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UNITED STATES DISTRICT COURT

FOR THE SOUTHERN DISTRICT OF CALIFORNIA

CHRISTINA BORQUEZ, TRISH FALCON, RANDI GARDNER, and ALICIA HINESTROSA, on behalf of themselves and all others similarly situated,

Plaintiffs,

v.

OLLY PUBLIC BENEFIT CORPORATION,

Defendant.

Case No. '26CV4524 JO AHG
Pleading Type: Class Action

CLASS ACTION COMPLAINT FOR VIOLATIONS OF:

THE UNFAIR COMPETITION LAW, THE FALSE ADVERTISING LAW, AND THE CONSUMER LEGAL REMEDIES ACT

No Jury Demand

TABLE OF CONTENTS

Plaintiffs Christina Borquez, Trish Falcon, Randi Gardner, and Alicia Hinestrosa, on behalf of themselves, all others similarly situated, and the general public, by and through their undersigned counsel, hereby sue Defendant Olly Public Benefit Corporation ("Olly" or "Defendant") and upon information and belief and investigation of counsel, allege as follows:

I. JURISDICTION AND VENUE

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

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

II. PARTIES

3. Defendant Olly Public Benefit Corporation is a Delaware corporation with its principal place of business in San Francisco, California.

4. During the class period, Olly manufactured, marketed, and sold Olly Kids Sleep ("Kids Sleep"). Defendant marketed Kids Sleep with illegal drug claims that deceptively promised prescription sleep disorder drug effects. In truth, the product was not safe for children.

5. Plaintiff Christina Borquez is a citizen and resident of California who purchased Kids Sleep during the class period for household consumption.

6. Plaintiff Trish Falcon is a citizen and resident of California who purchased

Kids Sleep during the class period for household consumption.

7. Plaintiff Randi Gardner is a citizen and resident of Arizona who purchased Kids Sleep during the class period for household consumption.

8. Plaintiff Alicia Hinestrosa is a citizen and resident of Wisconsin who purchased Kids Sleep during the class period for household consumption.

III. SUMMARY OF CLAIMS

9. During the class period, Olly marketed, distributed, and sold Kids Sleep. Defendant claims that Kids Sleep is a "gentle supporter of sleep" that "delivers a kid-friendly amount of melatonin to support healthy sleep cycles and help little one's rest" and "promote[s] peaceful slumber."

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

11. Defendant's representations mislead consumers into believing that Kids Sleep is safe and effective for its intended purposes.

12. Plaintiffs purchased Kids Sleep (1) in reliance on Defendant's deceptive safety and efficacy claims and (2) with the belief that the product was safe, (3) was effective, and (4) was sold in compliance with state and federal regulations.

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

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

IV. REGULATORY BACKGROUND

15. "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).

16. 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).

17. 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.

18. 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."

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

V. THE SALE OF UNAPPROVED DRUGS HARMS THE PUBLIC.

20. "Unapproved prescription drugs pose significant risks to patients because they

have not been reviewed by FDA for safety, effectiveness or quality."[1]

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

22. "Unapproved drugs have resulted in patient harm, and the [FDA] works to protect patients from the risks posed by these drugs." *Id.*

23. Unapproved drugs lack "labels and prescribing information that has" "been reviewed by FDA for accuracy and completeness."[2]

24. Consumers using unapproved drugs run the risk of "unexpected and undocumented safety concerns due to lack of rigorous pre- and postmarket safety surveillance." *Id.*

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

VI. MELATONIN, THE PRIMARY ACTIVE INGREDIENT IN KIDS SLEEP, IS NOT SAFE FOR CHILDREN

26. On the packaging of Kids Sleep, Olly claims that the product is a "mild blend" and "gentle supporter of sleep" that "works with little bodies to promote peaceful slumber." Olly further claims Kids Sleep is for "ages 4 and up."

27. On its website, Olly claims that "Kids Sleep delivers a kid-friendly amount of Melatonin to support healthy sleep cycles and help little ones rest."[3]

28. These claims are misleading, as melatonin supplements are not safe for children.

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[1] U.S. Food & Drug Admin., Unapproved Drugs (June 2, 2021), available at www.fda.gov/drugs/enforcement-activities-fda/unapproved-drugs.

[2] 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.

[3] Olly Public Benefit Corporation, Kids Sleep, available at www.olly.com/products/kids-sleep (last visited July 30, 2026).

29. The "use of melatonin supplements as a sleep aid for children is becoming more common. The number of children taking melatonin at least once a month has risen nearly 20-fold since 2018. From 2012 to 2021, calls to poison control centers reporting melatonin ingestion in children rose 530%, and sales of the supplement have doubled since 2017."[4]

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

31. "Melatonin is not recommended for children under 5." *Id.*

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

33. "Taking too much melatonin can have adverse effects . . . Exceeding the dosage recommended by a doctor can lead to daytime grogginess, while more severe effects include diarrhea, vomiting, confusion, short-term depression, and an increased risk of seizures." *Id.*

34. There "have been many reports of melatonin overdoses in children."[5]

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

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[4] Tufts U. School of Medicine. *Is Melatonin Safe for Kids?* (March 11, 2024), available at https://medicine.tufts.edu/news-events/news/melatonin-safe-kids.

[5] Claire McCarty, MD. *New advice on the use of melatonin in children*. Harvard University School of Public Health (October 6, 2022).

36. Children "don't need [melatonin] to get a good night's sleep." *Id.*

37. From "2012-2021, there were more than 260,000 child poisoning reports involving melatonin . . . [S]ome children needed hospital care and two children died."[6]

38. There are "concerns about how [melatonin] might affect a child's growth and development, particularly during puberty. Studies have also found that morning sleepiness, drowsiness, and possible increased urination at night are the most common side effects that occur while taking melatonin. Further, melatonin may interact with other medicines a child takes." *Id.*

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

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

41. "[N]early 20% of the poison-control calls reported some symptoms, which included gastrointestinal distress, cardiovascular symptoms, and more. Melatonin has not been well-studied in children, even though about 10% of U.S. parents have at least one child who takes it, according to *Consumer Reports*."[8]

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

[7] Kim CY, Yousef P, Gilad R, Shapiro CM. *The Use and Misuse of Over-the-Counter Melatonin in Children and Adolescents: A Commentary*. Can J Psychiatry. 2025 May.

[8] Weis, H. *Some Melatonin Supplements Have Dramatically Different Dosages Than Advertised, New Study Says*. Time (April 25, 2023).

42. 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.

43. "The great majority of melatonin gummy products were inaccurately labeled, with most products exceeding the declared amount of melatonin."[9]

44. 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 ±10% of the declared quantity." *Id.*

45. "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.*

46. "Administration of as little as 0.1 mg to 0.3 mg of melatonin to young adults can increase plasma concentrations into the normal nighttime range. **Consuming melatonin gummies as directed could expose children to between 40 and 130 times higher quantities of melatonin**." *Id.* (emphasis added).

47. "Unintentional ingestions could lead to consumption that greatly exceeds these dosages of melatonin." *Id.*

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[9] Cohen PA, Avula B, Wang Y, Katragunta K, Khan I. *Quantity of Melatonin and CBD in Melatonin Gummies Sold in the US*. JOURNAL OF THE AMERICAN MEDICAL ASSOCAITION. 2023;329(16):1401–1402.

48. "Given these findings, clinicians should advise parents that pediatric use of melatonin gummies may result in ingestion of unpredictable quantities of melatonin." *Id.*

49. The Mayo Clinic likewise notes that it is "unclear whether melatonin supplements are safe for children."[10]

50. "When sleep issues are a long-term problem for children, evaluating sleep habits and the environment can identify the causes of those issues. Many sleep-related disturbances in children can be addressed with a consistent nighttime and sleep routine." *Id.*

51. "In gummy form, melatonin supplements can be enticing for children, leading to a risk of overconsumption. Taking a large dose of melatonin can cause gastrointestinal issues or irritability. A large dose also can keep your child's body from naturally producing melatonin to make them sleepy." *Id*.

52. The concern stated here is for American adults, who average 170lbs, taking "0.1 mg to 0.3 mg" of melatonin. Olly's dosage for small children weighing as little as 20lbs is to take one or two 0.5mg gummies. This is absolutely reckless advice and amounts to giving a small developing brains mega-doses of a hormone. There are no studies of the effects of giving small children such amounts over an extended period, but strong concerns that it is unsafe to do so.

53. A 2023 review article determined that

> Children who use melatonin are likely to experience non-serious adverse events, yet the actual extent to which melatonin leads to non-serious adverse events and the long-term consequences remain uncertain. This major gap of knowledge on safety calls for caution against complacent use of melatonin in children and adolescents with chronic insomnia and for more research to inform clinicians and

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

guideline panels on this key issue.[11]

54. Another recent review article noted that

> Melatonin is the leading cause of unsupervised medication exposure and overdose in emergency departments for young children (aged 0-6 years). Existing literature has documented the benefits of melatonin in older children (aged 7-18 years) with neurologic conditions but has yet to examine young children.[12]

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

56. Olly's representations that Kids Sleep is a "mild blend" and a "gentle supporter of sleep that works with little bodies," and that it "delivers a kid-friendly amount of Melatonin to support healthy sleep cycles and help little ones rest," are separately misleading because melatonin supplements are not safe for children and do not "support healthy sleep cycles."

57. 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."[13]

VII. KIDS SLEEP'S SPECIFIC MISREPRESENTATIONS, MATERIAL OMISSIONS, AND DRUG CLAIMS.

A. Kids Sleep's Packaging

58. During the class period, Olly marketed Kids Sleep with deceptive efficacy

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[11] Händel MN, et al. *The short-term and long-term adverse effects of melatonin treatment in children and adolescents: a systematic review and GRADE assessment*. EClinicalMedicine. 2023 Jul 6;61:102083.

[12] Kracht CL, et al. *Melatonin Use in Young Children: A Systematic Review.* JAMA Netw Open. 2026 Jan 2.

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

claims that suggest that the product can affect the structure or function of the human body by treating insomnia and sleeplessness and by promoting healthy sleep cycles.

59. These claims are misleading, as none of the ingredients in Kids Sleep, either individually or in combination, safely and effectively treats insomnia or sleeplessness in children.

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

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

62. The packaging of Kids Sleep is pictured below.

63. During the Class Period, the "Kids Sleep" label claimed that the product is a "gentle supporter of sleep" that "works with little bodies to promote peaceful slumber" and "is just the right thing for those occasional restless nights." Defendant further claims that the product is "for occasional sleeplessness" and "for occasional sleep support."

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

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

B. Olly's Web and Amazon Pages for Kids Sleep

66. Olly advertises Kids Sleep with further deceptive efficacy claims online that suggest the product can provide prescription sleep disorder drug benefits.

67. The Kids Sleep label, Defendant's website, olly.com, and the Kids Sleep Amazon page, which Olly controls, contained the following claims, which show that the product is intended to affect the structure and function of the body, and to cure, mitigate, treat, or prevent disease, during the Class Period:

- "Kids Sleep"
- "For occasional sleeplessness"
- "When bedtime needs a boost"
- "works well with little bodies to promote peaceful slumber"
- "This mild blend is just the thing for those occasional restless nights."
- "Sleep gummy"
- "OLLY Kids Sleep delivers a kid-friendly amount of Melatonin to support healthy sleep cycles and help little ones rest"
- "EASY AS 1, 2, ZZZ's: When kids need a little bit of sleep support to catch some ZZZ's reach for OLLY Sleep"
- "Sleep is on the way"
- "Helps you fall asleep and stay asleep"
- "helps little ones maintain healthy sleep cycles"

68. These claims suggest Kids Sleep can treat insomnia and sleeplessness in children and affect the structure and function of the human body by improving sleep and promoting healthy sleep cycles.

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

70. True and correct copies of screenshots of the Kids Sleep page from Defendant's website, olly.com, are attached hereto as **Exhibit 1.**

71. True and correct copies of screenshots of the Amazon page for Kids Sleep, which Olly controls, are attached hereto as **Exhibit 2**.

72. Olly failed to obtain FDA approval prior to marketing, distributing, and selling Kids Sleep.

VIII. KIDS SLEEP IS AN UNAPPROVED NEW DRUG.

73. "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).

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

75. The claims on the packaging of Kids Sleep, Olly's website, and Olly's Amazon page for Kids Sleep render the product an unapproved new drug.

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

- "is used for insomnia, sleep apnea" (**Exhibit 3**, FDA Warning Letter to SANA Group, LLC);
- "most commonly used for sleep disorders, especially the inability to sleep (insomnia)" (**Exhibit 3**);
- "Maintain and aid healthy sleep cycles" (**Exhibit 4**, FDA Warning Letter to MB Solutions, LLC/BioSpectrum CBD).

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

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

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

80. Defendant's failure to comply with these regulations puts consumers at risk and gives Olly an unfair advantage over competitors that do commit the time and expense

of complying with such necessary regulations.

81. Kids Sleep does not qualify for the reduced level of regulation applicable to certain nutritional supplement products for several reasons. The Kids Sleep label, Olly's website, and Olly's marketing materials neither describe the role of any nutrient or dietary ingredient intended to affect the structure or function in humans, characterize the documented mechanism by which any nutrient or dietary ingredient acts to maintain such structure or function, nor describe general well-being from consumption of any nutrient or dietary ingredient. 21 U.S.C. § 343(r)(6)(A).

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

IX. DEFENDANT'S PRACTICES WERE "UNFAIR" WITHIN THE MEANING OF THE UNFAIR COMPETITION LAW.

83. Defendant's practices as described herein are "unfair" within the meaning of the California Unfair Competition Law because Olly'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.

84. In particular, while Defendant's marketing of Kids Sleep with deceptive safety, efficacy, and "drug" claims as defined by 21 U.S.C. § 321(g) and absent FDA approval to do so allowed Olly 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.

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

85. Defendant's practices as described herein are "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 have been adopted by California:

- **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.

86. The fraudulent marketing and advertising of Kids Sleep also violates the CLRA and False Advertising Law and further constitutes a violation of the FDCA and the Sherman Law and, as such, violates the "unlawful" prong of the UCL.

87. 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.

88. 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.

89. 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.

XI. PLAINTIFFS' PURCHASES OF KIDS SLEEP

90. Plaintiff Christina Borquez repeatedly purchased Kids Sleep for household use primarily from CVS, Walmart, and Target locations in the San Jose area. Her first purchase occurred in approximately 2021, and her most recent purchase occurred in late 2025.

91. Plaintiff Trish Falcon repeatedly purchased Kids Sleep for household use primarily from Target locations in the Anaheim area. Her first purchase occurred in approximately 2024, and her most recent purchase occurred in 2026. She purchased the product approximately once every four to six months during this period.

92. Plaintiff Randi Gardner repeatedly purchased Kids Sleep for household use primarily from Walmart locations in the Tucson, Arizona area and from Amazon. Her first purchase occurred in early 2026, and her most recent purchase occurred in June 2026. She purchased Kids Sleep approximately three times during this period.

93. Plaintiff Alicia Hinestrosa repeatedly purchased Kids Sleep for household use primarily from Walmart locations in the Racine, Wisconsin area. Her first purchase occurred in early 2025, and her most recent purchase occurred in late 2025. She purchased Kids Sleep twice.

94. In deciding to purchase Kids Sleep, Plaintiffs relied on Defendant's deceptive safety and efficacy representations and fraudulent omissions.

95. Plaintiffs used Kids Sleep as directed, but the product failed to deliver the advertised benefits.

96. Because Plaintiffs expected these statements to be true and honest, but they were not, they did not receive the benefit of their purchases.

XII. RELIANCE AND INJURY

97. Plaintiffs purchased and used Kids Sleep in reliance on Defendant's deceptive safety and efficacy representations described herein and would not have purchased the product absent Defendant's deceptive advertising.

98. When Plaintiffs purchased Kids Sleep, they were seeking a safe and effective product that would treat insomnia and sleeplessness in children and promote healthy sleep cycles in children.

99. Plaintiffs purchased Kids Sleep with the natural assumption that products sold in stores and online by large companies would be safe, would deliver the advertised benefits, and would be sold in compliance with applicable state and federal law.

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

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

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

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

XIII. CLASS ACTION ALLEGATIONS

104. 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.

105. The California Subclass is defined as:

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

106. The Arizona Subclass is defined as:

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

107. The Wisconsin Subclass is defined as:

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

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

a. Whether Defendant's conduct constituted a violation of the unfair prong of California's Unfair Competition Law;

b. Whether Defendant's conduct constituted a violation of the unlawful prong of California's Unfair Competition Law;

c. Whether Defendant's conduct constituted a violation of the fraudulent prong of California's Unfair Competition Law;

d. Whether Olly communicated safety and efficacy messages through Kids Sleep's labeling, packaging, and website;

e. Whether those messages were material, or likely to be material, to a reasonable consumer;

f. Whether those messages were false, at variance with the truth, misleading, likely to deceive, and/or had the capacity to deceive the public and/or a reasonable consumer;

g. Whether Olly fraudulently omitted material information in advertising Kids Sleep as safe and effective;

h. Whether Olly sold and distributed Kids Sleep to the public in misleading packaging that was likely to deceive the public;

i. Whether Kids Sleep is an unapproved new drug;

j. Whether Defendant's conduct was immoral, unethical, unscrupulous, or substantially injurious to consumers;

k. Whether the slight utility Defendant realized as a result of its conduct outweighs the gravity of the harm the conduct caused to its victims;

l. Whether Defendant's conduct violated public policy as declared by specific constitutional, statutory, or regulatory provisions;

m. Whether the injury to consumers from Defendant's practices is substantial;

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

o. Whether Class members are entitled to restitution;

p. Whether Class members are entitled to damages and/or punitive damages;

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

r. Whether Class members are entitled to any further relief.

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

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

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

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

113. Class representation is superior to other options for the resolution of the

controversy. The relief sought for each Class member is small, as little as $10 for some Class members. Absent the availability of class action procedures, it would be infeasible for Class members to redress the wrongs done to them.

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

CAUSES OF ACTION

First Cause of Action

Unfair Competition Law, Unlawful Prong

Bus. & Prof. Code § 17200 et seq.

(On behalf of Borquez, Falcon, the Class, and the California Subclass)

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

116. The acts, omissions, misrepresentations, practices, and nondisclosures of Defendant as alleged herein constitute "unlawful" business acts and practices in that Defendant's conduct violates the California False Advertising Law and the California Consumer Legal Remedies Act, as alleged herein.

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

118. The fraudulent marketing of Kids Sleep described herein constitutes a violation of the FDCA and the Sherman Law and, as such, violated the "unlawful" prong of the UCL.

119. Had Plaintiffs known that Kids Sleep was not safe and effective and offered for sale in violation of California and federal regulations, they would not have purchased it.

120. Plaintiffs 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, effective, legal, less expensive, and do not make misleading or false drug claims on their packaging.

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

122. Had Plaintiffs been aware of Defendant's false and misleading advertising tactics, they would not have purchased Kids Sleep, and had Defendant not advertised Kids Sleep in a fraudulent manner, Plaintiffs would have paid less for it.

123. 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, Fraudulent Prong

Bus. & Prof. Code § 17200 et seq.

(On behalf of Borquez, Falcon, the Class, and the California Subclass)

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

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

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

127. 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.

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

129. 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, Unfair Prong

Bus. & Prof. Code § 17200 et seq.

(On behalf of Borquez, Falcon, the Class, and the California Subclass)

130. The acts, omissions, misrepresentations, practices, and nondisclosures of Defendant as alleged herein constitute "unfair" business acts and practices because Defendant's conduct:

- 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.

131. 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.

Fourth Cause of Action

False Advertising Law

Cal. Bus. & Prof. Code § 17500 et seq.

(On behalf of Borquez, Falcon, the Class, and the California Subclass)

132. In violation of Cal. Bus. & Prof. Code § 17500 et seq., the advertisements, labeling, policies, acts, and practices described herein were designed to, and did, result in the purchase and use of Kids Sleep without the knowledge that the product makes misleading and unapproved claims.

133. Defendant knew and reasonably should have known that the claims made on Kids Sleep's label, packaging, and website were untrue and misleading.

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

135. 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; awarding Plaintiffs and the Class restitution of all monies from the sale of Kids Sleep in an amount of $5 million or a greater amount to be proven at trial, actual and punitive damages, and interest to Plaintiffs, an incentive award to Plaintiffs in conjunction with a class award or injunction, and for attorneys' fees and costs to be awarded by the Court in accordance with applicable law, including the Private Attorney General Statute.

Fifth Cause of Action

Consumer Legal Remedies Act

Civil Code § 1750 et seq.

(On behalf of Borquez, Falcon, the Class, and the California Subclass)

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

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

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

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

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

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

141. Defendant received Plaintiffs' written notice.

Sixth Cause of Action

Arizona Consumer Fraud Act

A.R.S. § 44-1521 et seq.

(On behalf of Gardner and the Arizona Subclass)

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

143. Plaintiff Randi Gardner brings this claim on behalf of herself and the Arizona Subclass.

144. Plaintiff Gardner and Subclass members are "persons" within the meaning of the Arizona Consumer Fraud Act.

145. Kids Sleep constitutes "merchandise" under A.R.S. § 44-1521.

146. Defendant's marketing, solicitation, communications, and transaction materials constitute "advertisements" within the meaning of the Act.

147. In connection with the sale or advertisement of merchandise, Defendant used deception, deceptive or unfair acts or practices, false promises, misrepresentations, and/or concealment, suppression, or omission of material facts.

148. Specifically, Defendant represented that Kids Sleep safely and effectively treated sleeplessness and insomnia in children and could promote healthy sleep cycles.

149. Those representations were false or misleading because Kids Sleep is not safe for children, is not recommended by pediatricians, and is an unapproved drug.

150. Defendant also concealed or omitted that Kids Sleep is not safe for children.

151. Defendant intended that consumers rely on the omission and proceed with the transaction without knowing the concealed fact.

152. Defendant's representations and omissions were material because they concerned the safety and quality of Kids Sleep.

153. Plaintiff Gardner was exposed to and relied on Defendant's deceptive representation or omission when she purchased Kids Sleep.

154. Plaintiff's reliance was actual and caused her either to pay money she otherwise would not have paid or to pay more than she otherwise would have paid.

155. Subclass members were subjected to Defendant's materially uniform representations and course of conduct and suffered the same form of economic injury.

156. Defendant's conduct directly and proximately caused Plaintiff and Subclass members actual damages.

157. Defendant's conduct was knowing, deliberate, and undertaken despite notice that its representations were false or misleading.

158. Plaintiff Gardner and Subclass members are entitled to recover actual damages and all other relief permitted by Arizona law.

159. Plaintiff Gardner also seeks punitive damages to the extent the evidence

establishes the requisite aggravated, malicious, fraudulent, or consciously wrongful state of mind.

Seventh Cause of Action

Wis. Stat. § 100.18

(On behalf of Hinestrosa and the Wisconsin Subclass)

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

161. Plaintiff Alicia Hinestrosa brings this claim on behalf of herself and the Wisconsin Subclass.

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

> [N]o person, firm, corporation or association, . . . with intent to sell, distribute, increase the consumption of or in any wise dispose of any . . . merchandise . . . or anything offered by such person, firm, corporation or association, . . . directly or indirectly, to the public for sale, hire, use or other distribution, or with intent to induce the public in any manner to enter into any contract or obligation relating to the purchase, sale, hire, use or lease of any . . . merchandise, . . . shall make, publish, disseminate, circulate, or place before the public, or cause, directly or indirectly, to be made, published, disseminated, circulated, or placed before the public, in this state, . . . an advertisement, announcement, statement or representation of any kind to the public relating to such purchase, sale, hire, use or lease of such . . . merchandise, . . . or to the terms or conditions thereof, which . . . contains any assertion, representation or statement of fact which is untrue, deceptive or misleading.

Wis. Stat. § 100.18(1).

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

164. Defendant's representations were untrue, deceptive, or misleading within the

meaning of Wis. Stat. § 100.18(1).

165. Defendant's representations were material to a reasonable consumer's purchasing decision.

166. In promoting Kids Sleep with deceptive and unlawful safety and efficacy claims, Defendant engaged in a multifaceted advertising campaign directed to Ms. Hinestrosa and other members of the Wisconsin Subclass through Kids Sleep product labels, Defendant's website, Amazon pages, and other marketing materials, all of which Defendant controlled. Through that campaign, Defendant touted Kids Sleep as a safe and effective treatment for sleeplessness and insomnia in children.

167. Defendant's advertising and marketing materials originated at Defendant's headquarters in California and were then disseminated to consumers throughout the United States, including in Wisconsin to Hinestrosa and the Wisconsin Subclass.

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

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

170. 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.

171. 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.

172. 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.

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

174. 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.

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

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

177. 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 attorneys' 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 Christina Borquez, Trish Falcon, Randi Gardner, and Alicia Hinestrosa as Class representatives and appointing their undersigned counsel as Class counsel, 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 Plaintiff;

c) An order requiring Defendant to pay $5 million or a greater amount to be proven at trial in restitution, damages, and punitive damages to Class members, and $15,000 to each Plaintiff as an incentive award, or such greater amount the Court deems fair and reasonable;

d) An order requiring Defendant to disgorge any benefits it received from Plaintiffs and any unjust enrichment it 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 Defendant 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 temporary and permanent injunction prohibiting the conduct described in the Complaint;

i) An award of prejudgment and postjudgment interest;

j) An award of attorneys' 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: August 7, 2026

Respectfully Submitted,

s/Gregory S. Weston
Gregory S. Weston

Counsel for Plaintiffs

EXHIBIT 1

Kids Sleep

$13.99

4.5 (267) Write a review

For occasional sleep support*

Size: **25 Servings**

- 25 Servings $13.99
- 35 Servings $17.99
- 30 Serving Pouch $14.99

- (●) One time purchase $13.99
- ( ) Subscribe & Save ~~$13.99~~ $11.89

Save 15% when you subscribe

Deliver Every 1 month (Most Popular)

1 ADD TO CART

You may also like

Kids Chillax
$13.99
AMOUNT

Metabolism Gummy Rings
$19.99
AMOUNT

DETAILS HOW TO TAKE IT

Ages 4 and up, start with 1 OLLY Sleep gummy and give up to 2 gummies as needed 30 minutes before bedtime. Chew thoroughly before swallowing.

DETAILS HOW TO TAKE IT

Kiddos thrive on routine, so troublesome bedtimes can be a real setback. This mild blend is just the thing for those occasional restless nights.* Sweet dreams little one.

- Razzzberry flavored with other natural flavors
- A blend of Melatonin, L-Theanine & Botanical Extracts

Frequently Bought Together

This item:

Kids Sleep

$13.99

Kids Chillax

$13.99

Kids Multi & Probiotic Multi Vitamins

$13.99

Metabolism Gummy Rings

$19.99

Total Price: $61.96

ADD TO CART

How It Works

OLLY Kids Sleep delivers a kid-friendly amount of Melatonin to support healthy sleep cycles and help little ones rest* and a traditional botanical extracts blend.

The Goods Inside

MELATONIN

This gentle supporter of sleep works with little bodies to promote peaceful slumber.*

BOTANICAL EXTRACTS

A blend of traditionally used herbal helpers: Chamomile, Passionflower and Lemon Balm Extracts.

DELIGHTFULLY TASTY

Blissful red raspberry flavored with other natural flavors.

NSF Certified

CONTENTS CERTIFIED NSF

NSF certification helps consumers identify products that have been independently tested and certified to meet rigorous standards for quality, safety, and label claims.

*These statements have not been evaluated by the Food and Drug Administration. This product is not intended to diagnose, treat, cure or prevent any disease.

Melatonin may cause drowsiness or sleepiness; do not take when driving, operating machinery, or engaging in any activity that requires alertness. This product is not intended to treat insomnia or other sleep disorders.

Frequently Asked Questions

What is OLLY Kids Sleep for?

It’s a mild blend for occasional sleep support that helps little ones maintain healthy sleep cycles.*

Who can take OLLY Kids Sleep and how much should they have?

It’s for ages 4 and up; start with 1 gummy and give up to 2 as needed 30 minutes before bedtime, and chew thoroughly.

How much melatonin is in each gummy?

Each gummy contains 0.5 mg of melatonin.

What ingredients are inside?

A blend of melatonin, L-Theanine, and traditional botanical extracts: chamomile, passionflower, and lemon balm.

What does it taste like?

Blissful red raspberry flavored with other natural flavors.

Is OLLY Kids Sleep intended to treat insomnia or sleep disorders?

No—this product is for occasional sleep support and is not intended to treat insomnia or other sleep disorders.

Are there any cautions I should know about?

Melatonin may cause drowsiness; do not give when your child needs to be alert or active.

Is OLLY Kids Sleep NSF Certified?

Yes, it’s NSF Certified to meet rigorous standards for quality, safety, and label claims.

What sizes are available?

25 servings, 35 servings, and a 30-serving pouch.

Do you offer a melatonin-free kids sleep option?

Yes—OLLY also offers Kids Melatonin Free Sleep.


OLLY
KIDS
SLEEP
For Occasional Sleep Support*
Melatonin, L-Theanine
& Botanicals
50
GUMMIES
DIETARY SUPPLEMENT
RAZZBERRY
Flavored with other Natural Flavors


OLLY
WHEN BEDTIME NEEDS A BOOST
Kiddos thrive on routine, so trouble-some bedtimes can be a real setback. This mild blend is just the thing for those occasional restless nights.* Sweet dreams, little one.
THE GOODS INSIDE
MELATONIN
This gentle supporter of sleep works with little bodies to promote peaceful slumber.*
BOTANICAL EXTRACTS
A blend of traditionally used herbal helpers: Chamomile, Passionflower and Lemon Balm.
No Synthetic Flavors or Colors
Gluten Free
For more info on Kids Sleep visit OLLY.com
‡Reduce dose if excessive sleepiness occurs.
* THESE STATEMENTS HAVE NOT BEEN EVALUATED BY THE FOOD AND DRUG ADMINISTRATION. THIS PRODUCT IS NOT INTENDED TO DIAGNOSE, TREAT, CURE OR PREVENT ANY DISEASE.
50
GUMMIES


OLLY
RAZZBERRY
Flavored with other Natural Flavors
Supplement Facts
Serving Size 1 or 2 Gummies
Servings Per Container 50 or 25
Amount Per Serving
% DV for Children 4 Yrs of Age & Older (1 Gummy)
% DV for Children 4 Yrs of Age & Older (2 Gummies)
Calories 10 15
Total Carbohydrate 2 g <1%† 3 g 1%†
Total Sugars 1 g ** 2 g **
Incl. Added Sugars 1 g 2%† 2 g 4%†
Sodium <5 mg <1% 5 mg <1%
Melatonin 0.5 mg ** 1 mg **
L-Theanine 15 mg ** 30 mg **
Chamomile Extract (flower) 2.5 mg ** 5 mg **
Passionflower Extract (aerial parts) 2.5 mg ** 5 mg **
Lemon Balm Extract (aerial parts) 2.5 mg ** 5 mg **
†Percent Daily Values (DV) are based on a 2,000 calorie diet. **DV not established.
Other Ingredients: Glucose Syrup, Sugar, Water, Gelatin, Pectin, Citric Acid, Natural Flavor, Sodium Citrate, Coloring (from carrot and black currant juices), Vegetable Oil (coconut) and Carnauba Wax (to prevent sticking).


OLLY
acts
Distributed by: OLLY Public Benefit Corp. San Francisco, CA 94111
hello@OLLY.com · 1-844-HEY-OLLY
Suggested Use: Ages 4 and up, start with 1 gummy and give up to 2 gummies as needed 30 minutes before bedtime‡ Chew thoroughly before swallowing.
Processed in a facility with products that may contain soy, egg, peanuts, tree nuts, milk, fish, shellfish, wheat and sesame.
For occasional sleeplessness. Not for use in children under the age of 4. Discuss with child's health care professional prior to use. Use only as directed and do not exceed suggested use. For occasional, short-term use only. Limit any consecutive use to less than 2 weeks. OLLY Kids Sleep should never substitute for healthy sleep practices including a regular, age-appropriate bedtime and bedtime routine.
To ensure quality and potency through expiration, this product is manufactured with higher active ingredient levels than the indicated amount per serving.
CAUTION: Melatonin may cause drowsiness or sleepiness; do not take when driving, operating machinery, or engaging in any activity that requires alertness. This product is not intended to treat insomnia or other sleep disorders.
Do not use if inner seal is broken or missing. Store in a cool, dry place.
KEEP OUT OF THE REACH OF CHILDREN.
Discard Seal, Empty & Replace Cap
how2recycle.info
PLASTIC BOTTLE
OLLY.com
CONTENTS CERTIFIED NSF
Certified B Corporation
8 50004 46206 5
© 2024 OLLY PBC 300351.02
* THESE STATEMENTS HAVE NOT BEEN EVALUATED BY THE FOOD AND DRUG ADMINISTRATION. THIS PRODUCT IS NOT INTENDED TO DIAGNOSE, TREAT, CURE OR PREVENT ANY DISEASE.

EXHIBIT 2

Health & Household › Vitamins, Minerals & Supplements › Sleep Supplements

Click to see full view

Ask Rufus

Do these gummies have a chewy texture?

Can these gummies be taken with other supplements?

Are these gummies made with natural ingredients?

Ask something else

OLLY Kids Sleep Gummies, 0.5mg Melatonin, L Theanine, Chamomile, and Lemon Balm, Raspberry - 70 Count

Visit the OLLY Store

4.7 ★★★★½ (5,772) | Search this page

Best price

Overall Pick

9K+ bought in past month

-14% $15.47 ($0.22 / count)

List Price: ~~$17.99~~ | Price history

Save 30% on 1 when you buy 2

Shop items ›

With **Amazon Business**, you would have **saved $176.78** in the last year. Create a free account and **save up to 15%** today. Available at a lower price from other sellers that may not offer free Prime shipping.

Style: **Bottle**

Size: **70 Count (Pack of 1)**

50 Count (Pack of 1)	70 Count (Pack of 1)	90 Count (Pack of 1)	
$11.47 ($0.23 / count) ~~$13.99~~	$15.47 ($0.22 / count) ~~$17.99~~	$17.87 ($0.20 / count) ~~$21.99~~	See 1 options with no featured offers

Brand	OLLY
Primary Supplement Type	Melatonin
Flavor	Kid's Sleep
Unit Count	70 Count
Item Form	Gummy

See more

About this item

- OLLY KIDS SLEEP GUMMIES: Kiddos thrive on routine so troublesome bedtimes can be a real setback. This mild blend for sleep support is just the thing for those occasional restless nights. Sweet dreams little one*
- THE GOODS INSIDE: Kids Sleep supplement gummies deliver a mild blend of Melatonin (0.5mg) to support healthy sleep cycles*, including L-Theanine and a mix of traditionally used herbal helpers: Chamomile, Passionflower and Lemon Balm Extracts.

prime

Enjoy fast, free delivery, exclusive deals, and award-winning movies & TV shows.

Join Prime

One-time purchase: $15.47 ($0.22 / count)

FREE delivery **Saturday, January 24** on orders shipped by Amazon over $35

Or Prime members get FREE delivery **Today 2 PM - 6 PM** on eligible orders. Order within 1 hr 31 mins. Join Prime

Deliver to David - San Diego 92116

In Stock

Quantity: 1

Add to cart

Buy Now

Shipper / Seller	Amazon.com
Returns	Non-returnable due to Food safety reasons
Payment	Secure transaction

See more

Subscribe & Save $14.70 ($0.21 / count)

FREE delivery Saturday, January 24 on orders shipped by Amazon over $35

Shipper / Seller: Amazon.com

Add to List

Other sellers on Amazon

New (3) from $15.45 & **FREE Shipping** ›

amazon business

Save up to 15% on this product with business-only pricing.

Create a free account

Click to see full view

Rufus

ese gummies have a chewy texture?

nese gummies be taken with other supplements?

ese gummies made with natural ingredients? Ask something else

- HOW TO TAKE: Ages 4 and up, start with 1 gummy and give up to 2 gummies as needed 30 minutes before bedtime. Chew thoroughly before swallowing.
- DELIGHTFULLY TASTY: OLLY Sleep gummies come in Razzzberry flavor with other natural flavors, no synthetic colors or flavors and are gluten free. These sleep support* supplements are a delightful blend of drug-free ingredients. 50 gummies per bottle.
- MIX AND MATCH: We create products that are just as effective as they are delicious— wellness boost gummies, powders, premium softgels and more ways to feel happy inside out.
- EASY AS 1, 2, ZZZ's: When kids need a little bit of sleep support to catch some ZZZ's reach for OLLY Sleep supplements because life doesn't come with a snooze button. Sleep support to help kids age 4+ fall into a sweet slumber.*
- NEW NEWS: We've made improvements to the taste and texture of our products—with the same OLLY goodness inside each gummy

Report an issue with this product or seller

Important information

Safety Information

Not for use in children under the age of 4. Discuss with child's healthcare professional prior to use. Use only as directed and do not excess suggested dose. For occasional short term use only. Limit any consecutive use to less than 2 weeks. Olly Kids Sleep should never substitute for healthy sleep practice including a regular age appropriate bedtime and bedtime routine.

Ingredients

L-Theanine, Melatonin, Chamomile Extract (flower), Passionflower Extract, Lemon Balm Extract, Glucose Syrup, Beet Sugar, Water, Gelatin, Citric Acid, Natural Flavors, Coloring (from carrot and blackcurrant juices), Pectin, Vegetable Oil (coconut, canola), Carnauba Wax (to prevent sticking)

Directions

Ages 4 and up, start with 1 gummy and give up to 2 gummies as needed 30 minutes before bedtime.

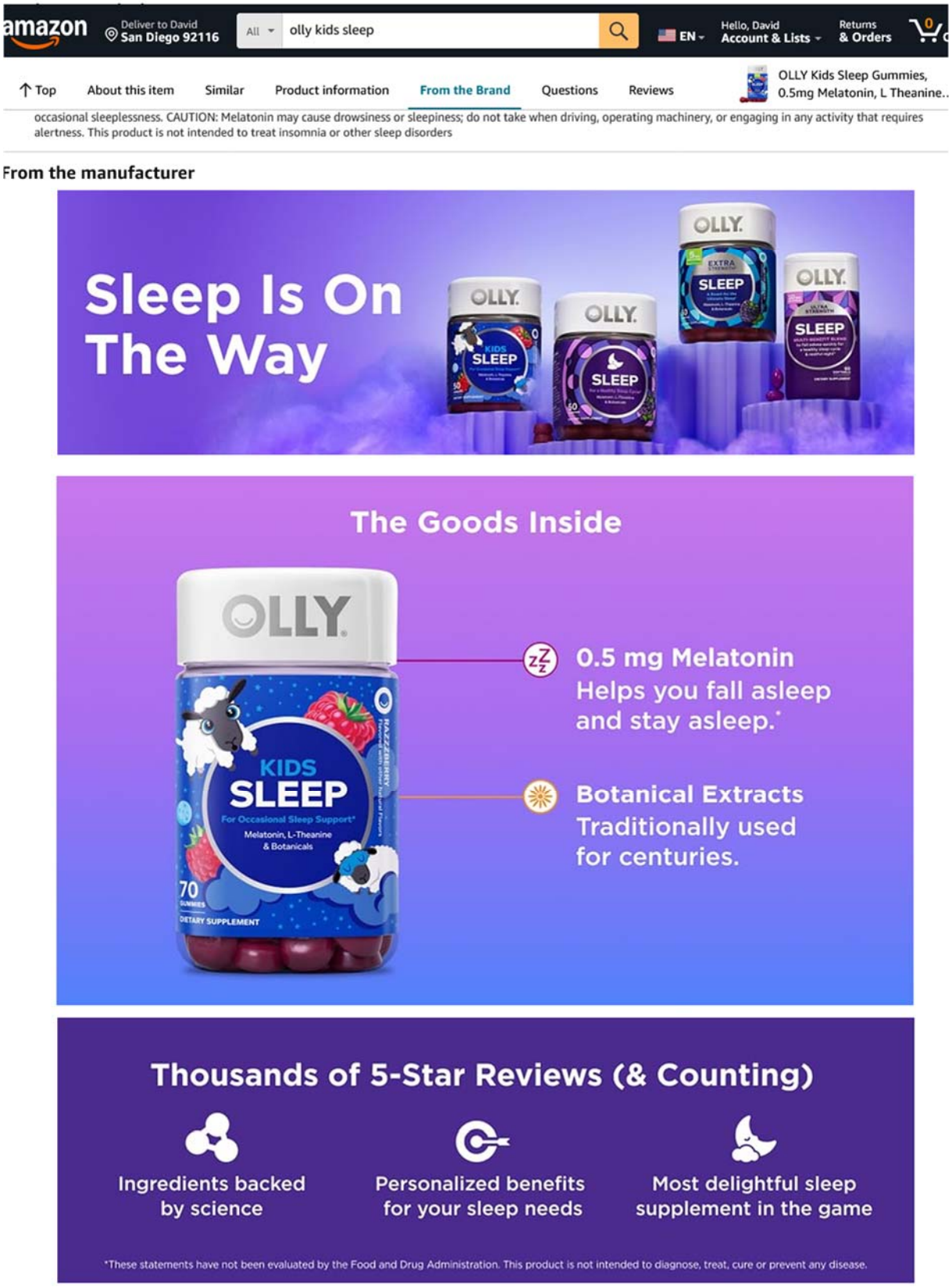
Legal Disclaimer

Statements regarding dietary supplements have not been evaluated by the FDA and are not intended to diagnose, treat, cure, or prevent any disease or health condition.

Disclaimer: While we work to ensure that product information is correct, on occasion manufacturers may alter their ingredient lists. Actual product packaging and materials may contain more and/or different information than that shown on our Web site. We recommend that you do not solely rely on the information presented and that you always read labels, warnings, and directions before using or consuming a product. For additional information about a product, please contact the manufacturer. Content on this site is for reference purposes and is not intended to substitute for advice given by a physician, pharmacist, or other licensed health-care professional. You should not use this information as self-diagnosis or for treating a health problem or disease. Contact your health-care provider immediately if you suspect that you have a medical problem. Information and statements regarding dietary supplements have not been evaluated by the Food and Drug Administration and are not intended to diagnose, treat, cure, or prevent any disease or health condition. Amazon.com assumes no liability for inaccuracies or misstatements about products.

Product Description

Kiddos thrive on routine, so troublesome bedtimes can be a real setback. This mild blend is just the thing for those occasional restless nights.* Sweet dreams little one. These Kids Sleep gummy supplements have 0.5 mg Melatonin per gummy to support healthy sleep cycles,* blended with L-Theanine and a mix of traditionally used herbal helpers: Chamomile, Passionflower and Lemon Balm Extracts. Ages 4 and up, start with 1 gummy and give up to 2 gummies as needed 30 minutes before bedtime. Chew thoroughly before swallowing. OLLY Kids Sleep gummies are red raspberry flavored with other natural flavors. These gummies are happily drug free, gluten free and formulated with no synthetic flavors or colors. *These statements have not been evaluated by the Food and Drug Administration. This product is not intended to diagnose, treat, cure or prevent any disease. For occasional sleeplessness. CAUTION: Melatonin may cause drowsiness or sleepiness; do not take when driving, operating machinery, or engaging in any activity that requires alertness. This product is not intended to treat insomnia or other sleep disorders


amazon
Deliver to David
San Diego 92116
All
olly kids sleep
EN
Hello, David
Account & Lists
Returns
& Orders
Top
About this item
Similar
Product information
From the Brand
Questions
Reviews
OLLY Kids Sleep Gummies, 0.5mg Melatonin, L Theanine..
occasional sleeplessness. CAUTION: Melatonin may cause drowsiness or sleepiness; do not take when driving, operating machinery, or engaging in any activity that requires alertness. This product is not intended to treat insomnia or other sleep disorders
From the manufacturer
Sleep Is On The Way
OLLY
KIDS SLEEP
SLEEP
EXTRA STRENGTH
ULTRA STRENGTH
The Goods Inside
KIDS
SLEEP
For Occasional Sleep Support*
Melatonin, L-Theanine & Botanicals
70
DIETARY SUPPLEMENT
0.5 mg Melatonin
Helps you fall asleep and stay asleep.*
Botanical Extracts
Traditionally used for centuries.
Thousands of 5-Star Reviews (& Counting)
Ingredients backed by science
Personalized benefits for your sleep needs
Most delightful sleep supplement in the game
*These statements have not been evaluated by the Food and Drug Administration. This product is not intended to diagnose, treat, cure or prevent any disease.


OLLY
0.5 MG
MELATONIN
PER 1 GUMMY
RAZZBERRY
Flavored with other Natural Flavors
KIDS
SLEEP
For Occasional Sleep Support*
Melatonin, L-Theanine & Botanicals
70
GUMMIES
DIETARY SUPPLEMENT
OLLY


The Goods Inside
OLLY
OLLY
0.5 mg Melatonin
This sleepy time superstar ingredient helps little ones fall asleep and stay asleep.*
Botanical Extracts
Traditionally used for centuries.
Flavor:
Razzzberry
Ages 4 and up, start with 1 gummy and give up to 2 gummies as needed 30 minutes before bed.


More Reasons to Love 'Em
No synthetic colors or flavors
NSF Certified
Gluten free
Drug free


OLLY
KIDS
SLEEP
For Occasional Sleep Support*
Melatonin, L-Theanine
& Botanicals
RAZZBERRY
Flavored with other Natural Flavors
70
GUMMIES
DIETARY SUPPLEMENT

Supplement Facts

Serving Size 1 or 2 Gummies
Servings Per Container 70 or 35

Amount Per Serving	% DV for Children 4 Yrs of Age & Older (1 Gummy)		% DV for Children 4 Yrs of Age & Older (2 Gummies)	
Calories	10		15	
Total Carbohydrate	2 g	<1%†	3 g	1%†
Total Sugars	1 g	**	2 g	**
Includes Added Sugars	1 g	2%†	2 g	4%†
Sodium	<5 mg	<1%	5 mg	<1%
Melatonin	0.5 mg	**	1 mg	**
L-Theanine	15 mg	**	30 mg	**
Chamomile Extract (flower)	2.5 mg	**	5 mg	**
Passionflower Extract (aerial parts)	2.5 mg	**	5 mg	**
Lemon Balm Extract (aerial parts)	2.5 mg	**	5 mg	**

†Percent Daily Values (DV) are based on a 2,000 calorie diet. **DV not established.

Other Ingredients: Glucose Syrup, Sugar, Water, Gelatin, Pectin, Citric Acid, Natural Flavor, Sodium Citrate, Coloring (from carrot and black currant juices), Vegetable Oil (coconut) and Carnauba Wax (to prevent sticking).


OLLY
RAZZZBERRY
Flavored with other Natural Flavors
Suggested Use: Ages 4 and up, start with 1 gummy and give up
as needed 30 minutes before bedtime.‡ Chew thoroughly before s
Supplement Fa
Serving Size 1 or 2 Gummies
Servings Per Container 70 or 35
Amount Per Serving
% DV for Children 4 Yrs of Age & Older (1 Gummy)
% DV 4 Yrs of
Calories 10
Total Carbohydrate 2g <1%†
Total Sugars 1g **
Includes Added Sugars 1g 2%†
Sodium <5 mg <1%
Melatonin 0.5 mg **
L-Theanine 15 mg **
Chamomile Extract (flower) 2.5 mg **
Passionflower Extract (aerial parts) 2.5 mg **
Lemon Balm Extract (aerial parts) 2.5 mg **
†Percent Daily Values (DV) are based on a 2,000 calorie diet. **DV n
Other Ingredients: Glucose Syrup, Sugar, Water, Gelatin, Pect
Natural Flavor, Sodium Citrate, Coloring (from carrot and black
juices), Vegetable Oil (coconut) and Carnauba Wax (to prevent s
Distributed by: OLLY Public Benefit Corp. San Francisco, CA 94111
hello@OLLY.com · 1-844-HEY-OLLY
Processed in a facility with products that may contain soy, egg, peanut
fish, shellfish, wheat and sesame.
‡Reduce dose if excessive sleepiness occurs.

EXHIBIT 3

WARNING LETTER

SANA Group LLC

MARCS-CMS 612256 — FEBRUARY 18, 2021

More Warning Letters (/inspections-compliance-enforcement-and-criminal-investigations/compliance-actions-and-activities/warning-letters)

Delivery Method:

Via Overnight Delivery

Product:

Food & Beverages

Recipient:

Jason W. Harris

Owner

SANA Group LLC

1200 E. Woodhurst S-200

Springfield, MO 65804

United States

Issuing Office:

Center for Food Safety and Applied Nutrition (CFSAN)

United States

RE: [CMS:612256]

Dear Mr. Harris,

This is to advise you that the Food and Drug Administration (FDA) reviewed your website at the Internet address, www.sleepsana.com, in December 2020 and has determined that you take orders there for your Sleep Sana “Sleep Drops” and “Sleep Shots” products. The claims on your website establish that your products are drugs under section 201(g)(1)(B) of the Federal Food, Drug, and Cosmetic Act (the Act) [21 U.S.C. § 321(g)(1)(B)] because they are intended for use in the cure, mitigation, treatment, or prevention of disease. As explained further below, introducing or delivering this product for introduction into interstate commerce violates the Act. You can find the Act and FDA regulations through links on FDA’s home page at www.fda.gov (/home).

Examples of some of the website claims that provide evidence that your “Sleep Drops” and “Sleep Shots” are intended for use as drugs include:

On the webpage for Sleep Sana “Sleep Drops” and “Sleep Shots” ingredients:

- "GABA (an ingredient in your Sleep Sana “Sleep Drops” and “Sleep Shots” products) is taken by mouth for relieving anxiety, ...

and treating attention deficit hyperactivity disorder (ADHD). It is also used for ... stabilizing blood pressure, and relieving pain."

- "L-tryptophan (an ingredient in your Sleep Sana “Sleep Drops” and “Sleep Shots” products) is used for insomnia, sleep apnea, depression, anxiety, facial pain, a severe form of premenstrual syndrome called premenstrual dysphoric disorder (PMDD), ... attention deficit-hyperactivity disorder (ADHD), Tourette's syndrome...."
- "Valerian (an ingredient in your Sleep Sana “Sleep Drops” and “Sleep Shots” products) is most commonly used for sleep disorders, especially the inability to sleep (insomnia)."
- "[Y]our body may produce melatonin (an ingredient in your Sleep Sana “Sleep Drops” and “Sleep Shots” products) either earlier or later in the day than usual. This change can lead to symptoms of seasonal affective disorder (SAD), or winter depression."

Your “Sleep Drops” and “Sleep Shots” products are not generally recognized as safe and effective for the above referenced uses and, therefore, these products are “new drugs” under section 201(p) of the Act [21 U.S.C. § 321(p)]. With certain exceptions not applicable here, new drugs may not be legally introduced or delivered for introduction into interstate commerce without prior approval from FDA, as described in sections 301(d) and 505(a) of the Act [21 U.S.C. §§ 331(d), 355(a)]. FDA approves a new drug on the basis of scientific data and information demonstrating that the drug is safe and effective.

A drug is misbranded under section 502(f)(1) of the Act [21 U.S.C. § 352(f)(1)] if the drug fails to bear adequate directions for its intended use(s). “Adequate directions for use” means directions under which a layperson can use a drug safely and for the purposes for which it is intended (21 C.F.R. § 201.5). Prescription drugs, as defined in section 503(b)(1)(A) of the Act [21 U.S.C. § 353(b)(1)(A)], can only be used safely at the direction, and under the supervision, of a licensed practitioner.

Your “Sleep Drops” and “Sleep Shots” products are intended for treatment of one or more diseases that are not amenable to self-diagnosis or treatment without the supervision of a licensed practitioner. Therefore, it is impossible to write adequate directions for a layperson to use your product safely for their intended purposes. Accordingly, your “Sleep Drops” and “Sleep Shots” products fail to bear adequate directions for their intended use and, therefore, the products are misbranded under section 502(f)(1) of the Act [21 U.S.C. § 352(f)(1)]. The introduction or delivery for introduction into interstate commerce of these misbranded drugs violates section 301(a) of the Act [21 U.S.C. § 331(a)].

The violations cited in this letter are not intended to be an all-inclusive statement of violations that exist in connection with your marketed products. You are responsible for investigating and determining the causes of any violations and for preventing their recurrence or the occurrence of other violations. It is your responsibility to ensure that your firm complies with all requirements of federal law, including FDA regulations.

You should take prompt action to address the violates cited in this letter. Failure to promptly correct these violations may result in legal action without further notice, including, without limitation, seizure and injunction.

Please notify FDA in writing, within fifteen working days of receipt of this letter, of the specific steps that you have taken to address these violations. Include an explanation of each step being taken to prevent the recurrence of violations, as well as copies of related documentation. If you believe that your products are not in violation of the Act, include your reasoning and any supporting information for our consideration. If you cannot complete addressing these violations within fifteen working days, state the reason for the delay and the time within which you will do so. Your reply should be sent via e-mail to FDAAdvisory@fda.hhs.gov (mailto:FDAAdvisory@fda.hhs.gov).

Sincerely,

/S/

William A. Correll Jr.

Director
Office of Compliance
Center for Food Safety and Applied Nutrition
Food and Drug Administration

Was this page helpful? * (required)

Yes

No

Submit

EXHIBIT 4

WARNING LETTER

MB Solutions, LLC/BioSpectrum CBD

MARCS-CMS 610649 — JULY 22, 2021

More Warning Letters (/inspections-compliance-enforcement-and-criminal-investigations/compliance-actions-and-activities/warning-letters)

Delivery Method:

Via Email

Product:

Animal & Veterinary
Drugs
Food & Beverages

Recipient:

Frederic A. Melius, MD

MB Solutions, LLC/BioSpectrum CBD

5980 Executive Dr. Suite A

Madison, WI 53719

United States

Info@biospectrumcbd.com (mailto:Info@biospectrumcbd.com)

Issuing Office:

Center for Drug Evaluation and Research

United States

WARNING LETTER

July 22, 2021

RE: 610649

Dear Dr. Melius:

This letter is to advise you that the U.S. Food and Drug Administration (FDA) reviewed your websites at www.biospectrumcbd.com and www.nasadol.com from April 2021 through July 2021 and has determined that you take orders there for several products, including “Regular Strength Nasadol CBD Nasal Spray,” “Extra Strength Nasadol CBD Nasal Spray,” “Pain Relief Roll-On,” “CBD Oil Tincture” (500 mg and 1500 mg), “Sour Gummy Worms” (250 mg and 500 mg), “CBD Gummy Worms” (250 mg and 500 mg), “CBD Peach Rings” (250 mg and 500 mg), “Watermelon Slices” (250 mg, 500 mg, and 1000 mg), “CBD Gummy Bears” (500 mg and 1000 mg), “1,000mg Canine CBD Oil,” and “CBD Dog Treats,” all of which are represented as containing cannabidiol (CBD).[1] We have also reviewed your social media websites at www.facebook.com/BioSpectrumCBD and www.instagram.com/biospectrum.cbd/; these websites direct consumers to

your website www.biospectrumcbd.com to purchase your products.

Claims on your websites establish that your "Regular Strength Nasadol CBD Nasal Spray," "Extra Strength Nasadol CBD Nasal Spray," and "Pain Relief Roll-On," are unapproved new drugs introduced or delivered for introduction into interstate commerce in violation of sections 505(a) and 301(d) of the FD&C Act, 21 U.S.C. 355(a) and 331(d). Furthermore, your "Pain Relief Roll-On" product is misbranded in violation of section 502(ee), 21 U.S.C. 352(ee). In addition, your "Regular Strength Nasadol CBD Nasal Spray" and "Extra Strength Nasadol CBD Nasal Spray" are misbranded under 502(f)(1) of the FD&C Act, 21 U.S.C. 352(f)(1). The introduction or delivery for introduction into interstate commerce of a misbranded drug is prohibited under section 301(a) of the FD&C Act, 21 U.S.C. 331(a).

In addition, your "1,000mg Canine CBD Oil," and "CBD Dog Treats," are unapproved new animal drugs that are unsafe under section 512(a) of the FD&C Act, 21 U.S.C. 360b(a), and are adulterated under section 501(a)(5) of the FD&C Act, 21 U.S.C. 351(a)(5).

Currently, a nonprescription drug product containing CBD cannot be legally marketed without an approved new drug application, regardless of whether the CBD is represented on the labeling as an active ingredient or an inactive ingredient. To date, no CBD-containing drug has met applicable FDA requirements to be legally marketed for nonprescription use. As explained below, nonprescription drug products that include CBD as an active ingredient are not generally recognized as safe and effective (GRASE) and are new drugs that require an approved application to be legally marketed. Furthermore, even if CBD could be considered an inactive ingredient in a nonprescription drug product, that product would still need an approved new drug application to be legally marketed, because the product would not meet the general requirements for nonprescription drug products under section 505G of the FD&C Act. In particular, such product would not meet the general requirement with respect to the safety and suitability of inactive ingredients under 21 CFR 330.1(e).

Your "Nasadol CBD Nasal Spray" products are intended to be sprayed into the nose and absorbed into the bloodstream. For example, from your website http://nasadol.com/, you state "Our water soluble CBD in the nose is immediately and efficiently absorbed, and directly transferred to within the brain. When you spray Nasadol into your nose, you will start to feel the health effects of our precise dosing right away." Further, on your website https://www.biospectrumcbd.com/, you state "[T]he product that revolutionized the way CBD is delivered to the brain . . . requires less product for greater relief . . . [w]orks within 30 seconds . . . [i]mproved [b]ioavailability of CBD . . . [b]ypasses blood brain barrier in seconds." These products are especially concerning from a public health perspective because intranasal drug products may be rapidly absorbed through the highly vascularized nasal mucosa directly into systemic blood circulation, where they may exert undesirable systemic effects such as increased heart rate or elevated blood pressure. If toxic substances are introduced directly into the nose, harmful local effects such as bleeding, ulceration, or nasal septal perforation may occur.

FDA has also determined that your "Sour Gummy Worms," "CBD Gummy Worms," "CBD Peach Rings," "Watermelon Slices," "CBD Gummy Bears," "CBD Oil Tincture," and "CBD Dog Treats" products are adulterated within the meaning of section 402(a)(2)(C)(i) of the FD&C Act, 21 U.S.C. 342(a)(2)(C)(i), because they bear or contain an unsafe food additive. Furthermore, it is a prohibited act to introduce your "Sour Gummy Worms," "CBD Gummy Worms," "CBD Peach Rings," "Watermelon Slices," "CBD Gummy Bears," "CBD Oil Tincture", and "CBD Dog Treats" products into interstate commerce under section 301(ll) of the FD&C Act, 21 U.S.C. 331(ll).

As explained further below, introducing or delivering these products for introduction into interstate commerce violates the FD&C Act. You can find the FD&C Act and FDA regulations through links on FDA's home page at www.fda.gov. (//www.fda.gov.) (http://www.fda.gov/about-fda/website-policies/website-disclaimer) You can find specific information about how FDA regulates CBD at https://www.fda.gov/news-events/public-health-focus/fda-regulation-cannabis-and-cannabis-derived-products-including-cannabidiol-cbd (/news-events/public-health-focus/fda-regulation-cannabis-and-cannabis-derived-products-including-cannabidiol-cbd).

Top ()

Unapproved New Drugs

Based on a review of your websites, your “Regular Strength Nasadol CBD Nasal Spray,” “Extra Strength Nasadol CBD Nasal Spray,” and “Pain Relief Roll-On,” are drugs under section 201(g)(1) of the FD&C Act, 21 U.S.C. 321(g)(1), because they are intended for use in the diagnosis, cure, mitigation, treatment, or prevention of disease, and/or intended to affect the structure or any function of the body.

Examples of claims from your websites www.nasadol.com and www.biospectrumcbd.com that provide evidence of the intended use of these products as drugs include, but may not be limited to, the following:

From www.nasadol.com

• A webpage that features a graphic of Nasadol CBD Nasal Sprays states that “[c]linical trials and other scientific research illustrate CBD’s usefulness in treating pain, anxiety, inflammation, depression, addiction and many other conditions.”

From www.biospectrumcbd.com

• “Regular Strength Nasadol CBD Nasal Spray”
• “Benefits
  o Supports sense of calm*
  o For Focus and Anti-Anxiety*
  o Manage Stress*
  o Relieves Headaches*
  o Relieves Sinus Pressure*
  o Allergy relief*
  o Maintain and aid healthy sleep cycles*”
• “BioSpectrum CBD engineered this Pain Relief Roll-On to provide powerful long lasting relief from aches and pains. By using FDA approved pain relievers; Lidocaine, Menthol, Camphor, along with Broad Spectrum CBD Distillate, this product is truly unique and effective.”

Based on the above labeling claims, your “Regular Strength Nasadol CBD Nasal Spray,” “Extra Strength Nasadol CBD Nasal Spray,” and “Pain Relief Roll-On” products are drugs. We are not aware of any adequate and well-controlled clinical trials in the published literature that support a determination that any of these products are GRASE for use under the conditions prescribed, recommended or suggested in their labeling. Thus, “Regular Strength Nasadol CBD Nasal Spray,” “Extra Strength Nasadol CBD Nasal Spray,” and “Pain Relief Roll-On” are “new drugs” within the meaning of section 201(p) of the FD&C Act, 21 U.S.C. 321(p). New drugs may not be introduced or delivered for introduction into interstate commerce without an approved application from FDA in effect, as described in section 505(a) of the FD&C Act, 21 U.S.C. 355(a), unless they are nonprescription drugs governed by and lawfully marketed under section 505G[2] of the FD&C Act, among other exceptions not applicable here. No FDA-approved application pursuant to section 505 of the FD&C Act, 21 U.S.C. 355, is in effect for “Regular Strength Nasadol CBD Nasal Spray,” “Extra Strength Nasadol CBD Nasal Spray,” or “Pain Relief Roll-On,” nor do they meet the requirements for marketing without an approved application under section 505G of the FD&C Act, as described below. Accordingly, these products are unapproved new drugs marketed in violation of sections 505(a) and 301(d) of the FD&C Act, 21 U.S.C 355(a) and 331(d).

We note that section 505G of the FD&C Act governs nonprescription drugs marketed over-the-counter (or "OTC") without an approved drug application, such as your “Pain Relief Roll-On” product.[3] Under section 505G, certain nonprescription drug products may be lawfully marketed without an approved application if applicable requirements are met. However, your “Pain Relief Roll-On” product does not meet the requirements for marketing under section 505G. Specifically, it does not meet the applicable conditions under section 505G(a)(1) or (2) of the FD&C Act, 21 U.S.C. 355h(a)(1), (2), under which nonprescription drugs marketed without an approved application are deemed GRASE and not considered “new drugs” by operation of law. Among these conditions is that a drug conforms with the general requirements for nonprescription drugs and that it conforms with the requirements for nonprescription use of a final monograph issued under 21 CFR part 330 or, for drugs classified in Category I for safety and effectiveness under a tentative final monograph (TFM), that a drug

conforms with the proposed requirements of such TFM. Your “Pain Relief Roll-On” does not meet these conditions, notably because its active ingredient CBD is not an active ingredient in any applicable final monograph or TFM.[4]

Although CBD is not explicitly identified as the active ingredient in your “Pain Relief Roll-On,” the product labeling clearly represents CBD as an active ingredient, which is a component of a drug intended to furnish pharmacological activity or other direct effect in the diagnosis, cure, mitigation, treatment, or prevention of disease, or to affect the structure or function of the body (see 21 CFR 201.66(b)(2)). For instance, your product label for “Pain Relief Roll-On” prominently highlights on the principal display panel that it contains “1000mg CBD,” the company name on the label is Bio Spectrum CBD, the product is available on your website under the subheading “Shop CBD,” and your product page includes a lab analysis highlighting the product’s CBD content.

We note that you list CBD as an “other ingredient” on your “Pain Relief Roll-On” product label. Drug products only contain “active ingredients” or “inactive ingredients.” To the extent that CBD is intended to be an inactive ingredient in your “Pain Relief Roll-On” product, it would still need an approved drug application to be legally marketed because it does not meet the conditions under section 505G of the FD&C Act. In particular, the product would not meet the conditions under section 505G(a)(1) or (2) insofar that the product does not conform to the general requirement in 21 CFR 330.1(e) that inactive ingredients must be safe and suitable.[5] A suitable inactive ingredient generally provides a beneficial formulation function, such as a tablet binder or preservative, or improves product delivery (e.g., enhances absorption or controls release of the drug substance).[6] CBD has no known functional role as an inactive ingredient in a finished drug product. Additionally, an inactive ingredient should not exert pharmacological effects[7] and must be safe when used at the intended dosage.[8] CBD, however, has known pharmacological activity with demonstrated risks.[9] It is unknown whether the levels of CBD used in your “Pain Relief Roll-On” have pharmacological activity or pose any concern for safety events. Accordingly, CBD cannot be considered a safe and suitable inactive ingredient as required under 21 CFR 330.1(e). Consequently, if CBD is intended to be an inactive ingredient in your “Pain Relief Roll-On” product, this product would not meet the general requirements for nonprescription drugs needed for legal marketing under section 505G(a)(1) of the FD&C Act.

In addition to not meeting section 505G(a)(1) of the FD&C Act, your “Pain Relief Roll-On” product does not meet the other conditions under section 505G under which nonprescription drug products can be lawfully marketed without an approved application. Specifically, it does not satisfy the requirements under sections 505G(a)[10] nor is its marketing permitted by an order issued under section 505G(b).[11] In addition, your “Regular Strength Nasadol CBD Nasal Spray” and “Extra Strength Nasadol CBD Nasal Spray” also do not meet the conditions under section 505G for legal marketing without an approved application.[12]

For the reasons described above, your Regular Strength Nasadol CBD Nasal Spray,” “Extra Strength Nasadol CBD Nasal Spray,” and “Pain Relief Roll-On” are unapproved new drugs marketed in violation of sections 505(a) and 301(d) of the FD&C Act, 21 U.S.C. 355(a), 331(d).

Misbranded Drugs

Your “Regular Strength Nasadol CBD Nasal Spray,” “Extra Strength Nasadol CBD Nasal Spray,” and “Pain Relief Roll-On” are misbranded drugs introduced or delivered for introduction into interstate commerce in violation of sections 502 and 301(a) of the FD&C Act, 21 U.S.C. 352 and 331(a).

OTC External Analgesic Drug

In particular, your “Pain Relief Roll-On” product is a nonprescription drug subject to section 505G of the FD&C Act, 21 U.S.C. 355h, but does not comply with the requirements for marketing under that section, and is not the subject of an application approved under section 505 of the FD&C Act, 21 U.S.C. 355. Accordingly, this product is misbranded under section 502(ee) of the FD&C Act, 21 U.S.C. 352(ee).

Top ()

Nasal Spray Drugs

In addition, your “Regular Strength Nasadol CBD Nasal Spray” and “Extra Strength Nasadol CBD Nasal Spray” products are misbranded within the meaning of section 502(f)(1) of the FD&C Act, 21 U.S.C. 352(f)(1), in that their labeling fails to bear adequate directions for use. “Adequate directions for use” means directions under which a layperson can use a drug safely and for the purposes for which it is intended. See 21 CFR 201.5. The aforementioned products are offered for conditions that are not amenable to self-diagnosis and treatment by individuals who are not medical practitioners, including depression, anxiety, and addiction; therefore, adequate directions for use cannot be written so that a layperson can use these drugs safely for their intended purposes. FDA-approved prescription drugs that bear their FDA-approved labeling are exempt from the requirements that they bear adequate directions for use by a layperson. However, your “Regular Strength Nasadol CBD Nasal Spray” and “Extra Strength Nasadol CBD Nasal Spray” products are not exempt from the requirement that their labeling bear adequate directions for use, 21 CFR 201.100(c)(2) and 201.115, because no FDA-approved applications are in effect for them.

The introduction or delivery for introduction into interstate commerce of misbranded drugs violates section 301(a) of the FD&C Act, 21 U.S.C. 331(a).

301(ll) and Adulterated Human Foods

Furthermore, it is a prohibited act under section 301(ll) of the FD&C Act, 21 U.S.C. 331(ll), to introduce or deliver for introduction into interstate commerce any food to which has been added a drug approved under section 505 of the FD&C Act or for which substantial clinical investigations have been instituted and for which the existence of such investigations has been made public. Based on available evidence, FDA has concluded that the prohibition in section 301(ll) applies to CBD.[13] There is an exception if the substance was marketed in food before the drug was approved or before the substantial clinical investigations involving the drug had been instituted. However, based on the available evidence, FDA has concluded that this is not the case for CBD. FDA is not aware of any evidence that would call into question its current conclusion that section 301(ll) of the FD&C Act prohibits the introduction into interstate commerce of any food to which CBD has been added, but you may present FDA with any evidence bearing on this issue.

According to your product labeling, your “Sour Gummy Worms,” “CBD Gummy Worms,” “CBD Peach Rings,” “Watermelon Slices,” “CBD Gummy Bears,” and “CBD Oil Tincture” products are foods to which CBD has been added. Therefore, the introduction or delivery for introduction into interstate commerce of those products is a prohibited act under section 301(ll) of the FD&C Act.

You should also be aware that, as defined in section 201(s) of the FD&C Act, 21 U.S.C. 321(s), the term "food additive" refers to any substance the intended use of which results in its becoming a component of any food, unless the substance is generally recognized as safe (GRAS) among qualified experts under the conditions of its intended use, or unless the substance meets a listed exception.[14]

Food additives require premarket approval based on data demonstrating safety. Any food additive that has not been approved for its intended use in food is deemed to be unsafe under section 409(a) of the FD&C Act, 21 U.S.C. 348(a), and causes the food to be adulterated under section 402(a)(2)(C)(i) of the FD&C Act, 21 U.S.C. 342(a)(2)(C)(i). Introduction of an adulterated food into interstate commerce is prohibited under section 301(a) of the FD&C Act, 21 U.S.C. 331(a).

There is no food additive regulation which authorizes the use of CBD. We are not aware of any information to indicate that CBD is the subject of a prior sanction (see 21 CFR Part 181). Furthermore, we are not aware of any basis to conclude that CBD is GRAS for use in conventional foods. FDA's regulations in 21 CFR 170.30(a)-(c) describe the criteria for eligibility for classification of a food ingredient as GRAS. The use of a food substance may be GRAS based on either scientific procedures or, for a substance used in food before 1958, through experience based on common use in food (see 21 CFR 170.30).

We know of no basis for general recognition of safety for CBD based either on scientific procedures or common use in food prior to January 1, 1958. Based on our review of published, scientific literature, existing data and information do not provide

an adequate basis to conclude that the use of CBD in food meets the criteria for GRAS status. Many unanswered questions and data gaps about CBD toxicity exist, and some of the available data raise serious concerns about potential harm from CBD. Our review of publicly available data associated with the one FDA-approved CBD drug, as well as our review of published scientific literature, identified potential for liver injury from CBD and potentially harmful interactions with certain drugs. In addition, studies in animals have shown that CBD can interfere with the development and function of testes and sperm, decrease testosterone levels, and impair sexual behavior in males. Therefore, based on our review, the use of CBD in your products does not satisfy the criteria for GRAS status under 21 CFR 170.30.

FDA is not aware of any other exception to the food additive definition that would apply to CBD for use as an ingredient in a conventional food. Therefore, CBD added to a conventional food is a food additive under section 201(s) of the FD&C Act and is subject to the provisions of section 409 of the FD&C Act. Under section 409, a food additive is deemed unsafe unless it is approved by FDA for its intended use prior to marketing. CBD is not approved for use in any conventional food. Food containing an unsafe food additive within the meaning of section 409 is adulterated within the meaning of section 402(a)(2)(C)(i) of the FD&C Act. Therefore, “Sour Gummy Worms,” “CBD Gummy Worms,” “CBD Peach Rings,” “Watermelon Slices,” “CBD Gummy Bears,” and “CBD Oil Tincture” are adulterated within the meaning of section 402(a)(2)(C)(i) of the FD&C Act. Introduction of these adulterated food into interstate commerce is prohibited under section 301(a) of the FD&C Act, 21 U.S.C. 331(a).

Unapproved New Animal Drugs

During our review of your website, www.biospectrumcbd.com, and your social media websites, www.facebook.com/BioSpectrumCBD and www.instagram.com/biospectrum.cbd/, FDA determined that your firm is marketing the unapproved new animal drugs “1,000mg Canine CBD Oil” and “CBD Dog Treats”. Based on our review of your website and social media websites, your “1,000mg Canine CBD Oil” and “CBD Dog Treats” are drugs under section 201(g)(1) of the FD&C Act, 21 U.S.C. 321(g)(1), because they are intended for use in the diagnosis, cure, mitigation, treatment, or prevention of disease in animals and/or intended to affect the structure or any function of the body of an animal. Further, as discussed below, these products are unapproved new animal drugs and marketing them violates the FD&C Act.

Examples of claims observed on your social media websites that establish the intended use of your “1,000mg Canine CBD Oil” and “CBD Dog Treats” as drugs include, but are not limited to, the following:

• On your Facebook and Instagram social media websites at www.facebook.com/BioSpectrumCBD and www.instagram.com/biospectrum.cbd/ respectively, March 22, 2021 postings with a photograph of your “1,000mg Canine CBD Oil” and “CBD Dog Treats” products:
  o “We have CBD products your pups will be begging for! Did you know CBD may help reduce anxiety, pain and inflammation in dogs? CBD isn’t just for humans anymore!”

Your “1,000mg Canine CBD Oil” and “CBD Dog Treats” products are “new animal drugs” under section 201(v) of the FD&C Act, 21 U.S.C. 321(v), because they are not generally recognized, among experts qualified by scientific training and experience to evaluate the safety and effectiveness of animal drugs, as safe and effective for use under the conditions prescribed, recommended, or suggested in the labeling.

To be legally marketed, a new animal drug must have an approved new animal drug application, conditionally approved new animal drug application, or index listing under sections 512, 571, and 572 of the FD&C Act, 21 U.S.C. 360b, 360ccc, and 360ccc-l. These product are not approved or index listed by the FDA, and therefore these products are considered unsafe under section 512(a) of the FD&C Act, 21 U.S.C. 360b(a), and adulterated under section 501(a)(5) of the FD&C Act, 21 U.S.C. 351(a)(5). Introduction of these adulterated drugs into interstate commerce is prohibited under section 301(a) of the FD&C Act, 21 U.S.C. 331(a).

301(ll) and Adulterated Animal Foods

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Furthermore, it is a prohibited act under section 301(ll) of the FD&C Act, 21 U.S.C. 331(ll), to introduce or deliver for introduction into interstate commerce any animal food, to which has been added a drug approved under section 505 of the FD&C Act or for which substantial clinical investigations have been instituted and for which the existence of such investigations has been made public. Based on available evidence, FDA has concluded that the prohibition in section 301(ll) applies to CBD, as described above.

According to your product labeling, your "CBD Dog Treats" product is an animal food to which CBD has been added. Specifically, your product label depicted on your website, www.biospectrumcbd.com, refers to this product as a "Dog Treat" and as "Steak Bites." Additionally, the product label includes a "Guaranteed Analysis" section, which promotes the product as a source of protein, fat, and fiber. Therefore, the introduction or delivery for introduction into interstate commerce of this product is a prohibited act under section 301(ll) of the FD&C Act.

You should also be aware that, as defined in section 201(s) of the FD&C Act (21 U.S.C. 321(s)), the term "food additive" refers to any substance the intended use of which results in its becoming a component of any animal food, unless the substance is generally recognized as safe (GRAS) among qualified experts under the conditions of its intended use, or unless the substance meets a listed exception.[15]

Food additives require premarket approval based on data demonstrating safety. Any food additive that has not been approved for its intended use in animal food is deemed to be unsafe under section 409(a) of the FD&C Act, 21 U.S.C. 348(a), and causes the animal food to be adulterated under section 402(a)(2)(C)(i) of the FD&C Act, 21 U.S.C. 342(a)(2)(C)(i). Introduction of an adulterated animal food into interstate commerce is prohibited under section 301(a) of the FD&C Act, 21 U.S.C. 331(a).

There is no food additive regulation that authorizes the use of CBD in animal food. We are not aware of any information to indicate that CBD is the subject of a prior sanction (i.e., a sanction or approval granted prior to the enactment of the Food Additives Amendment of 1958 under the FD&C Act, the Poultry Products Inspection Act, or the Meat Inspection Act). Furthermore, we are not aware of any basis to conclude that CBD is GRAS for use in animal food. FDA's regulations in 21 CFR 570.30(a)-(c) describe the criteria for eligibility for classification of an animal food ingredient as GRAS. The use of an animal food substance may be GRAS based on either scientific procedures or, for a substance used in animal food before 1958, through experience based on common use in animal food (see 21 CFR 570.30).

We know of no basis for general recognition of safety for CBD based either on scientific procedures or common use in animal food prior to January 1, 1958. Based on our review of the publicly available literature, the data and information necessary to support the safe use of CBD in animal food are lacking. In fact, literature reports have raised safety concerns for animals consuming CBD, including, but not limited to, male reproductive toxicity and liver toxicity. Therefore, based on our review, the use of CBD in animal products does not satisfy the criteria for GRAS status under 21 CFR 570.30.

FDA is not aware of any other exception to the food additive definition that would apply to CBD for use as an ingredient in animal food. Therefore, CBD added to animal food is a food additive under section 201(s) of the FD&C Act and is subject to the provisions of section 409 of the FD&C Act, 21 U.S.C. 348. Under section 409 of the FD&C Act, 21 U.S.C. 348, an animal food additive is deemed unsafe unless it is approved by FDA for its intended use prior to marketing. CBD is not approved for use in any animal food. Animal food containing an unsafe food additive within the meaning of section 409 is adulterated within the meaning of section 402(a)(2)(C)(i) of the FD&C Act, 21 U.S.C. 342(a)(2)(C)(i). Therefore, your "CBD Dog Treats" is adulterated within the meaning of section 402(a)(2)(C)(i) of the FD&C Act. Introduction of this adulterated animal food into interstate commerce is prohibited under section 301(a) of the FD&C Act, 21 U.S.C. 331(a).

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The violations cited in this letter are not intended to be an all-inclusive statement of violations that exist in connection with your marketed products. You are responsible for investigating and determining the causes of any violations and for preventing their recurrence or the occurrence of other violations. According to your website, you manufacture many other

types of CBD containing products. It is your responsibility to ensure that your firm complies with all requirements of federal law, including FDA regulations.

You should take prompt action to address the violations cited in this letter. Failure to promptly address these violations may result in legal action without further notice, including, without limitation, seizure and injunction.

This letter notifies you of our findings and provides you an opportunity to address the above violations. Please notify FDA in writing, within fifteen working days of receipt of this letter, of the specific steps you have taken to address any the violations. Include an explanation of each step being taken to prevent the recurrence of any violations, as well as copies of related documentation. If you believe that your products are not in violation of the FD&C Act, include your reasoning and any supporting information for our consideration. If you cannot completely address any violations within fifteen working days, state the reasons for the delay and your schedule for completion.

Your response should be sent to U.S. Food and Drug Administration, CDER/OC/Office of Unapproved Drugs and Labeling Compliance, 10903 New Hampshire Avenue, WO51, Silver Spring, MD 20993-0002 or by email to FDAADVISORY@fda.hhs.gov.

Sincerely,
/S/

Donald D. Ashley
Director
Office of Compliance
Center for Drug Evaluation and Research
Food and Drug Administration

/S/
Michael Dutcher
Acting Director of Compliance
Office of Surveillance & Compliance
Center for Veterinary Medicine
Food and Drug Administration

/S/
Michael W. Roosevelt
Acting Director
Office of Compliance
Center for Food Safety and Applied Nutrition
Food and Drug Administration

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1 From your website, www.nasadol.com, when you click “BUY NOW,” it directs to biospectrum.com and all of the products available on that website.

2 Section 505G of the FD&C Act was added under title III, subtitle F ("Over-the-Counter Drugs") of the CARES Act, Pub. L 116-136 (March 27, 2020).

3 We note that your “Pain Relief Roll-On” is made available for purchase by consumers without a prescription and that the label for that product includes ostensible "Drug Facts," which is part of the content and format required for OTC drug labeling under 21 CFR 201.66.

4 We note that OTC drug products such as your “Pain Relief Roll-On,” intended for external analgesic indications, such as the relief of pain, were addressed in the Tentative Final Monograph (TFM) for External Analgesic Drug Products for Over-the-Counter Human Use (external analgesic TFM; 48 FR 5852, February 8, 1983). CBD was not included as an active ingredient under this TFM.

5 21 CFR 330.1(e) requires that "the product contains only suitable inactive ingredients which are safe in the amounts administered and do not interfere with the effectiveness of the preparation or with suitable tests or assays to determine if the product meets its professed standards of identity, strength, quality, and purity".

6 See e.g., "Using the Inactive Ingredient Database" Guidance for Industry (July 2019), p. 1 at https://www.fda.gov/media/128687/download, and "Nonclinical Studies for the Safety Evaluation of Pharmaceutical Excipients" Guidance for Industry (May 2005), pp. 1-2 at https://www.fda.gov/media/72260/download (/media/72260/download).

7 See e.g., 21 CFR 314.3(b) and 21 CFR 210.3(b)(7), which define an active ingredient as “any component that is intended to furnish pharmacological activity or other direct effect in the diagnosis, cure, mitigation, treatment, or prevention of disease, or to affect the structure or any function of the body of man.” All other components of a finished drug product are considered inactive ingredients (see CFR 314.3(b), 21 CFR 210.3(b)(8)).

8 See 21 CFR 330.1(e).

9 For example, the labeling for Epidiolex (cannabidiol) prescription oral solution includes risks for the drug such as liver injury, interactions with other drugs or supplements, potential for male reproductive toxicity, somnolence, insomnia, diarrhea, decreased appetite, abdominal pain, upset stomach, changes in mood, irritability, and agitation. See https://www.accessdata.fda.gov/drugsatfda_docs/label/2020/210365s005s006s007lbl.pdf (https://www.accessdata.fda.gov/drugsatfda_docs/label/2020/210365s005s006s007lbl.pdf).

10 Under 505G(a) of the FD&C Act, drugs in a final monograph and drugs that were classified as Category III for safety and effectiveness in a TFM that is the most recently applicable proposal or determination issued under 21 CFR Part 330 -- and that were not classified in such a TFM as Category II for safety or effectiveness -- are not required to have an approved application under section 505 in order to be marketed, as long as they are in conformity with the relevant conditions of use outlined in the applicable final monograph or TFM, including labeling conditions, and comply with all other applicable requirements for nonprescription drugs. Drugs containing CBD as an active ingredient were not classified under any final monograph or any TFM as Category III for safety and effectiveness. Thus, your “CBD Containing Products” do not meet the conditions under section 505G(a) for lawful marketing absent an approved application.

11 Your “Pain Relief Roll-On” product is not the subject of an order issued under section 505G(b)(1) of the FD&C Act, 21 U.S.C 355h(b)(1), under which it is considered GRASE and can be lawfully marketed without an approved application.

12 As noted above, CBD, the active ingredient in “Regular Strength Nasadol CBD Nasal Spray” and “Extra Strength Nasadol CBD Nasal Spray,” is not an active ingredient in any applicable final monograph or TFM. Moreover, the website labeling for these products includes indications such as depression, anxiety, and addiction, which are indications not covered under any applicable final monograph or TFM.

13 CBD is the active ingredient in the approved drug product Epidiolex. Furthermore, the existence of substantial clinical investigations regarding CBD has been made public. For example, two such substantial clinical investigations include GW Pharmaceuticals’ investigations regarding Sativex and Epidiolex. (See Sativex Commences US Phase II/III Clinical Trial in Cancer Pain and GW Pharmaceuticals Receives Investigational New Drug (IND) from FDA for Phase 2/3 Clinical Trial of Epidiolex in the Treatment of Dravet Syndrome). FDA considers a substance to be “authorized for investigation as a new drug” if it is the subject of an Investigational New Drug application (IND) that has gone into effect. Under 21 CFR 312.2, unless a clinical investigation meets the limited criteria in that regulation, an IND is required for all clinical investigations of products that are subject to section 505 of the FD&C Act.

14 Under section 201(s) of the FD&C Act (21 U.S.C. 321(s)), the following types of substances are excluded from the food additive definition: (1) pesticide chemical residues in or on a raw agricultural commodity or processed food, (2) pesticide chemicals, (3) color additives, (4) substances used in accordance with a "prior sanction" (i.e., a sanction or approval granted prior to the enactment of the Food Additives Amendment of 1958 under the FD&C Act, the Poultry Products Inspection Act, or the Meat Inspection Act), (5) new animal drugs, and (6) dietary ingredients in or intended for use in a dietary supplement.

15 Under section 201(s)(5) of the FD&C Act (21 U.S.C. 321(s)(5)), new animal drugs are excluded from the food additive definition. If a new animal drug is unsafe within the meaning of section 512 because it is not approved for use in animal food, then the animal food is adulterated under section 402(a)(2)(C)(ii) of the FD&C Act.

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