# UNITED STATES DISTRICT COURT NORTHERN DISTRICT OF ILLINOIS

LYNDA CALDERON, individually and of	on
behalf of all others similarly situated	

Case No.

Plaintiff,

JURY TRIAL DEMANDED

vs.

The Procter & Gamble Company

Defendant.

**Class Action Complaint** 

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#### I. Introduction.

- 1. Melatonin is a neurohormone that regulates the brain's sleep cycle. Millions of consumers take over-the-counter melatonin supplements to help them sleep. Because melatonin alters brain chemistry, it is important that these supplements are accurately dosed and labelled.
- 2. A few years ago, scientists tested Canadian melatonin supplements and found that, for a number of brands, the true amount of melatonin varied wildly from the label. Scientists and the National Institute of Heath have warned that the same may be true here in the U.S.
- 3. Procter & Gamble's Vicks Pure Zzzs is a major U.S. brand of melatonin supplements, sold nationwide at retailers like Walmart, Walgreens, and Target. Each bottle claims to have a specific dose of melatonin per serving. For example:



4. Like millions of other consumers, Ms. Calderon bought Pure Zzzs Melatonin and trusted the accuracy of the dosing and labelling. To determine how much melatonin is really in Pure Zzzs, a university mass-spectrometry laboratory tested bottles of Pure Zzzs, including Plaintiff's bottle. The results were alarming—the bottles were substantially (and seemingly randomly) overdosed. The true amount of melatonin was 150% to 164% of the amount claimed. P&G systematically misrepresents how much melatonin is in the supplements it sells. Consumers are being misled, overcharged, and put at risk.

#### II. Parties.

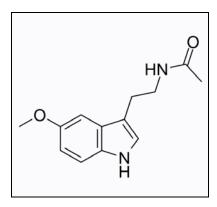
- Plaintiff Lynda Calderon is domiciled in Chicago, Illinois. She bought a bottle of
   Pure Zzzs in Illinois. The proposed class includes citizens of every state.
- 6. Defendant The Procter & Gamble Company ("P&G") is a citizen of Ohio. It is an Ohio corporation with its principal place of business in Cincinnati, Ohio.

#### III. Jurisdiction and Venue.

- 7. This Court has subject matter jurisdiction under 28 U.S.C. § 1332(d)(2). The amount in controversy exceeds \$5,000,000, exclusive of interest and costs, and the matter is a class action in which one or more members of the proposed class are citizens of a state different from Defendant.
- 8. The Court has personal jurisdiction over Defendant because it sold Pure Zzzs
  Melatonin to consumers in Illinois, including Plaintiff. P&G has been doing business in Illinois
  during all relevant times. Directly and through its agents, P&G has substantial contacts with Illinois,
  has purposefully availed itself of the Illinois market, and has received substantial benefits and
  income from Illinois.
- 9. Venue is proper under 28 U.S.C. § 1391(b)(1) and 28 U.S.C. § 1391(d) because Defendant would be subject to personal jurisdiction in this District if this District were a separate state, given that Defendant sold the Pure Zzzs Melatonin Products to consumers in this District, including Plaintiff. Venue is also proper under 28 U.S.C. § 1391(b)(2) because a substantial part of Defendant's conduct giving rise to the claims occurred in this District, including Defendant's sale to Plaintiff.

#### IV. Facts.

- A. It is important to consumers that over-the-counter melatonin is accurately dosed and labelled.
- 10. Melatonin (N-acetyl-5-methoxytryptamine) is a neurohormone produced by the pineal gland in the brain. It regulates the brain's circadian rhythm and sleep cycle.



The chemical structure of melatonin

- 11. Millions of U.S. consumers take melatonin supplements to treat sleep problems, anxiety, and other issues. Melatonin is one of the most popular over-the-counter supplements in the U.S., and its use has "significantly increased" in the last 20 years. <sup>1</sup> Its use to help children fall asleep is becoming increasingly popular too. <sup>2</sup>
- 12. As scientists explained in the Journal of Clinical Sleep Medicine, because melatonin is "self-prescribed" (i.e., purchased directly by consumers who are not experts), it is particularly "important that labels are informative and representative of the product," i.e., that the "label claim values for the active ingredient are accurate." <sup>3</sup> When melatonin is falsely labeled, lower doses of melatonin "might be ineffective," while "higher doses could lead to unpleasant/unexpected side effects." <sup>4</sup> Side effects of melatonin include headaches, dizziness, nausea, or excessive or unwanted sleepiness. <sup>5</sup> "Many experts recommend starting with the smallest available dosage 0.5 milligrams

<sup>&</sup>lt;sup>1</sup> JAMA Research Letter, Trends in Use of Melatonin Supplements Among US Adults, 1999-2018, 327(5) JAMA 483 (2022).

<sup>&</sup>lt;sup>2</sup> The New York Times, *Parents Are Relying on Melatonin to Help Their Kids Sleep. Should They?*, https://www.nytimes.com/2020/05/18/parenting/melatonin-sleep-kids.html

<sup>&</sup>lt;sup>3</sup> Erland, L. & Saxena, P., *Melatonin Natural Health Products and supplements: Presence of serotonin and significant variability of melatonin content*, 13 Journal of Clinical Sleep Medicine 275–281 (2017).

<sup>&</sup>lt;sup>4</sup> Grigg-Damberger, M. & Ianakieva, D., *Poor quality control of over-the-counter melatonin: What they say is often not what you get*, 13 Journal of Clinical Sleep Medicine 163–165 (2017).

<sup>&</sup>lt;sup>5</sup> NIH National Library of Medicine Medline Plus, Melatonin, https://medlineplus.gov/druginfo/natural/940.html

to 1 milligram." <sup>6</sup> And regardless of side effects, consumers don't want to take random, uncontrolled amounts of a neurohormone that alters brain chemistry.

- B. Scientific research reveals serious problems with the accuracy of melatonin dosing and labelling in Canada. Scientists warn that the same is likely true of some U.S. brands.
- 13. In 2017, a study of Canadian melatonin brands found "high variability, ranging from -83% to +478%, of the labeled concentration of melatonin content in melatonin supplements." <sup>7</sup> For over 70% of the tested brands, the true amount of Melatonin varied more than 10% from the listed amount. The amount of melatonin also varied highly between different lots (manufacturing batches) of the same product. The researchers concluded that "manufacturers require increased controls to ensure melatonin supplements" are accurately labeled.
- 14. U.S. scientists warned that this Canadian study "herald[s] what may also be true in OTC melatonin supplements marketed in the United States." <sup>8</sup> Likewise, the National Institute of Health has warned that "some melatonin supplements may not contain what's listed on the product label." <sup>9</sup> And Consumer Reports warned: "The findings ... offer the latest proof of something supplement industry critics have long warned about: When it comes to this poorly regulated corner of modern medicine, consumers often don't know what they're buying." <sup>10</sup>
  - C. P&G sells over-the-counter melatonin supplements to millions of U.S. consumers.

<sup>&</sup>lt;sup>6</sup> The New York Times, *Melatonin Isn't a Sleeping Pill. Here's How to Use It*, https://www.nytimes.com/2022/01/11/well/mind/melatonin-sleep-insomnia.html

<sup>&</sup>lt;sup>7</sup> Lauren, *Melatonin Natural Health Products and supplements*, 13 Journal of Clinical Sleep Medicine at 276.

<sup>&</sup>lt;sup>8</sup> Madeleine, *Poor quality control of over-the-counter melatonin*, 13 Journal of Clinical Sleep Medicine at 163.

<sup>&</sup>lt;sup>9</sup> NIH National Center for Complementary and Integrative Health, *Melatonin:What You Need To Know*, <a href="https://www.nccih.nih.gov/health/melatonin-what-you-need-to-know">https://www.nccih.nih.gov/health/melatonin-what-you-need-to-know</a>

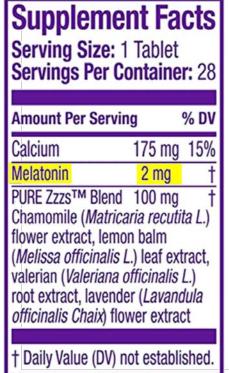
<sup>&</sup>lt;sup>10</sup> Consumer Reports, New Study Questions Ingredient Levels in Some Melatonin Supplements, https://www.consumerreports.org/melatonin/study-questions-ingredient-levels-some-melatonin-supplements/

- 15. P&G makes, markets and sells Pure Zzzs Melatonin supplements in the U.S. ("Pure Zzzs Melatonin"). Pure Zzzs is a major U.S. brand, available at retailers like Walmart, Target, and Walgreens. Millions of U.S. consumers buy Pure Zzzs Melatonin and rely on the accuracy of its labelling.
- 16. P&G makes and sells several varieties of Pure Zzzs Melatonin, including the following non-limiting examples: Pure Zzzs Melatonin, Pure Zzzs Sleep+ Immune Support, and Pure Zzzs Triple Action. For each product, the label claims a specific amount of melatonin per serving, e.g., 2 mg or 6 mg. Example products are shown below:











Amount Per Serving		% DV
Calories	25	
Total Carbohydrate	6 g	2%*
Total Sugars	5 g	1
Includes 5 g Added Sugars		9%*
Sodium	15 mg	<1%
Melatonin	6 mg	t
PURE Zzzs™ Triple Action Blend Ashwagandha (Withania somnifera) r (Matricaria recutita L.) flower extract, officinalis L.) leaf extract, valerian (Va extract, lavender (Lavendula officinal	, lemon balm ( <i>M</i> aleriana officina	felissa lis L.) root



Serving Size: 2 Gummies Servings Per Container: 24	1	
Amount Per Serving	0	% DV
Calories	25	
Total Carbohydrate	6 g	2%*
Total Sugars	5 g	t
Includes 5 g Added Sugars		9%*
Sodium	15 mg	<1%
Melatonin	1 mg	t
PURE Zzzs™ Kidz Blend 30 mg † Chamomile ( <i>Matricaria recutita L</i> .) flower extract, lavender ( <i>Lavandula officinalis Chaix</i> ) flower extract		

- 17. All Pure Zzzs Melatonin products are substantially similar. They all advertise melatonin as a key, active ingredient and claim to have a specific amount of melatonin per serving.
  - D. Scientific testing reveals that Pure Zzzs Melatonin has substantial overdoses of melatonin.
- 18. Liquid Chromatography-Mass Spectrometry analysis (LC-MS) can accurately measure the true amount of melatonin in an over-the-counter supplement. For Pure Zzzs Melatonin, a university mass-spectrometry lab used LC-MS to test Pure Zzzs Melatonin. The lab tested different bottles and types of Pure Zzzs Melatonin. The results are summarized below:

Pure Zzzs Type	Claimed melatonin dose (mg / gummy or tablet) <sup>11</sup>	True melatonin dose (mg / gummy or tablet) <sup>12</sup>	True melatonin dose (%) <sup>13</sup>
Pure Zzzs Melatonin (Gummies)	1	1.64	+163%
Pure Zzzs Nightly Sleep (Tablets)	1	1.5	+150%

<sup>&</sup>lt;sup>11</sup> The serving size for each bottle is 2 gummies or tablets /serving. Accordingly, the pertablet or per-gummy claimed amount of melatonin is half the per-serving claimed amount.

<sup>&</sup>lt;sup>12</sup> The lab tested three gummies or tablets per bottle and averaged the results. There was little variance in the melatonin content between gummies or tablets in the same bottle.

<sup>&</sup>lt;sup>13</sup> The percentage ratio of the true dose to the claimed dose.

19. As the results show, the melatonin content of Pure Zzzs is consistently overdosed. The bottle of Pure Zzzs Melatonin had over one and a half times the amount of melatonin listed on the label, and the bottle of Pure Zzzs Nightly Sleep had one and a half times the amount of listed melatonin. Something is systematically and seriously wrong with P&G's dosing and labelling.

#### E. P&G's labelling is false and misleading to reasonable consumers.

- 20. By selling a melatonin supplement for sleep (i.e., a supplement that alters brain chemistry), P&G is representing to consumers that its products are accurately dosed and labelled. When a consumer picks up a bottle of Pure Zzzs Melatonin, they reasonably expect that it actually has the dosage for which P&G designed the recommended serving. No reasonable consumer expects that a melatonin supplement has a random and substantial overdose of melatonin, compared to what it is supposed to have. More specifically, when a bottle of Pure Zzzs Melatonin says it has a specific amount of melatonin per serving (e.g., 2 mg), consumers expect this to be accurate.
- 21. At a bare minimum, reasonable consumers would expect that if the true amount of melatonin in Pure Zzzs Melatonin's supplements was substantially (and randomly) higher than the listed amount, P&G would prominently disclose this fact. Consumers do not know the accuracy of Pure Zzzs Melatonin's dosing—that is exclusively within P&G's knowledge. And P&G affirmatively represents that its products have a specific amount of melatonin, e.g., 2 mg and 6 mg.
- 22. P&G's labelling is false and misleading to consumers in multiple respects. The dosage of Pure Zzzs Melatonin is not well-controlled and consistent with the dosages for which P&G designed the recommended servings. Pure Zzzs Melatonin does not have the amount of melatonin claimed on the label. And P&G does not even mention that the actual dosage may vary.
- 23. The inaccurate dosing and labelling of Pure Zzzs Melatonin is highly material to reasonable consumers. Consumers need melatonin supplements to be accurately dosed and labelled,

so that consumers aren't unknowingly ingesting more neurohormone than they intend to take. No reasonable consumer wants to buy and ingest a supplement containing a random, undisclosed amount of melatonin. No reasonable consumer wants a product that even has a material risk of such problems.

- 24. P&G recognizes that its consumers demand accuracy in dosing and labelling. P&G sells different types of Pure Zzzs Melatonin, with different claimed strengths, so that consumers can choose what is right for them. The Pure Zzzs website and Pure Zzzs bottles claim that "Pure Zzzs products are made with an optimal amount of melatonin (1-2mg) per dose shown to help regulate your sleep cycle for no next day grogginess." <sup>14</sup> P&G says this because consumers want this to be true. But it is not true.
- 25. P&G also admits that it is undesirable and even dangerous for consumers to ingest more melatonin than the recommended dosage on the bottles. The PureZzzs website states: "The likelihood of these side effects [headaches, upset stomach, grogginess, sleeplessness, irritability and dizziness] increases with the dosage, which is why we recommend you take no more than 2mg of melatonin per night." <sup>15</sup> But due to Defendant's inaccurate dosing and labelling, P&G's customers are unknowingly doing exactly what P&G recommends against (exceeding the recommended dosage of melatonin per serving).
- 26. P&G knows, or reasonably should know, that its labels are inaccurate and that it is misleading consumers. As described above, P&G recognizes the importance of monitoring and controlling the dosage of its melatonin supplements.

<sup>14</sup> https://www.zzzquil.com/en-us/faq/zzzquil-pure-zzzs-melatonin-faq

<sup>15</sup> https://www.zzzquil.com/en-us/faq/zzzquil-pure-zzzs-melatonin-faq

#### F. P&G overcharges millions of consumers.

- P&G's false and misleading labelling drives the demand for Pure Zzzs Melatonin. As explained above, consumers demand melatonin that is accurately dosed and labelled. This is recognized by scientists, Consumer Reports, and P&G itself. If P&G told the truth—that its dosing and labelling was seriously inaccurate—the price of its products would crater. For example, on the Target website, a bottle of Pure Zzzs Melatonin gummies costs \$16.99. If consumers knew the truth—that this bottle likely has some random and excessive amount of melatonin per serving—P&G could not sell it for anything close to \$16.99 (or even sell it at all). Plaintiff and each class member paid a substantial price premium driven by P&G's false and misleading labelling.
- 28. In fact, without accurate dosing and labelling, Pure Zzzs Melatonin is worthless. What reasonable consumer wants to buy a supplement that alters brain chemistry, knowing that it may be randomly and substantially overdosed? There is no melatonin product on the market that tells its customers that its dosing is seriously inaccurate because such a product could not sell. Plaintiff and each class member paid for Pure Zzzs Melatonin products that are, in truth, worthless. Thus, the full economic injury here is the entire price of the Pure Zzzs Melatonin that Plaintiff and class members purchased.

#### G. Plaintiff was misled and harmed by P&G's misleading labelling.

- 29. Like millions of other consumers, Ms. Calderon bought Pure Zzzs Melatonin and relied on the accuracy of P&G's dosing and labelling.
- 30. In or around 2020, Lynda Calderon purchased a bottle of PureZzzs Nightly Sleep (Lot # 9073C60401) from a Target or Walgreens in Chicago. Because she was buying a melatonin supplement that could alter brain chemistry, she relied on the fact that P&G's dosages were well-controlled (i.e., that the actual dosage would match the recommended dosages). She read and relied on the accuracy of the melatonin content on the label when buying the product and deciding to take

it. She would not have purchased the product if she knew that P&G had serious problems with the accuracy of its dosing and labelling. In fact, knowing the truth, the product is worthless to her.

31. Plaintiff wants P&G to fix its manufacturing practices and sell its Pure Zzzs Melatonin products with accurate dosing and labelling. If P&G fixes its products, so that they are accurately dosed and labelled, Plaintiff would buy them again. But given P&G's past deception, Plaintiff cannot rely on P&G's word alone that it has fixed the problem. Plaintiff faces an imminent threat of harm because she will not be able to rely on P&G's labels in the future, and will not be able to buy Pure Zzzs Melatonin, even if P&G claims to have fixed the issue. To buy Pure Zzzs Melatonin products again, Plaintiff needs the Court to enter an order forbidding P&G from selling its melatonin unless it has fixed the dosing and labelling problem. With that Court order in hand, Plaintiff could and would buy Pure Zzzs Melatonin again. And with that order in hand, millions of other consumers will be protected from being deceived like Plaintiff was deceived.

#### V. Class action allegations.

32. Plaintiff brings her claims individually and on behalf of the following class and subclasses:

Class or Subclass Name	Definition
Nationwide Class	All persons who purchased
	Pure Zzzs Melatonin in the
	United States during the
	applicable statute of
	limitations.
Multi-State Consumer	All persons who purchased
Protection Subclass	Pure Zzzs Melatonin in the
	identified states (see Count 1)
	during the applicable statute of
	limitations.
Illinois Subclass	All persons who purchased
	Pure Zzzs Melatonin in Illinois
	during the applicable statute of
	limitations.

33. The following people are excluded from the class and the subclasses: (1) any Judge or Magistrate Judge presiding over this action and the members of their family; (2) Defendant, Defendant's subsidiaries, parents, successors, predecessors, and any entity in which the Defendant or its parents have a controlling interest and their current employees, officers and directors; (3) persons who properly execute and file a timely request for exclusion from the Class; (4) persons whose claims in this matter have been finally adjudicated on the merits or otherwise released; (5) Plaintiff's counsel and Defendant's counsel, and their experts and consultants; and (6) the legal representatives, successors, and assignees of any excluded persons.

#### Numerosity

34. The proposed class contains members so numerous that separate joinder of each member of the class is impractical. There are millions of proposed class members.

#### Commonality

- 35. There are questions of law and fact common to the proposed class. Common questions of law and fact include, without limitation:
  - Whether Pure Zzzs Melatonin products are accurately dosed and labelled;
  - Whether Pure Zzzs Melatonin labelling is misleading to reasonable consumers;
  - Whether P&G violated state consumer protection laws;
  - Damages needed to reasonably compensate Plaintiff and the proposed class.

#### **Typicality**

36. Plaintiff's claims are typical of the proposed class. Like the proposed class, Plaintiff purchased Pure Zzzs Melatonin.

#### Predominance and Superiority

37. The prosecution of separate actions by individual members of the proposed class would create a risk of inconsistent or varying adjudication with respect to individual members,

which would establish incompatible standards for the parties opposing the class. For example, individual adjudication would create a risk that Pure Zzzs Melatonin labelling is found to be misleading for some consumers, but not other similarly-situated consumers.

- 38. Common questions of law and fact predominate over any questions affecting only individual members of the proposed class. These common legal and factual questions arise from central issues that do not vary from class member to class member, and which may be determined without reference to the individual circumstances of any particular class member. For example, a core liability question is common: whether P&G's labelling is misleading to reasonable consumers.
- 39. A class action is superior to all other available methods for the fair and efficient adjudication of this litigation because individual litigation of each claim is impractical. It would be unduly burdensome to separately litigate millions of individual claims.

#### VI. Claims.

## Count 1: Violations of State Consumer Protection Acts (on behalf of Plaintiff and the Multi-State Consumer Protection Subclass)

- 40. Plaintiff incorporates each and every factual allegation set forth above.
- 41. As alleged below, Plaintiff brings individual and subclass claims based on Illinois consumer protection law. For the Multi-State Consumer Protection Subclass, Plaintiff brings this count for violations of state consumer protection laws that are materially-similar to the laws of Illinois, including:

State	Statute
California	Cal. Bus. & Prof. Code § 17200, and the following;
	Id. §17500, and the following; Cal. Civ. Code §1750
	and the following.
Connecticut	Conn. Gen Stat. Ann. § 42- 110, and the following.
Illinois	815 ILCS § 501/1, and the following.
Maryland	Md. Code Ann. Com. Law, § 13-301, and the
	following.
Missouri	Mo. Rev. Stat. § 407, and the following.
New York	N.Y. Gen. Bus. Law § 349, and the following.

- 42. Each of these statutes is materially similar. Each broadly prohibits deceptive conduct in connection with the sale of goods to consumers. No state requires individualized reliance, or proof of defendant's knowledge or intent. Instead, it is sufficient that the deceptive conduct is misleading to reasonable consumers and that the conduct proximately caused harm.
- 43. As alleged in detail above, P&G's misrepresentations and omissions are misleading to reasonable consumers in a material way. P&G's false and misleading labelling was a substantial factor in Plaintiff's purchase decisions and the purchase decisions of class members.
- 44. Plaintiff and class members were injured as a direct and proximate result of P&G's conduct because: (a) they would not have purchased Pure Zzzs Melatonin if they had known that P&G has serious and systematic problems with its dosing and labelling; (b) they overpaid for the products because the products are sold at a price premium due to P&G's misleading labelling; or (c) they received products that were, in truth, worthless.

### Count 2: Illinois Consumer Fraud and Deceptive Business Practices Act 815 ILCS 505/2 (on behalf of Plaintiff and the Illinois Subclass)

- 45. Plaintiff incorporates by reference each and every factual allegation set forth above.
- 46. Plaintiff brings this cause of action individually and for the Illinois Subclass.
- 47. Plaintiff and the Subclass purchased Pure Zzzs Melatonin products in Illinois.
- 48. Defendant's false and misleading labelling had the capacity to deceive a substantial portion of the public into believing that the Pure Zzzs Melatonin is accurately dosed and labeled.
- 49. Defendant's inaccurate dosing and labeling were material. As alleged in detail above, this false and misleading labelling was important to consumers and affected their choice to purchase Pure Zzzs Melatonin.

- 50. Defendant labeled the products this way because it intended consumers to rely on the labels and to believe that the products were accurately dosed and labelled.
- 51. Defendant's misrepresentations and omissions occurred in the conduct of trade or commerce affecting the people of the State of Illinois.
- 52. Plaintiff and class members were injured as a direct and proximate result of P&G's conduct because: (a) they would not have purchased Pure Zzzs Melatonin if they had known that Pure Zzzs Melatonin has serious and systematic problems with its dosing and labelling; (b) they overpaid for the products because the products are sold at a price premium due to P&G's misleading labelling; or (c) they received products that were, in truth, worthless.

## Count 3: Unjust Enrichment/Quasi-Contract (on behalf of Plaintiff and the Nationwide Class)

- 53. Plaintiff incorporates each and every factual allegation set forth above.
- 54. Plaintiff brings this claim individually and on behalf of the Nationwide Class.
- 55. As alleged in detail above, P&G's false and misleading labelling caused Plaintiff and the class to purchase Pure Zzzs Melatonin and overpay for it.
- 56. In this way, P&G received a direct and unjust benefit, at the expense of Plaintiff and the class.
  - 57. Plaintiff and the class seek the equitable return of this unjust benefit.

#### VII. Jury Demand.

58. Plaintiff demands a jury trial on all issues so triable.

#### VIII. Prayer for Relief.

- 59. Plaintiff seeks the following relief individually and for the proposed class and subclasses:
  - An order certifying the asserted claims, or issues raised, as a class action;
  - A judgment in favor of Plaintiff and the proposed class;

- Damages;
- Restitution, disgorgement, and other just equitable relief;
- An injunction;
- Pre- and post-judgment interest;
- Reasonable attorneys' fees and costs, as allowed by law; and
- Any additional relief that the Court deems reasonable and just.

Dated: June 24, 2022 Respectfully submitted,

By: <u>/s/ Jonas Jacobson</u>

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Counsel for Plaintiff

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# **ClassAction.org**

This complaint is part of ClassAction.org's searchable class action lawsuit database and can be found in this post: <u>Vicks ZzzQuil Pure Zzzs Melatonin Supplements Are 'Overdosed,' Class Action Alleges</u>