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10 **UNITED STATES DISTRICT COURT**
11 **FOR THE SOUTHERN DISTRICT OF CALIFORNIA**
12

13
14 MAYRA MARTINEZ and ALICIA
15 HINESTROSA, on behalf of
16 themselves and all others similarly
17 situated,

18 Plaintiffs,

19 v.

20 MOM ENTERPRISES, LLC,

21 Defendant.
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Case No. **'26CV5834 JES DEB**

Pleading Type: Class Action

**CLASS ACTION COMPLAINT FOR
VIOLATIONS OF:**

**THE UNFAIR COMPETITION LAW, THE
CONSUMER LEGAL REMEDIES ACT,
AND FOR BREACH OF IMPLIED
WARRANTY OF MERCHANTABILITY**

No Jury Demand

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1 Plaintiffs Mayra Martinez and Alicia Hinestrosa on behalf of themselves and all
2 others similarly situated hereby sue Defendant Mom Enterprises, LLC (“Mom Enterprises”
3 or “Defendant”) and allege as follows:

4 **I. JURISDICTION AND VENUE**

5 1. The Court has original jurisdiction over this action under 28 U.S.C. §
6 1332(d)(2) (The Class Action Fairness Act) because the matter in controversy exceeds the
7 sum or value of \$5,000,000 exclusive of interest and costs and because more than two-
8 thirds of the members of the class defined herein reside in states other than the state of
9 which Defendant resides.

10 2. Venue is proper in this Court pursuant to 28 U.S.C. § 1391 because hundreds
11 or thousands of class members reside in this District and suffered injuries as a result of
12 Defendant’s conduct in this District; many of the acts and transactions giving rise to this
13 action occurred in this District; and Defendant (1) is authorized to conduct business in this
14 District, and has intentionally availed itself of the laws and markets of this District through
15 the distribution and sale of its products in this District, and (2) is subject to personal
16 jurisdiction in this District.

17 **II. PARTIES**

18 3. Defendant Mom Enterprises, LLC is a Delaware corporation with its principal
19 place of business in Richmond, California.

20 4. During the class period, Defendant owned, manufactured, marketed,
21 distributed, and sold Mommy’s Bliss Kids Sleep melatonin supplements (“Kids Sleep”).
22 Mom Enterprises marketed Kids Sleep with deceptive safety and efficacy claims that
23 suggest that the product can safely treat insomnia and sleeplessness and promote healthy
24 sleep cycles in children. However, Kids Sleep is dangerous for children to consume.

25 5. Plaintiff Mayra Martinez is a citizen and resident of California who purchased
26 Kids Sleep during the class period.

27 6. Plaintiff Alicia Hinestrosa is a citizen and resident of Wisconsin who
28 purchased Kids Sleep during the class period.

III. SUMMARY OF CLAIMS

7. Defendant claims that Kids Sleep will “promote restful sleep and bring bliss back to bedtime” and “support your child’s natural sleep process” and is suitable for consumers “age three years +.” The gummy, liquid, and chewable tablet forms of Kids Sleep are pictured below.







8. These claims are misleading, as melatonin, the primary active ingredient in Kids Sleep, is unsafe for children.

9. Further, Mom Enterprises markets Kids Sleep with the same efficacy claims used on prescription sleep drugs.

10. Such claims are prohibited by the Food, Drug, and Cosmetic Act, 21 U.S.C. § 301 *et seq.* (“FDCA”), unless they are approved by the FDA, on pain of liability for the sale of an unapproved new drug.

1 11. Mom Enterprises misleads consumers into believing that Kids Sleep is legal,
2 safe, and effective for its intended purposes.

3 12. Plaintiffs Mayra Martinez and Alicia Hinestrosa purchased Kids Sleep in
4 reliance on Defendant's deceptive safety, efficacy, and drug claims and with the belief that
5 the product was safe for their children, effective, and sold in compliance with state and
6 federal law.

7 13. Plaintiffs' children consumed Kids Sleep as directed, but the product was not
8 satisfactory because it was an unlawful new drug, with an unlawful label, and because it
9 was not safe for children.

10 14. This action is brought to remedy Defendant's fraudulent, unfair, and unlawful
11 conduct. On behalf of the class defined herein, Plaintiffs seek an order compelling Mom
12 Enterprises to, *inter alia*: (1) cease marketing and selling Kids Sleep as an illegal
13 unapproved new drug; (2) conduct a corrective advertising campaign; (3) destroy all
14 unlawful products and labeling; (4) award Plaintiffs and the Class members restitution and
15 damages; and (5) pay costs, expenses, and attorney fees.

16 **IV. MELATONIN IS NOT SAFE FOR CHILDREN**

17 15. On the packaging of Kids Sleep and Defendant's website, and the Amazon
18 page for the product, which Defendant controls, Mom Enterprises deceptively claims that
19 the product is "designed for kids 3 years and above" and is "a safe supplement for
20 children." Defendant further claims that the product is "[f]ormulated with child-safe, non-
21 habit-forming melatonin," contains "safe & trusted ingredients" and is a "gentle formula
22 for little ones." Moreover, Defendant claims that "melatonin is a safe supplement for
23 children" and that Kids Sleep "safely and effectively promote[s] restful sleep."

24 16. These claims are false and misleading, as melatonin supplements are not safe
25 for children.

26 17. The "use of melatonin supplements as a sleep aid for children is becoming
27 more common. The number of children taking melatonin at least once a month has risen
28 nearly 20-fold since 2018. From 2012 to 2021, calls to poison control centers reporting

1 melatonin ingestion in children rose 530%, and sales of the supplement have doubled since
2 2017.”¹

3 18. The “recent uptick in use has started to concern doctors, who worry that adults
4 and children may be taking unnecessary amounts of the supplement rather than addressing
5 sleep problems with healthier habits.” *Id.*

6 19. “Melatonin is not recommended for children under 5.” *Id.*

7 20. “The long-term effects of taking melatonin are not well understood . . . There
8 are not a lot of major studies. If children use melatonin for too long, they may develop a
9 tolerance to it, leading to higher and higher doses needed to be effective.” *Id.*

10 21. Adverse effects of melatonin in children include “daytime grogginess” and
11 “diarrhea, vomiting, confusion, short-term depression, and an increased risk of seizures.”
12 *Id.*

13 22. There “have been many reports of melatonin overdoses in children.”²

14 23. The “American Academy of Sleep Medicine (AASM) recently issued a health
15 advisory with warnings about” melatonin use, noting that “the amount of actual melatonin
16 in tablets or liquid can vary, from less than what the label says to much more. The greatest
17 variation is found in the chewable tablets, which are unfortunately the ones children are
18 most likely to take. It’s also hard — impossible, even — to know what else might be in the
19 supplement. The AASM reports that some melatonin products also contain serotonin, a
20 hormone and neurotransmitter that requires a prescription.” *Id.*

21 24. Children “don’t need [melatonin] to get a good night’s sleep.” *Id.*

22 25. From “2012-2021, there were more than 260,000 child poisoning reports
23
24

25 ¹ Tufts U. School of Medicine. *Is Melatonin Safe for Kids?* (March 11, 2024), available at
26 medicine.tufts.edu/news-events/news/melatonin-safe-kids.

27 ² Claire McCarty, MD. *New advice on the use of melatonin in children*. Harvard
28 University School of Public Health (October 6, 2022), available at
www.health.harvard.edu/blog/new-advice-on-melatonin-use-in-children-202210062832.

1 involving melatonin . . . [S]ome children needed hospital care and two children died.”³

2 26. Further, there are “concerns about how [melatonin] might affect a child’s
3 growth and development, particularly during puberty. Studies have also found that morning
4 sleepiness, drowsiness, and possible increased urination at night are the most common side
5 effects that occur while taking melatonin. Further, melatonin may interact with other
6 medicines a child takes.” *Id.*

7 27. “There have been deaths reported in young children in the US after taking off-
8 label melatonin supplements. Since 2015, seven deaths of infants and toddlers, aged 2
9 months to 3 years, were investigated in North Carolina, USA. Melatonin levels in these
10 children’s post-mortem whole blood ranged from 3 to 1,400 ng/mL, far exceeding the
11 endogenous concentrations.”⁴

12 28. Between “2012 and 2021 there was a 530% rise in calls to US Poison Control
13 Centers for pediatric melatonin ingestions. This resulted in 27,795 emergency department
14 and clinic visits, 4,097 hospitalizations, 287 intensive care unit admissions and 2 deaths.”
15 *Id.*

16 29. Emergency rooms report children have been admitted with “gastrointestinal
17 distress, cardiovascular symptoms, and more. Melatonin has not been well-studied in
18 children, even though about 10% of U.S. parents have at least one child who takes it,
19 according to *Consumer Reports*.”⁵

21 ³ Anna Esparham, MD, *Melatonin for Kids: What Parents Should Know About This Sleep*
22 *Aid*. American Academy of Pediatrics (April 27, 2023), available at
23 www.healthychildren.org/English/healthy-living/sleep/Pages/melatonin-and-childrens-sleep.aspx

24 ⁴ Kim CY et al. *The Use and Misuse of Over-the-Counter Melatonin in Children and*
25 *Adolescents: A Commentary*. Can J Psychiatry. (Feb. 2026)
26 doi:10.1177/07067437251340683.

27 ⁵ Weis, H. *Some Melatonin Supplements Have Dramatically Different Dosages Than*
28 *Advertised, New Study Says*. Time Magazine (April 25, 2023), describing
Cohen PA et al. *Quantity of Melatonin and CBD in Melatonin Gummies Sold in the US*.
JOURNAL OF THE AMERICAN MEDICAL ASSOCIATION. 2023;329(16):1401–1402.
doi:10.1001/jama.2023.2296

30. Since melatonin is a hormone made in the brain, released to make us feel tired when it gets dark outside, companies will often highlight in their marketing that the top-off provided by a melatonin supplement is “natural.” But many of their actual doses far exceed what the body makes on its own, says Cohen. “What we know is that if you give a 20-year-old adult a very small amount of melatonin in the morning—like a 10th of a milligram, or three 10ths of a milligram—it raises their levels up to the normal nighttime levels,” says Cohen. Popular over-the-counter supplements often claim to contain as much as five or even 10 milligrams per dose. Considering the unpredictable dosages found in Cohen’s study, a nighttime melatonin routine could add many times what the body is able to produce.

Id.

31. A single Kids Sleep gummy has one milligram of melatonin. Thus, Defendant encourages parents to dose their children with three to ten times the amount of melatonin that will cause an adult to have a night-time level of melatonin. Given that a three-year-old typically weighs 1/6 the weight of a median American adult, and children have faster metabolisms than adults, a single Kids Sleep gummy would be as much as 60 times the level needed to produce nighttime levels of melatonin.

32. Worse still, the “great majority of melatonin gummy products were inaccurately labeled, with most products exceeding the declared amount of melatonin.”⁶

33. In a recent study examining the accuracy of labeling of melatonin products, “the actual quantity of melatonin ranged from 74% to 347% of the labeled quantity. Twenty-two of 25 products (88%) were inaccurately labeled, and only 3 products (12%) contained a quantity of melatonin that was within $\pm 10\%$ of the declared quantity.” *Id.*

34. “A Canadian study had similar results: analysis of 16 Canadian melatonin brands found that the actual dose of melatonin ranged from 17% to 478% of the declared quantity.” *Id.*

35. “Administration of as little as 0.1 mg to 0.3 mg of melatonin to young adults

⁶ Quantity of Melatonin, *supra* note 5.

1 can increase plasma concentrations into the normal nighttime range. **Consuming**
2 **melatonin gummies as directed could expose children to between 40 and 130 times**
3 **higher quantities of melatonin.”** *Id.* (emphasis added).

4 36. “Unintentional ingestions could lead to consumption that greatly exceeds
5 these dosages of melatonin.” *Id.*

6 37. “Given these findings, clinicians should advise parents that pediatric use of
7 melatonin gummies may result in ingestion of unpredictable quantities of melatonin.” *Id.*

8 38. The Mayo Clinic likewise notes that it is “unclear whether melatonin
9 supplements are safe for children.”⁷

10 39. “When sleep issues are a long-term problem for children, evaluating sleep
11 habits and the environment can identify the causes of those issues. Many sleep-related
12 disturbances in children can be addressed with a consistent nighttime and sleep routine.”
13 *Id.*

14 40. “In gummy form, melatonin supplements can be enticing for children, leading
15 to a risk of overconsumption. Taking a large dose of melatonin can cause gastrointestinal
16 issues or irritability. A large dose also can keep your child’s body from naturally producing
17 melatonin to make them sleepy.” *Id.*

18 41. The concern stated here is for American adults, who average 170lbs, taking
19 “0.1 mg to 0.3 mg” of melatonin. Defendant’s dosage for small children weighing as little
20 as 20lbs is to take one 1 mg gummy. This is absolutely reckless advice and amounts to
21 giving a small developing brains mega-doses of a hormone. There are no studies of the
22 effects of giving small children such amounts over an extended period, but strong concerns
23 that it is unsafe to do so.

24 42. A 2023 review article determined that
25 Children who use melatonin are likely to experience non-serious adverse events,

26
27 ⁷ Mayo Clinic, *Melatonin use in children: Is a sleep aid supplement safe?* (March 21,
28 2024), available at
www.mayoclinichealthsystem.org/hometown-health/speaking-of-health/melatonin-use-in-children

1 yet the actual extent to which melatonin leads to non-serious adverse events and
2 the long-term consequences remain uncertain. This major gap of knowledge on
3 safety calls for caution against complacent use of melatonin in children and
4 adolescents with chronic insomnia and for more research to inform clinicians and
5 guideline panels on this key issue.⁸

6 43. Another recent review article noted that
7 Melatonin is the leading cause of unsupervised medication exposure and
8 overdose in emergency departments for young children (aged 0-6 years). Existing
9 literature has documented the benefits of melatonin in older children (aged 7-18
10 years) with neurologic conditions but has yet to examine young children.⁹

11 44. The study's "findings suggest a global rise in prescriptions without efficacy
12 data on use in children with typical development, underscoring the need to identify
13 strategies to prevent and reduce melatonin use in young children, as well as to improve
14 adherence by pediatricians to evidence-based practice standards." Id.

15 45. Moreover, recent research published by the American Heart Association
16 ("AHA") sheds further light on the dangers of regular melatonin supplementation.

17 46. The AHA's "review of 5 years of health records for more than 130,000 adults
18 with insomnia who had used melatonin for at least a year found they were more likely to
19 be diagnosed with heart failure, require hospitalization for the condition or die from any
20 cause."¹⁰

21 47. "The association between melatonin and increased risk of heart failure or
22 death found in this study" "raises safety concerns about the use of melatonin, which is

23 ⁸ Händel MN, et al. *The short-term and long-term adverse effects of melatonin treatment*
24 *in children and adolescents: a systematic review and GRADE assessment*.
25 *EClinicalMedicine*. July 6 2023;61:102083. doi: 10.1016/j.eclinm.2023.102083

26 ⁹ Kracht CL, et al. *Melatonin Use in Young Children: A Systematic Review*. *JAMA*
27 *Network Open*. Jan. 2 2006 doi:10.1001/jamanetworkopen.2025.51958

28 ¹⁰ American Heart Association. *Long-term use of melatonin supplements to support sleep*
may have negative health effects (November 3, 2025), available at
[newsroom.heart.org/news/long-term-use-of-melatonin-supplements-to-support-sleep-may-](https://newsroom.heart.org/news/long-term-use-of-melatonin-supplements-to-support-sleep-may-have-negative-health-effects)
[have-negative-health-effects](https://newsroom.heart.org/news/long-term-use-of-melatonin-supplements-to-support-sleep-may-have-negative-health-effects).

1 widely available, and may warrant more research on melatonin to assess its cardiovascular
2 safety, researchers said.” *Id.*

3 48. The study’s primary analysis found:

- 4 • Among adults with insomnia, those whose electronic health records indicated
5 long-term melatonin use (12 months or more) had about a 90% higher chance
6 of incident heart failure over 5 years compared with matched non-users (4.6%
7 vs. 2.7%, respectively).
- 8 • There was a similar result (82% higher) when researchers analyzed people who
9 had at least 2 melatonin prescriptions filled at least 90 days apart. (Melatonin
10 is only available by prescription in the United Kingdom.)

11 49. A secondary analysis found:

- 12 • Participants taking melatonin were nearly 3.5 times as likely to be hospitalized
13 for heart failure when compared to those not taking melatonin (19.0% vs.
14 6.6%, respectively).
- 15 • Participants in the melatonin group were nearly twice as likely to die from any
16 cause than those in the non-melatonin group (7.8% vs. 4.3%, respectively) over
17 the 5-year period.

18 50. “Melatonin supplements are widely thought of as a safe and ‘natural’ option
19 to support better sleep, so it was striking to see such consistent and significant increases in
20 serious health outcomes, even after balancing for many other risk factors.” *Id.*

21 51. “In the U.S., melatonin can be taken as an over-the-counter supplement and
22 people should be aware that it should not be taken chronically without a proper indication,”
23 said Marie-Pierre St-Onge, Ph.D., C.C.S.H., FAHA, chair of the writing group for the
24 American Heart Association’s 2025 scientific statement.” *Id.*

25 52. Defendant claims that “melatonin is a safe supplement for children” and that
26 Kids Sleep is “child-safe melatonin.” Defendant further claims that “[m]elatonin works
27 with your child’s natural sleep process to safely and effectively promote restful sleep.”
28 These claims are misleading in that melatonin supplements are not safe for children.

53. Rather, doctors recommend evaluating sleep habits and advise against
medication, noting that “[m]any sleep-related disturbances in children can be addressed

with a consistent nighttime and sleep routine.”¹¹

V. REGULATORY BACKGROUND CONCERNING THE SALE OF UNAPPROVED DRUGS

54. “The term ‘drug’ means . . . (B) articles intended for use in the diagnosis, cure, mitigation, treatment, or prevention of disease in man or other animals; and (C) articles (other than food) intended to affect the structure or any function of the body of man or other animals.” 21 U.S.C. § 321(g)(1).

55. A “new drug” is any drug “not generally recognized, among experts qualified by scientific training and experience to evaluate the safety and effectiveness of drugs, as safe and effective for use under the condition prescribed, recommended, or suggested in the labeling thereof” 21 U.S.C. § 321(p)(1).

56. Pursuant to 21 U.S.C. § 355(a), “No person shall introduce or deliver for introduction into interstate commerce any new drug . . .” without approval by the FDA.

57. Further, 21 U.S.C. § 331(a) prohibits the “introduction or delivery for introduction into interstate commerce of any food, drug, device, tobacco product, or cosmetic that is adulterated or misbranded.”

58. Under 21 U.S.C. § 352(f), drugs are required to have adequate instructions for safe use.

¹¹ Mayo Clinic, *Melatonin use in children* (supra, note 7)

VI. MOM ENTERPRISES MARKETING KIDS SLEEP WITH DECEPTIVE AND UNLAWFUL SAFETY AND EFFICACY CLAIMS.

A. Kids Sleep's Packaging









59. During the class period, Mom Enterprises marketed Kids Sleep with deceptive safety and efficacy claims that suggest that the product can safely and effectively treat insomnia and sleeplessness and promote healthy sleep cycles in children.

60. These claims are misleading, melatonin supplements are not safe for young children.

61. These claims also render Kids Sleep a “drug” within the meaning of 21 U.S.C. § 321(g).

62. Mom Enterprises failed to obtain FDA approval to market Kids Sleep in violation of 21 U.S.C. § 355 and Health & Safety Code § 111550.

63. During the Class Period, the “Kids Sleep” label claimed that the product

1 “helps support your child’s natural sleep process,” “promote[s] restful sleep” and “bring
2 bliss back to bedtime.” Further, Defendant claims that Kids Sleep is for “age 3+ years.”

3 64. Kids Sleep does not deliver the advertised benefits in that it is not a safe and
4 effective treatment for insomnia and sleeplessness in children.

5 65. These safety and efficacy claims, in addition to being misleading, render Kids
6 Sleep a “drug” as defined by 21 U.S.C. § 321(g).

7 **B. Defendant’s Online Advertising**

8 66. Mom Enterprises also advertises Kids Sleep with deceptive safety and
9 efficacy claims online that suggest the product can provide prescription sleep disorder drug
10 benefits.

11 67. The Kids Sleep label, Defendant’s website, MommysBliss.com, and the Kids
12 Sleep Amazon page, which Mom Enterprises controls, contained the following claims,
13 which show that the product is intended to affect the structure and function of the body,
14 and to cure, mitigate, treat, or prevent disease, during the Class Period:

- 15 • “Kids Sleep”
- 16 • “helps support your child’s natural sleep process”
- 17 • “child-safe melatonin”
- 18 • “melatonin is a safe supplement for children”
- 19 • “supports restful sleep”
- 20 • “good for the whole family, ages 3+”
- 21 • “1mg child-safe, non-habit forming melatonin to support your child’s natural
- 22 sleep process”
- 23 • “help kids fall asleep naturally into a restful sleep”
- 24 • “natural sleep supplement for children 3 years and older”
- 25 • “promote restful sleep for children 3 years and older and bring bliss back to
- 26 bedtime”
- 27 • “help kids sleep with 1mg of melatonin per gummy to help your child's natural
- 28 sleep process”

68. These claims deceptively convey that Kids Sleep can safely treat insomnia

1 and sleeplessness in children and affect the structure and function of the human body by
2 improving sleep and promoting healthy sleep cycles.

3 69. Further, these claims render Kids Sleep a “drug” within the meaning of 21
4 U.S.C. § 321(g)(1).

5 70. True and correct copies of screenshots of the Kids Sleep pages from
6 Defendant’s website, MommysBliss.com, are attached hereto as **Exhibit 1**.

7 71. True and correct copies of screenshots of the Amazon pages for Kids Sleep,
8 which Defendant controls, are attached hereto as **Exhibit 2**.

9 72. Defendant failed to obtain FDA approval prior to marketing, distributing, and
10 selling Kids Sleep.

11 **VII. KIDS SLEEP IS AN UNAPPROVED NEW DRUG.**

12 73. “The term ‘drug’ means . . . (B) articles intended for use in the diagnosis, cure,
13 mitigation, treatment, or prevention of disease in man or other animals; and (C) articles
14 (other than food) intended to affect the structure or any function of the body of man or
15 other animals.” 21 U.S.C. § 321(g)(1).

16 74. Kids Sleep is a “drug” because it is advertised as a product which will affect
17 the structure or function of the body and cure, mitigate, treat, or prevent disease.

18 75. The claims on the packaging of Kids Sleep, Defendant’s website, and
19 Defendant’s Amazon page for Kids Sleep render the product an unapproved new drug.

20 76. The FDA has determined that the following claims, which are similar to those
21 Defendant made regarding Kids Sleep, constitute “drug claims”:

- 22 • “is used for insomnia, sleep apnea” (**Exhibit 3**, FDA Warning Letter to SANA
23 Group, LLC);
- 24 • “most commonly used for sleep disorders, especially the inability to sleep
25 (insomnia)” (**Exhibit 3**);
- 26 • “Maintain and aid healthy sleep cycles” (**Exhibit 4**, FDA Warning Letter to
27 MB Solutions, LLC/BioSpectrum CBD);

28 77. A “new drug” is any drug “not generally recognized, among experts qualified
by scientific training and experience to evaluate the safety and effectiveness of drugs, as

1 safe and effective for use under the condition prescribed, recommended, or suggested in
2 the labeling thereof” 21 U.S.C. § 321(p)(1). Here, Kids Sleep is a “new drug” within
3 the meaning of the FDCA because it is not generally recognized as safe and effective for
4 the intended uses. See Title 21 of the Code of Federal Regulations, Chapter I, Subchapter
5 D; 21 C.F.R. § 330.1.

6 78. Defendant has not received approval from the FDA to sell Kids Sleep.

7 79. The sale of unapproved new drugs is illegal and dangerous. First, consumers
8 risk purchasing and using a product that will endanger their health. Second, consumers risk
9 purchasing a product that will not effectively treat their condition, forgoing actual treatment
10 of that condition in lieu of an unapproved new drug which may not treat their condition.
11 The FDA’s regulatory regimen helps ensure that such products are kept away from
12 consumers.

13 80. Defendant’s failure to comply with these regulations puts consumers at risk
14 and gives Mom Enterprises an unfair advantage over competitors that do commit the time
15 and expense of complying with such necessary regulations.

16 81. Kids Sleep does not qualify for the reduced level of regulation applicable to
17 certain nutrition supplement products for several reasons. The Kids Sleep label,
18 Defendant’s website, and Defendant’s marketing materials do not describe the role of any
19 nutrient or dietary ingredient intended to affect the structure or function in humans,
20 characterize the documented mechanism by which any nutrient or dietary ingredient acts
21 to maintain such structure or function, or describe general well-being from consumption of
22 any nutrient or dietary ingredient. 21 U.S.C. § 343(r)(6)(A).

23 82. California similarly prohibits the sale of unapproved new drugs. Health &
24 Safety Code § 111550.

25 **VIII. THE SALE OF UNAPPROVED DRUGS HARMS THE PUBLIC.**

26 83. “Unapproved prescription drugs pose significant risks to patients because they
27
28

1 have not been reviewed by FDA for safety, effectiveness or quality.”¹²

2 84. “Without FDA review, there is no way to know if these drugs are safe and
3 effective for their intended use, whether they are manufactured in a way that ensures
4 consistent drug quality or whether their label is complete and accurate.” *Id.*

5 85. “Unapproved drugs have resulted in patient harm, and the [FDA] works to
6 protect patients from the risks posed by these drugs.” *Id.*

7 86. Unapproved drugs lack “labels and prescribing information that” have “been
8 reviewed by FDA for accuracy and completeness.”¹³

9 87. Consumers using unapproved drugs run the risk of “unexpected and
10 undocumented safety concerns due to lack of rigorous pre- and postmarket safety
11 surveillance.” *Id.*

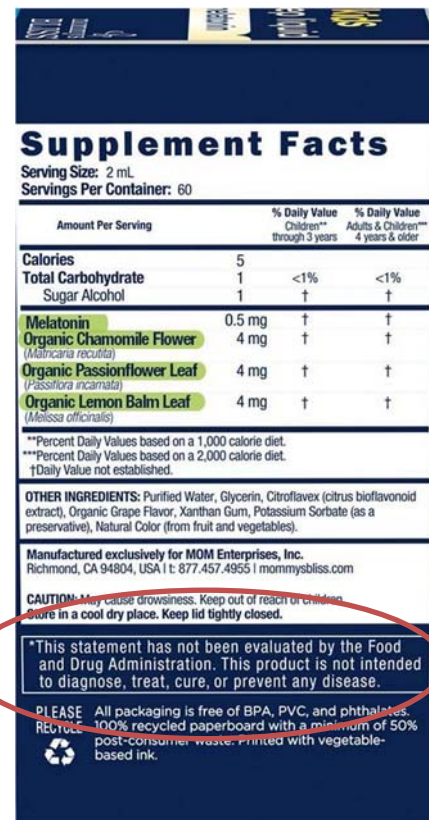
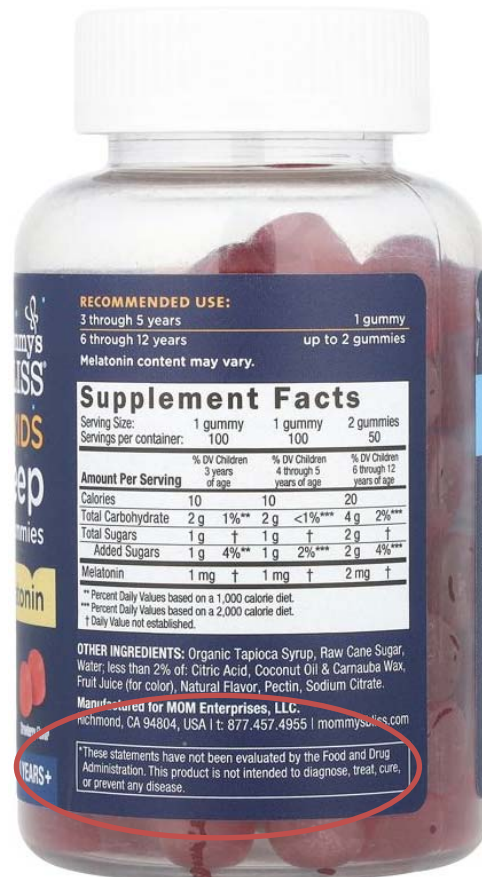
12 88. Additionally, unapproved drugs lead consumers in need of medical treatment
13 to forgo medically proven therapies.

14 **IX. KIDS SLEEP’S LABEL VIOLATES 21 C.F.R. § 101.93(d).**

15 89. The back panel of the packaging of Kids Sleep contains a disclaimer which
16 reads, “These statements have not been evaluated by the Food and Drug Administration.
17 This product is not intended to diagnose, treat, cure, or prevent any disease.”
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26 ¹² U.S. Food & Drug Admin., Unapproved Drugs (June 2, 2021), available at
27 www.fda.gov/drugs/enforcement-activities-fda/unapproved-drugs.

28 ¹³ U.S. Food & Drug Admin., Unapproved Drugs and Patient Harm (June 2, 2021),
www.fda.gov/drugs/enforcement-activities-fda/unapproved-drugs-and-patient-harm.





90. However, the disclaimer is improperly positioned in violation of 21 C.F.R. § 101.93(d) governing structure/function claims, which provides:

The disclaimer shall be placed adjacent to the statement with no intervening material or linked to the statement with a symbol (e.g., an asterisk) at the end of each such statement that refers to the same symbol placed adjacent to the disclaimer specified in paragraphs (c)(1) or (c)(2) of this section. On product labels and in labeling (e.g., pamphlets, catalogs), the disclaimer shall appear on each panel or page where there such is a statement. The disclaimer shall be set off in a box where it is not adjacent to the statement in question.

91. Here, on the front of the packaging of Kids Sleep, Defendant makes efficacy claims about the product and includes asterisks next to these claims, linking them to the FDA's required disclaimer.

92. 21 C.F.R. § 101.93(d) requires that "the disclaimer shall appear on each panel

or page where there such is a statement.” (emphasis added)

93. Defendant makes efficacy claims on the front or principal display panel, but the disclaimer does not appear on the principal display panel. Rather, the disclaimer only appears on different back panels.



94. Thus, Defendant’s placement of the disclaimer violates 21 C.F.R. § 101.93(d).

X. DEFENDANT’S PRACTICES WERE “UNFAIR” WITHIN THE MEANING OF THE UNFAIR COMPETITION LAW.

95. Defendant’s practices as described herein are “unfair” within the meaning of the California Unfair Competition Law because Defendant’s conduct is immoral, unethical, unscrupulous, and substantially injurious to consumers, and the utility of this conduct to Defendant does not outweigh the gravity of the harm to Defendant’s victims.

96. In particular, while Defendant’s marketing of Kids Sleep with deceptive safety and “drug” claims as defined by 21 U.S.C. § 321(g) and absent FDA approval to do so allowed Mom Enterprises to realize higher profit margins than if it did not use unlawful marketing tactics, this utility is small and far outweighed by the gravity of the economic harm and potential physical harm that Defendant inflicts upon consumers. Further, the

injury to consumers from Defendant's practices is substantial, not outweighed by benefits to consumers or competition, and not an injury that consumers themselves could reasonably have avoided.

XI. DEFENDANT'S PRACTICES WERE "UNLAWFUL" WITHIN THE MEANING OF THE CALIFORNIA UNFAIR COMPETITION LAW.

97. The acts, omissions, misrepresentations, practices, and non-disclosures of Defendant as alleged herein constitute "unlawful" business acts and practices in that Defendant's conduct violates the California Consumer Legal Remedies Act, as alleged herein.

98. Defendant's practices as described herein are further "unlawful" within the meaning of the California Unfair Competition Law because the marketing, sale, and distribution of Kids Sleep violate California's Sherman Food, Drug, and Cosmetic Law, including federal provisions that California has adopted:

- **Health & Safety Code § 110110**, which adopts all FDA regulations relating to new drugs and premarket approval;
- **Health & Safety Code § 110111**, which adopts all FDA nonprescription drug regulations;
- **Health & Safety Code § 111330**, "Any drug or device is misbranded if its labeling is false or misleading in any particular.";
- **Health & Safety Code § 110398**, "It is unlawful for any person to advertise any food, drug, device, or cosmetic that is adulterated or misbranded.";
- **Health & Safety Code § 111440**, "It is unlawful for any person to manufacture, sell, deliver, hold, or offer for sale any drug or device that is misbranded.";
- **Health & Safety Code § 111445**, "It is unlawful for any person to misbrand any drug or device.";
- **Health & Safety Code § 111450**, "It is unlawful for any person to receive in commerce any drug or device that is misbranded or to deliver or proffer for delivery any drug or device.";
- **Health & Safety Code § 111550**, prohibiting sale of new drugs unless approved under 21 U.S.C. § 355;

- **21 U.S.C. § 331(a)**, prohibiting the “introduction or delivery for introduction into interstate commerce of any food, drug, device, tobacco product, or cosmetic that is adulterated or misbranded”;
- **21 U.S.C. § 331(b)**, prohibiting the “adulteration or misbranding of any food, drug, device, tobacco product, or cosmetic in interstate commerce”;
- **21 U.S.C. § 352(f)(1)**, requiring drugs to have adequate directions for use;
- **21 U.S.C. § 355(a)**, prohibiting the sale of unapproved new drugs; and
- **21 C.F.R. § 101.93(d)**, governing the placement of disclaimers in relation to structure/function claims.

99. The marketing and advertising of Kids Sleep constitute violations of the FDCA and the Sherman Law and, as such, violate the “unlawful” prong of the UCL.

100. Defendant’s unlawful acts allowed it to sell more units of Kids Sleep than it would have otherwise, and at a higher price and a higher margin.

101. In accordance with Cal. Bus. & Prof. Code § 17203, Plaintiffs seek an order enjoining Defendant from continuing to conduct business through unlawful, unfair, and/or fraudulent acts and practices and requiring Defendant to commence a corrective advertising campaign.

102. Plaintiffs also seek an order for the disgorgement and restitution of all revenue received by Defendant from the sale of Kids Sleep and have no adequate remedy at law.

XII. PLAINTIFFS’ PURCHASES OF KIDS SLEEP

103. Plaintiff Mayra Martinez repeatedly purchased Kids Sleep for household use primarily from Walmart locations in the Pomona, California area. Her first purchase occurred in April 2025, and her most recent purchase occurred in early 2026. She purchased Kids Sleep approximately once a month during this period.

104. Plaintiff Alicia Hinestroza repeatedly purchased Kids Sleep for household use primarily from Walmart locations in Racine, Wisconsin and Antioch, Illinois. Her first purchase occurred in approximately 2022, and her most recent purchase occurred in early 2026. She purchased Kids Sleep as much as once per month from 2022 until early 2026.

105. In deciding to purchase Kids Sleep, Plaintiffs relied on Defendant’s deceptive

1 safety, efficacy, and drug claims and fraudulent omissions.

2 106. Plaintiffs' families used Kids Sleep as directed, but the product was not
3 satisfactory because it was an unlawful new drug and because it was not safe for children.

4 107. Because Kids Sleep was both an unlawful new drug and unsafe for children,
5 Plaintiffs did not receive the benefit of their purchases.

6 **XIII. RELIANCE AND INJURY**

7 108. Plaintiffs purchased and used Kids Sleep in reliance on Defendant's deceptive
8 safety, efficacy, and drug claims described herein and would not have purchased the
9 product absent Defendant's advertising.

10 109. When Plaintiffs purchased Kids Sleep, they were seeking a lawful, safe, and
11 effective product which would treat insomnia and sleeplessness in children and promote
12 healthy sleep cycles in children.

13 110. Plaintiffs purchased Kids Sleep with the natural assumption that products sold
14 in stores and online by large companies would be safe and would be sold in compliance
15 with applicable state and federal law.

16 111. Plaintiffs suffered economic injury when they purchased Kids Sleep because
17 the product was not safe and effective for its intended purposes and was sold in violation
18 of federal regulations and California law.

19 112. Plaintiffs would not have purchased Kids Sleep had they known that it was
20 not safe and effective for its intended purposes and was sold in violation of federal
21 regulations and California law.

22 113. Kids Sleep was offered for sale in violation of California and federal law and
23 had a value of \$0 because it is illegal and unsafe.

24 114. Plaintiffs would consider purchasing Kids Sleep in the future if they could be
25 assured that the product (1) would deliver the advertised benefits, (2) would be safe and
26 effective, and (3) would be sold in compliance with all FDA regulations and California
27 law.

XIV. CLASS ACTION ALLEGATIONS

115. Plaintiffs bring this action on behalf of themselves and all others similarly situated (the “Class”), excluding Defendant’s officers, directors, and employees, and the Court, its officers and their families. The Class is defined as:

All citizens and residents of the United States who purchased Kids Sleep in the United States for their own personal or household use, and not for resale, from January 1, 2019 to the present.

116. The California Subclass is defined as:

All individuals who purchased Kids Sleep in California for their own personal or household use, and not for resale, from January 1, 2019 to the present.

117. The Wisconsin Subclass is defined as:

All individuals who purchased Kids Sleep in Wisconsin for their own personal or household use, and not for resale, from January 1, 2019 to the present.

118. The Illinois Subclass is defined as:

All individuals who purchased Kids Sleep in Illinois for their own personal or household use, and not for resale, from January 1, 2019 to the present.

119. Questions of law and fact common to Plaintiffs, the Class, and the Subclasses include:

- a. Whether Defendant’s conduct violated the California Unfair Competition Law;
- b. Whether Defendant’s conduct violated the CLRA;
- c. Whether Mom Enterprises communicated deceptive safety, efficacy, and drug claims through Kids Sleep’s labeling, packaging, and website;
- d. Whether those messages were material, or likely to be material, to a reasonable consumer;
- e. Whether those messages were false, at variance with the truth, misleading, likely to deceive, and/or had the capacity to deceive the public
- f. Whether Mom Enterprises fraudulently omitted material information in advertising Kids Sleep as safe and effective;
- g. Whether Kids Sleep is an unapproved new drug;
- h. Whether Defendant’s conduct was immoral, unethical, unscrupulous, or

1 substantially injurious to consumers;

2 i. Whether the injury to consumers from Defendant's practices is outweighed by
3 benefits to consumers or competition;

4 j. Whether Class members are entitled to restitution, damages and punitive
5 damages;

6 k. Whether Class members are entitled to an injunction and, if so, its terms; and

7 120. By purchasing Kids Sleep, all Class members were subjected to the same
8 wrongful conduct.

9 121. Plaintiffs' claims are typical of the Class's claims because all Class members
10 were subjected to the same economic harm when they purchased Kids Sleep and suffered
11 economic injury.

12 122. Plaintiffs will fairly and adequately protect the interests of the Class, have no
13 interests that are incompatible with the interests of the Class, and have retained counsel
14 competent and experienced in class litigation.

15 123. The Class is sufficiently numerous, as it includes thousands of individuals
16 who purchased Kids Sleep during the Class Period.

17 124. Class representation is superior to other options for the resolution of the
18 controversy. The relief sought for each Class member is small, as little as \$10 for some
19 Class members. Absent the availability of class action procedures, it would be infeasible
20 for Class members to redress the wrongs done to them.

21 125. Questions of law and fact common to the Class predominate over any
22 questions affecting only individual members.

23 **CAUSES OF ACTION**

24 **First Cause of Action**

25 **Unfair Competition Law, Unlawful Prong**

26 **Bus. & Prof. Code § 17200 et seq.**

27 **(On behalf of Martinez, the Class, and the California Subclass)**

28 126. In this and every cause of action, Plaintiffs reallege and incorporate the
preceding allegations as if fully set forth herein.

1 127. Plaintiff Mayra Martinez brings this claim on behalf of herself, the Class, and
2 the California Subclass.

3 128. The acts, omissions, misrepresentations, practices, and non-disclosures of
4 Defendant as alleged herein constitute “unlawful” business acts and practices in that
5 Defendant’s conduct violates the California Consumer Legal Remedies Act, as alleged
6 herein.

7 129. Defendant’s practices as described herein are “unlawful” within the meaning
8 of the California Unfair Competition Law because the marketing, sale, and distribution of
9 Kids Sleep violate California’s Sherman Food, Drug, and Cosmetic Law, including federal
10 provisions that California has adopted:

- 11 • **Health & Safety Code § 110110**, which adopts all FDA regulations relating to new
12 drugs and premarket approval;
- 13 • **Health & Safety Code § 110111**, which adopts all FDA nonprescription drug
14 regulations;
- 15 • **Health & Safety Code § 111330**, “Any drug or device is misbranded if its labeling
16 is false or misleading in any particular.”;
- 17 • **Health & Safety Code § 110398**, “It is unlawful for any person to advertise any
18 food, drug, device, or cosmetic that is adulterated or misbranded.”;
- 19 • **Health & Safety Code § 111440**, “It is unlawful for any person to manufacture, sell,
20 deliver, hold, or offer for sale any drug or device that is misbranded.”;
- 21 • **Health & Safety Code § 111445**, “It is unlawful for any person to misbrand any
22 drug or device.”;
- 23 • **Health & Safety Code § 111450**, “It is unlawful for any person to receive in
24 commerce any drug or device that is misbranded or to deliver or proffer for delivery
25 any drug or device.”;
- 26 • **Health & Safety Code § 111550**, prohibiting sale of new drugs unless approved
27 under 21 U.S.C. § 355;
- 28 • **21 U.S.C. § 331(a)**, prohibiting the “introduction or delivery for introduction
into interstate commerce of any food, drug, device, tobacco product, or
cosmetic that is adulterated or misbranded”;

- **21 U.S.C. § 331(b)**, prohibiting the “adulteration or misbranding of any food, drug, device, tobacco product, or cosmetic in interstate commerce”;
- **21 U.S.C. § 352(f)(1)**, requiring drugs to have adequate directions for use;
- **21 U.S.C. § 355(a)**, prohibiting the sale of unapproved new drugs; and
- **21 C.F.R. § 101.93(d)**, governing the placement of disclaimers in relation to structure/function claims.

130. The marketing and advertising of Kids Sleep constitute violations of the FDCA and the Sherman Law and, as such, violate the “unlawful” prong of the UCL.

131. Defendant’s unlawful acts allowed it to sell more units of Kids Sleep than it would have otherwise, and at a higher price and higher margin.

132. In accordance with Cal. Bus. & Prof. Code § 17203, Plaintiffs seek an order enjoining Defendant from continuing to conduct business through unlawful, unfair, and fraudulent acts and practices; requiring Defendant to commence a corrective advertising campaign; and awarding the Class restitution of all monies Defendant obtained from the sale of Kids Sleep. Plaintiffs have no adequate remedy at law.

Second Cause of Action

Unfair Competition Law, Unfair Prong

Bus. & Prof. Code § 17200 et seq.

(On behalf of Martinez, the Class, and the California Subclass)

133. Plaintiff Mayra Martinez brings this claim on behalf of herself, the Class, and the California Subclass.

134. The acts, omissions, misrepresentations, practices, and non-disclosures of Defendant as alleged herein constitute “unfair” business acts and practices because Defendant’s conduct is:

- immoral, unethical, unscrupulous, and offends public policy;
- the gravity of Defendant’s conduct outweighs any conceivable benefit of such conduct; and

- the injury to consumers caused by Defendant's conduct is substantial, not outweighed by any countervailing benefits to consumers or competition, and not one that consumers themselves could reasonably have avoided.

135. In accordance with Cal. Bus. & Prof. Code § 17203, Plaintiffs seek an order enjoining Defendant from continuing to conduct business through unlawful, unfair, and fraudulent acts and practices; requiring Defendant to commence a corrective advertising campaign; and awarding the Class restitution of all monies Defendant obtained from the sale of Kids Sleep. Plaintiffs have no adequate remedy at law.

Third Cause of Action

Unfair Competition Law, Fraudulent Prong

Bus. & Prof. Code § 17200 et seq.

(On behalf of Martinez, the Class, and the California Subclass)

136. Plaintiff Mayra Martinez brings this claim on behalf of herself, the Class, and the California Subclass.

137. Cal. Bus. & Prof. Code § 17200 prohibits any "unlawful, unfair or fraudulent business act or practice."

138. The acts, omissions, misrepresentations, practices, and non-disclosures of Defendant as alleged herein constitute "fraudulent" business acts and practices in that Defendant's conduct has a likelihood, capacity, or tendency to deceive Plaintiff, the Class, and the general public.

139. Defendant leveraged its deception to induce Plaintiffs and members of the Class to purchase products that were of lesser value and quality than advertised.

140. Plaintiffs and Class members suffered injury in fact and lost money or property as a result of Defendant's deceptive advertising: they were denied the benefit of the bargain when they decided to purchase Kids Sleep over competing products, which are safe, legal, less expensive, and do not make misleading or false drug claims on their packaging and websites.

141. Had Plaintiffs been aware of Defendant's false and misleading advertising tactics, they would not have purchased Kids Sleep, and had Defendant not advertised it in

1 a fraudulent manner, Plaintiffs would have paid less for it.

2 142. In accordance with Cal. Bus. & Prof. Code § 17203, Plaintiffs seek an order
3 enjoining Defendant from continuing to conduct business through unlawful, unfair, and
4 fraudulent acts and practices; requiring Defendant to commence a corrective advertising
5 campaign; and awarding the Class restitution of all monies Defendant obtained from the
6 sale of Kids Sleep. Plaintiffs have no adequate remedy at law.

7 **Fourth Cause of Action**

8 **Consumer Legal Remedies Act**

9 **Civil Code §§ 1750, *et seq.***

10 **(On behalf of Martinez, the Class, and the California Subclass)**

11 143. Plaintiff Mayra Martinez brings this claim on behalf of herself, the Class, and
12 the California Subclass.

13 144. The CLRA prohibits deceptive practices in connection with the conduct of a
14 business that provides goods, property, or services primarily for personal, family, or
15 household purposes.

16 145. Defendant's policies, acts and practices were designed to, and did, result in
17 the purchase and use of Kids Sleep for personal, family, or household purposes, and
18 violated and continue to violate the following sections of the CLRA:

- 19 • **Civil Code § 1770(a)(5)**, representing that goods have characteristics, uses, or
20 benefits which they do not have;
- 21 • **Civil Code § 1770(a)(7)**, representing that goods are of a particular standard,
22 quality, or grade if they are of another;
- 23 • **Civil Code § 1770(a)(9)**, advertising goods with intent not to sell them as
24 advertised; and
- 25 • **Civil Code § 1770(a)(16)**, representing the subject of a transaction has been
26 supplied in accordance with a previous representation when it has not.

27 146. As a result, Plaintiffs, the Class, and the general public are entitled to
28 injunctive and equitable relief, restitution, and an order for the disgorgement of the funds
by which Defendant was unjustly enriched.

1 147. As a further result, Plaintiffs and the Class have suffered damages, and
2 because the conduct was deliberate, immoral, oppressive, made with malice and contrary
3 to public policy, they are entitled to punitive or exemplary damages.

4 148. Pursuant to section 1782 *et seq.* of the CLRA, Plaintiffs notified Mom
5 Enterprises in writing by certified mail of the particular violations of § 1770 of the Act as
6 to Kids Sleep and demanded that Defendant rectify the problems associated with the
7 actions detailed above and give notice to all affected consumers of its intent to so act.

8 149. Defendant received Plaintiffs' written notice more than 30 days prior to the
9 filing of this Complaint, but neither responded nor abated the unlawful conduct.

10 **Fifth Cause of Action**

11 **Breach of Implied Warranty of Merchantability**

12 **(On behalf of Martinez, the Class, and the California Subclass)**

13 150. Plaintiff Mayra Martinez brings this claim on behalf of herself, the Class, and
14 the California Subclass.

15 151. Through its marketing and sale of Kids Sleep, Mom Enterprises made an
16 implied warranty to Plaintiffs and the Class that Kids Sleep was of merchantable quality
17 and suitable for its ordinary and intended purpose—the treatment of sleeplessness and
18 insomnia and promoting healthy sleep cycles in children.

19 152. Through the conduct alleged herein, Mom Enterprises has breached the
20 implied warranty of merchantability. Kids Sleep is not fit for the ordinary and intended
21 purpose for which Plaintiffs and the Class purchased it—treatment of sleep disorders and
22 promotion of healthy sleep cycles in children—because Kids Sleep contains melatonin, an
23 ingredient which is not safe for children to consume. Mom Enterprises knew that Plaintiffs
24 and the Class were purchasing Kids Sleep for this purpose and marketed the product for
25 this purpose.

26 153. Mom Enterprises knew or had reason to know that Plaintiffs and the Class
27 were influenced to purchase Kids Sleep through Defendant's expertise, skill, judgment,
28 and knowledge in furnishing Kids Sleep for its intended use. Kids Sleep was not of

1 merchantable quality and was not fit for its ordinary purpose because it contained
2 melatonin, an ingredient which is not safe for infants and children to consume.

3 154. Defendant's actions, as complained of herein, breached its implied warranty
4 that Kids Sleep was of merchantable quality and fit for such use, in violation of the UCC,
5 the common law of this State, as well as the common law and statutory laws of other states.

6 155. Mom Enterprises has not sufficiently disclaimed the implied warranty of
7 merchantability (specifically and conspicuously).

8 156. Mom Enterprises is in privity with Plaintiffs and the Class by law and/or by
9 fact.

10 157. Mom Enterprises is estopped from limiting claims for common law and
11 statutory violations based on a defense of lack of privity.

12 158. Plaintiffs and the Class have incurred damage as described herein as a direct
13 and proximate result of the failure of Defendant to honor its implied warranty. In particular,
14 Plaintiffs and the Class would not have purchased Kids Sleep had they known that it
15 contained an ingredient that was not safe for children to consume; nor would they have
16 suffered damages.

17 **Sixth Cause of Action**

18 **Wis. Stat. § 100.18**

19 **(On behalf Hinestrosa and the Wisconsin Subclass)**

20 159. Plaintiffs repeat and reallege the preceding paragraphs as if fully set forth
21 herein.

22 160. Plaintiff Alicia Hinestrosa brings this claim on behalf of herself and the
23 Wisconsin Subclass.

24 161. Section 100.18 of the Wisconsin Statutes ("Section 100.18") prohibits a
25 company from making false, deceptive, or misleading advertisements to the public, which
26 are designed to sell the company's products. The statute states in pertinent part that:

27 [N]o person, firm, corporation or association, . . . with intent to sell, distribute,
28 increase the consumption of or in any wise dispose of any . . . merchandise . . .
or anything offered by such person, firm, corporation or association, . . . directly

1 or indirectly, to the public for sale, hire, use or other distribution, or with intent
2 to induce the public in any manner to enter into any contract or obligation relating
3 to the purchase, sale, hire, use or lease of any . . . merchandise, . . . shall make,
4 publish, disseminate, circulate, or place before the public, or cause, directly or
5 indirectly, to be made, published, disseminated, circulated, or placed before the
6 public, in this state, . . . an advertisement, announcement, statement or
7 representation of any kind to the public relating to such purchase, sale, hire, use
8 or lease of such . . . merchandise, . . . or to the terms or conditions thereof, which
9 . . . contains any assertion, representation or statement of fact which is untrue,
10 deceptive or misleading.

11 Wis. Stat. § 100.18(1).

12 162. Defendant, with intent to sell, distribute, increase the consumption of, or in any
13 wise dispose of merchandise, services, or other things offered to the public, made,
14 published, disseminated, circulated, or placed before the public assertions, representations,
15 or statements of fact concerning Kids Sleep.

16 163. Defendant's representations were untrue, deceptive, or misleading within the
17 meaning of Wis. Stat. § 100.18(1).

18 164. Defendant's representations were material to a reasonable consumer's
19 purchasing decision.

20 165. In promoting Kids Sleep with deceptive and unlawful safety and efficacy
21 claims, Defendant engaged in a multifaceted advertising campaign—through Kids Sleep
22 product labels and Defendant's website, Amazon pages, and other marketing materials, all
23 of which are controlled by Defendant, to Ms. Hinestrosa and other members of the
24 Wisconsin Subclass, through which Defendant touted that Kids Sleep was a safe and
25 effective treatment for sleeplessness and insomnia in children.

26 166. Defendant's advertising and marketing materials originated from Defendant's
27 headquarters in California, which were then disseminated to consumers throughout the
28 United States, including in Wisconsin to Hinestrosa and the Wisconsin Subclass.

167. Further, Kids Sleep is offered for sale in retail stores such as Walmart
throughout Wisconsin.

168. Defendant's safety representations were false, as Kids Sleep is not safe for children.

169. Defendant had actual and/or constructive knowledge that Kids Sleep was not safe for children, but nonetheless chose to market Kids Sleep with deceptive and unlawful claims.

170. Accordingly, Hinestrosa and members of the Wisconsin Subclass have been exposed to Defendant's ongoing, deceptive advertising campaign and thus suffered monetary loss redressable under Section 100.18.

171. Neither Hinestrosa nor members of the Wisconsin Subclass would have purchased Kids Sleep had they known that the product was not safe for children and offered for sale in violation of federal regulations and Wisconsin law.

172. Kids Sleep had a value of \$0 because it is illegal and unsafe.

173. Defendant violated Section 100.18 by disseminating to the public—including Hinestrosa and members of the Wisconsin Subclass—false, deceptive, and misleading advertising materials about Kids Sleep's purported safety and efficacy.

174. Hinestrosa and the Wisconsin Subclass reasonably relied on Defendant's representations as a material inducement to enter the transactions at issue.

175. Accordingly, Hinestrosa and the Wisconsin Subclass have suffered monetary damages.

176. Pursuant to Wis. Stat. § 100.18(11)(b)(2), Hinestrosa and the Wisconsin Subclass are entitled to recover such pecuniary loss, together with costs, including reasonable attorney's fees.

Seventh Cause of Action

Illinois Consumer Fraud and Deceptive Trade Practices Act

815 ILCS 505/1, et seq.

(On behalf Hinestrosa and the Illinois Subclass)

177. Plaintiffs repeat and reallege the preceding paragraphs as if fully set forth herein.

1 178. Plaintiff Alicia Hinestrosa brings this claim on behalf of herself and the Illinois
2 Subclass.

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

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

6 181. Plaintiff Hinestrosa and the proposed Illinois Subclass are “consumers” who
7 purchased Kids Sleep for personal, family or household use within the meaning of the
8 ICFA, 815 ILCS 505/1(e).

9 182. The ICFA does not apply to “[a]ctions or transactions specifically authorized
10 by laws administered by any regulatory body or officer of this State or the United States.”
11 815 ILCS 505/10b(1).

12 183. The FDCA prohibits the sale of unapproved and misbranded drugs. See 21
13 U.S.C. § 355(a) and 21 U.S.C. § 331(a).

14 184. As set forth above, Kids Sleep is an unapproved and misbranded drug.

15 185. As Kids Sleep is adulterated and misbranded, the FDCA specifically prohibits
16 introduction into interstate commerce, and thus, actions under the ICFA related to Kids
17 Sleep being adulterated and misbranded are not barred by 815 ILCS 505/10b(1).

18 186. The ICFA prohibits engaging in any “unfair or deceptive acts or practices . . .
19 in the conduct of any trade or commerce.” ICFA, 815 ILCS 505/2.

20 187. The ICFA prohibits any deceptive, unlawful, unfair, or fraudulent business
21 acts or practices including using deception, fraud, false pretenses, false promises, false
22 advertising, misrepresentation, or the concealment, suppression, or omission of any
23 material fact, or the use or employment of any practice described in Section 2 of the
24 Uniform Deceptive Trade Practices Act (“UDTPA”). 815 ILCS § 505/2.

25 188. Plaintiff Hinestrosa and the other Illinois Subclass Members reasonably relied
26 upon the product name and Defendant’s representations that the Kids Sleep was safe for
27 children due to Defendant’s representations that “melatonin is a safe supplement for
28 children,” Kids Sleep is “child-safe melatonin,” and that “[m]elatonin works with your

1 child's natural sleep process to safely and effectively promote restful sleep." These claims
2 are misleading in that melatonin supplements are not safe for children.

3 189. Defendant's conduct, as described herein, took place within the State of
4 Illinois and constitutes unfair or deceptive acts or practices in the course of trade and
5 commerce, in violation of 815 ICFA 505/1, et seq.

6 190. Defendant engaged in unfair conduct in violation of the ICFA, including but
7 not limited to selling Kids Sleep with deceptive safety and efficacy claims that rendered
8 the product an unapproved and misbranded drug and selling a product that was intended
9 for children, but not safe for children to consume.

10 191. Defendant engaged in deceptive conduct, including but not limited to
11 misrepresenting that Kids Sleep was safe and effective for children.

12 192. Defendant violated the ICFA by representing that Kids Sleep has
13 characteristics or benefits that it does not have. 815 ILCS § 505/2; 815 ILCS § 510/2(7).

14 193. Defendant advertised Kids Sleep with intent not to sell them as advertised, in
15 violation of 815 ILCS § 505/2 and 815 ILCS § 510/2(9).

16 194. Defendant engaged in fraudulent and/or deceptive conduct which creates a
17 likelihood of confusion or of misunderstanding in violation of 815 ILCS § 505/2; 815 ILCS
18 § 510/2(3).

19 195. Prior to placing Kids Sleep into the stream of commerce and into the hands of
20 consumers to use on their bodies, Defendant knew or should have known that the Kids
21 Sleep was not safe for children to consume, but Defendant misrepresented that the product
22 was safe for children and omitted and concealed facts to consumers, including Plaintiff
23 Hinestrosa and Illinois Subclass Members.

24 196. Defendant intended that Plaintiff Hinestrosa and each of the other Illinois
25 Subclass Members would reasonably rely upon the misrepresentations, misleading
26 characterizations, warranties, and material omissions concerning the true nature of Kids
27 Sleep.

28 197. Given that Defendant is a major supplement retailer and that its products are

1 widely available in stores and online, Plaintiff Hinestrosa and reasonable consumers trusted
2 and relied on Defendant's representations and omissions regarding the safety and efficacy
3 of Kids Sleep.

4 198. Defendant's misrepresentations, concealment, omissions, and other deceptive
5 conduct were likely to deceive and cause misunderstanding and/or in fact caused Plaintiff
6 and each of the other Illinois Subclass Members to be deceived about the true nature of
7 Kids Sleep.

8 199. Plaintiff Hinestrosa and Illinois Subclass Members have been damaged as a
9 proximate result of Defendant's unfair and deceptive violations of the ICFA and have
10 suffered damages as a direct and proximate result of purchasing Kids Sleep.

11 200. As a direct and proximate result of Defendant's violations of the ICFA, as set
12 forth above, Plaintiff Hinestrosa and the Illinois Subclass Members have suffered
13 ascertainable losses of money caused by Defendant's unfair conduct of deceptively
14 marketing Kids Sleep as a safe and effective product for children when in truth, it was an
15 unsafe, adulterated, unapproved, and misbranded drug.

16 201. Had they been aware of the true nature of Kids Sleep, Plaintiff and the Illinois
17 Subclass Members either would have paid less for it or would not have purchased it at all.

18 202. Based on Defendant's unfair and/or deceptive acts or practices, Plaintiff
19 Hinestrosa and the Illinois Subclass Members are therefore entitled to relief, including
20 restitution, actual damages, treble damages, punitive damages, costs, and attorneys' fees,
21 under 815 ILCS 505/10a.

22 **Eighth Cause of Action**

23 **Illinois Consumer Fraud and Deceptive Trade Practices Act**

24 **815 ILCS 510/2, et seq.**

25 **(On behalf Hinestrosa and the Illinois Subclass)**

26 203. Plaintiffs repeat and reallege the preceding paragraphs as if fully set forth
27 herein.

28 204. Plaintiff Alicia Hinestrosa brings this claim on behalf of herself and the Illinois

Subclass.

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

206. Defendant engaged in deceptive trade practices in the conduct of its business, in violation of 815 Ill. Comp. Stat. §§ 510/2(a), including:

- a. Representing that goods or services have characteristics that they do not have;
- b. Representing that goods or services are of a particular standard, quality, or grade if they are of another;
- c. Advertising goods or services with intent not to sell them as advertised; and
- d. Engaging in other conduct that creates a likelihood of confusion or misunderstanding.

207. Defendant's deceptive trade practices include misrepresenting that Kids Sleep is a safe and effective product for children and selling a product that is not safe for children to consume, as described herein.

208. Defendant's representations and omissions were material because they were likely to deceive reasonable consumers, including Plaintiff Hinestrosa and the Illinois Subclass members, about the safety and efficacy of Kids Sleep.

209. The above unfair and deceptive practices and acts by Defendant were immoral, unethical, oppressive, and unscrupulous. These acts caused substantial injury to Plaintiff Hinestrosa and Illinois Subclass members that they could not reasonably avoid; this substantial injury outweighed any benefits to consumers or to competition.

210. As a direct and proximate result of Defendant's unfair, unlawful, and deceptive trade practices, Plaintiff Hinestrosa and Illinois Subclass members have suffered and will continue to suffer injury, ascertainable losses of money or property, and monetary and non-monetary damages.

211. Plaintiff Hinestrosa and Illinois Subclass members seek all monetary and non-monetary relief allowed by law, including injunctive relief and reasonable attorney's fees.

PRAYER FOR RELIEF

WHEREFORE, Plaintiffs, on behalf of themselves, all others similarly situated, and the general public, pray for judgment against Defendant as follows:

- a) An order confirming that this class action is properly maintainable as a class action as defined above, appointing Plaintiffs Mayra Martinez and Alicia Hinestrosa and their undersigned counsel to represent the Class and Subclasses and requiring Defendant to bear the cost of class notice;
- b) An order requiring Defendant to pay \$1,000 in restitution, damages, punitive damages, and interest to each named Plaintiff;
- c) An order requiring Defendant to pay \$10 million or a greater amount to be proven at trial in restitution, damages, and punitive damages to Class members, and \$15,000 to each named Plaintiff as an incentive award, or such greater amount the Court deems fair and reasonable;
- d) An order requiring Defendant to disgorge any benefits received from Plaintiffs and its unjust enrichment realized as a result of its improper and misleading advertising, marketing, sale, and distribution of Kids Sleep;
- e) An order declaring that the conduct complained of herein violates the Unfair Competition Law;
- f) An order requiring Mom Enterprises to cease and desist its deceptive, unconscionable, fraudulent, and unlawful practices;
- g) An order requiring Defendant to engage in a corrective advertising campaign;
- h) A preliminary and permanent injunction prohibiting the conduct described in the Complaint;
- i) An award of prejudgment and postjudgment interest;
- j) An award of attorney fees and costs of \$500,000, or such greater amount the Court awards as fair and reasonable; and
- k) Such other and further relief as this Court may deem just, equitable or proper.

NO JURY DEMAND

Plaintiffs do not demand a jury trial.

DATED: October 12, 2026

Respectfully Submitted,

s/ Gregory S. Weston

Gregory S. Weston

Counsel for Plaintiffs

ClassAction.org

This complaint is part of ClassAction.org's searchable [class action lawsuit database](#)
