

**UNITED STATES DISTRICT COURT  
MIDDLE DISTRICT OF FLORIDA  
ORLANDO DIVISION**

TIMOTHY SINGER, Individually  
and All Others Similarly Situated,

Plaintiff,

vs.

THE PROCTER & GAMBLE  
COMPANY,

Defendant.

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**CLASS ACTION COMPLAINT  
JURY TRIAL DEMANDED**

Plaintiff, Timothy Singer (“Plaintiff”), by and through his attorneys, brings this action individually and on behalf of all others similarly situated against THE PROCTER & GAMBLE COMPANY (“Defendant” or “P&G” as referred to hereafter). Plaintiff hereby alleges, on information and belief, except for information based on personal knowledge, which allegations are likely to have evidentiary support after further investigation and discovery, as follows:

**INTRODUCTION**

1. P&G manufactures, markets, advertises, and sells a line of “ZzzQuil PURE Zzzs” melatonin products with the tagline “HELPS YOU FALL ASLEEP NATURALLY” (the “Product” or “Products”). Each Product label highlights this tagline on the front of the label in all caps and bolded green lettering.



An image of an example Product label is shown above, all Product labels can be viewed at [zzzquil.com](http://zzzquil.com).

2. P&G uses the “naturally” branding strategy and labeling claim as the primary feature differentiating the Products from other sleep-aid products in the marketplace. However, P&G’s “naturally” advertising and marketing is false, deceptive, and misleading because the Products contain several artificial and synthetic ingredients, including the primary ingredient in the Products, Melatonin. The Melatonin in the Products is a highly synthesized chemical that does not exist in nature and is not

made by nature. It is made in a lab and requires the use of toxic solvents and chemical catalysts. These ingredients are not “natural” and, thus, cannot “naturally” help a consumer sleep.

3. Singer relied on P&G’s representation that the Products’ ingredients, including the Products’ primary ingredients such as Melatonin, work “naturally” and are not synthetic or artificial, and that representation was material to the decisions of Singer and the other members of the Class (defined below) to purchase the Products. The “naturally” branding strategy and labeling representation is key to the marketing and sale of the Products, which is why P&G places the “naturally” advertising claim in bold, capitalized font on the front and center of the label.

4. P&G chose green, a color known to refer to nature, as the color of the font for the “naturally” representation. The label also includes images to enhance the “naturalness” of the Products including chamomile and lavender. The net-effect or net-impression of the Products’ labeling on consumers is that the Products do not contain ingredients that are synthetic, artificial, and subject to significant chemical modification and processing. Reasonable consumers are deceived into thinking the primary ingredient of the Products (Melatonin) is not synthetically made.

5. A reasonable consumer would expect that a Product branded and labeled as “naturally” being capable of inducing sleep would not contain synthetic, artificial ingredients and ingredients subject to chemical modification and processing.

Reasonable consumers certainly would not expect the primary ingredient printed on the front of the label to be a non-natural, highly processed chemical. A synthetic chemical does not and cannot “naturally” help you fall asleep. Accordingly, P&G’s “naturally” representation is false, misleading, and likely to deceive reasonable consumers. P&G’s advertising and marketing campaign is designed to cause consumers to purchase the Products as a result of this deceptive message.

6. Listed below are many of the Products,<sup>1</sup> including the primary and “other ingredients” listed on the label:

- a. **Melatonin + Chamomile & Lavender Tablets (60 count)** (Exhibit 1 at 1): Primary Ingredients: Melatonin and PURE Zzzs Blend [Chamomile (*Matricaria recutita* L.) flower extract, lemon balm (*Melissa officinalis* L.) leaf extract, valerian (*Valeriana officinalis* L.) root extract, lavender (*Lavandula officinalis* Chaix) flower extract]. Other Ingredients: Microcrystalline cellulose, croscarmellose sodium, calcium phosphate, maltodextrin, corn starch; Less than 2% of: Magnesium stearate, silicon dioxide, polyvinyl alcohol, polyethylene glycol, titanium dioxide, talc, Red 40 Lake, Blue 2 Lake.
- b. **Melatonin + Chamomile & Lavender Gummies** (24, 30, 48, 72, and

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<sup>1</sup> P&G may have sold other Products during the statute of limitations period of which Plaintiff is unaware, including other Product sizes/counts.

110 count) (Exhibit 1 at 2-4): Primary Ingredients: Melatonin and PURE Zzzs Blend [Chamomile (*Matricaria recutita* L.) flower extract, lemon balm (*Melissa officinalis* L.) leaf extract, valerian (*Valeriana officinalis* L.) root extract, lavender (*Lavandula officinalis* Chaix) flower extract]. Other Ingredients: Corn syrup, water, sugar; Less than 2% of: hydrogenated coconut oil, pectin, maltodextrin, citric acid, sodium potassium tartrate, soy lecithin, natural flavor, sodium citrate, malic acid, sodium polyphosphate, Red 40, Blue 1.

c. **Enhanced Formula Melatonin** (100 count) (Exhibit 1 at 5): Primary Ingredients: Melatonin and PURE Zzzs Blend [Chamomile (*Matricaria recutita* L.) flower extract, lemon balm (*Melissa officinalis* L.) leaf extract, valerian (*Valeriana officinalis* L.) root extract, lavender (*Lavandula officinalis* Chaix) flower extract]. Other Ingredients: Corn syrup, water, sugar; Less than 2% of: hydrogenated coconut oil, pectin, natural flavors, maltodextrin, sodium potassium tartrate, citric acid, soy lecithin, sodium citrate, malic acid, sodium polyphosphate, Red 40, Blue 1.

d. **Sleep + Muscle Relaxation Gummies** (26 and 42 count) (Exhibit 1 at 6): Primary Ingredients: Melatonin and Proprietary Blend [Chamomile (*Matricaria recutita* L.) flower extract, lavender (*Lavandula officinalis*

Chaix) flower extract]. Other Ingredients: Corn syrup, sucrose, water; Less than 2% of: agar, natural flavors, fumaric acid, tapioca starch, citric acid, vegetable juice (color), locust bean gum.

- e. **Sleep + Next Day Energy Tablets** (21 count, 28 count, and two 28 count) (Exhibit 1 at 7): Primary Ingredients: Melatonin and PURE Zzzs Blend [Chamomile (*Matricaria recutita* L.) flower extract, lavender (*Lavandula officinalis* Chaix) flower extract]. Other Ingredients: Calcium carbonate, microcrystalline cellulose, maltodextrin, hydroxypropyl methylcellulose; Less than 2% of: stearic acid, magnesium stearate, croscarmellose sodium, silicon dioxide, turmeric (color), hydroxypropyl cellulose, vegetable juice (color).
- f. **Back to Sleep Tablets** (Exhibit 1 at 8): Primary Ingredients: Melatonin. Other Ingredients: D-Mannitol, microcrystalline cellulose, povidone, xylitol., dicalcium phosphate; Less than 2% of: silicon dioxide, magnesium stearate, acesulfame potassium, natural flavor, citric acid (flavor enhancer).
- g. **Kidz Melatonin + Chamomile & Lavender Gummies** (Exhibit 1 at 9-10) Primary Ingredients: Melatonin and PURE Zzzs Kidz Blend [Chamomile (*Matricaria recutita* L.) flower extract, lavender (*Lavandula officinalis* Chaix) flower extract]. Other Ingredients: Corn

syrup, water, sugar; Less than 2% of: hydrogenated coconut oil, pectin, natural flavors, maltodextrin, sodium potassium tartrate, citric acid, soy lecithin, sodium citrate, malic acid, sodium polyphosphate, Red 40, Blue 1.

6. The following ingredients in the Products are synthetic and, thus, do not and cannot “naturally” help one fall asleep: Melatonin, Acesulfame Potassium, Blue 1, Blue 2 Lake, Calcium Phosphate, Calcium Carbonate, Citric Acid, Croscarmellose Sodium, D-Mannitol, Fumaric Acid, Hydroxypropyl Cellulose, Hydroxypropyl Methylcellulose, Malic Acid, Maltodextrin, Magnesium Stearate, Polyethylene Glycol, Polyvinyl Alcohol, Red 40, Red 40 Lake, Silicon Dioxide, Sodium Citrate, Sodium Polyphosphate, Sodium Potassium Tartrate, Stearic acid, and Titanium Dioxide. See *infra* ¶¶ 29-53 (detailing why each is synthetic and non-natural).

7. Plaintiff brings this action individually and on behalf of other similarly situated consumers in Florida to halt the dissemination of P&G’s false and misleading advertising message, correct the false and misleading perception it has created in the minds of consumers, and obtain redress for those who have purchased the Products. As a consequence of P&G’s deceptive labeling of the Products, Singer alleges P&G has violated and is violating Florida’s Deceptive and Unfair Trade Practices Act, Fla. Stat. 501.201 et seq.

## **JURISDICTION AND VENUE**

8. This Court has jurisdiction over this matter under the Class Action Fairness Act (“CAFA”), 28 U.S.C. § 1332(d)(2)(A), as the amount in controversy exceeds \$5 million, exclusive of interests and costs; it is a class action of over 100 members; and the Plaintiff is a citizen of a state different from at least one Defendant.

9. This Court has personal jurisdiction over Defendant. Defendant has sufficient minimum contacts with the state of Florida and purposefully availed themselves, and continue to avail themselves, to the jurisdiction of Florida through the privilege of conducting its business ventures in the state of Florida, thus rendering the exercise of jurisdiction by the Court permissible under traditional notions of fair play and substantial justice.

10. Venue is proper in this district under 28 U.S.C. § 1391(a) because a substantial part of the events or omissions giving rise to Plaintiff’s claims occurred in this district, as Defendants do business throughout this district, and Plaintiff made his purchase of P&G “ZzzQuil Pure Zzzzs” melatonin products (“Zzzquil” melatonin or “Products”) in Brevard County, Florida, from a retailer in this district and the purchased P&G “ZzzQuil Pure Zzzzs” melatonin products (“Zzzquil” melatonin or “Products”) were delivered to, and used, in this district.



## **THE PARTIES**

11. Plaintiff Timothy Singer is a natural person and a citizen and resident of Brevard County, Florida. Plaintiff purchased P&G “ZzzQuil Pure Zzzzs” melatonin products (“Zzzquil” melatonin or “Products”) from a local Walmart Store. He purchased the Products for his personal use during the applicable statute of limitations in Brevard County, Florida. Plaintiff Timothy Singer’s most recent purchase was Defendant’s P&G “ZzzQuil Pure Zzzzs” melatonin products (“Zzzquil” melatonin or “Products”), which were purchased at a Walmart Store for approximately \$15.00 during the applicable time period. Prior to purchasing the Products, Plaintiff saw and read the packaging which is sold under the label Vick’s “Zzzquil” melatonin. Plaintiff reasonably believed that the product he purchased was comprised of natural ingredients. The Plaintiff was not aware that the product contained a variety synthetic ingredients.

12. Plaintiff would not have purchased the Product if he knew that the product was not formulated from natural ingredients but contained a variety of synthetic ingredients and did help the purchaser “fall asleep naturally” as advertised.

13. Plaintiff would purchase the Product in the future; however, Plaintiff cannot now or in the future rely on the representations on the Product’s labels because he cannot know whether the contents remain false, and he may reasonably, but incorrectly, assume the Products were improved.

14. Defendant PROCTER & GAMBLE is an Ohio Corporation, with its principal place of business located at One Procter & Gamble Plaza, Cincinnati, OH 45202.

15. PROCTER & GAMBLE has labeled, advertised, distributed, and sold the Class Products for sale at its locations in Florida during the statute of limitations period under its Vicks label brand.

16. Defendant manufactures, markets, advertises, and distributes the Products throughout the United States. Defendant created and/or authorized the false, misleading, and deceptive advertisements, packaging, and labeling of its Products.

## **FACTUAL ALLEGATIONS**

### **A. REASONABLE CONSUMERS RELY ON THE “NATURALLY” ADVERTISING**

17. There is a strong consumer demand for products that are “natural” and free of highly processed, artificial, and synthetic ingredients. This demand is especially strong for “naturally” made dietary supplements. A recent survey of over 1,000 adults conducted by the Trust Transparency Center concluded that Americans favor “natural” dietary supplements over synthetically processed products and think synthetic supplements should be specifically labeled as “synthetic.”<sup>2</sup> In fact, the

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<sup>2</sup> Traci Kantowski, New Survey Finds Consumers Skeptical of Synthetic Dietary Supplements; Favor Labeling on All Synthetic Vitamins and Supplements, TRUST TRANSPARENCY CTR. (Sept. 5, 2018), <https://trusttransparency.com/new-survey- finds-consumers-skeptical-of-synthetic-dietary-supplements-favor-labeling-on-all- synthetic-vitamins-and-supplements/> [<https://perma.cc/7AD8-TZZV>].

results of the survey were so compelling that the founder of the Trust Transparency Center observed that “Consumers expect brands to be transparent with their materials and the results of this survey support that consumers want to know if the product they’re buying is derived from synthetic material.”<sup>3</sup> Similarly, the medical community has noted that “nutraceuticals of plant origin (plant-derived foods) tend to be more accepted by consumer than others.”<sup>4</sup>

18. In recent years, consumers have poured billions of dollars into the “natural” personal care market. Consumers value natural products for their perceived benefits of avoiding the perceived negative health effects of synthetic and artificial substances, attaining health and wellness, helping the environment, assisting local farmers, assisting factory workers who would otherwise be exposed to synthetic and hazardous substances, and financially supporting the companies that share these values.<sup>5</sup> As such, there is a recognized association among consumers and the concept of nature (e.g., “natural” products) and positive feelings associated with nature. Peer-reviewed and published research has found that the perceived naturalness of a product is “very important” to consumers.<sup>6</sup> In response to consumers’ desire for natural products, many companies, including P&G, have

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<sup>3</sup> Id.

<sup>4</sup> Marino B. Arnao & Josefa Hernández-Ruiz, The Potential of Phytomelatonin as a Nutraceutical, 23(1) MOLECULES 238 (2018).

<sup>5</sup> Id.

<sup>6</sup> S. Roman et al., The importance of food naturalness for consumers: Results of a systematic review, 67 TRENDS FOOD SCI. & TECH. 44-57 (2017).

rushed to manufacture, market, and sell purported “natural” products in an effort to gain market share. Unfortunately, rather than creating the natural products consumers desire, P&G has instead chosen to “greenwash” the Products and market them through deceptive labeling and advertising (i.e., the “naturally” advertising claims, green font, and natural imagery) to convince consumers the Products are made with natural ingredients. In reality, they contain numerous synthetic, artificial, and highly processed ingredients.

19. A reasonable consumer understands the representation that a Product “naturally” helps sleep to mean that none of its ingredients are synthetically created. A synthetically created Product cannot and does not “naturally” help with sleep.

20. P&G reinforces the “naturally” claim by writing it in a bolded green font. Green is the universal visual cue used to trigger implicit ecological and natural inferences, “but green can be abused through greenwashing practices intended to mislead consumers.”<sup>7</sup> Research has shown consumers “clearly associate the word and colour green” with “natural/organic ingredients” and production standards.<sup>8</sup>

21. P&G also emphasizes the “naturally” claim through its use of natural imagery on the Product labels including images of chamomile and lavender.

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<sup>7</sup> Dongjae Lim et al., *Colour effects in green advertising*, 44 INT’L J. CONSUMER STUD. 552 (2020).

<sup>8</sup> Id. at 553 (citing peer-reviewed published research).

22. A reasonable consumer’s understanding of the term “naturally” comports with the common meaning of the terms, federal regulatory definitions, and the scientific community’s knowledge.

23. Webster’s New World Dictionary defines “natural” as “produced or existing in nature; not artificial or manufactured.”<sup>9</sup> Similarly, Dictionary.com defines “natural” as not “artificial.”<sup>10</sup> The Merriam-Webster online dictionary defines “naturally” as “without artificial aid.”<sup>11</sup>

24. The “FDA agrees that the use of the word ‘natural’ on products that contain any artificial ingredients is inappropriate.”<sup>12</sup> The FDA states that the term “natural” means “nothing artificial or synthetic.”<sup>13</sup> The United States Department of Agriculture (“USDA”) also states that the term “natural” means “(1) the product does not contain any artificial flavor or flavoring, coloring ingredient, or chemical preservative . . . or any other artificial or synthetic ingredient; and (2) the product

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<sup>9</sup> SIMON & SCHUSTER, Webster’s New World Dictionary of the American Language 947 (2d college ed. 1984) (“natural,” definition no. 2).

<sup>10</sup> 10 See Natural, DICTIONARY.COM (2023), <https://www.dictionary.com/browse/natural> [<https://perma.cc/K9L4-9T9U>].

<sup>11</sup> Naturally, MERRIAM-WEBSTER.COM (2024), <https://www.merriam-webster.com/dictionary/naturally> [<https://perma.cc/7WEW-ECPS>].

<sup>12</sup> Letter from Philip C, Spiller, DEP’T HEALTH & HUMAN SERVS., U.S. FOOD & DRUG ADMIN., to Urvashi Rangan & Michael Crupain, FOOD SAFETY & SUSTAINABILITY CTR., CONSUMERS UNION/CONSUMER REPS. (Dec. 11, 2014), available at [https://advocacy.consumerreports.org/wp-content/uploads/2019/05/12\\_11\\_14\\_Letter\\_from\\_FDA\\_Caramel\\_Color-1.pdf](https://advocacy.consumerreports.org/wp-content/uploads/2019/05/12_11_14_Letter_from_FDA_Caramel_Color-1.pdf).

<sup>13</sup> Id.

and its ingredients are not more than minimally processed.”<sup>14</sup> The USDA recognizes that any “solvent extraction, acid hydrolysis, and chemical bleaching would clearly be considered more than minimal processing.”<sup>15</sup> Congress has defined “nonsynthetic (natural)” as “[a] substance that is derived from mineral, plant, or animal matter and does not undergo a synthetic process . . . .” 7 C.F.R. § 205.2.

25. The scientific community defines “synthetic” as “something that is man-made.”<sup>16</sup> Published scientific literature provides a useful example: “chemically synthesized B12 vitamin . . . is not natural . . . (obtained from Nature), it is synthetic.”<sup>17</sup> In other words, any man-made product is not present in nature and is not “natural” and therefore cannot influence the body “naturally.”<sup>18</sup>

26. Although there is no disclosure that the Products are synthetically made, any fine-print disclosure would contradict the express “naturally” representation on the front of the packaging. Further, a fine-print disclosure is not an effective or meaningful communication to consumers.<sup>19</sup> Reasonable consumers, like Singer, do

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<sup>14</sup> OFF. POL’Y, PROGRAM & EMP. DEV., FOOD SAFETY & INSPECTION SERV., U.S. DEP’T AGRIC., Food Standards and Labeling Policy Book (2024), available at <https://www.fsis.usda.gov/sites/default/files/import/Labeling-Policy-Book.pdf>.

<sup>15</sup> Id.

<sup>16</sup> Peter E. Nielsen, Natural – synthetic – artificial!, 1:1 ARTIFICIAL DNA: PNA & XNA 58-59 (2010).

<sup>17</sup> Id.

<sup>18</sup> Id.

<sup>19</sup> See, e.g., Karen Russo France & Paula Fitzgerald Bone, Policy Makers’ Paradigms and Evidence from Consumer Interpretations of Dietary Supplement Labels, 39(1) J. CONSUMER AFFS. 27-51 (2005); Marlys J. Mason et al., The Impact of Warnings, Disclaimers, and Product Experience on Consumers’ Perceptions of Dietary Supplements, 41(1)J.CONSUMER AFFS. 74-99 (2007); Aaron S. Kesselheim et al., Mandatory Disclaimers On Dietary Supplements Do Not Reliably

not notice such a fine-print, illegible disclosure, especially considering the bolded, highlighted, and prominent “Naturally” representation on the front label that would contradict the disclosure.

**B. COMPETITORS DO NOT USE “NATURAL” OR “NATURALLY” ADVERTISING**

27. The vast majority of P&G’s competitors do not use the deceptive “naturally” labeling claim. P&G uses the “naturally” advertising to obtain an unfair competitive advantage over its competitors and to increase sales because consumers are willing to pay more for products which are advertised as “naturally” influencing the body. Below are several examples of other sleep-aids which do not implement deceptive “natural” advertising:

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Communicate The Intended Issues, 34(3) HEALTH AFFS. 438-46, 445 (2015) (“We found ample evidence that such disclaimers are often misunderstood or ignored by consumers and had no effects on consumers’ ability to understand messages about health care products and critically evaluate potentially unsupported statements about effectiveness or safety.”); Tonya Dodge, Consumers’ perceptions of the dietary supplement health and education act: implications and recommendations, 8 DRUG TESTING & ANALYSIS 407-09, 409 (2016) (“[R]esearch suggests that the labelling requirements of DSHEA have little reliable impact on consumer beliefs about the risk and effectiveness of dietary supplements.”).



**C. THE PRODUCTS ARE NOT NATURAL AND, THUS, CANNOT HELP YOU “NATURALLY” FALL ASLEEP**

28. Despite P&G’s advertising claims, the Products are not “natural” and, thus, do not and cannot “naturally” help one fall asleep. For example, testosterone is a natural hormone when made by the body, similar to the Melatonin that is made by the body, but taking exogenous testosterone is not a “natural” way to increase testosterone levels. The medical community states that “natural options” for



increasing testosterone are losing weight and eating healthy.<sup>20</sup> “Medication options” include consuming or absorbing synthetically created testosterone.<sup>21</sup> This is why it is called “testosterone replacement therapy” and not simply a product that “naturally” increases testosterone levels.

29. Specific to the primary ingredient in the Products, Melatonin, the Mayo Clinic states that “[t]he term ‘natural’ means the hormones in the product come from plant or animal sources. They’re not made in a lab.”<sup>22</sup> The American Academy of Family Physicians explains for Melatonin “[t]here are two types: natural and synthetic (manmade). Natural melatonin is made from the pineal gland of animals. This form could be contaminated with a virus, so it’s not recommended.”<sup>23</sup>

30. The Products contain the following artificial or synthetic ingredients:

31. **Melatonin**, the primary ingredient in all the Products and printed on the front-facing label of the Products, is a non-natural, synthetically manufactured ingredient. Melatonin is made in a lab and is chemically synthesized, which requires the use of toxic solvents and catalysts. Melatonin is not extracted from natural sources.

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<sup>20</sup> UT SOUTHWESTERN MED. CTR., How low testosterone treatment can help – and harm – a man’s sex drive and fertility (Jan. 6, 2021), <https://utswmed.org/medblog/low-testosterone-symptoms-causes-treatment/> [<https://perma.cc/V3P7-3AMT>].

<sup>21</sup> *Id.*

<sup>22</sup> Tatnai Burnett, Bioidentical hormones: Are they safer?, MAYO CLINIC (Dec. 7, 2022), <https://www.mayoclinic.org/diseases-conditions/menopause/expert-answers/bioidentical-hormones/faq-20058460> [<https://perma.cc/UHY4-SQSK>].

<sup>23</sup> AM. ACAD. FAM. PHYSICIANS, Melatonin (Aug. 2023), <https://familydoctor.org/melatonin/> [<https://perma.cc/7VST-SQQ3>].

Melatonin was first isolated and characterized by the methoxy derivative of serotonin from bovine pineal tissue in an experiment which was published in 1960.<sup>24</sup> The experiment utilized 100 kg of bovine pineal glands to isolate Melatonin. The isolation required the use of the solvents methanol, ethanol, propanol, ethyl acetate, benzene, and heptane. Analytical grade petroleum ether was also utilized.

Today, melatonin is not commercially synthesized from bovine pineal glands due to risks of viral contamination. Instead, it is synthesized utilizing abundantly available toxic solvents and catalysts. For example, in 1960, Szmuszkovicz et al. reported two novel chemical pathways to synthesize Melatonin utilizing commercially available starting materials.<sup>25</sup> In the first synthesis, a displacement reaction was produced using 5-methoxyindole and cyanide, lithium aluminum hydride reduction, and acetylation.<sup>26</sup> In the second synthesis, 5-methoxyindole-3-aldehyde was condensed with nitromethane and the resulting unsaturated nitro compound was reduced with lithium aluminum hydride and acetylated. More

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<sup>24</sup> Aaron B. Lerner et al., Isolation of Melatonin and 5-Methoxyindole-3-acetic Acid from Bovine Pineal Glands, 235(7) J. BIOLOGICAL CHEMISTRY 1992-97 (1960).

<sup>25</sup> J. Szmuszkovicz et al., Synthesis of N-Acetyl-5-methoxytryptamine, 25(5)J. ORG. CHEM. 857-59 (1960).

<sup>26</sup> Cyanide is toxic by skin absorption, ingestion, and inhalation. See NAT'L CTR. BIOTECH. INFO., NAT'L LIBR. MED., NAT'L INSTS. HEALTH, Cyanide Ion, PUBCHEM (accessed Dec. 26, 2024), <https://pubchem.ncbi.nlm.nih.gov/compound/Cyanide-ion> [<https://perma.cc/26M2-2FVZ>]. Lithium aluminum hydride is an inorganic compound and a well-known "reducing agent" in the field of organic chemistry. See A. E. Finholt et al., Lithium Aluminum Hydride, Aluminum Hydride and Lithium Gallium Hydride, and Some of their Applications in Organic and Inorganic Chemistry, 69(5)J. AM. CHEM. SOC'Y 1199-1203 (1947).

recently, it was reported in Synthetic Communications that melatonin is synthesized by preparing phthalimide through a four-pot reaction which requires the use of microwave irradiation, a heating process which produces a higher Melatonin yield.<sup>27</sup> Phthalimide, the starting material for Melatonin synthesis, is produced from reacting phthalic anhydride and ammonia in a reaction tube at 250-80 degrees Celsius.<sup>28</sup> Exogenous Melatonin can be made from plants which has been recently called “Phytomelatonin” in a peer-reviewed article published in Molecules.<sup>29</sup> The authors explained the “differences between synthetic melatonin and phytomelatonin” in the publication. The authors note that “[p]ractically all melatonin supplements that are marketed are made from synthetic or animal origin” and “phytomelatonin” refers to melatonin made from plant precursors. The authors explain for synthetically created Melatonin, like the Melatonin in the Products, “[t]here are various production methods involving several synthetic routes.”<sup>30</sup> These include chemical syntheses utilizing the precursor chemicals: 5-Methoxy-3- indolylacetonitrile, 5-Methoxy-3-(2-nitroethyl)-indole, 5-Methoxytryptamine, and Phthalimide.<sup>31</sup> The authors explain that these synthetic processes yield “a large number of side products, i.e., residual

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<sup>27</sup> Ling He, Microwave Assisted Synthesis of Melatonin, 33(5) SYNTHETIC COMMUNICATIONS 741-47 (2003).

<sup>28</sup> Peter M. Lorz et al., Phthalic Acid and Derivatives, in ULLMANN’S ENCYCLOPEDIA OF INDUSTRIAL CHEMISTRY (2007).

<sup>29</sup> Arnao, supra note 4, at 238.

<sup>30</sup> Id. at 246

<sup>31</sup> Id. at 247 (Table 3).

compounds of the melatonin preparation processes also appear.”<sup>32</sup> The “most common of these which are present in the commercially available synthetic melatonin preparations”<sup>33</sup> are listed below<sup>34</sup>:

Table 4. Common contaminants in synthetic melatonin preparations.

Contaminant Compounds
1,2,3,4-tetrahydro- $\beta$ -carboline-3-carboxylic acid
3-(phenylamino)alanine
1,1'-ethylidenebis-(tryptophan) (so-called peak E)
2-(3-indolylmethyl)-tryptophan
formaldehyde-melatonin
formaldehyde-melatonin condensation products
hydroxymelatonin isomers
5-hydroxy-tryptamine derivatives
5-methoxy-tryptamine derivatives
N-acetyl- and diacetyl-indole derivatives
1,3-diphthalimidopropane
hydroxy-bromo-propylphthalimide
chloropropylphthalimide

The authors note that “[u]p to 14 contaminants have been described in the organic synthesis of melatonin . . . .”<sup>35</sup> The authors further note that the phthalimide synthesis is “subject to multiple toxicological investigations,”<sup>36</sup> and “the fact that phthalimide is present in toxic compounds such as pesticides and fungicides, suggests that some degree of toxicity is to be expected.”<sup>37</sup> As such, there is a “degree of risk involved in taking chemically synthesized melatonin supplements.”<sup>38</sup> The authors note that only “five commercial formulations exclusively composed of phytomelatonin are

<sup>32</sup> Id. at 246.

<sup>33</sup> Id.

<sup>34</sup> Id. at 247 (Table 4).

<sup>35</sup> Id.

<sup>36</sup> Id. at 248.

<sup>37</sup> Id.

<sup>38</sup> Id.

known.”<sup>39</sup> The Products do not include phytemelatonin. Synthetic Melatonin is the primary ingredient in all of the Products.

32. **Acesulfame Potassium**, also known as Ace-K, is an artificial sweetener. It was discovered in 1967 and is synthesized through a multistep chemical process. Acetoacetic acid is reacted with hydrochloric acid and ammonia to form an intermediate compound called acetoacetamide. Acetoacetamide is then reacted with potassium hydroxide to form potassium acetoacetamide. Sulfuryl chloride is added to potassium acetoacetamide to form the final product, acesulfame potassium. The resulting product is purified through a series of filtration and crystallization steps to obtain a fine powder of acesulfame potassium.

33. **Blue 1** is a synthetic food coloring. It is synthesized from petroleum-based chemicals through a multi-step process. The starting material is typically naphthalene, which is chemically modified through a series of reactions that can include sulfonation, oxidation, and diazotization. The resulting compound is then further processed to produce the final dye molecule. Studies have indicated that Blue 1 has known adverse health effects. The Center for Science in the Public Interest has published a report noting that an unpublished study has reported that potential kidney

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<sup>39</sup> Id. at 249; see also id. (Table 5).

tumors can result from ingestion of Blue 1.<sup>40</sup> Another study found possible adverse effects on nerve cells. Blue 1 “can cause hypersensitivity reactions.”

34. **Blue 2 Lake** is a synthetic food coloring. It is created by mixing Blue 2 (Indigo Carmine) with a substrate, such as alumina or calcium carbonate, and applying heat and pressure to form a crystalline structure that is insoluble in water. Blue 1 and Blue 2 Lake are two different forms of the same synthetic food color additive, Indigo Carmine (also known as Indigotine). The primary differences between the two are in their physical form and properties. Blue 2 Lake is chemically treated to make it insoluble in water.

35. The ingredient Calcium Phosphate in the Products is a non-natural, synthetically manufactured ingredient. “Calcium phosphate” is the common name for compounds containing one or more calcium and phosphate ions. It is produced by reacting phosphoric acid (H<sub>3</sub>PO<sub>4</sub>) with solid calcium hydroxide Ca(OH)<sub>2</sub>. Dicalcium phosphate anhydrate is used in cements, polishing agents, and dietary supplements.<sup>41</sup> It does not occur in normal or pathological calcifications.<sup>42</sup> Purified phosphate rock is reacted with calcium carbonate in the presence of an acid, which is typically hydrochloric acid. Hydrochloric acid is a strong, corrosive acid that can

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<sup>40</sup> Sarah Kobylewski & Michael F. Jacobson, CTR. SCI. PUB. INT., Food Dyes: A Rainbow of Risks v, 10, 12 (2010).

<sup>41</sup> Sergey V. Dorozhkin & Matthias Epple, Biological and Medical Significance of Calcium Phosphates, 41(17) ANGEWANDTE CHEMIE INT’L ED. 3130-46 (2002).

<sup>42</sup> Id.

be used industrially to process steel used in the building and construction industry.<sup>43</sup> It is used in the chemical industry in the large-scale production of vinyl chloride used to make polyvinyl chloride (PVC) plastic, and it is one of the chemicals that is used to produce polyurethane foam and calcium chloride. Hydrochloric acid is also used to make many other chemicals and as a disinfectant and slimicide, a chemical that prevents the growth of slime in paper stock. Other common end uses for hydrochloric acid include household cleaners, pool maintenance, and food manufacturing. Hydrochloric acid in its concentrated, liquid form has a strong irritating odor and is very corrosive. The food industry uses hydrochloric acid to process a variety of food products. The reaction of the phosphate rock, calcium carbonate, and hydrochloric acid produces calcium phosphate. Calcium phosphate can also be made by reacting calcium oxide or calcium hydroxide and phosphoric acid. The reactants are mixed together either by adding phosphoric acid to calcium oxide or by adding calcium oxide to phosphoric acid. The mixing is done under controlled conditions to ensure the appropriate temperature, pH, and other reaction parameters are maintained. The mixing of reactants results in the formation of different types of calcium phosphate such as monocalcium phosphate (MCP), dicalcium phosphate (DCP), and tricalcium phosphate (TCP). The synthesized

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<sup>43</sup> Hydrochloric Acid, CHEMICALSAFETYFACTS.ORG (Oct. 14, 2022), <https://www.chemicalsafetyfacts.org/chemicals/hydrochloric-acid/> [<https://perma.cc/M38R-EK75>].

product is then purified by removing any impurities or by-products formed during the reaction. Purification is typically done through filtration, centrifugation, or other methods. The synthetic extraction process for calcium phosphate is the most common method of production as it is a reliable and consistent method for producing the substance for use in dietary supplements.

36. The ingredient Calcium Carbonate in the Products is a non-natural, synthetically manufactured ingredient. Like calcium phosphate, calcium carbonate used for food and pharmaceuticals begins with quarrying marble. The process involves more than merely crushing rocks into dust. After a coarse grinding of the rock, mineral impurities are floated out of a slurry using a chemical flotation agent known as tall oil. Tall oil is a by-product mixture of saponified fatty acids (30%–60%), resin acids (40%–60%, including mostly abietic and pimaric acids), and unsaponifiables (5%–10%) derived from the wood extractives of softwoods. Crude tall oil is isolated from acidified skimming of partially concentrated black liquor. Black liquor is an industrial chemical. It is an aqueous solution of lignin residues, hemicellulose, and the inorganic chemicals used in the process. The black liquor comprises 15% solids by weight of which two thirds are organic chemicals and the remainder are inorganic. The isolated tall oil is then collected and refined at specialized processing plants. The refined products are sold commercially for soaps, rosin size, etc. Typically, 30–50 kg/t (60–100 lbs/ton) on pulp may be recovered



from highly resinous species representing about 30%–70% recovery.<sup>44</sup> The wash water and impurities are pumped outside the plant and into a series of unlined settling cells and former quarries. Processing begins after the calcium carbonate is retrieved and checked for impurities. The specified aggregate is then transferred to the Calcium Carbonate plant, in which it is milled and graded to various granular. Limestone is converted into calcium oxide and carbon dioxide by means of calcification at temperatures in excess of 900°C. The calcification process must be carried out by using natural gas. After the calcined lime has been slaked with water, the result lime is purified and carbonated with the carbon dioxide obtained from the calcification process. Following total carbonation, a suspension of CaCO<sub>3</sub> results. A cake comprising 40% - 60% solid matter is then obtained by filtration. Depending on the chemical composition of the milk of lime used and on the purifying stages during production, both technical as well as foodstuff and pharmaceutical grades such as antacids can be produced using the Precipitated Calcium Carbonate CenterManufacturing Process. The Precipitated Calcium Carbonate (“PCC”) CenterManufacturing production process consists of decarbonating limestone, which separates the CaO (calcium oxide) and CO<sub>2</sub> (carbon dioxide). Precipitated calcium carbonate is produced by slaking high-calcium quicklime to create a lime slurry that is then combined with captured carbon dioxide. An even precipitation

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<sup>44</sup> Pratima Bajpai, *BIERMANN’S HANDBOOK OF PULP AND PAPER VOL. 1* (3d ed. 2018).

process allows good control of the crystallization and particle size of the PCC. Lime reactivity is key to achieving a finer particle size distribution and particle shape of PCC, as well as the stability of the process.<sup>45</sup>

37. **Citric Acid** in the Products is a synthetic, non-natural ingredient. Citric acid is not extracted from citrus fruits, but industrially manufactured via microbial fermentation with typically genetically modified black mold (*Aspergillus niger*) by feeding it highly processed and/or genetically modified corn syrup. The FDA has recognized citric acid as a “chemical preservative.”<sup>46</sup> In fact, the FDA has issued letters to companies warning them that a product is deceptively labeled if it is advertised as natural when it contains citric acid.<sup>47</sup>

38. **Croscarmellose Sodium** is a synthetic, non-natural polymer. It is commonly used as a disintegrant in pharmaceuticals to promote the rapid release and dissolution of the active ingredients.<sup>48</sup> Croscarmellose sodium is made by first reacting cellulose with a solution of sodium hydroxide and monochloroacetic acid to produce sodium

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<sup>45</sup> CARMEUSE, Precipitated Calcium Carbonate (2024) <https://www.carmeuse.com/na-en/pcc-and-pulp-paper/precipitated-calcium-carbonate> [<https://perma.cc/F3Q8-4HSD>] [<https://perma.cc/9ZG7-6TKQ>].

<sup>46</sup> See David Bellm, Food packaging: FDA says Chiquita labels are misleading, PACKAGING DIGEST (Mar. 11, 2015), <https://www.packagingdigest.com/trends-issues/food-packaging-fda-says-chiquita-labels-are-misleading> [<https://perma.cc/3GAY-MTNU>].

<sup>47</sup> See Warning Letter from FDA to Hirzel Canning Co. (Aug. 29, 2001); Warning Letter from FDA to Richard Classey, Oak Tree Dairy Farm (Aug. 16, 2001).

<sup>48</sup> PARCHEM, Croscarmellose Sodium and Microcrystalline Cellulose are highly functional and efficient raw materials (2024), <https://www.parchem.com/news-articles/Croscarmellose-Sodium-and-Microcrystalline-Cellulose-are-highly-functional-and-efficient-raw-materials-N000121.aspx> [<https://perma.cc/KQ5H-XSMC>].

carboxymethylcellulose. Sodium Carboxymethylcellulose is then reacted with an agent such as epichlorohydrin in an alkaline environment. The resulting product is treated with acid to produce croscarmellose sodium. In large doses, croscarmellose sodium can create intestinal blockage—industrial workers producing this polymer are at the greatest risk.<sup>49</sup>

39. **D-Mannitol** is a highly processed ingredient which is sourced from the byproduct of industrial sugar processing. Mannitol is hydrogenated using hydrogen gas and a catalyst such as palladium. This converts the fructose into mannitol by adding hydrogen atoms to the fructose molecule. It is then filtered to remove the catalyst. Mannitol is used as a preoperative bowel cleanser.<sup>50</sup>

40. **Fumaric Acid** is synthesized commercially through the catalytic isomerization of maleic acid. The chemical process involves using a catalyst, such as a metal oxide, which is added to the maleic acid solution and the mixture is heated to a high temperature. The maleic acid is converted into fumaric acid through a chemical reaction catalyzed by the metal oxide. Fumaric acid is sometimes used in combination with other acids, such as citric acid, to create a sour taste that is similar to that of natural fruit juices.

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<sup>49</sup> NB ENTREPRENEURS, Croscarmellose Sodium – The Polymer in Demand (2018), <https://nb-cellulose.com/blog/croscarmellose-sodium-the-polymer-in-demand/> [https://perma.cc/E2RD-27Z9].

<sup>50</sup> Hany Shawkat et al., Mannitol: a review of its clinical uses, 12(2) CONTINUING EDUC. ANAESTHESIA, CRITICAL CARE & PAIN 82-85 (2012).

41. **Hydroxypropyl Cellulose** is a non-natural, synthetic ingredient. The production of Hydroxypropyl Cellulose involves multiple steps. First, cellulose is treated with a mixture of propylene oxide and caustic soda (sodium hydroxide) to introduce hydroxypropyl groups onto the cellulose backbone. Propylene Oxide is a synthetic, highly-flammable, volatile, colorless liquid that is soluble in water and miscible with many organic solvents. Propylene oxide is used primarily as a chemical intermediate in the production of polyethers and propylene glycol. It is also used as a pesticide and a fumigant for the sterilization of packaged foods and plastic medical instruments. Acute inhalation exposure to vapors of this compound can result in respiratory tract irritation, coughing, difficulty in breathing (dyspnea) and buildup of fluid in the lungs (pulmonary edema) that can possibly lead to pneumonia.<sup>51</sup> The propylene oxide and caustic soda reaction occurs at elevated temperature and pressure and is typically carried out in a reactor. After the etherification reaction is complete, the resulting product is neutralized with an acid to remove excess caustic soda and then washed several times to remove impurities.

42. **Hydroxypropyl Methylcellulose** is similar to hydroxypropyl cellulose as are both modified cellulose derivatives. Hydroxypropyl Methylcellulose is a methyl ether of cellulose that has been further modified with hydroxypropyl groups, while

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<sup>51</sup> NAT'L CTR.BIOTECH.INFO., NAT'L LIBR. MED., NAT'L INSTS. HEALTH, Propylene Oxide, PUBCHEM (accessed Dec. 26, 2024), <https://pubchem.ncbi.nlm.nih.gov/compound/Propylene-oxide> [<https://perma.cc/B7UT-6VG6>].

hydroxypropyl cellulose is a straight-chain ether of cellulose that has been modified with hydroxypropyl groups. It is made by treating cellulose with an alkaline solution to remove impurities and create a cellulose pulp. The cellulose pulp is then treated with a mixture of methanol and sodium hydroxide to form a cellulose alkali. Propylene oxide is added to the cellulose alkali under controlled conditions of temperature and pressure, and the reaction is allowed to proceed until the desired degree of substitution is achieved. The resulting product is then treated with hydrochloric acid to remove any unreacted materials and neutralize the alkali.

43. **Malic Acid** in the Products is a synthetic, non-natural ingredient. Malic acid is a dicarboxylic acid which is produced synthetically through various methods. Malic acid can be made using fumaric acid, a dicarboxylic acid, that can be converted into malic acid through hydration. Fumaric acid is made industrially through the use of catalytic oxidation of benzene or butane. Fumaric acid is used in the production of various polymers, resins, and coatings, as well as in the manufacture of certain types of plastics. The fumaric acid reaction is catalyzed by certain enzymes or acid catalysts. This method is commonly used in the food industry to produce malic acid. Malic acid can also be produced through fermentation of sugars or starches by certain microorganisms, such as *Aspergillus oryzae*, *Schizosaccharomyces pombe*, and *Lactobacillus plantarum*. Malic acid can

be produced synthetically through chemical reactions using various starting materials such as acetylene, carbon monoxide, and formaldehyde.

44. **Maltodextrin** is a non-natural, synthetic ingredient. Maltodextrin is a type of carbohydrate and “undergoes intense processing.”<sup>52</sup> It is manufactured by heating raw starch materials and then adding acids or enzymes to break it down through a process called enzymatic hydrolysis.<sup>53</sup> In this process, the starch slurry is mixed with water and heated to a specific temperature to activate the enzymes. Enzymes like amylase are added to the solution to break down the starch into shorter chains of glucose molecules. A diet with excess Maltodextrin will increase the risk of developing type 2 diabetes and high cholesterol.<sup>54</sup>

45. Magnesium Stearate is a magnesium salt that is listed as a synthetic ingredient under 7 C.F.R § 205.605(b); this ingredient is “prohibited in agricultural products labeled ‘organic.’” § 205.605(b). Magnesium Stearate is manufactured by using crude stearic acid which is distilled. Next, the stearic acid is then mixed with magnesium hydroxide in a reactor vessel. The mixture is heated and agitated to promote the reaction, which results in the formation of magnesium stearate and water.

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<sup>52</sup> WEBMD, What Is Maltodextrin? (July 10, 2023), <https://www.webmd.com/diet/what-is-maltodextrin> [<https://perma.cc/2RTM-AGD6>].

<sup>53</sup> Z. Rayhani et al., Classification of dextrose equivalent analysis maltodextrin starch seeds through enzymatic hydrolysis reaction, 420 IOP CONF. SERIES: MATERIALS SCI. & ENG’G 012072 (2018).

<sup>54</sup> WEBMD, *supra* note 52.

46. Polyethylene Glycol (PEG) is synthetically made by polymerizing ethylene oxide monomers, which are chemically modified to produce the final PEG polymer. PEG is made by the following steps. Ethylene oxide production: Ethylene oxide is produced by the direct oxidation of ethylene using a silver oxide catalyst. The resulting ethylene oxide gas is then purified through distillation to remove impurities. Polymerization: Ethylene oxide gas is then polymerized in the presence of a catalyst, such as a potassium hydroxide or ethylene diamine. The polymerization process can be carried out using either a batch or continuous process. During polymerization, the ethylene oxide monomers react with each other to form long chains of PEG. Purification: The resulting PEG polymer is typically purified through a series of washing and filtration steps to remove any unreacted ethylene oxide or catalysts. The PEG may also be subjected to additional processing steps, such as drying, milling, or blending with other materials, depending on the intended use of the material.

47. **Polyvinyl Alcohol** is a synthetic polymer. It is derived from the polymerization of vinyl acetate monomers, which are chemically modified to produce the final polymer. Polyvinyl alcohol is made using the following steps. Hydrolysis: Vinyl acetate monomers are first reacted with water in the presence of a catalyst, such as sodium hydroxide or sulfuric acid. This causes the vinyl acetate to undergo hydrolysis, resulting in the formation of vinyl alcohol monomers.

Polymerization: The vinyl alcohol monomers are then polymerized through a process called chain-growth polymerization. This involves the addition of a free radical initiator, such as potassium persulfate, which triggers the polymerization reaction and causes the monomers to link together to form the polymer. Purification: The resulting polymer is purified through a series of washing and filtration steps to remove any unreacted monomers, catalysts, or impurities. Polyvinyl alcohol is subjected to additional processing steps, such as drying, grinding, or blending with other materials, depending on the intended use of the material.

48. **Red 40** is a synthetic food coloring. Red 40 is synthesized from petroleum-based chemicals through a multi-step process. The main starting materials are petroleum-derived aromatic compounds such as benzene, toluene, or naphthalene. These compounds are chemically modified through a series of reactions that can include nitration, reduction, and sulfonation. The resulting compound is then further processed to produce the final dye molecule. The use of Red 40 has been the subject of controversy, with studies indicating that it may have adverse health effects. Published research<sup>55</sup> has noted that Red 40 has been found to be contaminated with benzidine or other carcinogens. Red 40 is known to cause hypersensitivity reactions.

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<sup>55</sup> Sarah Kobylewski & Michael F. Jacobson, Toxicology of food dyes, 18(3) INT'L J. OCCUPATIONAL & ENV'T HEALTH 220-46 (2012).



49. **Red 40 Lake** is a type of Red 40 that has been chemically treated to make it insoluble in water. Red 40 Lake is created by combining Red 40 with a substrate, such as alumina or calcium carbonate, and applying heat and pressure to form a crystalline structure.

50. **Silicon Dioxide** in the Products is a non-natural, synthetic ingredient. Silicon dioxide used in dietary supplements is produced using the precipitation method or the sol-gel process. The precipitation method involves adding a silica precursor, such as sodium silicate, to an acid solution. The acid reacts with the sodium silicate to form a silica gel, which is then washed and dried to produce a powder. The resulting silica powder is then milled to the desired particle size. The sol-gel process involves the hydrolysis and condensation of a silica precursor, such as tetraethyl orthosilicate (TEOS), in a solvent. The reaction is typically carried out at room temperature or slightly higher, and the resulting gel is dried and calcined to produce silica particles. The silica particles are then milled to the desired particle size.

51. **Sodium Citrate** in the Products is a synthetic, non-natural ingredient. Sodium Citrate is the trisodium salt of citric acid, which is synthetically created by mycological fermentation of crude sugar stocks. Sodium citrate is listed as being “synthetic” under 7 C.F.R. § 205.605.

52. **Sodium Polyphosphate** is a synthetic ingredient that is commonly used in food production and processing. It is a type of polyphosphate that is composed of

multiple linked phosphate units, and it is used primarily as a sequestrant and emulsifier. Sodium polyphosphate is made by the chemical reaction of sodium carbonate with phosphoric acid. The resulting compound is a white, odorless powder that is highly soluble in water. Sodium Polyphosphate is used in a variety of industrial applications, including water treatment, detergents, and ceramics.

53. **Sodium Potassium Tartrate** is produced synthetically by combining potassium tartrate (also known as cream of tartar) with sodium carbonate or sodium hydroxide in water. The resulting solution is then crystallized to produce the salt. Sodium hydroxide, also known as caustic soda, is a highly caustic and reactive compound that is commonly used in industry and manufacturing. It is a strong base that can dissolve in water to produce a highly alkaline solution. Sodium hydroxide is highly corrosive and can cause severe burns and other injuries if not handled properly.

54. **Stearic acid**, also known as octadecanoic acid, is a non-natural, synthetic ingredient. It is manufactured by heating fats and oils with an alkaline catalyst, such as sodium hydroxide or potassium hydroxide, to break the ester bonds between the fatty acids and glycerol. The resulting mixture of fatty acids is then separated through fractional distillation. This process separates the fatty acids based on their boiling points and produces a purer form of stearic acid. The stearic acid is separated from any liquid fatty acids or glycerol. The stearic acid may then be hydrogenated

to produce a more stable and higher melting point product. Hydrogenation involves adding hydrogen gas to the stearic acid in the presence of a catalyst, typically nickel or palladium, to saturate the carbon-carbon double bonds in the fatty acid chains.

55. **Titanium Dioxide** is synthetically manufactured. The chemical process involves using chlorine gas in a high temperature reactor to produce titanium tetrachloride. The titanium tetrachloride is then oxidized in the presence of air or oxygen to produce titanium dioxide particles. The oxidation process can be carried out using either a sulfate or a chloride process, depending on the intended use of the titanium dioxide. The resulting titanium dioxide particles are typically purified through a series of washing and filtration steps to remove any impurities, such as residual chloride ions or heavy metals. In January 2020, the European Food Safety Authority (EFSA) issued a scientific opinion on the safety of titanium dioxide as a food additive, in which they concluded that there was insufficient evidence to establish a safe level for daily intake. As a result, the European Commission has proposed a ban on the use of titanium dioxide as a food additive, which came into effect in 2022. This ban applies to all uses of titanium dioxide in food, including its use as a whitening agent and opacifier in confectionery, bakery products, and other food products.

56. As a result of the presence of these artificial and synthetic ingredients in the Products, reasonable consumers have been misled by P&G's false and misleading

representation that the Products “naturally” help one to sleep. Consumers lack the meaningful ability to test or independently ascertain the truthfulness of labeling claims such as “natural” and “naturally,” especially at the point of sale. Consumers would not know the true nature of the ingredients merely by reading the ingredient label; its discovery requires investigation beyond the retail store and knowledge of chemistry beyond that of the average consumer. Thus, reasonable consumers must and do rely on companies such as P&G to honestly report the nature of a supplement’s ingredients, and companies such as P&G intend and know that consumers rely upon labeling statements in making their purchasing decisions. There is a reason P&G places the “naturally” claim prominently on the front label—to influence consumers’ purchasing decisions when deciding to buy the Products.

57. P&G’s representation that the Products help you “naturally” sleep is a material representation because consumers attach importance to “naturally” claims when making purchase decisions, especially for products they consume like dietary supplements. P&G markets and advertises that the Products “naturally” help one to sleep in order to differentiate the Products from other sleep-aids, increase sales, and persuade consumers to purchase the Products. Singer and the members of the Class were intended consumers of P&G’s deceptive and misleading representation and reasonably relied to their detriment on P&G’s misleading “naturally” representations.

58. P&G's false, misleading, and deceptive misrepresentations are likely to deceive and mislead reasonable consumers and the general public. As a result of P&G's false, misleading, and deceptive representation that its Products "naturally" provide sleep, P&G injured Singer and the members of the Class in that Singer and the members of the Class: paid a sum of money for Products that were not as represented; were deprived of the benefit of the bargain because the Products they purchased were different from what P&G warranted; were deprived of the benefit of the bargain because the Products they purchased had less value than what P&G represented; received Products that were of a different quality than what P&G promised; and were denied the benefit of truthful labels.

59. Singer and the members of the Class would not have purchased the Products if they had known that the Products were not "natural," and thus cannot and do not "naturally" provide sleep. Alternatively, Singer and the members of the Class would not have purchased the Products at the price paid had they known that the Products contained artificial and synthetic ingredients and are thus, not "natural" and do not "naturally" provide sleep. Accordingly, Singer and the members of the Class have suffered injury in fact, lost money or property, and suffered economic damages as a result of P&G's wrongful conduct.

60. Singer and the members of the Class seek damages and equitable relief, including, but not limited to, injunctive relief, restitution, and disgorgement.

#### **D. THE IMPACT OF DEFENDANT’S WRONGFUL CONDUCT**

61. P&G conveyed and continues to convey that the Products will “naturally” help you fall asleep when the Products are comprised almost entirely of synthetic ingredients. Thus, the Products do not and cannot not “naturally” help you fall asleep because they are not natural. Synthetic and highly processed ingredients do not “naturally” influence the body.

62. As the manufacturer and distributor of the Products, P&G possesses specialized knowledge regarding its content and effects of its ingredients, and P&G is in a superior position to know whether the Products are deceptively advertised. In fact, P&G acknowledges that its “ZzzQuil was developed by the trusted sleep experts at Vicks.”<sup>56</sup>

63. Specifically, P&G knew, but failed to disclose, or should have known, that the Products’ “naturally” labeling is deceptive as the Products are not natural and do not and cannot help a person “naturally” fall asleep.

64. P&G knew, but failed to disclose, or should have known, that the Products could only synthetically work.

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<sup>56</sup> WALMART, Vicks PURE Zzzs Melatonin Sleep Aid Gummies, 1mg, Dietary Supplement, 48 Ct (2024), <https://www.walmart.com/ip/Vicks-PURE-Zzzs-Melatonin-Sleep-Aid-Gummies-1mg-Dietary-Supplement-48-Ct/963752291>.

65. P&G knew, but failed to disclose, or should have known, that the Products primary ingredients are synthetically created by industrial processes and are not natural and are not produced by natural processes as the front-facing label indicates.

66. Singer and the Class members have been and will continue to be deceived by P&G's deceptive representations.

67. P&G's affirmative "naturally" representations and omissions about the synthetic ingredients were a material factor in influencing Singer' and the Class members' decisions to purchase the Products. P&G's conduct has injured Singer and the Class members because the Product's do not work "naturally" or influence sleep "naturally." Had Singer and other reasonable consumers known this, they would not have purchased the Products or would not have paid the prices they paid.

68. The Products retail for approximately \$15 per unit. Because of P&G's unlawful and deceptive advertising, the Products have become one of the highest selling products in the sleep-aid product category. P&G claims the Products are the "WORLD'S #1 SLEEP AID BRAND."<sup>57</sup>

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<sup>57</sup> Id.

### **PLAINTIFF SPECIFIC ALLEGATIONS**

69. Plaintiff Timothy Singer is a Florida resident who places a high priority on consuming and utilizing products that are comprised of natural ingredients, and on the adverse health consequences of synthetic ingredients in products that he buys. In shopping for groceries and food products for himself, Plaintiff was particularly concerned about cost-effectiveness and purchasing natural sleep aids. Based on the statements made by Defendants, their widely recognized name, and lack of information that the Products contained synthetic ingredients, its labels claiming that the product was “natural”, Plaintiff believed the Zzzquil was natural and safe to consume. Plaintiff paid an ascertainable premium in the purchase price for Defendants’ product and should also be entitled to a full refund. Defendants’ representations and omissions of other ingredients on the label were material to Plaintiff.

70. Plaintiff bought and consumed P&G “ZzzQuil Pure Zzzzs” melatonin products throughout the applicable time period. Plaintiff was unaware when he bought the “ZzzQuil Pure Zzzzs” melatonin products that the Product contained other synthetic ingredients. Had Defendants been truthful and told Plaintiff that the Zzzquil was not natural, he would not have purchased P&G “ZzzQuil Pure Zzzzs” melatonin products.



71. Plaintiff suffered an ascertainable economic loss because of Defendant's statements and misrepresentations in that he bought the "ZzzQuil Pure Zzzzs" melatonin products that he would not have bought but for Defendant's statements and misrepresentations.

### **CLASS ACTION ALLEGATIONS**

72. **Class Definition:** Plaintiff brings this action on behalf of himself and the following Classes pursuant to Federal Rule of Civil Procedure 23(a), (b)(2) and/or (b)(3). Specifically, the Class are defined as:

All persons in the State of Florida who purchased the Products during the fullest period of law.

73. Plaintiff reserves the right to amend the Class definitions if further investigation and discovery indicates that the Class definitions should be narrowed, expanded, or otherwise modified.

74. **Numerosity and Ascertainability:** Plaintiff does not know the exact number of members of the putative classes. Due to Plaintiff's initial investigation, however, Plaintiff is informed and believes that the total number of Class members is at least in the tens of thousands, and that members of the Class are numerous and geographically dispersed throughout Florida. While the exact number and identities of the Class members are unknown at this time, such information can be ascertained

through appropriate investigation and discovery, including Defendants' records, either manually or through computerized searches.

**75. Typicality and Adequacy:** Plaintiff's claims are typical of those of the proposed Class, and Plaintiff will fairly and adequately represent and protect the interests of the proposed Class. Plaintiff does not have any interests that are antagonistic to those of the proposed Class. Plaintiff has retained counsel competent and experienced in the prosecution of this type of litigation.

**76. Commonality:** The questions of law and fact common to the Class members, some of which are set out below, predominate over any questions affecting only individual Class members:

- a. whether Defendant committed the conduct alleged herein;
- b. whether Defendants' conduct constitutes the violations of laws alleged herein;
- c. whether Defendants' labeling, sale and advertising set herein are unlawful, untrue, or are misleading, or reasonably likely to deceive;
- d. whether the P&G "ZzzQuil Pure Zzzzs" melatonin products ("Zzzquil" melatonin or "Products") are adulterated and/or misbranded under Florida or federal law;

e. whether Defendants knew or should have known that the representations were false or misleading in that the product advertises that it “helps you fall asleep naturally” ;

f. whether Defendants knowingly concealed or misrepresented material facts for the purpose of inducing consumers into spending money on the P&G “ZzzQuil Pure Zzzzs” melatonin products (“Zzzquil” melatonin or “Products”);

g. whether Defendants’ representations, concealments and non-disclosures concerning the P&G “ZzzQuil Pure Zzzzs” melatonin products (“Zzzquil” melatonin or “Products”) are likely to deceive the consumer;

h. whether Defendants’ representations, concealments and non-disclosures concerning the P&G “ZzzQuil Pure Zzzzs” melatonin products (“Zzzquil” melatonin or “Products”) violate FDUTPA and/or the common law;

i. whether Defendants should be permanently enjoined from making the claims at issue; and

j. whether Plaintiff and the Class are entitled to restitution and damages.

**77. Predominance and Superiority:** Common questions, some of which are set out above, predominate over any questions affecting only individual Class members.

A class action is the superior method for the fair and just adjudication of this

controversy. The expense and burden of individual suits makes it impossible and impracticable for members of the proposed Class to prosecute their claims individually and multiplies the burden on the judicial system presented by the complex legal and factual issues of this case. Individualized litigation also presents a potential for inconsistent or contradictory judgments. In contrast, the class action device presents far fewer management difficulties and provides the benefits of single adjudication, economy of scale, and comprehensive supervision by a single court on the issue of Defendants' liability. Class treatment of the liability issues will ensure that all claims and claimants are before this Court for consistent adjudication of the liability issues. A class action is superior to other available methods for the fair and efficient adjudication of this controversy for at least the following reasons:

- a. given the complexity of issues involved in this action and the expense of litigating the claims, few, if any, Class members could afford to seek legal redress individually for the wrongs that Defendant committed against them, and absent Class members have no substantial interest in individually controlling the prosecution of individual actions;
- b. when Defendants' liability has been adjudicated, claims of all Class members can be determined by the Court;

- c. this action will cause an orderly and expeditious administration of the Class claims and foster economies of time, effort and expense, and ensure uniformity of decisions; and
- d. without a class action, many Class members would continue to suffer injury, and Defendants' violations of law will continue without redress while Defendants continue to reap and retain the substantial proceeds of their wrongful conduct.

78. **Manageability:** The trial and litigation of Plaintiff's and the proposed Class claims are manageable. Defendants have acted and refused to act on grounds generally applicable to the Class, making appropriate final injunctive relief and declaratory relief with respect to the Class as a whole.

### **COUNT I**

#### **For Violations of Florida's Deceptive and Unfair Trade Practices Act, Fla. Stat. 501.201 et seq.**

79. Plaintiff realleges and incorporates by reference each of the allegations contained in the paragraphs above as if fully set forth herein.

80. Plaintiff brings this claim on their own behalf and on behalf of each member of the Class.

81. Defendants violated and continue to violate Florida's Deceptive and Unfair Trade Practices Act by engaging in unfair methods of competition, unconscionable

acts and practices, and unfair and deceptive acts and practices in the conduct of their business.

82. The material misstatements and omissions alleged herein constitute deceptive and unfair trade practices, in that they were intended to and did deceive Plaintiff and the general public into believing that the P&G “ZzzQuil Pure Zzzzs” melatonin products (“Zzzquil” melatonin or “Products”) were purely comprised of Zzzquil.

83. Plaintiff and Class members relied upon these advertisements in deciding to purchase the P&G “ZzzQuil Pure Zzzzs” melatonin products (“Zzzquil” melatonin or “Products”).

84. Plaintiff’s reliance was reasonable because of Defendants’ reputation as a reliable company.

85. Had Plaintiff known that the P&G “ZzzQuil Pure Zzzzs” melatonin products (“Zzzquil” melatonin or “Products”) were not as advertised, they would not have purchased the product. As a result of Defendants’ deceptive and unfair acts, Plaintiff and Class members have been damaged.

86. Defendants’ conduct offends established public policy, and is immoral, unethical, oppressive, and unscrupulous to consumers.

87. Plaintiff and Class members are entitled to a refund or damages in an amount to be proven at trial.

88. Defendants should also be ordered to cease their deceptive advertising and should be made to engage in a corrective advertising campaign to inform consumers that its P&G “ZzzQuil Pure Zzzzs” melatonin products (“Zzzquil” melatonin or “Products”) contain other oils.

**PRAYER FOR RELIEF**

WHEREFORE, Plaintiff prays this Court:

- a. Certify this action as a class action;
- b. Award a full refund, compensatory, statutory damages as to all Counts where such relief is permitted by law;
- c. Enjoin Defendants’ conduct and order Defendants to engage in a corrective advertising and labeling/disclosure campaign;
- d. Award equitable monetary relief, including a full refund or other restitution;
- e. Award pre-judgment and post-judgment interest at the legal rate;
- f. Award Plaintiff and Class members the costs of this action, including reasonable attorneys’ fees, costs, and expenses; and
- g. Award such other and further legal and equitable relief as this Court may deem just and proper.

**JURY DEMAND**

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

DATED: January 12, 2025

s/William C. Wright

WILLIAM WRIGHT  
FL Bar No. 138861  
willwright@wrightlawoffice.com  
KELLY MATA  
FL Bar No. 1015921  
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CIVIL COVER SHEET

The JS 44 civil cover sheet and the information contained herein neither replace nor supplement the filing and service of pleadings or other papers as required by law, except as provided by local rules of court. This form, approved by the Judicial Conference of the United States in September 1974, is required for the use of the Clerk of Court for the purpose of initiating the civil docket sheet. (SEE INSTRUCTIONS ON NEXT PAGE OF THIS FORM.)

I. (a) PLAINTIFFS

Timothy Singer, individually and on behalf of all others similarly situated

(b) County of Residence of First Listed Plaintiff Brevard (EXCEPT IN U.S. PLAINTIFF CASES)

(c) Attorneys (Firm Name, Address, and Telephone Number) The Wright Law Office P.A., 515 N Flagler Dr. Ste P300 West Palm Beach FL 33401-4326 (561) 514-0904

DEFENDANTS

The Procter & Gamble Company

County of Residence of First Listed Defendant Out of District (IN U.S. PLAINTIFF CASES ONLY)

NOTE: IN LAND CONDEMNATION CASES, USE THE LOCATION OF THE TRACT OF LAND INVOLVED.

Attorneys (If Known)

II. BASIS OF JURISDICTION (Place an "X" in One Box Only)

- 1 U.S. Government Plaintiff, 2 U.S. Government Defendant, 3 Federal Question (U.S. Government Not a Party), 4 Diversity (Indicate Citizenship of Parties in Item III)

III. CITIZENSHIP OF PRINCIPAL PARTIES (Place an "X" in One Box for Plaintiff and One Box for Defendant)

Table with columns for Plaintiff (PTF) and Defendant (DEF) citizenship and business location. Includes categories like Citizen of This State, Citizen of Another State, and Foreign Country.

IV. NATURE OF SUIT (Place an "X" in One Box Only)

Click here for: Nature of Suit Code Descriptions

Large table with columns: CONTRACT, REAL PROPERTY, TORTS, CIVIL RIGHTS, PRISONER PETITIONS, FORFEITURE/PENALTY, LABOR, IMMIGRATION, BANKRUPTCY, SOCIAL SECURITY, FEDERAL TAX SUITS, OTHER STATUTES. Contains various legal codes and descriptions.

V. ORIGIN (Place an "X" in One Box Only)

- 1 Original Proceeding, 2 Removed from State Court, 3 Remanded from Appellate Court, 4 Reinstated or Reopened, 5 Transferred from Another District, 6 Multidistrict Litigation - Transfer, 8 Multidistrict Litigation - Direct File

VI. CAUSE OF ACTION

Cite the U.S. Civil Statute under which you are filing (Do not cite jurisdictional statutes unless diversity): 28 U.S.C. § 1332. Brief description of cause: False advertising

VII. REQUESTED IN COMPLAINT:

CHECK IF THIS IS A CLASS ACTION UNDER RULE 23, F.R.Cv.P. DEMAND \$ 5,000,000. CHECK YES only if demanded in complaint: JURY DEMAND: Yes No

VIII. RELATED CASE(S) IF ANY

(See instructions):

JUDGE DOCKET NUMBER

DATE January 12, 2025 SIGNATURE OF ATTORNEY OF RECORD /s/ William Wright

FOR OFFICE USE ONLY

RECEIPT # AMOUNT APPLYING IFP JUDGE MAG. JUDGE

AO 440 (Rev. 06/12) Summons in a Civil Action

UNITED STATES DISTRICT COURT
for the
MIDDLE DISTRICT OF FLORIDA

TIMOTHY SINGER, individually and on behalf
of all others similarly situated,

Plaintiff(s)

v.

THE PROCTER & GAMBLE COMPANY,

Defendant(s)

Civil Action No.

SUMMONS IN A CIVIL ACTION

To: (Defendant's name and address) The Procter & Gamble Company
c/o CT Corporation System
4400 Easton Cmns Ste 125
Columbus OH 43219-6223

A lawsuit has been filed against you.

Within 21 days after service of this summons on you (not counting the day you received it) — or 60 days if you
are the United States or a United States agency, or an officer or employee of the United States described in Fed. R. Civ.
P. 12 (a)(2) or (3) — you must serve on the plaintiff an answer to the attached complaint or a motion under Rule 12 of
the Federal Rules of Civil Procedure. The answer or motion must be served on the plaintiff or plaintiff's attorney,
whose name and address are: William Wright, The Wright Law Office, P.A., 515 N Flagler Dr. Suite 350 West
Palm Beach FL 33401-4326, (561) 514-0904

If you fail to respond, judgment by default will be entered against you for the relief demanded in the complaint.
You also must file your answer or motion with the court.

CLERK OF COURT

Date:

Signature of Clerk or Deputy Clerk

AO 440 (Rev. 06/12) Summons in a Civil Action (Page 2)

Civil Action No. \_\_\_\_\_

**PROOF OF SERVICE**

*(This section should not be filed with the court unless required by Fed. R. Civ. P. 4 (l))*

This summons for *(name of individual and title, if any)* \_\_\_\_\_  
was received by me on *(date)* \_\_\_\_\_.

I personally served the summons on the individual at *(place)* \_\_\_\_\_  
\_\_\_\_\_ on *(date)* \_\_\_\_\_ ; or

I left the summons at the individual's residence or usual place of abode with *(name)* \_\_\_\_\_  
\_\_\_\_\_, a person of suitable age and discretion who resides there,  
on *(date)* \_\_\_\_\_, and mailed a copy to the individual's last known address; or

I served the summons on *(name of individual)* \_\_\_\_\_, who is  
designated by law to accept service of process on behalf of *(name of organization)* \_\_\_\_\_  
\_\_\_\_\_ on *(date)* \_\_\_\_\_ ; or

I returned the summons unexecuted because \_\_\_\_\_ ; or

Other *(specify)*:

My fees are \$ \_\_\_\_\_ for travel and \$ \_\_\_\_\_ for services, for a total of \$ \_\_\_\_\_.

I declare under penalty of perjury that this information is true.

Date: \_\_\_\_\_

\_\_\_\_\_  
*Server's signature*

\_\_\_\_\_  
*Printed name and title*

\_\_\_\_\_  
*Server's address*

Additional information regarding attempted service, etc: