UNITED STATES DISTRICT COURT
NORTHERN DISTRICT OF ILLINOIS

PATRICIA GURROLA, DEENA JOHNSON, EILEEN AVILES, & SUSHMADAVI LAKERAM, individually and on behalf of those similarly situated, Plaintiffs, v. CHATTEM, INC., Defendant.	Case No. 1:25-cv-366 **CLASS ACTION COMPLAINT** **JURY TRIAL DEMANDED**

CLASS ACTION COMPLAINT

Plaintiffs Patricia Gurrola, Deena Johnson, Eileen Aviles, and Sushmadavi Lakeram ("**Plaintiffs**"), by their undersigned counsel, on behalf of themselves and all persons similarly situated who purchased ACT "Kids" mouthrinse for their preschool children, bring this class action lawsuit against defendant Chattem, Inc. ("**Defendant**"). Plaintiffs allege the following upon information and belief, except for those allegations that pertain to Plaintiffs, which are based on Plaintiffs' personal knowledge.

INTRODUCTION

1. Defendant manufactures and sells a popular kids mouthrinse product called ACT Anticavity Fluoride Rinse (hereafter, "**ACT Rinse**" or "**ACT**").

2. ACT Rinse comes in a variety of bright colors, and prominently features candy, fruit, and cartoon imagery with the word "Kids" emblazoned on the front label in rainbow-colored crayon-styled font, all of which conveys the clear impression that the product is meant for and safe for young children to use.

3. In stark contrast to Defendant's labeling, fluoride mouthrinse is considered by the U.S. Food and Drug Administration ("**FDA**") to be too dangerous for children under 6 to use.

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

5. As far back as 1960, it was known that fluoride mouthrinses "should not be employed in children below school age."[1]

6. The FDA states that fluoride mouthrinses "are not indicated for use in children

[1] Ingrid Hellstrom, *Fluoride retention following sodium fluoride mouthwashing*, 18 ACTA ODONTOL SCAND. 263, 273 (1960).

under 6 years of age on an [over-the-counter] basis" and "should not be within easy reach of any children."[2]

7. The American Dental Association ("**ADA**") states that "Children younger than the age of 6 should not use mouthrinse, unless directed by a dentist, because they may swallow large amounts of the liquid inadvertently."[3]

8. The World Health Organization ("**WHO**") states that fluoride mouthrinses "are not recommended for children below the age of 6 years."[4]

9. The American Academy of Pediatrics ("**AAP**") states that fluoride mouth rinses should not be used until a child turns 6 and, even then, only "if the child can reliably swish and spit" and is at high risk of tooth decay.[5]

10. The U.S. Centers for Disease Control and Prevention ("**CDC**") states that "children under <6 years should not use fluoride mouthrinse without consultation with a dentist or other health care provider."[6]

11. According to Colgate, the second largest manufacturer of fluoridated dental products in the US, "babies and toddlers should not use [fluoride] mouthrinse" because "children under six may not have fully developed their swallowing reflexes and could swallow the

[2] FDA, *Anticaries Drug Products for Over-the-Counter Human Use; Final Monograph*, 60 Fed. Reg. 52474, 52486 (Oct. 6, 1995).

[3] ADA, *Mouthrinse (Mouthwash) – Key Points*, https://www.ada.org/resources/ada-library/oral-health-topics/mouthrinse-mouthwash (last accessed Jan. 13, 2025).

[4] WORLD HEALTH ORGANIZATION. FLUORIDES AND ORAL HEALTH 33 (1994).

[5] Melinda B. Clark, et al., *Fluoride Use in Caries Prevention in the Primary Care Setting*, 146 PEDIATRICS e2020034637, Tbl 1 (2020).

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

mouthrinse," which can "lead to side effects like vomiting, intoxication, and nausea."[7]

12. Defendant acknowledges, on a seldom traversed page on its website, that ACT Rinse is only approved by the ADA for children 6 years and older.[8] On the ACT Rinse bottle, however, Defendant boasts of ADA's approval without disclosing that ADA's approval is limited to older children.

13. Despite the overwhelming scientific consensus that fluoride mouthrinse should *not* be swallowed, ACT Rinse comes in juice flavors ("Groovy Grape," "Wild Watermelon," and "Pineapple Punch") and packaging that looks like a kids flavored *drink* product.

[7] Colgate, *What Parents Should Know About 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).

[8] Defendant appears to have removed this language from its website after Plaintiffs provided pre-suit notice of their claim. The language was previously located on the following webpage: https://www.actoralcareprofessional.com/kids-products/. On this page, Defendant had stated: "ADA accepted to reduce caries and protect enamel in kids aged 6+" (as can still be seen by searching this exact quote on Google). This language could not be found on this link on the date of this filing.

14. The above photo shows ACT Pineapple Punch next to a popular Hawaiian Punch children's drink. As can be seen, the two products bear a very similar appearance.

15. Presenting fluoride mouthrinse (a drug that should *not* be swallowed by any age group, especially young children) as a kids' flavored *drink* product is both dangerous and deceptive.

16. It is well recognized that presenting drugs as fruit- and candy-like products increases the risk of overdose, particularly for young children. In 1997, the *Journal of Public Health Dentistry* published a review, stating "The use of flavored consumer fluoride products increases the possibility that a child will ingest a toxic dose of fluoride."[9] A more recent review in the *Journal of Dental Hygiene* warned that boasting "pictures of fruit with flavoring to match" on kids fluoride products is "misleading" because pictures of fruit send a "common signal to a child that [the product] is intended to be consumed as if it were food."[10]

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

18. ACT Rinse has enough fluoride in it to kill a small child. A toddler who ingests just over half of the colorful candy-flavored liquid in the ACT bottle may suffer severe poisoning, including death. See *infra* ¶¶ 96-99.

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

20. A single 10 mL dose of ACT contains 2.3 milligrams of fluoride. A toddler who

[9] 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).

[10] Corey H. Basch & Sonali Rajan, *Marketing strategies and warning labels on children's toothpaste*, 88 J DENT HYG. 316, 316 (2014).

swallows this 10 mL dose can suffer nausea, vomiting, and other early symptoms of acute fluoride toxicity. See *infra* ¶¶ 89-95.

21. There are thousands of poison control reports each year for excess ingestion of fluoride mouthrinse by young children. But these reports represent only a fraction of the total number of incidents. See *infra* ¶¶ 100-103.

22. Another problem with young children using fluoride mouthrinse is that it can cause dental fluorosis.[11] Fluorosis is a defect of tooth enamel that is marked by "increased porosity" and "less than normal amounts of calcification in the teeth."[12] This defect causes visible, and sometimes disfiguring, staining of the enamel. See *infra* ¶¶ 86-88.

23. The FDA recognizes that preschool children who use fluoride mouthrinse are at risk of developing dental fluorosis, but did not require a fluorosis warning *because children under six are not supposed to be using the product*. To quote: "Because fluoride dental rinses and gels are recommended **only** for use in adults and children 6 years of age and older, the agency believes that a warning about discoloration of developing teeth in children under 6 years of age is not needed on an OTC market package."[13]

24. The health risks of preschool children using fluoride mouthrinse are of such magnitude that scientists have never even attempted to study the potential effect of fluoride mouthrinses on tooth decay in this age group. Therefore, there are no demonstrated benefits from

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[11] CDC, *About Fluoride*, https://www.cdc.gov/oral-health/prevention/about-fluoride.html ("If children repeatedly swallow mouth rinses, they may develop dental fluorosis.").

[12] NATIONAL RESEARCH COUNCIL, FLUORIDE IN DRINKING WATER: A SCIENTIFIC REVIEW OF EPA'S 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).

[13] FDA, *Anticaries Drug Products for Over-the-Counter Use; Tentative Final Monograph; Notice of Proposed Rulemaking*, 59 Fed. Reg. 39854, 39864 (Sept. 30, 1985) (emphasis added).

the use of fluoride mouthrinses for preschool children, particularly in the current context of widespread exposure to fluoride from toothpaste, fluoridated water, and processed foods.

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

26. By 1960, it was known that "**careful instruction** . . . **must be provided**" if fluoride mouthrinses are to be used on a daily basis.[14]

27. The FDA is concerned that many consumers will not appreciate that fluoride mouthrinses present dangers that are not present with ordinary cosmetic mouthrinses. According to the FDA, "based upon familiarity with cosmetic mouthrinse use, a consumer might overuse and/or misuse an OTC fluoride rinse."[15]

28. Because many consumers will not appreciate the risks posed by fluoride mouthrinse, the FDA has stressed that the "safe" use of fluoride mouthrinse requires "proper labeling."[16] Towards this end, the FDA specifically commands that the labeling for fluoride mouthrinses "**clearly instructs consumers to read the directions**."[17]

29. In order to ensure consumers read the directions, the FDA requires sellers of fluoride mouthrinse to "prominently" place a notice on the **front label** of the product.[18] The regulation states that "the following statement shall be prominently placed on the principal display panel: 'IMPORTANT: Read directions for proper use.'" 21 C.F.R. § 355.55.

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[14] Hellstrom, *supra* note 1, at 273 (emphasis added).

[15] FDA, *supra* note 2, at 52485.

[16] *Id.*

[17] *Id*. (emphasis added).

[18] *Id*.

30. Defendant is flagrantly violating this regulation.

31. Far from "prominently" displaying the notice on the front label, Defendant displays the notice in a font size that is smaller than all other text on the label. Unlike the statement "#1 DENTIST RECOMMENDED" that Defendant displays in **bold** font at the top center of the label, Defendant forgoes the use of bold text for the notice, and instead buries it at the bottom. This can be seen in the photos below.

32. The net effect of Defendant's intentional design decisions is that the required notice is **not** "prominently displayed" and will not be noticed by most people purchasing the product.

33. Defendant is well aware that ACT Rinse is popular among preschool children and their caregivers. The following are examples of customer reviews that can readily be found on major online retail sites, including Target and Amazon:

a. "I bought this product to introduce mouth wash to my **toddlers**! And the [bubble gum] flavor was perfect! Hard to convince them not to swallow it! But they loved that is didn't have the 'burning' sensation as traditional mouthwash!"

b. "Good for my **toddler**."

c. "So easy for my **toddler** to use, we love it"

d. "Perfect for my **toddler**"

e. "My **toddler** loves this product and even asks to use it after brushing."

f. "We liked the flavor. My **toddler** loves these mouth wash."

g. "I love that my **toddler** will ask to use this. It makes our bedtime routine so easy. No crying and she loves the [grape] flavor."

h. "**Toddler** enjoys this [grape] flavor and the pink one too."

i. "Got it for my **3 yr old** grandaughter and she can't brush her teeth enough during the day, she loves this stuff, and you can't go wrong with bubble gum flavor. (had to taste it myself lol)"

j. "My **3 year old** granddaughter absolutely loves her Act Kids Wild Watermelon"

k. "My daughter was struggling getting my then **3 year old** excited about brushing his teeth. I purchased this and he is now 4. It is night and day with the previous struggle of getting him excited."

l. "My 7 and **3 year old** daughters both love this [watermelon] mouthwash."

m. "I usually get the apple green or bubble gum flavors, however this came faster, so we gave it a chance. My **4 year old** loves this more out of all the flavors."

n. "It has a lid that portions out the correct amount by just squeezing the bottle,

it's easy enough that my **4 year old** can get her own correct amount. There's no alcohol and the kids seem to really love the flavor. It smells really sweet and watermeloney, I probably would not enjoy using it myself but the kids love it. At the end it smells like they were eating jolly ranchers."

o. "My **4 year old** loves it. She likes to squeeze and fill it up herself, she's motivated to use it day and night. As a mom it smells good and does the job."

p. "My two kids use this every night and love it. They are 6 & **4**."

q. "Our son who is **5yrs old** likes this one a lot. It's easy for him to portion out with the control squeeze top. We are now teaching our **2 1/2yr** old to use it as well. We will continue to buy."

34. The targeting of young children with brightly-colored, candy-flavored fluoride is believed to be one of the reasons for the increase in dental fluorosis that has been observed in recent decades.[19]

35. Since the introduction of candy-like fluoride products in the 1980s, the rate of dental fluorosis among U.S. schoolchildren has skyrocketed. In 1986-87, approximately 23% of U.S. children had fluorosis.[20] This rate tripled to a staggering 68% of U.S children by 2015-16.[21]

36. With millions of U.S. children showing visible signs of excess fluoride exposure, there is growing concern about other chronic health conditions that fluoride may be causing, including neurodevelopmental disorders and endocrine disruption. In August of 2024, the

[19] Christopher Neurath, et al., *Dental Fluorosis Trends in US Oral Health Surveys: 1986 to 2012*, 4 JDR CLIN TRANS RES. 298, 306 (2019).

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

[21] Man Hung et al., *A National Study Exploring the Association Between Fluoride Levels and Dental Fluorosis*, 6 JAMA NETW OPEN. e2318406 (2023).

prestigious National Toxicology Program (NTP) concluded that excess fluoride exposure is associated with IQ loss in children, and, in September 2024, a federal district court concluded that adding fluoride to drinking water presents an unreasonable risk of reduced IQ. See *infra* ¶¶ 107-111.

37. Plaintiffs bring this action to hold Defendant accountable for its false and misleading labeling of ACT Rinse, which puts the health of millions of children at risk.

38. Defendant's deceptive conduct violates the Federal Food Drug & Cosmetic Act ("**FDCA**"), 21 U.S.C. § 352(a),[22] and many state consumer fraud statutes, including, but not limited to, the Illinois Consumer Fraud and Deceptive Trade Practices Act, 815 ILCS § 505/2, California's Unfair Competition Act, Cal. Bus. & Prof. Code § 17200, and New York General Business Law §§ 349-50. In addition, Defendant's failure to prominently display FDA's required notice on the front label of ACT Rinse violates 21 C.F.R. § 355.55, as well as the prohibition on selling unlawful products under California's Unfair Competition Law, Cal. Bus. & Prof. Code § 17200.

39. Plaintiffs' claims in this action are exclusively limited to those elements of Act Rinse that Defendant *voluntarily* added to the product (as opposed to elements that federal law requires). Plaintiffs do not seek to impose any requirement that goes beyond, is not identical to, or is different from, the requirements that are imposed on Defendant under the FDCA and its accompanying regulations, including the FDA Monograph on fluoride mouthrinse. *See* C.F.R. §§ 355.50 & 355.55. Plaintiffs seek instead to hold Defendant responsible for the elements of its

[22] Plaintiffs recognize that there is no private right of action under FDCA and do not assert such a claim here. Instead, Plaintiffs' allegations that Defendant violated the requirements of the FDCA 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.").

products that are *not* required by the Monograph *and* which violate its obligations under both federal and state law. A judicial finding that these voluntarily added attributes are false, misleading, and/or violative of specific FDCA requirements would be harmonious and not in conflict with the FDCA.[23]

PARTIES

40. Plaintiff **Patricia Gurrola** is a citizen of Illinois.

41. Ms. Gurrola lives in Chicago, Illinois, where she has purchased ACT Rinse for her minor son G.K.

42. Ms. Gurrola began purchasing ACT Rinse for G.K. in 2021, when he was two years old. She continued purchasing the product for G.K. until 2024.

43. Ms. Gurrola purchased ACT Rinse for G.K. from CVS, Walgreens, Mariano's, and Walmart stores located in Chicago. She purchased ACT Rinses of various flavors at these stores, including Bubblegum, Wild Watermelon, and Groovy Grape.

44. Ms. Gurrola did not purchase the ACT Rinse at the direction of a dentist, doctor, or health care provider.

45. Based on Defendant's packaging, Ms. Gurrola believed ACT Rinse was specially formulated to be safe for young children and would not present any risks to G.K.

46. G.K. enjoyed the candy flavor of the rinse.

[23] *See, e.g.*, *Bell v. Publix Super Mkts., Inc.*, 982 F.3d 468, 485 (7th Cir. 2020) ("The FDCA's 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 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.").

47. If Ms. Gurrola had known that fluoride mouthrinse is contraindicated for children under 6 years of age, she would not have purchased ACT rinse, or any other fluoride rinse.

48. Plaintiff **Deena Johnson** is a citizen of Illinois.

49. Ms. Johnson lives in Danvers, Illinois and has purchased ACT Rinse for her minor daughter R.J. at the Walmart located in Bloomington, Illinois.

50. Ms. Johnson began purchasing ACT Rinse for R.J. in approximately 2020/2021 when she was two years old. She continued purchasing the product for R.J. until she was 5 years old.

51. Ms. Johnson did not purchase the ACT Rinse at the direction of a dentist, doctor, or health care provider.

52. Based on Defendant's packaging, Ms. Johnson believed ACT Rinse was specially formulated to be safe for young children and would not present any risks to R.J.

53. R.J. enjoyed the candy flavor of the rinse.

54. If Ms. Johnson had known that fluoride mouthrinse is contraindicated for children under 6 years of age, she would not have purchased ACT rinse, or any other fluoride mouthrinse.

55. Plaintiff **Eileen Aviles** is a citizen of California.

56. Ms. Aviles lives in Suisun City, California and has purchased ACT Rinse for her minor daughter I.A.C.

57. Ms. Aviles began purchasing ACT Rinses for I.A.C. in about 2022, when I.A.C. was approximately 2 years old. She continued purchasing the product for I.A.C. until 2024.

58. Ms. Aviles did not purchase the ACT Rinse at the direction of a dentist, doctor, or health care provider.

59. Based on Defendant's packaging, Ms. Aviles believed ACT Rinse was specially

formulated to be safe for young children and would not present any risks to I.A.C.

60. I.A.C. enjoyed the candy flavor of the rinse.

61. If Ms. Aviles had known that fluoride mouthrinse is contraindicated for children under 6 years of age, she would not have purchased ACT rinse, or any other fluoride mouthrinse.

62. Plaintiff **Sushmadavi Lakeram** is a citizen of New York.

63. Ms. Lakeram lives in Queens Village, New York and has purchased ACT Rinse for her minor son C.L.

64. Ms. Lakeram began purchasing ACT Rinses for C.L. in about 2020, when C.L. was approximately 1.5 years old. She continued purchasing the product for C.L. until 2024.

65. Ms. Lakeram did not purchase the ACT Rinse at the direction of a dentist, doctor, or health care provider.

66. Based on Defendant's packaging, Ms. Lakeram believed ACT Rinse was specially formulated to be safe for young children and would not present any risks to G.K.

67. C.L. enjoyed the candy flavor of the rinse.

68. If Ms. Lakeram had known that fluoride mouthrinse is contraindicated for children under 6 years of age, she would not have purchased ACT rinse, or any other fluoride mouthrinse.

69. Defendant **Chattem, Inc.** is, and at all times mentioned in this Complaint was, a corporation organized and existing under the laws of Tennessee with its principal place of business in Bridgewater, New Jersey.

JURISDICTION AND VENUE

70. 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.

71. This Court has personal jurisdiction over Defendant because the injuries upon which the Illinois Plaintiffs' action are based occurred or arose out of activities that Defendant specifically engaged in within the State of Illinois. Defendant knowingly and intentionally distributed its ACT Rinse products for sale in Illinois, and Plaintiffs Gurrola and Johnson thereupon purchased Defendant's products from retail stores located here in Illinois.

72. 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 Illinois, including within Cook County.

FACTUAL ALLEGATIONS

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

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

74. 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 not able to hold the fluoride preparation in their mouth and then expectorate properly."[24]

75. Between mouthrinse and toothpaste, the former poses a greater risk of excess

[24] FDA, *supra* note 13, at 39867.

ingestion for young children. This is because fluoride mouthrinses "do not contain an abrasive that can bind some of the fluoride ion and because a child under 6 is more likely to drink a flavored liquid than eat large amounts of toothpaste."[25]

76. The lack of a developed swallowing reflex is particularly acute for children under the age of three. In a study designed to estimate exposure from fluoride mouthrinse, "most 2 year old children and some 3 year old children could not perform mouthrinsing with water, but instead quickly swallowed the fluid."[26,27]

77. According to the CDC, "studies of the amount of fluoride swallowed by children aged 3-5 years using such rinses indicated that some young children might swallow substantial amounts."[28]

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

79. A 2-year-old child of average weight (~12 kg) who ingests a single dose of ACT[29] will ingest 0.19 mg/kg of fluoride, which is more than two times higher than EPA's reference dose (0.08 mg/kg/day) for fluoride. According to EPA, children who ingest more than 0.08 mg/kg/day are at risk of developing "*severe* dental fluorosis."[30]

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[25] FDA, *supra* note 2, at 52486.

[26] FDA, *supra* note 13, at 39867.

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

[28] CDC, *supra,* note 6, at 16.

[29] 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.

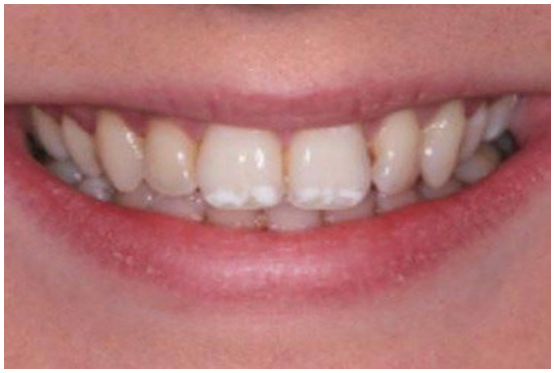
[30] ENVIRONMENTAL PROTECTION AGENCY: FLUORIDE: DOSE-RESPONSE ANALYSIS FOR NON-

B. Ingesting Fluoride Mouthrinse During Early Childhood Causes Dental Fluorosis

80. Dental fluorosis is "a permanent, mottled discoloration of the teeth"[31] that is caused by ingesting too much fluoride while the teeth are still developing. Once the teeth have finished forming, fluoride can no longer cause fluorosis. Ergo, only young children are at risk of developing this condition.

81. The first six years of life are the critical window of vulnerability for developing dental fluorosis, with fluoride exposures during the first 3 years of life being the most significant for causing fluorosis of the upper front teeth, which are the most cosmetically important teeth.[32]

82. Dental fluorosis comes in various degrees of severity.[33] The mild forms of fluorosis cause "permanent white lines or streaks" on the teeth, whereas the severe forms of fluorosis cause "brown, gray, or black patches and pits, typically on top of an irregular tooth surface."[34]



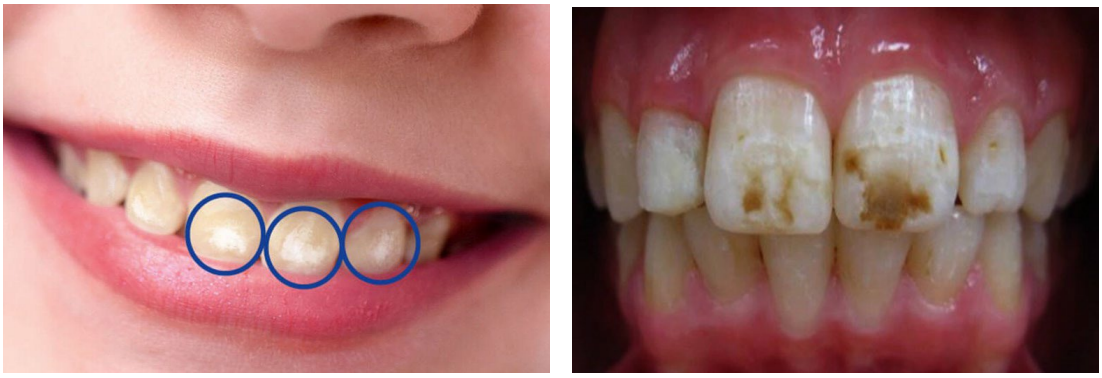
CANCER EFFECTS 107 (2010) (emphasis added).

[31] FDA, *supra* note 2, at 52487.

[32] Michael R. Franzman, et al., *Fluoride dentifrice ingestion and fluorosis of the permanent incisors*, 137 J AM DENT ASSOC. 645, 646 (2006).

[33] NATIONAL RESEARCH COUNCIL, *supra* note 12, at 103-111.

[34] Colgate, *Causes of Brown Spots on the Teeth*, Feb. 13, 2023, https://www.colgate.com/en-us/oral-health/adult-oral-care/brown-spots-on-teeth-causes



Photos of Dental Fluorosis

83. 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."[35] In short, "fluoride affects the forming enamel by making it more porous."[36]

84. 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."[37]

85. 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.[38]

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[35] Brian A. Burt, *The changing patterns of systemic fluoride intake.* 71 J DENT RES. 1228, 1228 (1992).

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

[37] CDC, *supra* note 11.

[38] Hung et al., *supra* note 21.

86. Dental fluorosis, even in its "mild" forms, is recognized to be cosmetically objectionable when present on a child's upper front teeth (i.e., maxillary anterior teeth).[39]

87. The following are some findings from the peer-reviewed dental literature regarding the disfiguring effects of "mild" fluorosis:

a. "Mild and moderate dental fluorosis had a negative aesthetic effect on the studied population, leading to a strong desire to seek dental treatment to change the appearance of affected teeth."[40]

b. "The key finding to emerge from this study was the negative psychosocial impact reported by some children with untreated enamel defects . . . . Over half of the children stated that they had been subject to unkind remarks about their teeth by their peers. A number of children described a reluctance to smile or a lack of confidence."[41]

c. "Fluorosis was associated with increased parental dissatisfaction with overall appearance, color, and blotchiness of their children's teeth."[42]

d. "The pupils' feedback was extremely useful, revealing that they believed the 'marks' on the teeth to be due to poor oral hygiene, despite a preliminary

[39] Susan O. Griffin et al., *Esthetically objectionable fluorosis attributable to water fluoridation*, 30 COMMUNITY DENT ORAL EPIDEMIOL. 199, 202-03 (2002).

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

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

[42] 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).

tutorial which indicated this was not the case."[43]

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 . . . ."[44]

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)."[45]

g. "A strong association between fluorosis and parental satisfaction was evident, even at a low level of severity."[46]

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."[47]

i. "[O]bservers felt that the appearance would increasingly embarrass the child as the TF score increased."[48]

88. Due to the objectionable appearance of fluorosis, many people with the condition

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[43] Maura Edwards, et al., *An assessment of teenagers' perceptions of dental fluorosis using digital stimulation and web-based testing*, 33 COMMUNITY DENT ORAL EPIDEMIOL. 298, 305(2005).

[44] Steven M. Levy, *An update on fluorides and fluorosis*, 69 J CAN DENT ASSOC. 286, 287 (2003).

[45] 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).

[46] 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).

[47] John Spencer, et al., *Water fluoridation in Australia*, 13 COMMUNITY DENT HEALTH 27 (1996).

[48] Paul J. Riordan, *Perceptions of dental fluorosis*, 72 J DENTAL RES 1268, 1268 (1993).

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.

C. Ingesting Fluoride Toothpaste Can Cause Stomach Flu Symptoms

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

90. According to a review in the *Journal of Public Health Dentistry*, "Parents or caregivers may not notice the symptoms associated with mild fluoride toxicity or may attribute them to colic or gastroenteritis, particularly if they did not see the child ingest fluoride. Similarly, because of the nonspecific nature of mild to moderate symptoms, a physician's differential diagnosis is unlikely to include fluoride toxicity without a history of fluoride ingestion."[49]

91. The mechanism by which fluoride causes stomach flu symptoms has been described as follows: "When above normal amounts of fluoride are ingested, the fluoride combines with hydrochloric acid in the stomach and forms hydrofluoric acid. As a result, the hydrofluoric acid has a burning effect on the gastric lining causing gastrointestinal (GI) symptoms such as nausea, vomiting, abdominal cramping, and discomfort."[50]

92. As with all toxicants, the dose of fluoride that causes symptoms of acute toxicity varies considerably across the population, with some children being much more vulnerable, and other children being much more resistant, than the "average child."[51]

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[49] 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, 157 (1997).

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

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

93. Symptoms of nausea and gastrointestinal distress have been reported at doses as low as 0.1 mg/kg.[52] A 2-year-old-child of average weight (~12 kg) will ingest this much fluoride by swallowing just over half of a single 10 mL dose of ACT Rinse.

94. In *adults*, a one-time ingestion of as little as 3 milligrams of fluoride in one sitting (or the equivalent of 13 mL of ACT Rinse) has been found to cause "widespread" erosions of the gastric mucosa in the stomach.[53] The dose that causes erosions in the stomach of children has not been studied (due to ethical constraints) but will almost certainly be less than 3 mg due to lower bodyweight and smaller stomach space.

95. If a 2 year-old-child ingests just 5 mL of ACT mouthrinse, or half of a single dose, the National Capital Poison Center recommends that the child take "Two tablets of chewable calcium or calcium plus vitamin D supplement," "Four ounces of milk," or "One tablespoon of liquid antacid containing magnesium or aluminum" in order to help prevent "nausea, vomiting, diarrhea."[54]

D. Half a Bottle of ACT Rinse Has Enough Fluoride to Kill a Toddler

96. Fluoride is a "protoplasmic poison"[55] that can kill humans at doses not that much higher than arsenic.[56] The potency of fluoride's acute toxicity is why fluoride has been used as

426 (1990).

[52] Kenji Akiniwa, *A Re-examination of acute toxicity of fluoride*, 30 FLUORIDE 89 (1997).

[53] Spak, *supra* note 51.

[54] *See* https://triage.webpoisoncontrol.org/ (last accessed Jan. 13, 2025).

[55] Editorial, *Chronic fluorine intoxication*, 123 J AM DENT ASSOC. 150, 150 (1943).

[56] The CDC states that "[a]s little as 1–2.5 mg/kg of arsenic trioxide is a potentially fatal dose." CDC, *Medical Management Guidelines for Arsenic (As) and Inorganic Arsenic Compounds*, https://wwwn.cdc.gov/TSP/MMG/MMGDetails.aspx?mmgid=1424&toxid=3. This is only slightly lower than the potentially fatal dose of fluoride (5 mg/kg), as discussed below. *See also* Floyd 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

the active ingredient in rodenticides (to kill rodents) and insecticides (to kill bugs).[57] As far back as 1895, it was observed that "sodium fluoride is an active poison for micro-organisms of all kinds, algae, and nerves and muscles of the higher organisms."[58]

97. The "Probable Toxic Dose" ("**PTD**") for fluoride is 5 mg/kg.[59] The PTD "is defined as the dose of ingested fluoride that should trigger immediate therapeutic intervention and hospitalization because of the likelihood of serious toxic consequences."[60] It is the "minimum dose that could cause toxic signs and symptoms, including death, and that should trigger immediate therapeutic intervention and hospitalization."[61]

98. Due to person-to-person variations in sensitivity to fluoride toxicity, not all people who ingest 5 mg/kg will experience significant toxicity. But, "if it is even suspected that 5.0 mg/kg or more of fluoride has been ingested, then it should be assumed that an emergency exists. Appropriate therapeutic measures and hospitalization should be instituted immediately."[62]

99. A tube of Act Rinse contains 112 milligrams of fluoride. A 1 year-old-child of average weight (~9 kg) would exceed the PTD if he ingested just 40% of Defendant's candy-flavored rinse, while a 2 year-old-child of average weight (~12 kg) would exceed the PTD if he ingested 54%.

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same group, as far as ability to cause some symptom of toxicity in minute dosage is concerned.").

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

[58] Herbert B. Baldwin, *The toxic action of sodium fluoride*, 21 J AM CHEM SOC. 517, 521 (1899) (quoting Czrellitzer 1895).

[59] Gary M. Whitford, *Fluoride in dental products: safety considerations*, 66 J DENT RES. 1056, 1056 (1987).

[60] *Id.*

[61] *Id.* at 1057.

[62] *Id.*

100. Each year there are over 4,000 reports to poison control centers related to ingestion of fluoride mouthrinses.[63] The vast majority of these calls are made on behalf of very young children.

101. The number of poisoning incidents from consumer products reported to poison control centers is recognized to "likely underestimate the total incidence and severity of poisonings."[64] This is the case even for poisonings that cause outcomes as severe as death.[65]

102. Consistent with the general recognition that poison control data underestimates the true extent and severity of poisonings, the reported number of poisonings from fluoride mouthrinse is also believed to "underestimate" the true extent of fluoride poisonings due to "substantial underreporting" of such incidents.[66]

103. Nevertheless, the FDA has cited the large number of poison control reports for fluoride mouthrinses as a justification for requiring a poison warning on these products.[67] FDA's required poison warning states as follows: "Keep out of reach of children. If more than used for rinsing is accidentally swallowed, get medical help or contact a Poison Control Center right away." 21 C.F.R. § 355.50(c)(2).

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[63] David D. Gummin et al., *2020 Annual Report of the American Association of Poison Control 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).

[64] Arthur Chang, et al., *Cleaning and Disinfectant Chemical Exposures and Temporal Associations 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).

[65] 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.

[66] Shulman & Wells, *supra* note 9, at 157.

[67] FDA, *supra* note 2, at 52486.

E. Other Health Concerns with Early Life Exposure to Fluoride

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

105. In 2006, the National Research Council ("**NRC**") of the National Academies of Science published a comprehensive review of fluoride toxicology which concluded, among other things, that excess fluoride exposure weakens bone, damages the brain, and disrupts the endocrine system, including the thyroid gland.[68] According to the NRC, fluoride has been credibly associated with impaired thyroid function in susceptible humans at doses as low as 0.01 to 0.03 mg/kg/day,[69] which is less than many children will routinely ingest from using fluoride mouthrinse.[70]

106. Another endocrine effect of fluoride exposure that the NRC flagged is impaired glucose metabolism, which is believed to be caused by fluoride's "inhibition of insulin production."[71] According to the NRC, blood fluoride levels of 0.1 mg/L are credibly associated with this effect.[72] A preschool child who ingests as little as 1/3 of a single dose of ACT Rinse will have blood fluoride levels that temporarily approximate or exceed this level.[73]

107. In August of 2024, the National Toxicology Program ("**NTP**"), which is part of the National Institutes of Health, published a systematic review in which it concluded that excess

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[68] NATIONAL RESEARCH COUNCIL, *supra* note 12, at 178-80, 220-22 & 260-66.

[69] *Id.* at 263 ("In humans, effects on thyroid function were associated with fluoride exposures of 0.05-0.13 mg/kg/day when iodine intake was adequate and 0.01-0.03 mg/kg/day when iodine intake was inadequate.").

[70] A 2 year-old-child of average weight (~12 kg) will ingest 0.03 mg/kg from ingesting just 1/6th of a single 10 mL dose of ACT Rinse.

[71] NATIONAL RESEARCH COUNCIL, *supra* note 12, at 264.

[72] *Id*.

[73] *See* Jan Ekstrand et al., *Plasma fluoride concentrations in pre-school children after ingestion of fluoride tablets and toothpaste*, 17 CARIES RES. 379 (1983).

fluoride exposure is "consistently associated with reduced IQ in children."[74]

108. In January of 2025, NTP scientists published a meta-analysis of 74 human studies on fluoride and IQ in the journal *JAMA Pediatrics*.[75] The NTP analysis "found inverse associations and a dose-response relationship between fluoride measurements in urine and drinking water and children's IQ across the large multicountry epidemiological literature."

109. The NTP has flagged mouthrinse as a source of childhood fluoride exposure that could contribute to the risk of neurodevelopmental problems. According to the NTP, "children may be getting more fluoride than they need because they now get fluoride from many sources including treated public water, water-added foods and beverages, teas, toothpaste, floss, and *mouthwash*, and the combined total intake of fluoride may exceed safe amounts."[76]

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

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

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[74] 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.

[75] 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).

[76] National Toxicology Program, *Fluoride Exposure: Neurodevelopment and Cognition*, https://ntp.niehs.nih.gov/whatwestudy/assessments/noncancer/completed/fluoride (last accessed Jan. 13, 2025).

F. The Problem with Presenting Fluoride Mouthrinse into a Candy-Like Drug

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

113. In 1992, the *Journal of Public Health Dentistry* published a consensus statement which read, in part, "The use of flavors that may increase the ingestion of fluoridated dentifrices by young children should be strongly discouraged."[77]

114. In 1994, the World Health Organization stated, "the production of candy-like flavours . . . should not be encouraged for use by children, as they may lead to an excessive ingestion of fluoride."[78]

115. In 1997, the *Journal of Public Health Dentistry* published a review, which stated "The use of flavored consumer fluoride products increases the possibility that a child will ingest a toxic dose of fluoride."[79]

116. Studies have empirically tested, and confirmed, that adding candy flavor to toothpaste increases the amount of paste that children add to their brush, as well as the amount of toothpaste that they ingest.[80] Similar studies have not been conducted on candy-flavored

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[77] James W. Bawden, et al. *Changing patterns of fluoride intake. Proceedings of the workshop. Part II*, 71 J PUBLIC HEALTH DENT. 1212, 1221 (1992).

[78] WORLD HEALTH ORGANIZATION, *supra* note 4, at 28.

[79] Shulman & Wells, *supra* note 9, at 150.

[80] Steven M. Levy, et al., *A pilot study of preschoolers' use of regular-flavored dentifrices and those flavored for children*, 14 PEDIATR DENT. 388 (1992); Steven M. Adair, et al., *Comparison of the use of a child and an adult dentifrice by a sample of preschool children*, 19 PEDIATR DENT. 99 (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).

mouthrinses. The absence of such studies is likely a result, in part, of the bioethical problem of intentionally exposing preschool children to a product that is contraindicated for this population.

117. According to the FDA, marketing dangerous products to children through the use of candy or food flavoring is a "misleading" marketing tactic that can render a product "misbranded" under the FDCA.[81]

G. FDCA Requirements for Fluoride Mouthrinse

General Requirements

118. The FDCA prohibits companies from selling over-the-counter drugs that are "misbranded." 21 U.S.C. § 331(a).

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

120. An over-the-counter drug is "not misbranded" if it satisfies "each of the conditions contained in any applicable monograph" **and** is "labeled in compliance" with 21 U.S.C. § 352 and the regulations issued pursuant thereto. 21 C.F.R. § 330.1(c)(1). Thus, a drug can meet each of the conditions of an applicable monograph and still be misbranded if it has additional textual or visual information on the package that is (a) *not* required by the monograph and (b) false and misleading.

Specific Requirements

121. The FDA has issued a Monograph for anti-cavity dental products, including fluoride mouthrinse. 21 C.F.R. § 355.50.

122. The FDA requires that all fluoride mouthrinse products provide the following

[81] *E.g.*, FDA Warning Letter to Electric Lotus, LLC, Nov. 29, 2018, *available at*: 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").

warning: "Keep out of reach of children. If more than used for rinsing is accidentally swallowed, get medical help or contact a Poison Control Center right away." 21 C.F.R. § 355.50(c)(2). The FDA requires that the first sentence of this warning be in bold type. *Id*.

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

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

Things that the FDA Does Not Require

125. The FDA does not require that the labeling of fluoride mouthrinse show the word "KIDS" in rainbow-colored crayon front.

126. The FDA does not require that the labeling of fluoride mouthrinse use cartoon imagery that appeals to preschool children.

127. The FDA does not require fluoride mouthrinse to have candy-like names (e.g. Bubble Gum Blowout, Groovy Grape, etc).

128. The FDA does not require fluoride mouthrinse to have names that sound like flavored kids drinks (e.g., Pineapple Punch).

[82] This is the concentration of ACT Rinse.

129. The FDA does not require fluoride mouthrinse to taste and smell like candy or flavored kids drinks.

H. The Deceptive Attributes of ACT Rinses

130. ACT Rinse has the following deceptive attributes which individually and collectively convey the false and misleading impression that the product is specially formulated to be safe for young children:

a. A front label which says "Kids" in a rainbow-colored crayon font, which signifies that the product is safe and age appropriate for very young children.

b. A front label which displays cartoon images of fruit and candy and boasts of fruit and candy flavors like Pineapple Punch, Groovy Grape, Wild Watermelon, and Bubble Gum Blowout. Since juice and candy are things that children ingest,

this signifies that the sweet-tasting colorful liquid in the bottle is safe to ingest.

c. A front label that prominently displays a seal of approval from the ADA without disclosing that ADA's approval of this product is for children age six and older.[83]

d. A front label that prominently states the product is "#1 DENTIST RECOMMENDED,"[84] but fails to prominently advise consumers of the importance of reading the directions for the product.

131. Each and every one of these deceptive attributes caused Plaintiffs to falsely believe that ACT Rinse is specially formulated to be safe for young children.

132. Plaintiffs relied upon these deceptive attributes, both individually and collectively, in deciding to purchase ACT Rinse.

133. Had Plaintiffs known that fluoride mouthrinses are contraindicated for children under six due to an unacceptable risk profile, Plaintiffs would *not* have purchased ACT Rinse, or any other fluoride or anticavity rinse.

I. Defendant's Violations of FDCA Requirements

134. Defendant has violated the FDCA in at least two ways.

135. First, Defendant has violated 21 C.F.R. § 355.55 by failing to prominently display on the front label the notice required by the FDA.

[83] The FDA does not prohibit showing ADA's seal of approval, but the agency has made clear that the inclusion of this seal is subject to the prohibition on false or misleading labeling. *See* FDA, *supra* note 13, 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.").

[84] Plaintiffs do not currently know the factual basis for this assertion, but to the extent discovery reveals that this is false or misleading, this will further contribute to the deceptive qualities of the packaging.

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

137. Defendant's violation of 21 U.S.C. § 352(a) is not cured by Defendant's inclusion of FDA's required warnings and instructions in the fine print on the back of the label.

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

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

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

140. 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 obligation to question the labels they see and to parse them as lawyers might for ambiguities, especially in the seconds usually spent picking a low-cost product. *See, e.g.*, *Danone, US, LLC v. Chobani, LLC*, 362 F. Supp. 3d 109, 123 (S.D.N.Y. 2019) ("[A] parent walking down the dairy aisle in a grocery store, possibly with a child or two in tow, is not likely to study with great diligence the

> contents of a complicated product package, searching for and making sense of fine-print disclosures . . . . Nor does the law expect this of the reasonable consumer. . . . We doubt it would surprise retailers and marketers if evidence showed that many grocery shoppers make quick decisions that do not involve careful consideration of all information available to them. *See, e.g.*, U.S. Food & Drug Admin., Guidance for Industry: Letter Regarding Point of Purchase Food Labeling (Oct. 2009) ("FDA's research has found that with [Front of Package] labeling, people are less likely to check the Nutrition Facts label on the information panel of foods (usually, the back or side of the package).")

141. Both of Defendant's violations of the FDCA were relied upon by Plaintiffs and were individually, and collectively, a material cause of Plaintiffs' decisions to purchase ACT Rinse.

J. Defendant's Deceptive Conduct Caused Economic Injury to Plaintiffs and Class Members

142. Defendant made the false and misleading representations described above to induce parents and caregivers of young children to purchase ACT Rinse who would not have purchased the drug if they knew it is contraindicated for children under six.

143. Defendant was, and remains, unjustly enriched each time parents and caregivers act on Defendant's false and misleading packaging by purchasing ACT Rinse for children for whom the drug is contraindicated.

144. Had Plaintiffs known that fluoride mouthrinses are contraindicated for children under 6 due to an unacceptable risk profile, they would not have purchased ACT 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.

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

children to use had they not been deceived.

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

147. Plaintiffs do not seek recovery for any personal injuries that they or their children may have suffered from using ACT Rinse, including any emotional harm stemming therefrom.

CLASS ALLEGATIONS

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

a. **Nationwide Class:** All persons in the United States who purchased ACT Rinse for children under the age of 6 within the applicable statutes of limitation and who did so in the absence of direction from a dentist, doctor, or health care provider.

b. **Alternative 15-Jurisdiction Class:** All persons in Arizona, California, Connecticut, Florida, Hawaii, Idaho, Illinois, Massachusetts, Minnesota, Missouri, New York, New Jersey, Virginia, Washington State, and Washington D.C., who purchased ACT Rinse for children under the age of 6 within the applicable statutes of limitation and who did so in the absence of direction from a dentist, doctor, or health care provider.

c. **Alternative 3-State Class:** All persons in California, Illinois, and New York who purchased ACT Rinse for children under the age of 6 within the applicable statutes of limitation and who did so in the absence of direction from a dentist, doctor, or

health care provider.

149. As used herein, the term "Class," although used in the singular, shall refer to each of the aforementioned putative classes.

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

151. The Class Period begins on the date established by the Court's determination of any applicable statute of limitations, after consideration of any tolling, discovery, knowing concealment, and accrual issues, and ending on the date of entry of judgment.

152. Plaintiffs reserve the right to amend the definition of the Class if discovery or further investigation reveals that the Class should be expanded or otherwise modified.

153. **Numerosity:** The members of the Class are so numerous that joinder of all class members is impracticable. On information and belief, there are hundreds of thousands of Class Members. Class Members may be notified of the pendency of this action by recognized, Court-approved notice dissemination methods, which may include U.S. mail, electronic mail, Internet postings, and/or published notice.

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

a) Whether the attributes of ACT Rinse that are not required by the FDA Monograph are false and/or misleading;

b) Whether Defendant knew or should have known that the packaging of ACT Rinse is false and/or misleading;

c) Whether Defendant has breached the implied warranty of implied merchantability;

d) Whether Defendant has violated the state consumer protection statutes alleged herein?

e) Whether Defendant has violated the FDCA, including 21 C.F.R. § 355.55 and 21 U.S.C. § 352(a);

f) Whether Defendant was unjustly enriched;

g) Whether Plaintiffs and Class members have suffered an ascertainable loss of monies or property or other value as a result of Defendant's deceptive and unlawful conduct;

h) Whether Plaintiffs and Class members are entitled to monetary damages and, if so, the nature of such relief.

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

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

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

a. The damages suffered by each individual member of the Class do not justify

the burden and expense of individual prosecution of the complex and extensive litigation necessitated by Defendant's conduct;

b. Even if individual members of the Class had the resources to pursue individual litigation, it would pose a crushing burden on the court system for these cases to be litigated on an individual basis;

c. Absent a class action mechanism, Plaintiffs and members of the Class will continue to suffer harm as a result of Defendant's unlawful conduct because individual litigation is wholly impractical and cost prohibitive; and

d. This action presents no difficulty that would impede its management by the Court as a class action.[85]

FIRST CAUSE OF ACTION
Breach of Implied Warranty of Merchantability

158. Plaintiffs incorporate the preceding paragraphs as if fully written herein.

159. Plaintiffs bring this claim on behalf of themselves and all members of the Nationwide Class.

160. All states have adopted Article 2 of the Uniform Commercial Code (UCC), or a

[85] Each claimant's eligibility for relief can be determined through self-identifying affidavits, a mechanism that courts have widely endorsed in cases, such as the one at bar, involving low-priced consumer goods. *See, e.g., Beaton v. SpeedyPC Software*, 907 F.3d 1018, 1030 (7th Cir. 2018); *Mullins v. Direct Dig., Ltd. Liab. Co*., 795 F.3d 654, 658 (7th Cir. 2015); *Langan v. Johnson & Johnson Consumer Cos*., 897 F.3d 88 (2d Cir. 2018); *Benson v. Newell Brands, Inc*., No. 19 C 6836, 2021 U.S. Dist. LEXIS 220986, at *30-32 (N.D. Ill. Nov. 16, 2021); *Hasemann v. Gerber Prods. Co*., No. 15-CV-2995 (MKB) (RER), 2019 U.S. Dist. LEXIS 28770, at *53-54 (E.D.N.Y. Feb. 20, 2019); *Suchanek v. Sturm Foods, Inc*., 311 F.R.D. 239, 259-60 (S.D. Ill. 2015); *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); *Cf. Pella Corp. v. Saltzman*, 606 F.3d 391, 396 (7th Cir. 2010) ("Under Rule 23, district courts are permitted to 'devise imaginative solutions to problems created by the presence in a class action litigation of individual damages issues.'").

materially identical equivalent,[86] which imposes upon Defendant a duty requiring that the products it sells be reasonably fit for the ordinary purposes for which they are used. This implied warranty of merchantability is part of the basis of the bargain between Defendant, on the one hand, and Plaintiffs and Class members, on the other.

161. A good is deemed "merchantable" for the purposes of an implied warranty of merchantability if it is fit for the ordinary purpose for which the product is sold.

162. A good may also be deemed "merchantable" where it conforms to the promises or affirmations of fact made on its packaging.

163. The ACT Rinse is a good contemplated by Article 2 of the U.C.C.

164. The purchase of ACT Rinse by Plaintiffs and class members constitutes a sale of goods under the U.C.C. and corresponding state statutes.

165. Defendant is a merchant of ACT Rinse.

166. The ordinary purpose for which ACT Rinse is sold is to provide anticavity protection for young children.

167. In reliance upon Defendant's skill and judgment and the implied warranty that ACT Rinse is fit for the ordinary purpose of preventing cavities in young children, Plaintiffs and the members of the Class purchased ACT Rinse for their preschool children.

168. At all times relevant to this Complaint, Act Rinse was not merchantable because it was contraindicated for children under the age of six, as determined by the FDA, and was thus not fit for the ordinary purpose for which it is sold.

169. Because ACT Rinse was not fit for its ordinary purpose and/or failed to conform to the promises or affirmations of fact on the container or label, Defendant breached the implied

[86] Louisiana is the only state that has not adopted Article 2 of the UCC, but it has codified a materially equivalent warranty law. *See* La.C.C. Art. 2550, *et seq*.

warranty of merchantability.

170. As a proximate result of Defendant's breach of the implied warranty of merchantability, Plaintiffs and Class members have economic damages. More specifically, Plaintiffs and Class members would not have purchased ACT Rinse if they knew it was contraindicated for children under six.

171. Alternatively, to the extent that ACT Rinse is considered to have value for children under six, Plaintiffs and Class Members were harmed by purchasing a product whose true value, absent the deception, was far less than what they paid.

172. Because ACT Rinse is still being sold and is violative of the implied warranty of merchantability, the number of injured Class members continues to grow.

173. Plaintiffs have provided Defendant with the requisite pre-suit notice of claim demanding Defendant take remedial action. Defendant, however, has failed to remediate its breach.

174. Through its breach of the implied warranty of merchantability, Defendant has been unjustly enriched, and continues to be unjustly enriched, by unfairly obtaining money from members of the Class.

175. Based on Defendant's breach of the implied warranty of merchantability, Plaintiffs and the members of the Nationwide Class are entitled to relief.

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

176. Plaintiffs incorporate the preceding paragraphs as if fully written herein.

177. Plaintiffs Patricia Gurrola and Deena Johnson bring this claim individually and on behalf of the Illinois Class members for all proposed classes.

178. Plaintiff and other Class members are persons within the context of the Illinois Consumer Fraud and Deceptive Trade Practices Act ("**ICFA**"), 815 ILCS § 505/1(c).

179. Defendant is a person within the context of the ICFA, 815 ILCS § 505/1(c).

180. At all times relevant hereto, Defendant was engaged in trade or commerce as defined under the ICFA, 815 ILCS § 505/1(f).

181. Plaintiff and Class members are "consumers" who purchased the products identified herein for personal, family, or household use within the meaning of the ICFA, 815 ILCS § 505/1(e).

182. The ICFA prohibits "[u]nfair methods of competition and unfair or deceptive acts or practices," which includes "the use or employment of any . . . false pretense, false promise, misrepresentation or the concealment, suppression or omission of any material fact." 815 ILCS 505/2.

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

184. As described above, including but not limited to paragraph 130, Defendant has violated, and continues to violate, the ICFA by using deceptive acts and practices to sell its ACT Rinse. As described above, Defendant's labeling of the ACT Rinse provides the false pretense, false promise, and misrepresentation that the product is specially formulated to be safe for young children.

185. Defendant has also violated the concealment and suppression prongs of the ICFA by stating on the label of its ACT Rinse that the product is approved by the ADA while omitting that the ADA only approves the product for children ages 6 and older.

186. Plaintiffs and the other Illinois Class Members purchased ACT Rinse for their preschool children based on their reasonable reliance on Defendant's false and misleading labeling.

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

188. Alternatively, to the extent ACT Rinse is considered to have value for children under 6 despite its contraindication and unacceptable risk profile, Plaintiffs and Class Members were harmed by purchasing a product whose true value, absent the deception, was far less than what they paid.

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

190. Based on Defendant's deceptive acts or practices, Plaintiffs and the Illinois Class members are entitled to relief under 815 ILCS §505/10a.

THIRD CAUSE OF ACTION
Deceptive Business Practices in Violation of California's Unfair Competition Law (Cal. Bus. & Prof. Code § 17200)

191. Plaintiffs incorporate the preceding paragraphs as if fully written herein.

192. Plaintiff Eileen Aviles brings this claim individually and on behalf of the California Class members for all proposed classes.

193. California's Unfair Competition Law ("**UCL**") prohibits "fraudulent" acts or practices, which the statute defines to include any act or practice that is likely to deceive members of the consuming public. Cal. Bus. & Prof. Code §17200. An intention to defraud is not a necessary

element for demonstrating a fraudulent business practice under the UCL.

194. As described above, including but not limited to paragraph 130, Defendant has violated, and continues to violate, the UCL by using deceptive labeling for its ACT Rinse that is likely to deceive members of the consuming public into believing that the product is specially formulated to be safe for young children.

195. Plaintiff and the other California Class Members purchased ACT Rinse for their preschool children based on their reasonable reliance on Defendant's false and misleading labeling.

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

197. Alternatively, to the extent ACT Rinse is considered to have value for children under 6 despite its contraindication and unacceptable risk profile, Plaintiffs and Class Members were harmed by purchasing a product whose true value, absent the deception, was far less than what they paid.

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

199. Based on Defendant's deceptive acts or practices, Plaintiff and the California Class members are entitled to relief under the UCL.

FOURTH CAUSE OF ACTION
Unlawful Business Practices in Violation of California's UCL
Cal. Bus. & Prof. Code § 17200

200. Plaintiffs incorporate the preceding paragraphs as if fully written herein.

201. Plaintiff Eileen Aviles brings this claim individually and on behalf of the California Class members for all proposed classes.

202. California's UCL prohibits unfair business competition, which the statute defines to include any "unlawful" act. Cal. Bus. & Prof. Code § 17200.

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

204. Defendant has violated the 'unlawful' prong of the UCL by selling a product in California that violates federal law.

205. Federal law requires that the front label of all fluoride mouthrinses "prominently display" the following words: "IMPORTANT: Read directions for proper use." 21 C.F.R. § 355.55.

206. Defendant has failed to prominently display the notice required under 21 C.F.R. § 355.55 on its front label and is thus selling a product in California that violates the unlawful prong of the UCL. This conduct is actionable under the UCL separate and apart from Defendant's other deceptive conduct described above.

207. Plaintiff and the other California Class Members purchased ACT Rinse for their

preschool children based on their reasonable reliance on Defendant's unlawful labeling.

208. Plaintiffs and Class Members suffered economic harm as a proximate result of Defendant's violations of the UCL by purchasing a product they never would have purchased absent the unlawful practices given FDA's contraindication and the unacceptable risk the product poses to young children.

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

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

211. Based on Defendant's unlawful acts or practices, Plaintiff and the California Class members are entitled to relief under the UCL.

FIFTH CAUSE OF ACTION
Deceptive Business Practices in Violation of New York General Business Law §§ 349 & 350

212. Plaintiffs incorporate the preceding paragraphs as if fully written herein.

213. Plaintiff Sushmadavi Lakeramn brings this claim individually and on behalf of the New York Class members for the proposed classes.

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

215. As described above, including but not limited to paragraph 130, Defendant has violated, and continues to violate, GBL §§ 349-50 by using deceptive and misleading labeling for its ACT Rinse that is likely to deceive members of the consuming public into believing that the product is specially formulated to be safe for young children.

216. Plaintiff and the other New York Class Members purchased ACT Rinse for their preschool children based on their reasonable reliance on Defendant's false and misleading labeling.

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

218. Alternatively, to the extent ACT Rinse is considered to have value for children under 6 despite its contraindication and unacceptable risk profile, Plaintiffs and Class Members were harmed by purchasing a product whose true value, absent the deception, was far less than what they paid.

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

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

SIXTH CAUSE OF ACTION
Deceptive Business Practices in Violation of State Deceptive Practices Statutes that, for Purposes of Defendant's Conduct at Issue Here, Are Materially Identical to the ICFA, UCL, and NY GBL §§ 349-50

221. Plaintiffs incorporate the preceding paragraphs as if fully written herein.

222. Plaintiffs bring this claim on behalf of the Arizona, Connecticut, Florida, Hawaii, Idaho, Massachusetts, Minnesota, Missouri, New Jersey, Virginia, Washington State, and Washington D.C. members of the proposed Nationwide and Alternative 15-Jurisdiction classes.

223. As described above, including but not limited to paragraph 130, Defendant has engaged in deceptive practices in its marketing of ACT Rinse. Through these deceptive practices, Defendant has conveyed the false and misleading impression that ACT Rinse is specially formulated to be safe for young children. Through this conduct, which violated, and continues to violate, the ICFA (815 ILCS 505/2), the UCL (Cal. Bus. & Prof. Code §17200), and NY GBL §§ 349-50, Defendant has simultaneously violated, and continues to violate, the following state consumer protection statutes:

a. Arizona (A.R.S. § 44-1521, *et seq*.);

b. Connecticut (Conn. Gen. Stat. § 42-110a, *et seq*.);

c. Florida (Fla. Stat. §501.201, *et seq*.);

d. Hawaii (HRS § 481A-1, *et seq*.);

e. Idaho (Idaho Code § 48-601, *et seq*.);

f. Massachusetts (ALM GL ch. 93A, *et seq*.);

g. Minnesota (Minn. Stat. §325F.68, *et seq*.);

h. Missouri (Mo. Rev. Stat. §407.005, *et seq*.);

i. New Jersey (N.J.S.A.§56:8-1, *et seq*.);

j. Virginia (Va. Code Ann. § 59.1-196, *et seq*.);

k. Washington (Wash. Rev. Code §19.86.010, *et seq*.);

l. Washington D.C. (D.C. Code § 28-3904, *et seq*.)

224. Plaintiffs and the other Class Members purchased ACT Rinse for their preschool children based on their reasonable reliance on Defendant's false and misleading labeling.

225. Plaintiffs have provided Defendant with the requisite pre-suit notice of claim under ALM GL ch 93A, *et seq.* demanding that Defendant take remedial action. Defendant has failed to take said action.

226. Plaintiffs and Class Members suffered economic harm as a proximate result of Defendant's violations of these statutes by purchasing a product they never would have purchased absent the deceptive practices given FDA's contraindication and the unacceptable risk the product poses to young children.

227. Alternatively, to the extent ACT Rinse is considered to have value for children under 6 despite its contraindication and unacceptable risk profile, Plaintiffs and Class Members were harmed by purchasing a product whose true value, absent the deception, was far less than what they paid.

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

229. Based on Defendant's deceptive acts or practices, Plaintiffs and the Class members are entitled to relief under the aforementioned state statutes.

PRAYER FOR RELIEF

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

A. Certification of the proposed Nationwide Class, or one of the proposed Alternative Classes, including appointment of Plaintiffs' counsel as Class counsel and Plaintiffs as Class Representatives;

B. An award of compensatory damages in an amount to be determined at trial;

C. An award of restitution in an amount to be determined at trial;

D. An award of disgorgement in an amount to be determined at trial;

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 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 13, 2025

Respectfully Submitted,

By: */s/ Michael Connett*

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