

5 3. The label of Defendant’s Bubble Gum Rinse describes the candy-flavored liquid as  
6 a “unicorn splash” that “tastes magical” and “tastes like rainbows and sunshine (aka bubble gum).”  
7



4. In addition to showcasing its “delicious” and “magical” flavors, the Hello Rinse label boasts that the liquid does not contain harmful or unhealthy ingredients: “vegan. no alcohol.

1 no dyes. no artificial flavors. no SLS/sulfates. no brainer.”

2 5. While Defendant’s labeling conveys the impression that the rinse is specially  
3 formulated to be *safe* for young children, it is not. The reality is that fluoride mouthrinse is  
4 considered by the U.S. Food and Drug Administration (“**FDA**”) to be too dangerous for children  
5 under 6 to use.

6  
7 6. Hello Rinse, which has the same fluoride concentration as adult rinses, is actually  
8 *more* dangerous for young children than adult rinses because it comes in candy and fruit flavors  
9 that entice children to use and swallow more of the product.

10 7. As far back as 1960, it was known that fluoride mouthrinses “should not be  
11 employed in children below school age.”<sup>1</sup>

12 8. The FDA states that fluoride mouthrinses “are not indicated for use in children under  
13 6 years of age on an [over-the-counter] basis” and “should not be within easy reach of any  
14 children.”<sup>2</sup>

15  
16 9. The American Dental Association (“**ADA**”) states that “Children younger than the  
17 age of 6 should not use mouthrinse, unless directed by a dentist, because they may swallow large  
18 amounts of the liquid inadvertently.”<sup>3</sup>

19 10. The World Health Organization (“**WHO**”) states that fluoride mouthrinses “are not  
20 recommended for children below the age of 6 years.”<sup>4</sup>

21 11. The American Academy of Pediatrics (“**AAP**”) states that fluoride mouth rinses

22  
23 \_\_\_\_\_  
24 <sup>1</sup> Ingrid Hellstrom, *Fluoride retention following sodium fluoride mouthwashing*, 18 ACTA  
25 ODONTOL SCAND. 263, 273 (1960).  
26 <sup>2</sup> FDA, *Anticaries Drug Products for Over-the-Counter Human Use; Final Monograph*, 60 Fed.  
27 Reg. 52474, 52486 (Oct. 6, 1995).  
28 <sup>3</sup> ADA, *Mouthrinse (Mouthwash) – Key Points*, <https://www.ada.org/resources/ada-library/oral-health-topics/mouthrinse-mouthwash>  
<sup>4</sup> WORLD HEALTH ORGANIZATION. FLUORIDES AND ORAL HEALTH 33 (1994).

1 should not be used until a child turns 6 and, even then, only “if the child can reliably swish and  
2 spit” and is at high risk of tooth decay.<sup>5</sup>

3 12. The U.S. Centers for Disease Control and Prevention (“**CDC**”) states that “children  
4 under <6 years should not use fluoride mouthrinse without consultation with a dentist or other  
5 health care provider.”<sup>6</sup>

7 13. According to Defendant’s parent company Colgate-Palmolive Co., “babies and  
8 toddlers should not use [fluoride] mouthrinse” because “children under six may not have fully  
9 developed their swallowing reflexes and could swallow the mouthrinse,” which can “lead to side  
10 effects like vomiting, intoxication, and nausea.”<sup>7</sup>

11 14. Despite the scientific consensus that fluoride mouthrinses are contraindicated for  
12 children under six years of age, Defendant targets this age group with its Hello Rinse.

13 15. In its efforts to appeal to young children, Defendant presents fluoride mouthrinse (a  
14 drug that should *not* be swallowed by any age group, especially young children) as a juice-like and  
15 candy-like product. This is both deceptive and dangerous.

16 16. It is well recognized that presenting drugs as candy- and fruit-like products increases  
17 the risk of overdose, particularly for young children. In 1997, the *Journal of Public Health Dentistry*  
18 published a review, stating “The use of flavored consumer fluoride products increases the  
19 possibility that a child will ingest a toxic dose of fluoride.”<sup>8</sup> A more recent review in the *Journal*  
20

21  
22 \_\_\_\_\_  
23 <sup>5</sup> Melinda B. Clark, et al., *Fluoride Use in Caries Prevention in the Primary Care Setting*, 146  
PEDIATRICS e2020034637, Tbl 1 (2020).

24 <sup>6</sup> CDC, *Recommendations for using fluoride to prevent and control dental caries in the United*  
25 *States*. Centers for Disease Control and Prevention, 50 MMWR RECOMM REP. 1, 26 (2001).

26 <sup>7</sup> Colgate, *What Parents Should Know About Mouthwash for Children*,  
27 [https://www.colgate.com/en-us/oral-health/kids-oral-care/what-parents-should-know-about-](https://www.colgate.com/en-us/oral-health/kids-oral-care/what-parents-should-know-about-mouthwash-for-children)  
28 [mouthwash-for-children](https://www.colgate.com/en-us/oral-health/kids-oral-care/what-parents-should-know-about-mouthwash-for-children) (last accessed Jan. 13, 2025).

<sup>8</sup> Jay D. Shulman & Linda M. Wells, *Acute fluoride toxicity from ingesting home-use dental*  
*products in children, birth to 6 years of age*, 57 J PUBLIC HEALTH DENT. 150, 150 (1997).

1 of *Dental Hygiene* warned that boasting “pictures of fruit with flavoring to match” on kids fluoride  
2 products is “misleading” because pictures of fruit send a “common signal to a child that [the  
3 product] is intended to be consumed as if it were food.”<sup>9</sup>

4 17. Swallowing excessive amounts of fluoride is hazardous to health.

5 18. Hello Rinse has enough fluoride in it to kill a small child. A toddler who ingests just  
6 over half of the sweet flavored liquid in the bottle may suffer severe poisoning, including death.  
7 See *infra* ¶¶ 88-91.

8 19. The risk of toxicity is not limited to those children who intentionally drink the  
9 product. Even small amounts of the rinse can cause symptoms of acute toxicity if ingested.

10 20. A single 10 mL dose of Hello Rinse contains 2.3 milligrams of fluoride. A toddler  
11 who swallows this 10 mL dose can suffer nausea, vomiting, and other early symptoms of acute  
12 fluoride toxicity. See *infra* ¶¶ 81-87.

13 21. There are thousands of poison control reports for excess ingestion of fluoride  
14 mouthrinse by young children each year. But these reports represent only a fraction of the total  
15 number of incidents. See *infra* ¶¶ 92-95.

16 22. Another problem with young children using fluoride mouthrinse is that it can cause  
17 dental fluorosis.<sup>10</sup> Fluorosis is a defect of tooth enamel that is marked by “increased porosity” and  
18 “less than normal amounts of calcification in the teeth.”<sup>11</sup> This defect causes visible, and  
19  
20  
21

22  
23 <sup>9</sup> Corey H. Basch & Sonali Rajan, *Marketing strategies and warning labels on children's*  
24 *toothpaste*, 88 J DENT HYG. 316, 316 (2014).

25 <sup>10</sup> CDC, *About Fluoride*, <https://www.cdc.gov/oral-health/prevention/about-fluoride.html> (“If  
26 children repeatedly swallow mouth rinses, they may develop dental fluorosis.”).

27 <sup>11</sup> NATIONAL RESEARCH COUNCIL, *FLUORIDE IN DRINKING WATER: A SCIENTIFIC REVIEW OF EPA’S*  
28 *STANDARDS 104* (2006); Crest, *Dental Fluorosis: Causes, Treatments & Prevention*,  
<https://crest.com/en-us/oral-care-tips/tooth-enamel/dental-fluorosis-causes-treatments-prevention>  
(last accessed Jan. 13, 2025).

1 sometimes disfiguring, staining of the enamel. See *infra* ¶¶ 78-80.

2 23. The FDA recognizes that preschool children who use fluoride mouthrinse are at risk  
3 of developing dental fluorosis, but did not require a fluorosis warning *because children under six*  
4 *are not supposed to be using the product*. To quote: “Because fluoride dental rinses and gels are  
5 recommended only for use in adults and children 6 years of age and older, the agency believes that  
6 a warning about discoloration of developing teeth in children under 6 years of age is not needed on  
7 an OTC market package.”<sup>12</sup>

9 24. The health risks of preschool children using fluoride mouthrinse are of such  
10 magnitude that scientists have never even attempted to study the potential effect of fluoride  
11 mouthrinses on tooth decay in this age group. Therefore, there are no demonstrated benefits from  
12 the use of fluoride mouthrinses for preschool children, particularly in the current context of  
13 widespread exposure to fluoride from toothpaste, fluoridated water, and processed foods.

15 25. Due to the dangers posed by fluoride in mouthrinse form, it is critical that consumers  
16 be alerted of the need to take special precautions to avoid ingesting toxic levels of fluoride.

17 26. By 1960, it was known that “**careful instruction . . . must be provided**” if fluoride  
18 mouthrinses are to be used on a daily basis.<sup>13</sup>

19 27. The FDA is concerned that many consumers will not appreciate that fluoride  
20 mouthrinses present dangers that are not present with ordinary cosmetic mouthrinses. According  
21 to the FDA, “based upon familiarity with cosmetic mouthrinse use, a consumer might overuse  
22 and/or misuse an OTC fluoride rinse.”<sup>14</sup>

25 \_\_\_\_\_  
26 <sup>12</sup> FDA, *Anticaries Drug Products for Over-the-Counter Use; Tentative Final Monograph; Notice of Proposed Rulemaking*, 59 Fed. Reg. 39854, 39864 (Sept. 30, 1985).

27 <sup>13</sup> Hellstrom, *supra* note 1, at 273 (emphasis added).

28 <sup>14</sup> FDA, *supra* note 2, at 52485.

1 28. Because many consumers will not appreciate the risks posed by fluoride mouthrinse,  
2 the FDA has stressed that the “safe” use of fluoride mouthrinse requires “proper labeling.”<sup>15</sup>  
3 Towards this end, the FDA specifically commands that the labeling for fluoride mouthrinses  
4 “clearly instructs consumers to read the directions.”<sup>16</sup>  
5

6 29. In order to ensure consumers read the directions, the FDA requires sellers of fluoride  
7 mouthrinse to “prominently” place a notice on the **front label** of the product.<sup>17</sup> The regulation  
8 states that “the following statement shall be prominently placed on the principal display panel:  
9 ‘IMPORTANT: Read directions for proper use.’” 21 C.F.R. § 355.55.

10 30. Defendant is flagrantly violating this regulation as it does not provide this notice  
11 anywhere on the Hello Rinse, let alone in a prominent way on the front label.

12 31. Defendant is well aware that Hello Rinse is popular among preschool children and  
13 their caregivers. The following are examples of customer reviews that can readily be found on  
14 Defendant’s own website<sup>18</sup>:  
15

- 16 a. “I was given this product to try as part of the weeSpring Parent Panel. We tried  
17 the strawberry flavor mouthwash and, as predicted, my kids loved it. My young  
18 children (6 yr, **4 yr and 2 yr**) looked forward to using it every day after brushing.  
19 It tastes good, they like to keep it in their mouth for the requisite rinse time.”  
20  
21 b. “My only complaint would be they find a better way to measure the amounts in  
22 a spill proof way (my **3 year-old** proof essentially)”  
23  
24 c. “Toothbrushing time is already a not fun time in our household when you have

25 <sup>15</sup> *Id.*

26 <sup>16</sup> *Id.* (emphasis added).

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

28 <sup>18</sup> <https://www.hello-products.com/products/kids-fluoride-strawberry-mouthwash> (last accessed Jan. 13, 2025).



1  
2  
3  
4  
5  
6  
7  
8  
9  
10  
11  
12  
13  
14  
15  
16  
17  
18  
19  
20  
21  
22  
23  
24  
25  
26  
27  
28

a **5 and 3 year old!** This is their first time using a mouthwash and they really enjoyed the experience and flavor of it! It helps to keep their breath fresh, teeth cavity free, and mommy happy!”

d. “My **4 year old** son actually looks forward to using mouthwash. It used to just be another step in the routine but he gets so excited! After he spits it out, he says ‘Yummmm!’. Having tried it out myself before him, I’d have to agree! We love that it’s natural and effective. What we put in our kiddos bodies is SO important!”

e. “We are realllllly enjoying this strawberry rinse from Hello Kids--especially my **4y/o.**”

f. “Kids aren't supposed to get excited about dental hygiene, are they? Apparently I was wrong. My **4 year old** son's new favorite treat is Hello Wild Strawberry Rinse.”

g. “I’ve got a 6 year old and **almost 4 year old** and they both loved the wild strawberry flavor so much that and would remind me to open the mouth rinse if I forgot. I would recommend this to other parents. Definitely buying this again!”

h. “My daughter is **four and a half**, and doesn't brush her teeth very thoroughly, even with my assistance. . . . My daughter loves the taste, and actually looks forward to using it every day. It’s now her favorite flavor of fluoride rinse, and I plan on buying this for her whenever she runs out of it.

i. “My **5 year old** looooves the flavor. He asks to use it all the time:)”

j. “My **5 year old** loves using this rinse.”

k. “After receiving the mouthwash from weeSpring Parent Panel, we have concluded we love Hello Kids Flouride Rinse! My **5 year old** asks every night



1 now if he can swish. Why? Because this rinse is a delicious strawberry flavor,  
2 making it so kid friendly! It's also mom approved, since it's so natural.”

3 1. “My **5 year old** has sensory processing disorder so I was a little concerned on  
4 how he would handle trying a mouth rinse, what got me interested in the wild  
5 strawberry Hello kids flouride rinse was that it has no alcohol so no burning  
6 sensation. To assure him, I tried it first. Berry flavored is generally reserved for  
7 kids things but to my surprise, I liked it! When my son tried it he said, ‘Yum! It  
8 doesnt even burn my mouth!’”

9  
10 32. The targeting of young children with fruit- and candy-flavored fluoride products is  
11 believed to be one of the reasons for the increase in dental fluorosis that has been observed in recent  
12 decades.<sup>19</sup>

13  
14 33. Since the introduction of fruit- and candy-like fluoride products in the 1980s, the  
15 rate of dental fluorosis among U.S. schoolchildren has skyrocketed. In 1986-87, approximately  
16 23% of U.S. children had fluorosis.<sup>20</sup> This rate tripled to a staggering 68% of U.S children by 2015-  
17 16.<sup>21</sup>

18 34. With millions of U.S. children showing visible signs of excess fluoride exposure,  
19 there is growing concern about other chronic health conditions that fluoride may be causing,  
20 including neurodevelopmental disorders and endocrine disruption. In August of 2024, the  
21 prestigious National Toxicology Program (NTP) concluded that excess fluoride exposure is  
22

23  
24  
25 <sup>19</sup> Christopher Neurath, et al., *Dental Fluorosis Trends in US Oral Health Surveys: 1986 to 2012*,  
4 JDR CLIN TRANS RES. 298, 306 (2019).

26 <sup>20</sup> Keith E. Heller, *Dental caries and dental fluorosis at varying water fluoride concentrations*, 57  
J PUBLIC HEALTH DENT. 136, 139 Tbl 5 (1997).

27 <sup>21</sup> Man Hung et al., *A National Study Exploring the Association Between Fluoride Levels and*  
28 *Dental Fluorosis*, 6 JAMA NETW OPEN. e2318406 (2023).

1 associated with IQ loss in children, and, in September 2024, a federal district court concluded that  
2 adding fluoride to drinking water presents an unreasonable risk of reduced IQ. See *infra* ¶¶ 99-103.

3 35. Plaintiffs bring this action to hold Defendant accountable for its false, misleading,  
4 and unlawful labeling of Hello Rinse, which puts the health of millions of children at risk.

5 36. Defendant’s failure to prominently display FDA’s required notice on the label of  
6 Hello Rinse violates 21 C.F.R. § 355.55, as well as the prohibition on selling unlawful products  
7 under California’s Unfair Competition Law, Cal. Bus. & Prof. Code § 17200.

8 37. Defendant’s false and misleading labeling violates the Federal Food Drug &  
9 Cosmetic Act (“**FDCA**”), 21 U.S.C. § 352(a),<sup>22</sup> and many state consumer fraud statutes, including,  
10 but not limited to, California’s Unfair Competition Act, Cal. Bus. & Prof. Code § 17200, the Illinois  
11 Consumer Fraud and Deceptive Trade Practices Act, 815 ILCS § 505/2, and New York General  
12 Business Law §§ 349-50.

13 38. Plaintiffs do not seek to impose any requirement that goes beyond, is not identical  
14 to, or is different from, the requirements that are imposed on Defendant under the FDCA and its  
15 accompanying regulations, including the FDA Monograph on fluoride mouthrinse. See C.F.R. §§  
16 355.50 & 355.55. Plaintiffs seek instead to hold Defendant responsible for the elements of its  
17 products that are *not* required by the Monograph *and* which violate its obligations under both  
18 federal and state law. A judicial finding that these voluntary elements are false, misleading, and/or  
19 violative of specific FDCA requirements would be harmonious and not in conflict with the FDCA.<sup>23</sup>

20  
21  
22  
23  
24 <sup>22</sup> Plaintiffs recognize that there is no private right of action under FDCA and do not assert such a  
25 claim here. Instead, Plaintiffs’ allegations that Defendant violated the requirements of the FDCA  
26 serve as a prerequisite for their state law claims. See, e.g., *In re Beyond Meat, Inc.*, No. 23 C 669,  
2024 U.S. Dist. LEXIS 30397, at \*21 (N.D. Ill. Feb. 21, 2024) (“[T]o avoid preemption, a state law  
claim related to misleading labeling must allege a violation of the FDCA or its regulations.”).

27 <sup>23</sup> See, e.g., *Bell v. Publix Super Mkts., Inc.*, 982 F.3d 468, 485 (7th Cir. 2020) (“The FDCA’s  
28 preemption provision means that, while states may not require sellers to add further labeling that is  
not required by federal law, they may prevent sellers from voluntarily adding deceptive content that

**PARTIES**

1  
2  
3  
4  
5  
6  
7  
8  
9  
10  
11  
12  
13  
14  
15  
16  
17  
18  
19  
20  
21  
22  
23  
24  
25  
26  
27  
28

39. Plaintiff **Amber Miller** is a citizen of California.

40. Ms. Miller lives in San Marcos, California, where she has purchased Hello Rinse for her minor daughter I.M.

41. Ms. Miller began purchasing Hello Rinse for I.M. in 2022, when I.M. was two years old. She continued purchasing the product for I.M. until 2024.

42. Ms. Miller has purchased Hello Rinse for I.M. from a Walmart located in San Diego County.

43. Ms. Miller did not purchase the Hello Rinse at the direction of a dentist, doctor, or health care provider.

44. Based on Defendant’s packaging, Ms. Miller believed Hello Rinse was specially formulated to be safe for young children and would not present any risks to I.M.

45. I.M. enjoyed the flavor of the rinse.

46. If Ms. Miller had known that fluoride mouthrinse is contraindicated for children under 6 years of age, she would not have purchased Hello Rinse, or any other fluoride rinse.

47. Plaintiff **Josh Cook** is a citizen of Illinois.

48. Mr. Cook lives in Rockford, Illinois and has purchased Hello Rinse for his minor daughter Z.C.

49. Mr. Cook began purchasing Hello Rinse for Z.C. in about 2021 when she was 3 years old. He continued purchasing the product for Z.C. until 2023 when she was approximately 5

---

is not required by federal law.”); *Astiana v. Hain Celestial Grp., Inc.*, 783 F.3d 753, 758 (9th Cir. 2015) (“FDA regulations do not require Hain to label its products as ‘All Natural’ or ‘Pure Natural.’ If Astiana’s suit ultimately requires Hain to remove these allegedly misleading advertising statements from its product labels, such a result does not run afoul of the FDCA, which prohibits ‘requirement[s]’ that are ‘different from,’ ‘in addition to,’ or ‘not identical with’ federal rules.”).

1 years old.

2 50. Mr. Cook did not purchase the Hello Rinse at the direction of a dentist, doctor, or  
3 health care provider.

4 51. Based on Defendant’s packaging, Mr. Cook believed Hello Rinse was specially  
5 formulated to be safe for young children and would not present any risks to Z.C.  
6

7 52. Z.C. enjoyed the flavor of the rinse.

8 53. If Mr. Cook had known that fluoride mouthrinse is contraindicated for children  
9 under 6 years of age, he would not have purchased Hello Rinse, or any other fluoride rinse.

10 54. Plaintiff **Marina Vasilyeva** is a citizen of New York.

11 55. Ms. Vasilyeva lives in Manhattan, New York and has purchased Hello Rinse for her  
12 minor daughter C.B.

13 56. Ms. Vasilyeva began purchasing Hello Rinses for C.B. in about 2021, when C.B.  
14 was 3 years old. She continued purchasing the product for C.B. until 2024.

15 57. Ms. Vasilyeva did not purchase the Hello Rinse at the direction of a dentist, doctor,  
16 or health care provider.

17 58. Based on Defendant’s packaging, Ms. Vasilyeva believed Hello Rinse was specially  
18 formulated to be safe for young children and would not present any risks to C.B.  
19

20 59. C.B. enjoyed the flavor of the rinse.

21 60. If Ms. Vasilyeva had known that fluoride mouthrinse is contraindicated for children  
22 under 6 years of age, she would not have purchased Hello Rinse, or any other fluoride mouthrinse.

23 61. Defendant **Hello Products LLC** is, and at all times mentioned in this Complaint  
24 was, a Delaware limited liability company with a principal place of business in North Bergen, New  
25 Jersey.  
26  
27  
28

**JURISDICTION AND VENUE**

1  
2  
3  
4  
5  
6  
7  
8  
9  
10  
11  
12  
13  
14  
15  
16  
17  
18  
19  
20  
21  
22  
23  
24  
25  
26  
27  
28

62. This Court has subject matter jurisdiction over this case pursuant to 28 U.S.C. §1332(d)(2) and the Class Action Fairness Act of 2005 (“CAFA”), because (i) there are 100 or more class members; (ii) there is an aggregate amount in controversy exceeding \$5,000,000, exclusive of interest and costs; and (iii) there is minimal diversity because at least one member of the class and defendant are citizens of different states. This court has supplemental jurisdiction over the state law claims pursuant to 28 U.S.C. § 1367.

63. This Court has personal jurisdiction over Defendant because the injuries upon which the California Plaintiff’s action is based occurred or arose out of activities that Defendant specifically engaged in within the State of California. Defendant knowingly and intentionally distributed its mouthrinse products for sale in California, and Plaintiff thereupon purchased Defendant’s mouthrinse products from a retail store located in California.

64. Venue is proper in this District pursuant to 28 U.S.C. § 1391(b)(2) because a substantial part of the events or omissions giving rise to the claims occurred in the State of California, including within San Diego County.

**FACTUAL ALLEGATIONS**

**A. Fluoride Mouthrinse Poses a Much Greater Risk to Young Children than Adults**

65. For a multitude of reasons, young children are more vulnerable to suffering harm from fluoride mouthrinse than adolescents and adults.

66. Young children have poorly developed swallowing reflexes and, as a result, swallow a large percentage of the rinse that they put into their mouth, whether they want or intend to or not. This remains the case even when the child is instructed not to swallow. As the FDA has explained, “Children under 6 years of age . . . have not developed control of their swallowing reflex and are

1 not able to hold the fluoride preparation in their mouth and then expectorate properly.”<sup>24</sup>

2 67. Between mouthrinse and toothpaste, the former poses a greater risk of excess  
3 ingestion for young children. This is because fluoride mouthrinses “do not contain an abrasive that  
4 can bind some of the fluoride ion and because a child under 6 is more likely to drink a flavored  
5 liquid than eat large amounts of toothpaste.”<sup>25</sup>

6 68. The lack of a developed swallowing reflex is particularly acute for children under  
7 the age of three. In a study designed to estimate exposure from fluoride mouthrinse, “most 2 year  
8 old children and some 3 year old children could not perform mouthrinsing with water, but instead  
9 quickly swallowed the fluid.”<sup>26,27</sup>

10 69. According to the CDC, “studies of the amount of fluoride swallowed by children  
11 aged 3-5 years using such rinses indicated that some young children might swallow substantial  
12 amounts.”<sup>28</sup>

13 70. Even when ingesting the same amount of mouthrinse as an adult, young children  
14 receive a far higher fluoride dose by bodyweight (mg/kg/day) due to their smaller body size.

15 71. A 2 year old child of average weight (~12 kg) who ingests a single dose of Hello  
16 Rinse<sup>29</sup> will ingest 0.19 mg/kg of fluoride, which is more than two times higher than EPA’s

17  
18  
19  
20  
21 <sup>24</sup> FDA, *supra* note 12, at 39867.

22 <sup>25</sup> FDA, *supra* note 2, at 52486.

23 <sup>26</sup> FDA, *supra* note 12, at 39867.

24 <sup>27</sup> This study gave the children *water*. The study’s findings would likely have been even more  
25 troubling if the children were given *candy-flavored* rinse. When drugs taste and smell like candy,  
26 many young children are inclined to swallow it, irrespective of whether they have the necessary  
27 reflexes to control doing so. *Cf.*, CDC, *supra* note 6, at 14 (stating that children are “known to  
28 swallow toothpaste deliberately when they like its taste”).

<sup>28</sup> CDC, *supra* note 6, at 16.

<sup>29</sup> A single dose is 10 mL. At a concentration of 0.05% sodium fluoride (=0.023% fluoride ion), 10 mL of mouthrinse contains 2.3 mg of fluoride ion.

1 reference dose (0.08 mg/kg/day) for fluoride. According to EPA, children who ingest more than  
2 0.08 mg/kg/day are at risk of developing “severe dental fluorosis.”<sup>30</sup>

3 **B. Ingesting Fluoride Mouthrinse During Early Childhood Causes Dental Fluorosis**

4 72. Dental fluorosis is “a permanent, mottled discoloration of the teeth”<sup>31</sup> that is caused  
5 by ingesting too much fluoride while the teeth are still developing. Once the teeth have finished  
6 forming, fluoride can no longer cause fluorosis. Ergo, only young children are at risk of developing  
7 this condition.

9 73. The first six years of life are the critical window of vulnerability for developing  
10 dental fluorosis, with fluoride exposures during the first 3 years of life being the most significant  
11 for causing fluorosis of the upper front teeth, which are the most cosmetically important teeth.<sup>32</sup>

12 74. Dental fluorosis comes in various degrees of severity.<sup>33</sup> The mild forms of fluorosis  
13 cause “permanent white lines or streaks” on the teeth, whereas the severe forms of fluorosis cause  
14 “brown, gray, or black patches and pits, typically on top of an irregular tooth surface.”<sup>34</sup>



22  
23 <sup>30</sup> ENVIRONMENTAL PROTECTION AGENCY: FLUORIDE: DOSE-RESPONSE ANALYSIS FOR NON-  
24 CANCER EFFECTS 107 (2010) (emphasis added).

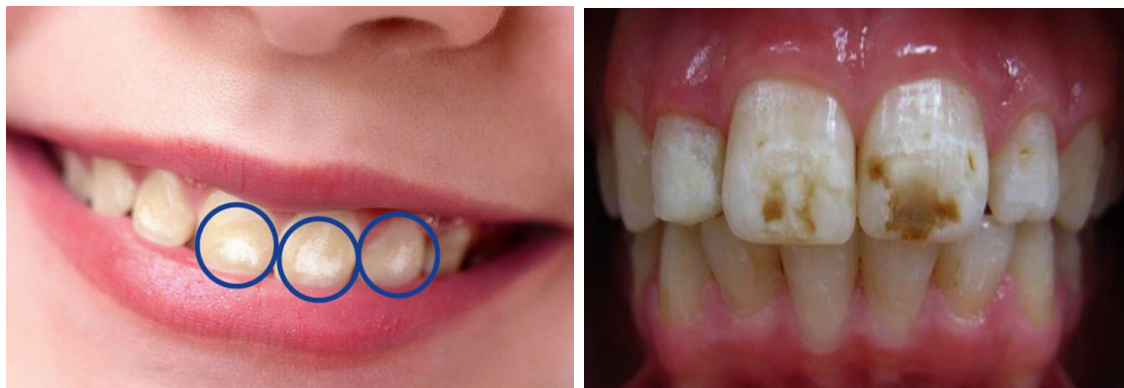
25 <sup>31</sup> FDA, *supra* note 2, at 52487.

26 <sup>32</sup> Michael R. Franzman, et al., *Fluoride dentifrice ingestion and fluorosis of the permanent*  
27 *incisors*, 137 J AM DENT ASSOC. 645, 646 (2006).

28 <sup>33</sup> NATIONAL RESEARCH COUNCIL, *supra* note 11, at 103-11.

<sup>34</sup> Colgate, *Causes of Brown Spots on the Teeth*, <https://www.colgate.com/en-us/oral-health/adult-oral-care/brown-spots-on-teeth-causes> (last accessed Jan. 13, 2025).





*Photos of Dental Fluorosis*

75. Microscopically, “dental fluorosis is a condition of permanent hypomineralized change, with increased surface and sub-surface enamel porosity resulting from excess fluoride reaching the developing tooth prior to eruption.”<sup>35</sup> In short, “fluoride affects the forming enamel by making it more porous.”<sup>36</sup>

76. The CDC agrees that ingesting fluoride mouthrinse can cause fluorosis. According to CDC, “[i]f children repeatedly swallow mouth rinses, they may develop dental fluorosis.”<sup>37</sup>

77. The ingestion of fluoridated dental products is considered to be a key reason for the skyrocketing prevalence of dental fluorosis in the US. In the 1940s, dental fluorosis was a rare condition that was generally found only in areas with elevated fluoride in water. Since that time, with the advent of water fluoridation programs and fluoridated dental products, the rate of dental fluorosis has steadily increased. The most recent national survey from the CDC, conducted in 2015-2016, found that 68.2% of children now have some form of dental fluorosis.<sup>38</sup>

78. Dental fluorosis, even in its “mild” forms, is recognized to be cosmetically

<sup>35</sup> Brian A. Burt, *The changing patterns of systemic fluoride intake*. 71 J DENT RES. 1228, 1228 (1992).

<sup>36</sup> Ana Karina Mascarenhas, *Risk factors for dental fluorosis: a review of the recent literature*, 22 PEDIATR DENT. 269, 274 (2000).

<sup>37</sup> CDC, *supra* note 10.

<sup>38</sup> Hung et al., *supra* note 21.

1 objectionable when present on a child’s upper front teeth (i.e., maxillary anterior teeth).<sup>39</sup>

2 79. The following are some findings from the peer-reviewed dental literature regarding  
3 the disfiguring effects of “mild” fluorosis:

4 a. “Mild and moderate dental fluorosis had a negative aesthetic effect on the  
5 studied population, leading to a strong desire to seek dental treatment to  
6 change the appearance of affected teeth.”<sup>40</sup>

7  
8 b. “The key finding to emerge from this study was the negative psychosocial  
9 impact reported by some children with untreated enamel defects . . . . Over  
10 half of the children stated that they had been subject to unkind remarks about  
11 their teeth by their peers. A number of children described a reluctance to  
12 smile or a lack of confidence.”<sup>41</sup>

13  
14 c. “Fluorosis was associated with increased parental dissatisfaction with  
15 overall appearance, color, and blotchiness of their children’s teeth.”<sup>42</sup>

16  
17 d. “The pupils’ feedback was extremely useful, revealing that they believed the  
18 ‘marks’ on the teeth to be due to poor oral hygiene, despite a preliminary  
19 tutorial which indicated this was not the case.”<sup>43</sup>

20  
21 <sup>39</sup> Susan O. Griffin et al., *Esthetically objectionable fluorosis attributable to water fluoridation*, 30  
COMMUNITY DENT ORAL EPIDEMIOL. 199, 202-03 (2002).

22 <sup>40</sup> Frederico Omar Gleber-Netto, et al. *Assessment of aesthetic perception of mild and moderate*  
23 *dental fluorosis levels among students from the Federal University of Minas Gerais-UFMG, Brazil*,  
9 ORAL HEALTH PREV DENT 339, 339 (2011).

24 <sup>41</sup> H.D. Rodd, et al., *Seeking children's perspectives in the management of visible enamel defects*,  
25 21 INT J PAEDIATR DENT. 89, 93 (2011); *see also* Zoe Marshman, et al., *The impact of*  
26 *developmental defects of enamel on young people in the UK*, 37 COMMUNITY DENT ORAL  
EPIDEMIOL. 45 (2008).

27 <sup>42</sup> Steven M. Levy, et al., *Factors associated with parents’ esthetic perceptions of children’s mixed*  
*dentition fluorosis and demarcated opacities*, 27 PEDIATR DENT. 486, 486 (2005).

28 <sup>43</sup> Maura Edwards, et al., *An assessment of teenagers’ perceptions of dental fluorosis using digital*

1  
2  
3  
4  
5  
6  
7  
8  
9  
10  
11  
12  
13  
14  
15  
16  
17  
18  
19  
20  
21  
22  
23  
24  
25  
26  
27  
28

- e. “Our studies of esthetic perceptions of dental fluorosis found that members of the public had strong preferences about variations from normal tooth appearance. For example, all respondents had a preference for teeth with normal color over teeth with mild fluorosis . . . .”<sup>44</sup>
- f. “Results show that not only is fluorosis noticeable, but it may be more of an esthetic concern than the other conditions (e.g. isolated opacities, tetracycline staining, or various types of malocclusion).”<sup>45</sup>
- g. “A strong association between fluorosis and parental satisfaction was evident, even at a low level of severity.”<sup>46</sup>
- h. “South Australian children 10- to 17-years-old were able to recognize very mild and mild fluorosis and register changes in satisfaction with the colour and appearance of teeth. Even mild changes were associated with psycho-behavioural impacts.”<sup>47</sup>
- i. “[O]bservers felt that the appearance would increasingly embarrass the child as the TF score increased.”<sup>48</sup>

80. Due to the objectionable appearance of fluorosis, many people with the condition pay for cosmetic treatment (e.g., abrasion of the tooth surface in mild cases, and veneers in severe cases). This treatment can be expensive and beyond the financial means for some families.

---

*stimulation and web-based testing*, 33 COMMUNITY DENT ORAL EPIDEMIOLOG. 298, 305(2005).

<sup>44</sup> Steven M. Levy, *An update on fluorides and fluorosis*, 69 J CAN DENT ASSOC. 286, 287 (2003).

<sup>45</sup> Carrie B. McKnight, et al., *A pilot study of esthetic perceptions of dental fluorosis vs. selected other dental conditions*, 65 ASDC J DENT CHILD 233, 233 (1998).

<sup>46</sup> James A. Lalumandier & R. Gary Rozier, *Parents’ satisfaction with children’s tooth color: fluorosis as a contributing factor*, 129 J AM DENT ASSOC. 1000, 1003 (1998).

<sup>47</sup> John Spencer, et al., *Water fluoridation in Australia*, 13 COMMUNITY DENT HEALTH 27 (1996).

<sup>48</sup> Paul J. Riordan, *Perceptions of dental fluorosis*, 72 J DENTAL RES 1268, 1268 (1993).

1 **C. Ingesting Fluoride Toothpaste Can Cause Stomach Flu Symptoms**

2 81. Ingesting too much fluoride mouthrinse can cause symptoms of acute toxicity that  
3 mimic the symptoms of stomach flu, including nausea, upset stomach, diarrhea, and vomiting.

4 82. According to a review in the *Journal of Public Health Dentistry*, “Parents or  
5 caregivers may not notice the symptoms associated with mild fluoride toxicity or may attribute  
6 them to colic or gastroenteritis, particularly if they did not see the child ingest fluoride. Similarly,  
7 because of the nonspecific nature of mild to moderate symptoms, a physician’s differential  
8 diagnosis is unlikely to include fluoride toxicity without a history of fluoride ingestion.”<sup>49</sup>

9 83. The mechanism by which fluoride causes stomach flu symptoms has been described  
10 as follows: “When above normal amounts of fluoride are ingested, the fluoride combines with  
11 hydrochloric acid in the stomach and forms hydrofluoric acid. As a result, the hydrofluoric acid has  
12 a burning effect on the gastric lining causing gastrointestinal (GI) symptoms such as nausea,  
13 vomiting, abdominal cramping, and discomfort.”<sup>50</sup>

14 84. As with all toxicants, the dose of fluoride that causes symptoms of acute toxicity  
15 varies considerably across the population, with some children being much more vulnerable, and  
16 other children being much more resistant, than the “average child.”<sup>51</sup>

17 85. Symptoms of nausea and gastrointestinal distress have been reported at doses as low  
18 as 0.1 mg/kg.<sup>52</sup> A 2 year-old-child of average weight (~12 kg) will ingest this much fluoride by  
19

20  
21  
22 \_\_\_\_\_  
23 <sup>49</sup> Shulman & Wells, *supra* note 8, at 157.

24 <sup>50</sup> Mary D. Cooper & Connie M. Kracher, *Are our patients guzzling too much fluoride?*, RDH  
25 MAGAZINE, Feb. 1, 1997, <https://www.rdhmag.com/patient-care/rinses-pastes/article/16406858/are-our-patients-guzzling-too-much-fluoride>.

26 <sup>51</sup> E.g., H.G. Eichler, et al., *Accidental ingestion of NaF tablets by children--report of a poison*  
27 *control center and one case*, 20 INT J CLIN PHARMACOL THER TOXICOL. 334 (1982). Cf. C.J. Spak,  
28 et al., *Studies of human gastric mucosa after application of 0.42% fluoride gel*, 69 J DENT RES. 426 (1990).

<sup>52</sup> Kenji Akiniwa, *A Re-examination of acute toxicity of fluoride*, 30 FLUORIDE 89 (1997).

1 swallowing just over half of a single 10 mL dose of Hello Rinse.

2 86. In *adults*, a one-time ingestion of as little as 3 milligrams of fluoride in one sitting  
3 (or the equivalent of 13 mL of Hello Rinse) has been found to cause “widespread” erosions of the  
4 gastric mucosa in the stomach.<sup>53</sup> The dose that causes erosions in the stomach of children has not  
5 been studied (due to ethical constraints) but will almost certainly be less than 3 mg due to lower  
6 bodyweight and smaller stomach space.  
7

8 87. If a 2 year-old-child ingests just 5 mL of Hello Rinse, or half of a single dose, the  
9 National Capital Poison Center recommends that the child take “Two tablets of chewable calcium  
10 or calcium plus vitamin D supplement,” “Four ounces of milk,” or “One tablespoon of liquid  
11 antacid containing magnesium or aluminum” in order to help prevent “nausea, vomiting,  
12 diarrhea.”<sup>54</sup>  
13

14 **D. Half a Bottle of Hello Rinse Has Enough Fluoride to Kill a Toddler**

15 88. Fluoride is a “protoplasmic poison”<sup>55</sup> that can kill humans at doses not that much  
16 higher than arsenic.<sup>56</sup> The potency of fluoride’s acute toxicity is why fluoride has been used as the  
17 active ingredient in rodenticides (to kill rodents) and insecticides (to kill bugs).<sup>57</sup> As far back as  
18 1895, it was observed that “sodium fluoride is an active poison for micro-organisms of all kinds,  
19

20 \_\_\_\_\_  
21 <sup>53</sup> Spak, *supra* note 51.

22 <sup>54</sup> See <https://triage.webpoisoncontrol.org/> (last accessed Jan. 13, 2025).

23 <sup>55</sup> Editorial, *Chronic fluorine intoxication*, 123 J AM DENT ASSOC. 150, 150 (1943).

24 <sup>56</sup> The CDC states that “[a]s little as 1–2.5 mg/kg of arsenic trioxide is a potentially fatal dose.”  
25 CDC, *Medical Management Guidelines for Arsenic (As) and Inorganic Arsenic Compounds*,  
26 <https://wwwn.cdc.gov/TSP/MMG/MMGDetails.aspx?mmgid=1424&toxid=3>. This is only slightly  
27 lower than the potentially fatal dose of fluoride (5 mg/kg), as discussed below. See also Floyd  
28 DeEds, *Fluorine in relation to bone and tooth development*, 33 J AM DENT ASSOC. 568, 570 (1936)  
 (“Such a comparison of toxicity data suggests that fluorine, lead and arsenic belong to the same  
 group, as far as ability to cause some symptom of toxicity in minute dosage is concerned.”).

<sup>57</sup> KAJ ROHOLM, FLUORINE INTOXICATION: A CLINICAL HYGIENIC STUDY WITH A REVIEW OF THE  
 LITERATURE AND SOME EXPERIMENTAL INVESTIGATIONS 301 (1937).

1 algae, and nerves and muscles of the higher organisms.”<sup>58</sup>

2 89. The “Probable Toxic Dose” (“PTD”) for fluoride is 5 mg/kg.<sup>59</sup> The PTD “is defined  
3 as the dose of ingested fluoride that should trigger immediate therapeutic intervention and  
4 hospitalization because of the likelihood of serious toxic consequences.”<sup>60</sup> It is the “minimum dose  
5 that could cause toxic signs and symptoms, including death, and that should trigger immediate  
6 therapeutic intervention and hospitalization.”<sup>61</sup>

7  
8 90. Due to person-to-person variations in sensitivity to fluoride toxicity, not all people  
9 who ingest 5 mg/kg will experience significant toxicity. But, “if it is even suspected that 5.0 mg/kg  
10 or more of fluoride has been ingested, then it should be assumed that an emergency exists.  
11 Appropriate therapeutic measures and hospitalization should be instituted immediately.”<sup>62</sup>

12  
13 91. A bottle of Hello Rinse contains 109 milligrams of fluoride. A 1 year-old-child of  
14 average weight (~9 kg) would exceed the PTD if he ingested just 41% of Defendant’s candy-  
15 flavored rinse, while a 2 year-old-child of average weight (~12 kg) would exceed the PTD if he  
16 ingested 55%.

17 92. Each year there are over 4,000 reports to poison control centers related to ingestion  
18 of fluoride mouthrinses.<sup>63</sup> The vast majority of these calls are made on behalf of very young  
19

20 <sup>58</sup> Herbert B. Baldwin, *The toxic action of sodium fluoride*, 21 J AM CHEM SOC. 517, 521 (1899)  
21 (quoting Czrellitzer 1895).

22 <sup>59</sup> Gary M. Whitford, *Fluoride in dental products: safety considerations*, 66 J DENT RES. 1056,  
23 1056 (1987).

24 <sup>60</sup> *Id.*

25 <sup>61</sup> *Id.* at 1057.

26 <sup>62</sup> *Id.*

27 <sup>63</sup> David D. Gummin et al., *2020 Annual Report of the American Association of Poison Control*  
28 *Centers' National Poison Data System (NPDS): 38th Annual Report*, 59 CLIN TOXICOL (Phila)  
1282, 1448 (2020); David D. Gummin et al., *2021 Annual Report of the National Poison Data*  
*System© (NPDS) from America's Poison Centers: 39th Annual Report*, 60 CLIN TOXICOL (Phila)  
1381, 1581 (2021).

1 children.

2 93. The number of poisoning incidents from consumer products reported to poison  
3 control centers is recognized to “likely underestimate the total incidence and severity of  
4 poisonings.”<sup>64</sup> This is the case even for poisonings that cause outcomes as severe as death.<sup>65</sup>

5  
6 94. Consistent with the general recognition that poison control data underestimates the  
7 true extent and severity of poisonings, the reported number of poisonings from fluoride mouthrinse  
8 is also believed to “underestimate” the true extent of fluoride poisonings due to “substantial  
9 underreporting” of such incidents.<sup>66</sup>

10 95. Nevertheless, the FDA has cited the large number of poison control reports for  
11 fluoride mouthrinses as a justification for requiring a poison warning on these products.<sup>67</sup> FDA’s  
12 required poison warning states as follows: “Keep out of reach of children. If more than used for  
13 rinsing is accidentally swallowed, get medical help or contact a Poison Control Center right away.”  
14 21 C.F.R. § 355.50(c)(2).

15  
16 **E. Other Health Concerns with Early Life Exposure to Fluoride**

17 96. Acute toxicity and dental fluorosis are not the only health concerns with excess  
18 ingestion of fluoride.

19 97. In 2006, the National Research Council (“NRC”) of the National Academies of  
20 Science published a comprehensive review of fluoride toxicology which concluded, among other  
21 things, that excess fluoride exposure weakens bone, damages the brain, and disrupts the endocrine  
22

23  
24 <sup>64</sup> Arthur Chang, et al., *Cleaning and Disinfectant Chemical Exposures and Temporal Associations*  
25 *with COVID-19 — National Poison Data System, United States, January 1, 2020–March 31, 2020*,  
69 MMWR MORB MORTAL WKLY REP. 16 496, 496-97 (2020).

26 <sup>65</sup> Christopher Hoyte, Medical Director of the Rocky Mountain Poison Center, Presentation to FDA  
Workshop “Defining ‘Candy-Like’ Nonprescription Drug Products,” Oct. 30, 2023, p. 232.

27 <sup>66</sup> Shulman & Wells, *supra* note 8, at 157.

28 <sup>67</sup> FDA, *supra* note 2, at 52486.



1 system, including the thyroid gland.<sup>68</sup> According to the NRC, fluoride has been credibly associated  
2 with impaired thyroid function in susceptible humans at doses as low as 0.01 to 0.03 mg/kg/day,<sup>69</sup>  
3 which is less than many children will routinely ingest from using fluoride mouthrinse.<sup>70</sup>

4  
5 98. Another endocrine effect of fluoride exposure that the NRC flagged is impaired  
6 glucose metabolism, which is believed to be caused by fluoride’s “inhibition of insulin  
7 production.”<sup>71</sup> According to the NRC, blood fluoride levels of 0.1 mg/L are credibly associated  
8 with this effect.<sup>72</sup> A preschool child who ingests as little as 1/3 of a single dose of Hello Rinse will  
9 have blood fluoride levels that temporarily approximate or exceed this level.<sup>73</sup>

10 99. In August of 2024, the National Toxicology Program (“NTP”), which is part of the  
11 National Institutes of Health, published a systematic review in which it concluded that excess  
12 fluoride exposure is “consistently associated with reduced IQ in children.”<sup>74</sup>

13  
14 100. In January of 2025, NTP scientists published a meta-analysis of 74 human studies  
15 on fluoride and IQ in the journal *JAMA Pediatrics*.<sup>75</sup> The NTP analysis “found inverse associations  
16

17  
18 <sup>68</sup> NATIONAL RESEARCH COUNCIL, *supra* note 11, at 178-80, 220-22 & 260-66.

19 <sup>69</sup> *Id.* at 263 (“In humans, effects on thyroid function were associated with fluoride exposures of  
20 0.05-0.13 mg/kg/day when iodine intake was adequate and 0.01-0.03 mg/kg/day when iodine intake  
21 was inadequate.”).

22 <sup>70</sup> A 2 year-old-child of average weight (~12 kg) will ingest 0.03 mg/kg from ingesting just 1/6<sup>th</sup> of  
23 a single 10 mL dose of Firefly rinse.

24 <sup>71</sup> *Id.* at 264.

25 <sup>72</sup> *Id.*

26 <sup>73</sup> See Jan Ekstrand et al., *Plasma fluoride concentrations in pre-school children after ingestion of*  
27 *fluoride tablets and toothpaste*, 17 CARIES RES. 379 (1983).

28 <sup>74</sup> NATIONAL TOXICOLOGY PROGRAM, NTP MONOGRAPH ON THE STATE OF THE SCIENCE  
CONCERNING FLUORIDE EXPOSURE AND NEURODEVELOPMENT AND COGNITION: A SYSTEMATIC  
REVIEW. Available online at [https://ntp.niehs.nih.gov/sites/default/files/2024-08/fluoride\\_final\\_508.pdf](https://ntp.niehs.nih.gov/sites/default/files/2024-08/fluoride_final_508.pdf).

<sup>75</sup> Kyla Taylor et al., *Fluoride exposure and children’s IQ scores: A systematic review and meta-analysis*, JAMA PED. doi: 10.1001/jamapediatrics.2024.5542 (published online on Jan. 6, 2025).

1 and a dose-response relationship between fluoride measurements in urine and drinking water and  
2 children’s IQ across the large multicountry epidemiological literature.”

3 101. The NTP has flagged mouthrinse as a source of childhood fluoride exposure that  
4 could contribute to the risk of neurodevelopmental problems. According to the NTP, “children may  
5 be getting more fluoride than they need because they now get fluoride from many sources including  
6 treated public water, water-added foods and beverages, teas, toothpaste, floss, and *mouthwash*, and  
7 the combined total intake of fluoride may exceed safe amounts.”<sup>76</sup>

9 102. On September 24, 2024, after hearing extensive expert testimony about NTP’s  
10 findings and other recent research, the Honorable Judge Edward Chen from the U.S. District Court  
11 for the Northern District of California concluded that the addition of fluoride to drinking water  
12 “poses an unreasonable risk of reduced IQ in children.” *Food & Water Watch, Inc. v. United States*  
13 *EPA*, No. 17-cv-02162-EMC, 2024 U.S. Dist. LEXIS 172635, at \*4 (N.D. Cal. Sep. 24, 2024).

15 103. Judge Chen’s detailed 80-page decision, along with the NRC and NTP reports,  
16 further highlights the need to limit children’s ingestion of fluoride.

17 **F. The Problem with Presenting Fluoride Mouthrinse as a Candy-Like Drug**

18 104. It is well recognized that presenting drugs as “candy-like” products increases the  
19 risk of overdose, particularly for young children. This problem has long been specifically flagged  
20 in the context of fluoridated dental products.

22 105. In 1992, the *Journal of Public Health Dentistry* published a consensus statement  
23 which read, in part, “The use of flavors that may increase the ingestion of fluoridated dentifrices  
24 by young children should be strongly discouraged.”<sup>77</sup>

26 <sup>76</sup> National Toxicology Program, *Fluoride Exposure: Neurodevelopment and Cognition*,  
27 <https://ntp.niehs.nih.gov/whatwestudy/assessments/noncancer/completed/fluoride> (last accessed  
28 Jan. 13, 2025).

<sup>77</sup> James W. Bawden, et al. *Changing patterns of fluoride intake. Proceedings of the workshop.*

1 106. In 1994, the World Health Organization stated, “the production of candy-like  
2 flavours . . . should not be encouraged for use by children, as they may lead to an excessive ingestion  
3 of fluoride.”<sup>78</sup>

4 107. In 1997, the *Journal of Public Health Dentistry* published a review, which stated  
5 “The use of flavored consumer fluoride products increases the possibility that a child will ingest a  
6 toxic dose of fluoride.”<sup>79</sup>

8 108. Studies have empirically tested, and confirmed, that adding candy flavor to  
9 toothpaste increases the amount of paste that children add to their brush, as well as the amount of  
10 toothpaste that they ingest.<sup>80</sup> Similar studies have not been conducted on candy-flavored  
11 mouthrinses. The absence of such studies is likely a result, in part, of the bioethical problem of  
12 intentionally exposing preschool children to a product that is contraindicated for this population.

13 109. According to the FDA, marketing dangerous products to children through the use of  
14 candy or food flavoring is a “misleading” marketing tactic that can render a product “misbranded”  
15 under the FDCA.<sup>81</sup>

16  
17  
18  
19 

---

*Part II*, 71 J PUBLIC HEALTH DENT. 1212, 1221 (1992).

20 <sup>78</sup> WORLD HEALTH ORGANIZATION, *supra* note 4, at 28.

21 <sup>79</sup> Shulman & Wells, *supra* note 8, at 150.

22 <sup>80</sup> Steven M. Levy, et al., *A pilot study of preschoolers' use of regular-flavored dentifrices and those*  
23 *flavored for children*, 14 PEDIATR DENT. 388 (1992); Steven M. Adair, et al., *Comparison of the*  
24 *use of a child and an adult dentifrice by a sample of preschool children*, 19 PEDIATR DENT. 99  
25 (1997); Claudia A. Kobayashi, et al., *Factors influencing fluoride ingestion from dentifrice by*  
*children*, 39 COMMUNITY DENT ORAL EPIDEMIOL. 426 (2011); Carrie A. Strittholt, et al., *A*  
*randomized clinical study to assess ingestion of dentifrice by children*, 75 REGUL TOXICOL  
PHARMACOL. 66 (2016).

26 <sup>81</sup> *E.g.*, FDA Warning Letter to Electric Lotus, LLC, Nov. 29, 2018, *available at:*  
27 [https://www.fda.gov/inspections-compliance-enforcement-and-criminal-investigations/warning-](https://www.fda.gov/inspections-compliance-enforcement-and-criminal-investigations/warning-letters/electric-lotus-llc-568710-11292018)  
28 [letters/electric-lotus-llc-568710-11292018](https://www.fda.gov/inspections-compliance-enforcement-and-criminal-investigations/warning-letters/electric-lotus-llc-568710-11292018) (warning liquid tobacco companies that their use of  
candy flavoring is “misleading” and “increases the likelihood that children will ingest the product  
as a food”).

1           **G. FDCA Requirements for Fluoride Mouthrinse**

2           *General Requirements*

3           110. The FDCA prohibits companies from selling over-the-counter drugs that are  
4 “misbranded.” 21 U.S.C. § 331(a).

5           111. A drug is misbranded if it has labeling that “is **false or misleading** in any particular.”  
6 21 U.S.C. § 352(a)(1) (emphasis added).

7           112. A drug is also misbranded if “any word, statement, or other information required . .  
8 . . to appear on the label or labeling is not **prominently** placed thereon with such conspicuousness  
9 (as compared with other words, statements, designs, or devices, in the labeling) and in such terms  
10 as to render it likely to be read and understood by the ordinary individual under customary  
11 conditions of purchase and use.” 21 U.S.C. § 352(c) (emphasis added).

12           113. Under the regulations issued pursuant to the FDCA, the warnings and directions on  
13 a label will fail to meet the prominence test if there is:

14           (4) Insufficiency of label space for the prominent placing of such word, statement, or  
15 information, resulting from the use of label space for any word, statement, design, or device  
16 which is not required by or under authority of the act to appear on the label;

17           (5) Insufficiency of label space for the prominent placing of such word, statement, or  
18 information, resulting from the use of label space to give materially greater conspicuousness  
19 to any other word, statement, or information, or to any design or device.

20 21 C.F.R. § 201.15(a).

21           114. An over-the-counter drug is “not misbranded” if it satisfies “each of the conditions  
22 contained in any applicable monograph” **and** is “labeled in compliance” with 21 U.S.C. § 352 and  
23 the regulations issued pursuant thereto. 21 C.F.R. § 330.1(c)(1). Thus, a drug can meet each of the  
24 conditions of an applicable Monograph and still be misbranded if it has additional text on the label  
25  
26  
27  
28

1 that is false and misleading, or fails to display the required warnings and directions in a sufficiently  
2 prominent manner.

3 *Specific Requirements*

4 115. The FDA has issued a Monograph for anti-cavity dental products, including fluoride  
5 mouthrinse. 21 C.F.R. §§ 355.50 & 355.55.

6  
7 116. The FDA requires that all fluoride mouthrinse products provide the following  
8 warning: “Keep out of reach of children. If more than used for rinsing is accidentally swallowed,  
9 get medical help or contact a Poison Control Center right away.” 21 C.F.R. § 355.50(c)(2). The  
10 FDA requires that the first sentence of this warning be in bold type. *Id.*

11 117. The FDA requires that fluoride mouthrinses containing 0.05% sodium fluoride<sup>82</sup>  
12 provide the following directions: “Adults and children 6 years of age and older: Use once a day  
13 after brushing your teeth with a toothpaste. Vigorously swish 10 milliliters of rinse between your  
14 teeth for 1 minute and then spit out. Do not swallow the rinse. Do not eat or drink for 30 minutes  
15 after rinsing. Instruct children under 12 years of age in good rinsing habits (to minimize  
16 swallowing). Supervise children as necessary until capable of using without supervision. Children  
17 under 6 years of age: Consult a dentist or doctor.” 21 C.F.R. § 355.50(d)(2)(ii).

18  
19 118. The FDA also requires that “the following statement shall be prominently placed on  
20 the principal display panel” of all fluoride mouthrinses: “IMPORTANT: Read directions for proper  
21 use.” 21 C.F.R. § 355.55.

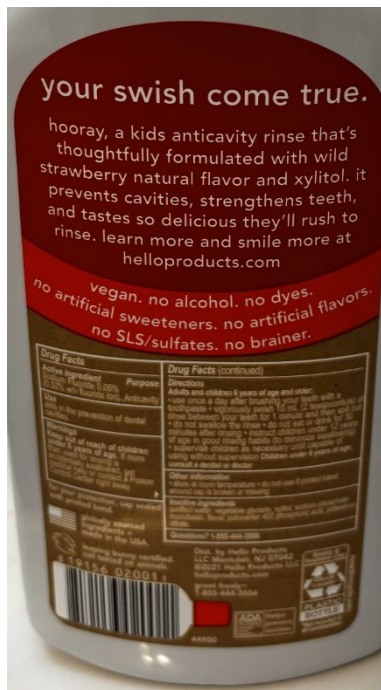
22  
23 *Things that the FDA Does Not Require*

24 119. The FDA does not require fluoride mouthrinse to taste and smell like candy or fruit  
25 juice.

26  
27  
28 <sup>82</sup> This is the concentration of Hello Rinse.

1 120. The FDA does not require the labeling of fluoride mouthrinse to boast that its kids-  
2 friendly favor “tastes awesome,” “tastes magical,” and “tastes delicious.”

3 121. The FDA does not require the labeling of fluoride mouthrinse to use language that  
4 encourages parents and caregivers to think of the product as harmless for children.  
5





1                   **H. The Deceptive Attributes of Hello Rinses**

2                   122. Hello Rinse has the following deceptive attributes which individually and  
3 collectively convey the false and misleading impression that the product is specially formulated to  
4 be safe for young children:

- 5                   a. The label makes repeated references to “kids” and “little brushers” to convey  
6 that the product is meant for children.  
7
- 8                   b. The label boasts of having juice and candy attributes and flavors (“Wild  
9 Strawberry” and “Unicorn Splash - Bubble Gum”) that will appeal to children.  
10 This signals that the product is age-appropriate for young children, and, since  
11 juice and candy are things that children ingest, also signals that liquid in the  
12 bottle is safe to ingest.  
13
- 14                  c. The label uses language that implies the product is safe to swallow, including  
15 “naturally friendly,” “thoughtfully formulated,” and “no alcohol. no dyes. no  
16 artificial sweeteners. no artificial flavors. no SLS/sulfates. no brainer.”  
17
- 18                  d. The language on the label is written in a playful, silly, kid-appealing tone that  
19 conveys the impression that this is a harmless product that does not need to be  
20 handled with caution or care (e.g., “tastes like rainbows and sunshine (aka  
21 bubble gum),” “tastes so delicious they’ll rush to rinse,” “your swish come true,”  
22 “tastes magical,” and “rinse away the nasty bits”).
- 23                  e. The back label gives far more prominence to puffery about the product than to  
24 FDA’s required warnings and directions. The font size, boldness, sharpness of  
25 text, and location of the puffery effectively drowns out and conceals the  
26 warnings and directions.  
27
- 28                  f. The front label of the Wild Strawberry Rinse displays a seal of approval from



1 the ADA without disclosing that ADA’s approval of the product is for children  
2 age six and older.<sup>83</sup>

3 g. The front label conceals the notice that FDA requires to be “prominently  
4 displayed.”

5  
6 123. The deceptive attributes identified in the foregoing paragraph, individually and  
7 collectively caused Plaintiffs to falsely believe that Hello Rinse is specially formulated to be safe  
8 for young children.

9 124. Plaintiffs relied upon these deceptive attributes, both individually and collectively,  
10 in deciding to purchase Hello Rinse.

11 125. Had Plaintiffs known that fluoride mouthrinses are contraindicated for children  
12 under six due to an unacceptable risk profile, Plaintiffs would *not* have purchased Hello Rinse, or  
13 any other fluoride rinse.

14  
15 **I. Defendant’s Violations of FDCA Requirements**

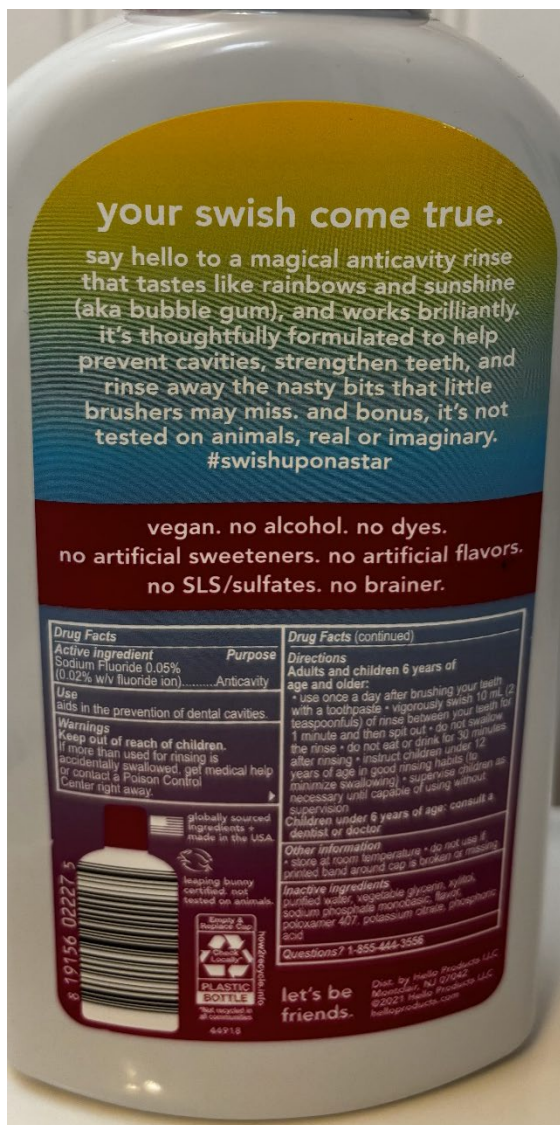
16 126. Defendant has violated the FDCA in at least three ways.

17 127. First, Defendant has violated 21 C.F.R. § 355.55 by failing to provide the notice that  
18 this FDA requires for fluoride mouthrinses.

19 128. Second, Defendant has violated 21 U.S.C. § 352(c) and 21 C.F.R. § 201.15(a)(4)(5)  
20 by failing to give sufficient prominence to FDA’s required warnings and directions. The back label  
21 of Hello Rinse focuses the consumer’s attention on the puffery and promotional claims which are  
22 prominently placed in the upper half of the label in large, bold font, with sufficient space between  
23

24  
25 \_\_\_\_\_  
26 <sup>83</sup> The FDA does not prohibit showing ADA’s seal of approval on fluoride mouthrinses, but the  
27 agency has made clear that the inclusion of this seal is subject to the prohibition on false or  
28 misleading labeling. *See* FDA, *supra* note 12, at 39868 (“As with other statements differing from  
the wording in the monograph, the ADA’s approval statement and seal may appear on product  
labeling subject to the prohibitions in 21 USC 352(a) against false or misleading labeling.”).

1 the letters to make the words clear and easy to read. By contrast, the warnings and directions are in  
2 a much smaller font on the bottom half of the label, with less space between the letters, less contrast  
3 with the background, and other design characteristics that make it unlikely an ordinary consumer  
4 will strain their eyes and concentration to read and understand.  
5



19  
20  
21  
22  
23  
24 129. This lack of prominence, while actionable for each and every Hello Rinse product  
25 sold, is particularly egregious with the Wild Strawberry Rinse, as the text is blurrier and has less  
26 contrast against the background.

27 130. The blurriness of the directions and warnings on the Wild Strawberry Rinse, while  
28

1 actionable for each unit, does vary, with some units being so blurry that the few consumers who  
2 take the time and effort to strain their eyes and concentration to read the already non-conspicuous  
3 text will have even greater difficulty doing so.

4 131. Third, for the reasons discussed above, Defendant has violated 21 U.S.C. § 352(a)  
5 by using packaging for Hello Rinse that conveys the false and misleading impression that this  
6 product is specially formulated to be safe for young children.

7 132. Defendant's violation of 21 U.S.C. § 352(a) is not cured by Defendant's inclusion  
8 of warnings and instructions in the fine print on the back of the label. This remains the case even *if*  
9 the Court were to find that Defendant's display of these warnings and directions complies with 21  
10 U.S.C. § 352(c) and 21 C.F.R. § 201.15(a)(4)(5).

11 133. Courts have recognized that false and misleading representations on the front of a  
12 label are not cured or absolved by including correct information in the fine print on the back, even  
13 when the fine print provides all of the requisite information required by the FDA. *See, e.g., Cooper*  
14 *v. Anheuser-Busch, LLC*, 553 F. Supp. 3d 83, 107-08 (S.D.N.Y. 2021) (citing cases).

15 134. As the Ninth Circuit explained in *Williams v. Gerber Prods. Co.*, 552 F.3d 934, 939-  
16 40 (9th Cir. 2008):

17 We disagree with the district court that reasonable consumers should  
18 be expected to look beyond misleading representations on the front  
19 of the box to discover the truth from the ingredient list in small print  
20 on the side of the box. The ingredient list on the side of the box  
21 appears to comply with FDA regulations and certainly serves some  
22 purpose. We do not think that the FDA requires an ingredient list so  
23 that manufacturers can mislead consumers and then rely on the  
24 ingredient list to correct those misinterpretations and provide a shield  
25 for liability for the deception. Instead, reasonable consumers expect  
26 that the ingredient list contains more detailed information about the  
27 product that confirms other representations on the packaging.

28 135. The Seventh Circuit has endorsed the Ninth Circuit's approach. In *Bell v. Publix*  
*Super Mkts., Inc.*, 982 F.3d 468, 476, 481 (7th Cir. 2020), the court explained:

Consumer-protection laws do not impose on average consumers an

1 obligation to question the labels they see and to parse them as lawyers  
2 might for ambiguities, especially in the seconds usually spent picking  
3 a low-cost product. *See, e.g., Danone, US, LLC v. Chobani, LLC*, 362  
4 F. Supp. 3d 109, 123 (S.D.N.Y. 2019) (“[A] parent walking down  
5 the dairy aisle in a grocery store, possibly with a child or two in tow,  
6 is not likely to study with great diligence the contents of a  
7 complicated product package, searching for and making sense of  
8 fine-print disclosures . . . . Nor does the law expect this of the  
9 reasonable consumer. . . . We doubt it would surprise retailers and  
10 marketers if evidence showed that many grocery shoppers make  
11 quick decisions that do not involve careful consideration of all  
12 information available to them. *See, e.g., U.S. Food & Drug Admin.,*  
13 *Guidance for Industry: Letter Regarding Point of Purchase Food*  
14 *Labeling* (Oct. 2009) (“FDA’s research has found that with [Front of  
15 Package] labeling, people are less likely to check the Nutrition Facts  
16 label on the information panel of foods (usually, the back or side of  
17 the package).”)

18 136. Each of Defendant’s violations of the FDCA were relied upon by Plaintiffs and were  
19 individually, and collectively, a material cause of Plaintiffs’ decisions to purchase Hello Rinse.

20 **J. Defendant’s Deceptive Conduct Caused Economic Injury to Plaintiffs and Class**  
21 **Members**

22 137. Defendant made the false, misleading, and unlawful representations/omissions  
23 described above to induce parents and caregivers of young children to purchase Hello Rinse who  
24 would not have purchased the product if they knew it is contraindicated for children under six.

25 138. Defendant was, and remains, unjustly enriched each time parents and caregivers act  
26 on Defendant’s false and misleading packaging by purchasing Hello Rinse for children for whom  
27 the product is contraindicated.

28 139. Had Plaintiffs known that fluoride mouthrinses are contraindicated for children  
under 6 due to an unacceptable risk profile, they would not have purchased Hello Rinse, or any  
other fluoride rinse, because they would not knowingly have allowed their children to be exposed  
to a drug that the FDA considers too dangerous for young children to safely use.

140. Plaintiffs and similarly situated class members have thus suffered injury in fact by  
losing money on their purchase of a product that they would never have purchased or allowed their

1 children to use had they not been deceived.

2 141. To the extent that fluoride mouthrinse is considered to have *any* value for children  
3 under 6 (which Plaintiffs dispute given the overwhelming evidence of an unacceptable risk profile  
4 for this young and vulnerable age group), the value is significantly less than what Plaintiffs and  
5 putative class members paid for it. Plaintiffs and class members thereby suffered economic loss by,  
6 at a minimum, purchasing the product for far more than its value.

7  
8 142. Plaintiffs do not seek recovery for any personal injuries that they or their children  
9 may have suffered from using Hello Rinse, including any emotional harm stemming therefrom.

10 **CLASS ALLEGATIONS**

11 143. Pursuant to Federal Rule of Civil Procedure 23(a) and (b)(3), Plaintiffs bring this  
12 action on behalf of the following Class:

13 a. **Multi-State Class:** All persons in California, Illinois, and New York who  
14 purchased Hello Rinse for children under the age of 6 within the applicable  
15 statutes of limitation and who did so in the absence of direction from a dentist,  
16 doctor, or health care provider.

17  
18 144. As used herein, the term “Class” shall refer to the aforementioned putative class.

19 145. Excluded from the Class are Defendant, its parents, subsidiaries, affiliates, officers,  
20 and directors; those who purchased the Products for resale; those who make a timely election to be  
21 excluded from the classes, and the judge to whom the case is assigned and any immediate family  
22 members thereof.

23  
24 146. The Class Period begins on the date established by the Court’s determination of any  
25 applicable statute of limitations, after consideration of any tolling, discovery, knowing  
26 concealment, and accrual issues, and ending on the date of entry of judgment.

27 147. Plaintiffs reserve the right to amend the definition of the Class if discovery or further  
28



1 investigation reveals that the Class should be expanded or otherwise modified.

2 148. **Numerosity**: The members of the Class are so numerous that joinder of all class  
3 members is impracticable. Class Members may be notified of the pendency of this action by  
4 recognized, Court-approved notice dissemination methods, which may include U.S. mail,  
5 electronic mail, Internet postings, and/or published notice.  
6

7 149. **Predominance of Common Questions of Law and Fact**: Questions of law and  
8 fact that are common to the members of the Class predominate over questions that are specific to  
9 individual members. These common questions of law and fact include, but are not limited to, the  
10 following:

- 11 a) Whether the attributes of Hello Rinse that are not required by the FDA Monograph are  
12 false and/or misleading;
- 13 b) Whether Defendant knew or should have known that the packaging of Hello Rinse is  
14 false and/or misleading;
- 15 c) Whether Defendant has violated the state consumer protection statutes alleged herein?
- 16 d) Whether Defendant has violated the FDCA, including 21 C.F.R. § 355.55, 21 U.S.C. §  
17 352(a), 21 U.S.C. § 352(c), and 21 C.F.R. § 201.15(a)(4)-(5);
- 18 e) Whether Defendant was unjustly enriched;
- 19 f) Whether Plaintiffs and Class members have suffered an ascertainable loss of monies  
20 or property or other value as a result of Defendant's deceptive and unlawful conduct;
- 21 g) Whether Plaintiffs and Class members are entitled to restitution, disgorgement, and  
22 any other form of relief, and, if so, the nature of such relief.
- 23
- 24

25 150. The consumer protection laws in the three states of the putative Multi-State  
26 Consumer Class are materially identical with respect to the causes of action for deceptive trade  
27 practices alleged herein. Thus, the same deceptive conduct by Defendant that violates California's  
28

1 Unfair Competition Law, CAL. BUS. & PROF. CODE §§ 17200, *et seq.*, simultaneously violates  
2 Illinois’s Consumer Fraud and Deceptive Business Practices Act, 815 ILCS 505, *et seq.*, and New  
3 York’s Consumer Protection from Deceptive Acts and Practices Act, N.Y. GEN. BUS. LAW §§ 349  
4 & 350. Additionally, the same conduct by Defendant that constitutes unjust enrichment under  
5 California law, also constitutes unjust enrichment under Illinois and New York law.  
6

7 151. **Typicality:** Plaintiffs’ claims are typical of those of other Class members because,  
8 like all members of the Class, Plaintiffs purchased Hello Rinse for children under 6 and sustained  
9 economic loss as a result. Defendant’s conduct that gave rise to the claims of Plaintiffs is the same  
10 for Plaintiffs and all members of the Class.

11 152. **Adequacy:** Plaintiffs will fairly and adequately protect the interests of the Class and  
12 have retained counsel that is experienced in litigating complex class actions. Plaintiffs have no  
13 interests which conflict with those of the Class. Plaintiffs and counsel are aware of their fiduciary  
14 responsibilities to the Class members and are determined to diligently discharge those duties by  
15 vigorously seeking the maximum possible recovery for Class members.  
16

17 153. **Superiority:** A class action is superior to any other available means for the fair and  
18 efficient adjudication of this controversy for the following reasons:

- 19 a. The extent of economic loss suffered by each individual member of the Class  
20 does not justify the burden and expense of individual prosecution of the complex  
21 and extensive litigation necessitated by Defendant’s conduct;
- 22 b. Even if individual members of the Class had the resources to pursue individual  
23 litigation, it would pose a crushing burden on the court system for these cases to  
24 be litigated on an individual basis;
- 25 c. Absent a class action mechanism, Plaintiffs and members of the Class will  
26 continue to suffer harm as a result of Defendant’s unlawful conduct because  
27  
28



1 individual litigation is wholly impractical and cost prohibitive; and

2 d. This action presents no difficulty that would impede its management by the  
3 Court as a class action.<sup>84</sup>

4 **FIRST CAUSE OF ACTION**  
5 **Unlawful Business Practices in Violation of California’s UCL**  
6 **Cal. Bus. & Prof. Code § 17200**

7 154. Plaintiffs incorporate the preceding paragraphs as if fully written herein.

8 155. Plaintiff Amber Miller brings this claim individually and on behalf of the California  
9 members of the Class.

10 156. California’s UCL prohibits unfair business competition, which the statute defines to  
11 include any “unlawful” act. Cal. Bus. & Prof. Code § 17200.

12 157. A business act or practice is “unlawful” under the UCL if it violates any established  
13 state or federal law. *See Graham v. Bank of Am., N.A.*, 226 Cal. App. 4th 594, 610 (2014) (“By  
14 proscribing ‘any unlawful’ business act or practice, the UCL borrows rules set out in other laws  
15 and makes violations of those rules independently actionable. A violation of another law is a  
16 predicate for stating a cause of action under the UCL’s unlawful prong.” (quotations and citations  
17 omitted)).

18  
19  
20 <sup>84</sup> Each claimant’s eligibility for relief can be determined through self-identifying affidavits, a  
21 mechanism that courts have widely endorsed in cases, such as the one at bar, involving low-priced  
22 consumer goods. *See, e.g., Beaton v. SpeedyPC Software*, 907 F.3d 1018, 1030 (7th Cir. 2018);  
23 *Mullins v. Direct Dig., Ltd. Liab. Co.*, 795 F.3d 654, 662 (7th Cir. 2015); *Langan v. Johnson &*  
24 *Johnson Consumer Cos.*, 897 F.3d 88, 91 n.2 (2d Cir. 2018); *Benson v. Newell Brands, Inc.*, No.  
25 19 C 6836, 2021 U.S. Dist. LEXIS 220986, at \*30-32 (N.D. Ill. Nov. 16, 2021); *Knapper v. Cox*  
26 *Communs., Inc.*, 329 F.R.D. 238, 246 n.2 (D. Ariz. 2019); *Hasemann v. Gerber Prods. Co.*, No.  
27 15-CV-2995 (MKB) (RER), 2019 U.S. Dist. LEXIS 28770, at \*53-54 (E.D.N.Y. Feb. 20, 2019);  
28 *Zakaria v. Gerber Prods. Co.*, No. LA CV15-00200 JAK (Ex), 2016 U.S. Dist. LEXIS 184861, at  
\*50 (C.D. Cal. Mar. 23, 2016); *Krueger v. Wyeth, Inc.*, 310 F.R.D. 468, 476 (S.D. Cal. 2015);  
*Suchanek v. Sturm Foods, Inc.*, 311 F.R.D. 239, 259-60 (S.D. Ill. 2015); *Morales v. Kraft Foods*  
*Grp., Inc.*, No. LA CV14-04387 JAK (PJWx), 2015 U.S. Dist. LEXIS 177918, at \*35-38 (C.D.  
Cal. June 23, 2015); *In re Conagra Foods, Inc.*, 302 F.R.D. 537, 566-67 (C.D. Cal. 2014); *Brown*  
*v. Hain Celestial Grp., Inc.*, No. C 11-03082 LB, 2014 U.S. Dist. LEXIS 162038, at \*29-30 (N.D.  
Cal. Nov. 18, 2014).

1 158. Defendant has violated the ‘unlawful’ prong of the UCL by selling a product in  
2 California that violates federal law in at least two ways.<sup>85</sup>

3 159. First, Defendant has violated, and continues to violate, 21 C.F.R. § 355.55 because  
4 it does not provide the required notice anywhere on the label, let alone in a “prominent” way.  
5 Defendant is thus selling a product in California that violates the unlawful prong of the UCL. This  
6 conduct is actionable under the UCL separate and apart from Defendant’s other deceptive conduct.  
7

8 160. Second, Defendant has violated 21 U.S.C. § 352(c) and 21 C.F.R. § 201.15(a)(4)(5)  
9 by failing to give sufficient prominence to FDA’s required warnings and directions. The back label  
10 of Hello Rinse focuses the consumer’s attention on the puffery and promotional claims which are  
11 prominently placed in the upper half of the label in large, bold font, with sufficient space between  
12 the letters to make the words clear and easy to read. By contrast, the warnings and directions are in  
13 a much smaller font on the bottom half of the label, with less space between the letters, less contrast  
14 with the background, and other design characteristics—including significant blurriness in the text  
15 of the Wild Strawberry Rinse—that make it unlikely an ordinary consumer will strain their eyes  
16 and concentration to read and understand.  
17

18 161. The aforementioned violations of specific federal laws are actionable under the UCL  
19 separate and apart from the false and misleading nature of the labeling.  
20

21 162. Plaintiff and the California Class members purchased Hello Rinse for their  
22 preschool children based on their reasonable reliance on Defendant’s unlawful labeling.

23 163. Plaintiffs and the California Class Members suffered economic harm as a proximate  
24 result of Defendant’s violations of the UCL by purchasing a product they never would have  
25

---

26 <sup>85</sup> In addition to the two violations of federal addressed in the First Cause of Action, Defendant is  
27 also violating 21 U.S.C. § 352(a) by using false and misleading labeling. Since this violation is  
28 entirely redundant to Plaintiff’s other causes of action, however, Plaintiff does not plead it as part  
of her “unlawful” cause of action.

1 purchased absent the unlawful practices given FDA’s contraindication and the unacceptable risk  
2 the product poses to young children.

3 164. Alternatively, to the extent Hello Rinse is considered to have value for children six  
4 under six despite its contraindication and unacceptable risk profile, Plaintiffs and California Class  
5 Members were harmed by purchasing a product whose true value, absent the unlawful conduct, was  
6 far less than what they paid.  
7

8 165. Through its unlawful acts and practices, Defendant has been unjustly enriched, and  
9 continues to be unjustly enriched, by unfairly obtaining money from members of the Class.

10 166. Based on Defendant’s unlawful acts or practices, Plaintiff and the California Class  
11 members are entitled to relief under the UCL.

12 **SECOND CAUSE OF ACTION**  
13 **Deceptive Business Practices in Violation of California’s UCL**  
14 **Cal. Bus. & Prof. Code § 17200**

15 167. Plaintiffs incorporate the preceding paragraphs as if fully written herein.

16 168. Plaintiff Amber Miller brings this claim individually and on behalf of the California  
17 Class members for all proposed classes.

18 169. California’s Unfair Competition Law (“UCL”) prohibits “fraudulent” acts or  
19 practices, which the statute defines to include any act or practice that is likely to deceive members  
20 of the consuming public. Cal. Bus. & Prof. Code §17200. An intention to defraud is not a necessary  
21 element for demonstrating a fraudulent business practice under the UCL.  
22

23 170. As described above, including but not limited to paragraph 122, Defendant has  
24 violated, and continues to violate, the UCL by using deceptive labeling for its Hello Rinse that is  
25 likely to deceive members of the consuming public into believing the product is specially  
26 formulated to be safe for young children.

27 171. Defendant intends for consumers of Hello Rinse to rely on the deceptive attributes  
28

1 of the labeling. Whether or not Defendant knows these attributes are deceptive, it specifically chose  
2 these attributes based on their ability to persuade consumers, including Plaintiff and Class  
3 members, to purchase the product.

4 172. Plaintiff and the other California Class Members purchased Hello Rinse for their  
5 preschool children based on their reasonable reliance on Defendant’s deceptive labeling.

6 173. Plaintiffs and Class Members have suffered economic harm as a proximate result of  
7 Defendant’s violations of the UCL by purchasing a product they never would have purchased  
8 absent the deceptive practices given FDA’s contraindication and the unacceptable risk the product  
9 poses to young children.  
10

11 174. Alternatively, to the extent Hello Rinse is considered to have value for children six  
12 under six despite its contraindication and unacceptable risk profile, Plaintiffs and California Class  
13 Members were harmed by purchasing a product whose true value, absent the deceptive conduct,  
14 was far less than what they paid.

15 175. Through its deceptive acts and practices, Defendant has been unjustly enriched, and  
16 continues to be unjustly enriched, by unfairly obtaining money from members of the Class.  
17

18 176. Based on Defendant’s deceptive acts or practices, Plaintiff and the California Class  
19 members are entitled to relief under the UCL.  
20

21 **THIRD CAUSE OF ACTION**  
22 **Deceptive Business Practices in Violation of**  
23 **Illinois Consumer Fraud and Deceptive Trade Practices Act (815 ILCS 505/1, et seq.)**

24 177. Plaintiffs incorporate the preceding paragraphs as if fully written herein.

25 178. Plaintiff Josh Cook brings this claim individually and on behalf of the Illinois Class  
26 members for all proposed classes.

27 179. The Illinois Consumer Fraud and Deceptive Trade Practices Act (“ICFA”) prohibits  
28 “[u]nfair methods of competition and unfair or deceptive acts or practices,” which includes “the

1 use or employment of any . . . false pretense, false promise, misrepresentation or the concealment,  
2 suppression or omission of any material fact.” 815 ILCS 505/2.

3 180. A “claim for ‘deceptive’ business practices under the [ICFA] does not require proof  
4 of intent to deceive.” *Wigod v. Wells Fargo Bank, N.A.*, 673 F.3d 547, 575 (7th Cir. 2012) (citation  
5 omitted).

6  
7 181. As described above, including but not limited to paragraph 122, Defendant has  
8 violated, and continues to violate, the ICFA by using deceptive acts and practices to sell its Hello  
9 Rinse. As described above, Defendant’s labeling of the Hello Rinse implies the false pretense, false  
10 promise, and misrepresentation that the product is specially formulated to be safe for young  
11 children.

12 182. Defendant intends for consumers of Hello Rinse to rely on the deceptive attributes  
13 of the labeling. Whether or not Defendant knows these attributes are deceptive, it specifically chose  
14 these attributes based on their ability to persuade consumers, including Plaintiff and Class  
15 members, to purchase the product.  
16

17 183. Plaintiffs and Illinois Class members purchased Hello Rinse for their preschool  
18 children based on their reasonable reliance on Defendant’s deceptive labeling.

19 184. Plaintiffs and Illinois Class Members suffered economic harm as a proximate result  
20 of Defendant’s violations of the ICFA by purchasing a product they never would have purchased  
21 absent the deceptive practices given FDA’s contraindication and the unacceptable risk the product  
22 poses to young children.

23  
24 185. Alternatively, to the extent Hello Rinse is considered to have value for children six  
25 under six despite its contraindication and unacceptable risk profile, Plaintiffs and Illinois Class  
26 Members were harmed by purchasing a product whose true value, absent the deceptive conduct,  
27 was far less than what they paid.  
28

1 186. Through its deceptive acts and practices, Defendant has been unjustly enriched, and  
2 continues to be unjustly enriched, by unfairly obtaining money from members of the Class.

3 187. Based on Defendant’s deceptive acts or practices, Plaintiff and the Illinois Class  
4 members are entitled to relief under 815 ILCS §505/10a.

5  
6 **FOURTH CAUSE OF ACTION**  
7 **Deceptive Business Practices in Violation of**  
8 **New York General Business Law §§ 349 & 350**

9 188. Plaintiffs incorporate the preceding paragraphs as if fully written herein.

10 189. Plaintiff Marina Vasilyeva brings this claim individually and on behalf of the New  
11 York Class members.

12 190. New York General Business Law (“**GBL**”) prohibits “deceptive acts or practices in  
13 the conduct of any business, trade, or commerce or in the furnishing of any service in this state.”  
14 NY GBL § 349. GBL also prohibits “[f]alse advertising in the conduct of any business, trade or  
15 commerce.” NY GBL § 350. GBL defines false advertising as including “labeling” of a product  
16 that is “misleading in a material respect.” *Id.* § 350a(1).

17 191. As described above, including but not limited to paragraph 122, Defendant has  
18 violated, and continues to violate, GBL §§ 349-50 by using deceptive and misleading labeling for  
19 its Hello Rinse that is likely to deceive members of the consuming public into believing that the  
20 product is specially formulated to be safe for young children.

21 192. Defendant intends for consumers of Hello Rinse to rely on the deceptive attributes  
22 of the labeling. Whether or not Defendant knows these attributes are deceptive, it specifically chose  
23 these attributes based on their ability to persuade consumers, including Plaintiff and Class  
24 members, to purchase the product.

25 193. Plaintiff and the other New York Class members purchased Hello Rinse for their  
26 preschool children based on their reasonable reliance on Defendant’s false and misleading labeling.  
27  
28

1 194. Plaintiffs and Class Members suffered economic harm as a proximate result of  
2 Defendant’s violations of the NY GBL §§ 349-50 by purchasing a product they never would have  
3 purchased absent the deceptive practices given FDA’s contraindication and the unacceptable risk  
4 the product poses to young children.

5  
6 195. Alternatively, to the extent Hello Rinse is considered to have value for children six  
7 under six despite its contraindication and unacceptable risk profile, Plaintiffs and New York Class  
8 Members were harmed by purchasing a product whose true value, absent the deceptive conduct,  
9 was far less than what they paid.

10 196. Through its deceptive and misleading acts and practices, Defendant has been  
11 unjustly enriched, and continues to be unjustly enriched, by unfairly obtaining money from  
12 members of the Class.

13  
14 197. Based on Defendant’s unlawful acts or practices, Plaintiff and the New York Class  
15 members are entitled to relief under NY GBL §§ 349-50.

16 **PRAYER FOR RELIEF**

17 WHEREFORE, Plaintiffs, on behalf of themselves and those similarly situated,  
18 respectfully request that the Court enter judgment against Defendant as follows:

- 19 A. Certification of the proposed Multi-State Class including appointment of Plaintiffs’
- 20 counsel as Class counsel and Plaintiffs as Class Representatives;
- 21
- 22 B. An award of compensatory damages in an amount to be determined at trial;
- 23
- 24 C. An award of restitution in an amount to be determined at trial;
- 25
- 26 D. An award of disgorgement in an amount to be determined at trial;
- 27
- 28 E. An award of statutory damages in an amount to be determined at trial, except as to  
those causes of action where statutory damages are not available by law;
- F. An award of treble damages, except as to those causes of action where treble



1  
2  
3  
4  
5  
6  
7  
8  
9  
10  
11  
12  
13  
14  
15  
16  
17  
18  
19  
20  
21  
22  
23  
24  
25  
26  
27  
28

damages are not available by law;

G. An award of punitive damages in an amount to be determined at trial, except as to those causes of action where punitive damages are not available by law;

H. An order requiring Defendant to pay both pre- and post-judgment interest on any amounts awarded;

I. For reasonable attorneys’ fees and the costs of suit incurred; and

J. For such further relief as this Court may deem just and proper.

**DEMAND FOR JURY TRIAL**

Plaintiffs hereby demand a trial by jury on all Counts and as to all issues.

Dated: January 15, 2025

Respectfully Submitted,

By: /s/ Michael Connett  
Michael Connett, SBN 300314  
SIRI & GLIMSTAD LLP  
700 S. Flower St., Suite 1000  
Los Angeles, CA 90017  
[mconnett@sirillp.com](mailto:mconnett@sirillp.com)  
Tel: (888) 747-4529

Aaron Siri (*pro hac vice* to be sought)  
Elizabeth A. Brehm (*pro hac vice* to be sought)  
**SIRI & GLIMSTAD LLP**  
745 Fifth Avenue, Suite 500  
New York, NY 10151  
[aaron@sirillp.com](mailto:aaron@sirillp.com)  
[ebrehm@sirillp.com](mailto:ebrehm@sirillp.com)  
[lconsidine@sirillp.com](mailto:lconsidine@sirillp.com)  
Tel: (888) 747-4529

*Attorneys for Plaintiffs and Putative Class*