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10 11 12 13 14	REESE LLP Michael R. Reese (State Bar No. 20677 100 West 93rd Street, 16th Floor New York, New York 10025 Telephone: (212) 643-0500 Facsimile: (212) 253-4272  Counsel for Plaintiff Valerie Perkins and the Proposed Class	3)
15 16	UNITED STATES	S DISTRICT COURT
17	SOUTHERN DISTRICT OF CALIFORNIA	
18		
19	and on behalf of all others similarly	Case No. 25CV0035 JO VET
20		CLASS ACTION COMPLAINT
21	Plaintiff,	JURY TRIAL DEMANDED
22	v.	
23	THE PROCTER & GAMBLE	
24	COMPANY,	
25	Defendant.	
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CLASS ACTION COMPLAINT

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Plaintiff Valerie Perkins ("Plaintiff" or "Perkins") brings this class action complaint against Defendant The Procter & Gamble Company ("Defendant" or "P&G"), and alleges upon personal knowledge as to her acts and experiences, and, as to all other matters, upon information and belief, including investigation by her attorneys, as follows.

### **INTRODUCTION**

P&G manufactures, markets, advertises, and sells a line of "ZzzQuil 1. 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 below.



Exemplars of the Products' front and back labeling are attached hereto as **Exhibit 1**.

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- 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 which 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.
- Perkins 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 Perkins 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.
- 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.
- 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 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

<sup>&</sup>lt;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.

1		Chaix) flower extract].
2		Other Ingredients: Corn syrup, water, sugar; Less than 2% of:
3		hydrogenated coconut oil, pectin, maltodextrin, citric acid,
4		sodium potassium tartrate, soy lecithin, natural flavor, sodium
5		citrate, malic acid, sodium polyphosphate, Red 40, Blue 1.
6	c.	Enhanced Formula Melatonin (100 count) (Exhibit 1 at 5):
7		Primary Ingredients: Melatonin and PURE Zzzs Blend
8		[Chamomile (Matricaria recutita L.) flower extract, lemon balm
9		(Melissa officinalis L.) leaf extract, valerian (Valeriana
10		officinalis L.) root extract, lavender (Lavandula officinalis
11		Chaix) flower extract].
12		Other Ingredients: Corn syrup, water, sugar; Less than 2% of:
13		hydrogenated coconut oil, pectin, natural flavors, maltodextrin,
14		sodium potassium tartrate, citric acid, soy lecithin, sodium
15		citrate, malic acid, sodium polyphosphate, Red 40, Blue 1.
16	d.	Sleep + Muscle Relaxation Gummies (26 and 42 count)
17		(Exhibit 1 at 6):
18		Primary Ingredients: Melatonin and Proprietary Blend
19		[Chamomile (Matricaria recutita L.) flower extract, lavender
20		(Lavandula officinalis Chaix) flower extract].
21		Other Ingredients: Corn syrup, sucrose, water; Less than 2% of:
22		agar, natural flavors, fumaric acid, tapioca starch, citric acid,
23		vegetable juice (color), locust bean gum.
24	e.	Sleep + Next Day Energy Tablets (21 count, 28 count, and two
25		28 count) (Exhibit 1 at 7):
26		Primary Ingredients: Melatonin and PURE Zzzs Blend
27		[Chamomile (Matricaria recutita L.) flower extract, lavender
28		(Lavandula officinalis Chaix) flower extract]. 4
		CLASS ACTION COMPLAINT

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.

7. 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).

8. Plaintiff brings this action individually and on behalf of other similarly situated consumers in California 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, Perkins alleges P&G has violated and is violating California's Consumers Legal Remedies Act, CAL. CIV. CODE § 1750 et seq. (the "CLRA"), and California's Unfair Competition Law, CAL. BUS. & PROF. CODE § 17200 et seq. (the "UCL").

### **JURISDICTION AND VENUE**

- 9. This Court has original jurisdiction over this action pursuant to 28 U.S.C. § 1332(d) because this is a class action in which: (1) there are over 100 members in the proposed class; (2) members of the proposed class have a different citizenship from Defendant; and (3) the claims of the proposed class members exceed \$5,000,000 in the aggregate, exclusive of interest and costs.
- 10. This Court has personal jurisdiction over P&G because P&G conducts and transacts business in the State of California, contracts to supply goods within the State of California, and supplies goods within the State of California. P&G, on its own and through its agents, is responsible for the formulation, ingredients, manufacturing, labeling, marketing, and sale of the Product in California, specifically in this district. The marketing of the Product, including the decision of what to include on the label, emanates from P&G. P&G maintains distribution centers in California and employs numerous employees in California. Thus, P&G has intentionally availed itself of the markets within California through its advertising, marketing, and sales of the Product to consumers, including Perkins.
- 11. Venue is appropriate in this Court pursuant to 28 U.S.C. § 1391 because a substantial part of the events or omissions giving rise to Perkins' claims occurred within this District, including Perkins' purchases of the Product based on P&G's

dissemination of false and misleading information about the nature, quality, and/or ingredients of the Product.

### **PARTIES**

- 12. Plaintiff Valerie Perkins is a citizen of and resides in California. Throughout 2022, Ms. Perkins purchased P&G's ZzzQuil Pure Zzzs Products in the tablet and gummy forms which had the "helps you fall asleep naturally" label for approximately \$15 per bottle at retail stores in El Cajon, California. When purchasing the Products, Perkins was exposed to, read, and relied on the "naturally" representation that was prominently displayed in green font on the Product's front label. At the time she made her purchases, Perkins believed that P&G's ZzzQuil Pure Zzzs "naturally" labeled Product was in fact natural, i.e., free of synthetic ingredients, and that the primary ingredient of the Products, Melatonin, was not a synthetically created substance. Perkins relied on P&G's representation that the ZzzQuil Pure Zzzs "naturally" labeled Product helped her sleep "naturally," and she would not have purchased the Products or would have paid less for the Products if she had known they were not naturally created but, instead, contained synthetic ingredients, including but not limited to the primary ingredient Melatonin. Perkins was injured in fact and lost money as a result of P&G's deceptive advertising.
- 13. Perkins would continue to purchase the Products at issue if they in fact contained only natural ingredients that, by definition, could work to "naturally" help her fall asleep. However, she is unable to rely on the Product's advertising or labeling in the future, and so will not purchase the Product although she would like to. Additionally, Perkins may purchase P&G's ZzzQuil Pure Zzzs "naturally" labeled Products in the future as she would still like to purchase a product that truthfully "naturally" helps with sleep, and she may reasonably, but incorrectly, assume the Product was improved.
- 14. Perkins did not notice any disclaimer, qualifier, or other explanatory statement or information on the Products' labels or packaging that contradicted the

prominent "naturally" front-facing labeling representation or otherwise suggested that the Products do not "naturally" help with sleep. At the time of Perkins' purchases, she did not know the Melatonin and other ingredients in the Products were synthetically manufactured and highly processed.

# REASONABLE CONSUMERS RELY ON THE "NATURALLY" ADVERTISING

15. 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." In fact, the 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." Similarly, the medical community has noted that "nutraceuticals of plant origin (plant-derived foods) tend to be more accepted by consumer than others."

16. 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

<sup>&</sup>lt;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), <a href="https://trusttransparency.com/new-survey-finds-consumers-skeptical-of-synthetic-dietary-supplements-favor-labeling-on-all-synthetic-vitamins-and-supplements/">https://trusttransparency.com/new-survey-finds-consumers-skeptical-of-synthetic-dietary-supplements-favor-labeling-on-all-synthetic-vitamins-and-supplements/</a> [https://perma.cc/7AD8-TZZV].

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

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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. 6 In response to consumers' desire for natural products, many companies, including P&G, have 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.

- 17. 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.
- 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."7 Research has shown consumers "clearly associate the word and colour *green*" with "natural/organic ingredients" and production standards.<sup>8</sup>
- 19. P&G also emphasizes the "naturally" claim through its use of natural imagery on the Product labels including images of chamomile and lavender.
  - A reasonable consumer's understanding of the term "naturally"

<sup>26</sup> S. Roman et al., The importance of food naturalness for consumers: Results of a ystematic review, 67 TRENDS FOOD SCI. & TECH. 44-57 (2017).

Dongjae Lim et al., Colour effects in green advertising, 44 INT'L J. CONSUMER 27

*Id.* at 553 (citing peer-reviewed published research).

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comports with the common meaning of the terms, federal regulatory definitions, and the scientific community's knowledge.

- 21. Webster's New World Dictionary defines "natural" as "produced or existing in nature; not artificial or manufactured." Similarly, Dictionary.com defines "natural" as not "artificial." The Merriam-Webster online dictionary defines "naturally" as "without artificial aid." 11
- 22. 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." 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 and its ingredients are not more than minimally processed."14 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.
  - The scientific community defines "synthetic" as "something that is

<sup>&</sup>lt;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> See Natural, DICTIONARY.COM (2023), <a href="https://www.dictionary.com/browse/natural">https://www.dictionary.com/browse/natural</a> [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].
12 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. <sup>13</sup> *Id*.

<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. 15 Id.

man-made." 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>

24. 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. 19 Reasonable consumers. like Perkins, do 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.

## **COMPETITORS DO NOT USE "NATURAL" OR "NATURALLY" ADVERTISING**

25. 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

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

<sup>18</sup> See id.

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 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.").

the body. Below are several examples of other sleep-aids which do not implement deceptive "natural" advertising:



















# THE PRODUCTS ARE NOT NATURAL AND, THUS, CANNOT HELP YOU "NATURALLY" FALL ASLEEP

26. 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. 20 "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.

- 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."22 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>
  - 28. The Products contain the following artificial or synthetic ingredients:
- 29. **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. 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.

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UT Southwestern Med. Ctr., How low testosterone treatment can help – and harm – a man's sex drive and fertility (Jan. 6, 2021), <a href="https://utswmed.org/medblog/">https://utswmed.org/medblog/</a> low-testosterone-symptoms-causes-treatment/ [https://perma.cc/V3P7-3AMT].

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

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

<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).

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 grands 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-3aldehyde was condensed with nitromethane and the resulting unsaturated nitro compound was reduced with lithium aluminum hydride and acetylated. More 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

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

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), <a href="https://pubchem.ncbi.nlm.nih.gov/compound/Cyanide-ion">https://pubchem.ncbi.nlm.nih.gov/compound/Cyanide-ion</a> [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).

Ling He, Microwave Assisted Synthesis of Melatonin, 33(5) SYNTHETIC COMMC'NS 741-47 (2003).

Peter M. Lorz et al., Phthalic Acid and Derivatives, in Ullmann's ENCYCLOPEDIA OF INDUSTRIAL CHEMISTRY (2007). Arnao, *supra* note 4, at 238.

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." These include chemical syntheses utilizing the precursor chemicals: 5-Methoxy-3-indolylacetonitrile, 5-Methoxy-3-(2-nitroethyl)-indole, 5-Methoxytryptamine, and Phthalimide. The authors explain that these synthetic processes yield "a large number of side products, i.e., residual compounds of the melatonin preparation processes also appear." The "most common of these which are present in the commercially available synthetic melatonin preparations" are listed below 34:

Table 4. Common contaminants in synthetic melatonin preparations.

# Contaminant Compounds 1,2,3,4-tetrahydro-β-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 . . . "35 The authors further note that the phthalimide synthesis is "subject to multiple toxicological investigations," 36 and "the fact that

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

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

<sup>32</sup> Id. at 246.
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<sup>&</sup>lt;sup>33</sup> *Id*. <sup>34</sup> *Id*. at 247 (Table 4).

 $<sup>28 \</sup>parallel \frac{33}{36} \stackrel{Id}{Id}$ . at 248.

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

- 30. 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.
- 31. **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 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."

<sup>37</sup> *Id*.

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

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

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- 32. **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.
- 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. 41 It does not occur in normal or pathological calcifications. 42 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 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

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

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 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.

34. 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. 44 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 Center-Manufacturing Process. The Precipitated Calcium Carbonate ("PCC") Center-Manufacturing 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 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>

35. Citric Acid in the Products is a synthetic, non-natural ingredient. Citric

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

<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].

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." 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. 47

- 36. **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 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>
- 37. **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

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

<sup>&</sup>lt;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-

tunctional-and-efficient-raw-materials-N000121.aspx [https://perma.cc/KQ5H-XSMC].

<sup>&</sup>lt;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].

catalyst. Mannitol is used as a preoperative bowel cleanser.<sup>50</sup>

- 38. **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.
- 39. **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. 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.
  - 40. **Hydroxypropyl Methylcellulose** is similar to hydroxypropyl cellulose

<sup>&</sup>lt;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).

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

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

- 41. **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.
- 42. **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

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

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>

- 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.
- **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

WEBMD, supra note 52.

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<sup>&</sup>lt;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).

intended use of the material.

- 45. **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 suing 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.
- 46. **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.
  - 47. Red 40 Lake is a type of Red 40 that has been chemically treated to

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

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- 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.
- 48. **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.
- 49. **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.
- 50. **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.
- 51. **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.

- 52. **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.
- 53. **Titanium Dioxide** is synthetically manufactured. The chemical process involves using chorine 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

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products, and other food products.

proposed a ban on the use of titanium dioxide as a food additive, which is expected to come into effect in late 2021. This ban applies to all uses of titanium dioxide in food, including its use as a whitening agent and opacifier in confectionery, bakery

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54. 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.

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55. 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. Perkins 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.

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P&G's false, misleading, and deceptive misrepresentations are likely to 56.

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- 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 Perkins and the members of the Class in that Perkins 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.
- 57. Perkins 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, Perkins 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, Perkins 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.
- 58. Perkins and the members of the Class seek damages and equitable relief, including, but not limited to, injunctive relief, restitution, and disgorgement.

### THE IMPACT OF DEFENDANT'S WRONGFUL CONDUCT

- 59. 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.
- 60. 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.

- 61. 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.
- 62. P&G knew, but failed to disclose, or should have known, that the Products could only synthetically work.
- 63. 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.
- 64. Perkins and the Class members have been and will continue to be deceived by P&G's deceptive representations.
- 65. P&G's affirmative "naturally" representations and omissions about the synthetic ingredients were a material factor in influencing Perkins' and the Class members' decisions to purchase the Products. P&G's conduct has injured Perkins and the Class members because the Product's do not work "naturally" or influence sleep "naturally." Had Perkins and other reasonable consumers known this, they would not have purchased the Products or would not have paid the prices they paid.
- 66. 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>

### NO ADEQUATE REMEDY AT LAW

67. Plaintiff and the Class members seek equitable relief, as no adequate

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

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- 68. The scope of actionable misconduct under the unfair prong of the UCL is broader than the other causes of action asserted herein. It includes P&G's overall unfair marketing scheme to promote and brand the Products with the "naturally" representations, across a multitude of media platforms, including the Products' labels and packaging, over a long period of time, in order to gain an unfair advantage over competitor products. The UCL also creates a cause of action for violations of law, and Perkins brings a claim for violation of the UCL's "unlawful prong." No other causes of actions allow this claim to proceed, and thus, there is no adequate remedy at law for this specific violation of the UCL's unlawful prong. Perkins' UCL unlawful prong claim does not rest on the same conduct as her other causes of action, and there is no adequate remedy at law for this specific claim. Perkins and the Class members may also be entitled to restitution under the UCL, while not entitled to damages under the CLRA (e.g., the CLRA is limited to certain types of plaintiffs (an individual who seeks or acquires, by purchase or lease, any goods or services for personal, family, or household purposes) and other statutorily enumerated conduct).
- 69. Injunctive relief is appropriate on behalf of Perkins and members of the Class because P&G continues to misrepresent the Products with the "naturally" representations. Injunctive relief is necessary to prevent P&G from continuing to engage in the unfair, fraudulent, and/or unlawful conduct described herein and to prevent future harm—none of which can be achieved through available legal remedies (such as monetary damages to compensate past harm). Injunctive relief, in the form of affirmative disclosures, is necessary to dispel the public misperception about the Products that has resulted from years of P&G's unfair,

fraudulent, and unlawful marketing efforts. Such disclosures would include, but are not limited to, publicly disseminated statements that the Products' labeling misrepresentations are not true and providing accurate information about the Products' true nature; and/or requiring prominent qualifications and/or disclaimers on the Products' front label concerning the Products' true nature. An injunction requiring affirmative disclosures to dispel the public's misperception, and prevent the ongoing deception and repeat purchases, is also not available through a legal remedy (such as monetary damages). In addition, Perkins is *currently* unable to accurately quantify the damages caused by P&G's future harm, because discovery and Perkins' investigation have not yet completed, rendering injunctive relief necessary. Further, a public injunction is available under the UCL, and damages will not adequately benefit the general public in a manner equivalent to an injunction.

70. It is premature to determine whether an adequate remedy at law exists. This is an initial pleading and discovery has not yet commenced and/or is at its initial stages. No class has been certified yet. No expert discovery has commenced and/or completed. The completion of fact/non-expert and expert discovery, as well as the certification of this case as a class action, are necessary to finalize and determine the adequacy and availability of all remedies, including legal and equitable, for Perkins' individual claims and any certified class or subclass. Perkins therefore reserves the right to amend this complaint and/or assert additional facts that demonstrate this Court's jurisdiction to order equitable remedies where no adequate legal remedies are available for either Plaintiff and/or any certified class or subclass. Such proof, to the extent necessary, will be presented prior to the trial of any equitable claims for relief and/or the entry of an order granting equitable relief.

**CLASS ALLEGATIONS** 

71. Plaintiff brings this action as a class action pursuant to Federal Rule of Civil Procedure 23(a), (b)(2), and(b)(3) on behalf of the following class:

**The Class.** All persons who purchased the Products for personal use in California within the applicable statute of limitations until the date class notice is disseminated.

- 72. Excluded from the Class are: (i) Defendant and its officers, directors, and employees; (ii) any person who files a valid and timely request for exclusion; and (iii) judicial officers and their immediate family members and associated court staff assigned to the case.
- 73. Plaintiff reserves the right to amend or otherwise alter the class definition presented to the Court at the appropriate time, or to propose or eliminate sub-classes, in response to facts learned through discovery, legal arguments advanced by P&G, or otherwise.
- 74. The Class is appropriate for certification because Perkins can prove the elements of the claims on a classwide basis using the same evidence as would be used to prove those elements in individual actions alleging the same claims.
- 75. <u>Numerosity</u>: The Class members are so numerous that joinder of all members is impracticable. Perkins believes there are thousands of consumers who are Class members described above who have been damaged by P&G's deceptive and misleading practices.
- 76. <u>Commonality and Predominance</u>: Common questions of law and fact affect all Class members, and common questions predominate. The questions of law and fact common to the Class members which predominate over any questions which may affect individual Class members include, but are not limited to:
  - a. whether P&G is responsible for the conduct alleged herein which was uniformly directed at all consumers who purchased the Product;
  - b. whether P&G's misconduct set forth in this Complaint

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demonstrates that P&G engaged in unfair, fraudulent, or unlawful business practices with respect to the advertising, marketing, and sale of the Product;

- whether P&G made false and/or misleading statements c. concerning the Product that were likely to deceive the public;
- whether Perkins and the Class are entitled to injunctive relief; d. and
- whether Perkins and the Class are entitled to money damages e. and/or equitable monetary relief under the same causes of action as the other Class members.
- Typicality: Perkins is a member of the Class she seeks to represent. Her 77. claims are typical of the claims of each Class member in that every member of the Class was susceptible to the same deceptive, misleading conduct and purchased the Product. Perkins seeks relief under the same claims as the other Class members.
- Adequacy: Perkins is an adequate Class representative because her interests do not conflict with the interests of the Class members she seeks to represent; the consumer fraud claims are common to all other members of the Class, and Perkins has a strong interest in vindicating her rights; and Perkins has retained counsel competent and experienced in complex class action litigation, and she intends to vigorously prosecute this action. Perkins has no interests which conflict with those of the Class. The Class members' interests will be fairly and adequately protected by Perkins and proposed Class Counsel.
- Superiority: a class action is superior to other methods for the fair and efficient adjudication of this controversy, since individual joinder of all members of the Class is impracticable and no other group method of adjudication of all claims asserted herein is more efficient and manageable. The prosecution of separate actions by individual Class members would create a risk of inconsistent and varying adjudications. The Class is properly brought and should be maintained as a class

action because a class action is superior to traditional litigation of this controversy. 2 A class action is superior to the other available methods for the fair and efficient adjudication of this controversy because: 3 the joinder of hundreds of individual Class members is 4 a. 5 impracticable, cumbersome, unduly burdensome, and a waste of judicial and/or litigation resources; 6 the individual claims of the Class members may be relatively 7 b. 8 modest compared with the expense of litigating the claim, 9 thereby making it impracticable, unduly burdensome, and 10 expensive to justify individual actions; 11 when P&G's liability has been adjudicated, all Class members' c. 12 claims can be determined by the Court and administered 13 efficiently in a manner far less burdensome and expensive than if it were attempted through filing, discovery, and trial of all 14 individual cases; 15 this class action will promote orderly, efficient, expeditious, and 16 d. 17 appropriate adjudication and administration of Class claims; Perkins knows of no difficulty to be encountered in the 18 e. 19 management of this action that would preclude its maintenance 20 as a class action; f. this class action will assure uniformity of decisions among Class 21 22 members; the Class is readily definable and prosecution of this action as a 23 g. class action will eliminate the possibility of repetitious litigation; 24 25 and Class members' interests in individually controlling the 26 h. 27 prosecution of separate actions is outweighed by their interest in efficient resolution by single class action. 28

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- 80. <u>Rule 23(b)(2)</u>: P&G has acted or refused to act on grounds generally applicable to the Class thereby making final declaratory and/or injunctive relief with respect to the members of the Class as a whole appropriate.
- 81. Unless the Class is certified, P&G will retain monies that were taken from Perkins and the Class members as a result of P&G's wrongful conduct. Unless a classwide injunction is issued, P&G will continue to commit the violations alleged and the members of the Class and the general public will continue to be misled.

### FIRST CLAIM FOR RELIEF

# Violation of California's Consumers Legal Remedies Act CAL. CIV. CODE § 1750 et seq.

- 82. Plaintiff realleges and incorporates by reference all allegations contained in this complaint, as though fully set forth herein.
- 83. Perkins brings this claim under the CLRA individually and on behalf of the Class against P&G.
- 84. At all times relevant hereto, Perkins and the members of the Class were "consumer[s]," as defined in California Civil Code section 1761(d).
- 85. At all relevant times, P&G constituted a "person," as defined in California Civil Code section 1761(c).
- 86. At all relevant times, the Products manufactured, marketed, advertised, and sold by P&G constituted "goods," as defined in California Civil Code section 1761(a).
- 87. The purchases of the Products by Perkins and the members of the Class were and are "transactions" within the meaning of California Civil Code section 1761(e).
- 88. P&G disseminated, or caused to be disseminated, through its advertising, false and misleading representations, including the Products' labeling that induce sleep "naturally," which they do not because the Products contain several artificial and/or synthetic ingredients, including primary ingredient

- a. P&G represented the Products have characteristics, ingredients, uses, and benefits which they do not have, CAL. CIV. CODE § 1770(a)(5);
- b. P&G represented the Products are of a particular standard, quality, or grade, which they are not, § 1770(a)(7);
- c. P&G advertised the Products with an intent not to sell the Products as advertised, § 1770(a)(9); and
- d. P&G represented that the subject of a transaction has been supplied in accordance with a previous representation when it has not, § 1770(a)(16).
- 89. P&G violated the CLRA because the Products are not "natural" and do not "naturally" help one sleep because they contain artificial and synthetic ingredients as discussed in detail above. P&G knew or should have known the Products were not "natural" and cannot "naturally" help one sleep because P&G created the Products using the artificial and synthetic ingredients described above.
- 90. P&G's actions as described herein were done with conscious disregard of Perkins' and the Class members' rights and were wanton and malicious.
- 91. P&G's wrongful business practices constituted, and constitute, a continuing course of conduct in violation of the CLRA, since P&G is still representing that the Products have characteristics which they do not have.
- 92. Pursuant to California Civil Code section 1782(d), Perkins and the members of the Class seek an order enjoining P&G from engaging in the methods, acts, and practices alleged herein, and for restitution and disgorgement.
- 93. Pursuant to California Civil Code section 1782, Perkins notified P&G in writing by certified mail of the alleged violations of the CLRA and demanded that P&G rectify the problems associated with the actions detailed above and give notice to all affected consumers of their intent to so act. P&G failed to rectify or

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agree to rectify the problems associated with the actions detailed herein and give notice to all affected consumers within 30 days of the date of written notice pursuant to section 1782 of the CLRA. Perkins therefore seeks actual, punitive, and statutory damages.

94. Pursuant to section 1780(d) of the CLRA, below is an affidavit showing that this action was commenced in a proper forum.

### SECOND CLAIM FOR RELIEF

### Violation of California's Unfair Competition Law

### CAL. BUS. & PROF. CODE § 17200 et seq.

- Plaintiff realleges and incorporates by reference all allegations 95. contained in this complaint, as though fully set forth herein.
- Perkins brings this claim under the UCL individually and on behalf of 96. the Class against P&G.
- The UCL prohibits any "unlawful," "fraudulent," or "unfair" business act or practice and any false or misleading advertising.
- P&G committed unlawful business acts or practices by making the representations (which also constitutes advertising within the meaning of California Business & Professions Code section 17200), as set forth more fully herein, and violating the CLRA. P&G's unlawful conduct is ongoing and continues to this date.
- 99. P&G committed "unfair" business acts or practices by: (1) engaging in conduct where the utility of such conduct is outweighed by the harm to Perkins and the members of the Class; (2) engaging in conduct that is immoral, unethical, oppressive, unscrupulous, or substantially injurious to Perkins and the members of the Class; and (3) engaging in conduct that undermines or violates the intent of the consumer protection laws alleged herein. There is no societal benefit from false advertising. Perkins and the other Class members paid for a Product that is not as advertised by P&G. While Perkins and the other Class members were harmed, P&G was unjustly enriched by their false misrepresentations. As a result, P&G's conduct

- 100. P&G committed "fraudulent" business acts or practices by making the representations of material fact regarding the Products set forth herein. P&G's business practices as alleged are "fraudulent" under the UCL because they are likely to deceive customers into believing the Products "naturally" help with sleep when the Products are not natural and do not work naturally because they contain artificial and synthetic ingredients.
- 101. Perkins and the other members of the Class have in fact been deceived as a result of their reliance on P&G's material representations. This reliance has caused harm to Perkins and the other members of the Class, each of whom purchased P&G's Products. Perkins and the other Class members have suffered injury in fact and lost money as a result of purchasing the Products and P&G's unlawful, unfair, and fraudulent practices.
- 102. P&G's wrongful business practices and violations of the UCL are ongoing.
- 103. Perkins and the Class seek pre-judgment interest as a direct and proximate result of P&G's unfair and fraudulent business conduct. The amount on which interest is to be calculated is a sum certain and capable of calculation, and Perkins and the Class seek interest in an amount according to proof.
- 104. Unless restrained and enjoined, P&G will continue to engage in the above-described conduct. Accordingly, injunctive relief is appropriate. Pursuant to California Business & Professions Code section 17203, Perkins, on behalf of herself and the Class, seeks (1) restitution from P&G of all money obtained from Perkins and the other Class members as a result of unfair competition; (2) an injunction prohibiting P&G from continuing such practices in the State of California that do not comply with California law; and (3) all other relief this Court deems

appropriate, consistent with California Business & Professions Code section 17203. 1 2 **REQUEST FOR RELIEF** 3 Plaintiff, individually, and on behalf of all others similarly situated, requests for relief pursuant to each claim set forth in this Complaint, as follows: 4 declaring that this action is a proper class action, certifying the Class as 5 requested herein, designating Plaintiff as Class Representative and appointing the 7 undersigned counsel as Class Counsel; 8 ordering restitution and disgorgement of all profits and unjust enrichment that Defendant obtained from Plaintiff and the Class members as a result 9 of Defendant's unlawful, unfair, and fraudulent business practices; 10 ordering injunctive relief as permitted by law or equity, including 11 12 enjoining Defendant from continuing the unlawful practices as set forth herein, and 13 ordering Defendant to engage in a corrective advertising campaign; 14 d. ordering damages for Plaintiff and the Class; ordering Defendant to pay attorneys' fees and litigation costs to 15 e. Plaintiff and the other members of the Class; 16 17 ordering Defendant to pay both pre- and post-judgment interest on any amounts awarded; and 18 19 ordering such other and further relief as may be just and proper. g. 20 **JURY DEMAND** 21 Plaintiff demands a trial by jury of all claims in this Complaint so triable. 22 Date: December 27, 2024 CROSNER LEGAL, P.C. 23 24 By: <u>/s/ Craig W. Straub</u> CRAIG W. STRAUB 25 Craig W. Straub 26 (a)crosnerlegal.com 27 zach@crosnerlegal.com 9440 Santa Monica Boulevard, Suite 301 28 Beverly Hills, California 90210

CLASS ACTION COMPLAINT

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9	Telephone: (212) 643-0500 Facsimile: (212) 253-4272			
10	Counsel for Plaintiff Valerie Perkins and the			
11	Proposed Class			
12	Civil Code Section 1780(d) Affidavit			
13	I am an attorney duly licensed to practice before all of the courts of the State			
14	of California. I am one of the counsel of record for Plaintiff. This declaration is			
15	made pursuant to § 1780(d) of the California Consumers Legal Remedies Act.			
16	Defendant has done, and are doing, business in California, including in this district.			
17	I declare under penalty of perjury under the laws of the State of California that the			
18	foregoing is true and correct. Executed January 7, 2025 at San Diego, California.			
19	By: /s/ Craig W. Straub			
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