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(54) Title: DOSAGE DELIVERY FILM

(57) Abstract: A dosage delivery film composition containing a botanical drug substance formable into a bioerodible dosage delivery film, the dosage delivery film composition including: (i) one or more of: a polymer, a plasticizer, a defoamer, or an antioxidant; (ii) a cannabinoid-cyclodextrin- terpene complex or a cannabinoid-terpene-surfactant micelle, and (iii) optionally, one or more of: a taste mask, a vasodilator, or a lipophilic vehicle to transport the botanical drug substance across the mucous membrane.



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DOSAGE DELIVERY FILM

This International Patent Cooperation Treaty Patent Application is a continuation of United States Non-Provisional Patent Application No. 15/611,581, filed June 1, 2017, hereby incorporated by reference herein.

5 I. TECHNICAL FIELD

Generally, a dosage delivery film for oral delivery of a dosage of a botanical drug substance. Specifically, a dosage delivery film composition containing a botanical drug substance formable into a bioerodible dosage delivery film, the dosage delivery film composition including: (i) one or more of: a polymer, a plasticizer, a defoamer, or an antioxidant; (ii) a cannabinoid-cyclodextrin-terpene complex or a cannabinoid-terpene-surfactant micelle, and (iii) optionally, 10 one or more of: a taste mask, a vasodilator, or a lipophilic vehicle to transport the botanical drug substance across the mucous membrane.

II. BACKGROUND

The administration, or method of delivery, of pharmaceutically active agents can be by 15 oral administration utilizing syrups, tablets, and dosage delivery films. Of these drug delivery methods, dosage delivery films have proven particularly effective for a class of patients with phagophobia, a fear of swallowing, pnigophobia, a fear of choking, and dysphagia, difficulty swallowing. In dosage delivery film applications, a pharmaceutically active agent can be contained in a dosage delivery film which dissolves within the mouth of the patient, delivering 20 the pharmaceutically active agent buccally or sublingually, obviating the need to swallow the pharmaceutically active agent. Further, the use of dosage delivery films may promote greater bioavailability of the pharmaceutically active agent, because the pharmaceutically active agent can be delivered directly to the capillaries of the mouth, and thereby, the bloodstream. This method of delivery avoids the need for the pharmaceutically active agent to be absorbed by the 25 stomach, and further avoids the first-pass effect of the liver, which can reduce bioavailability of the drug when given in tablet or liquid form.

With the legalization of marijuana in several states and the emerging promise of extracts from various species of *Cannabis* as natural pharmaceutical active agents, methods of delivery of the *Cannabis* extracts are of interest. Cannabinoid extracts derived from species of *Cannabis* 30 have been shown to be effective treatments for glaucoma, epilepsy, Dravet's syndrome, cancer, anxiety, Alzheimer's, muscle spasms, pain from multiple sclerosis, inflammatory bowel disease,

pain from arthritis, lupus, Parkinson's disease, post-traumatic stress disorder, pain and nausea accompanying chemotherapy, anorexia, and drug dependency and withdrawal. Currently, cannabinoids are often ingested as a component of an edible composition, whether as solids or liquids, or by inhalation of smoke from burning the leaves of or extracts obtained from the
5 *Cannabis* plant.

Each of these methods of delivery can have certain limitations or drawbacks. Inhalation of the smoke can irritate the lungs, leading to adverse health effects. Ingestion can reduce efficacy due to malabsorption across the gastrointestinal tract, the first-pass effect of the liver, or molecular modifications occurring during these processes. These limitations may be reduced or
10 inapplicable to dosage delivery films, which can be an effective method for delivering cannabinoids.

Therefore, there would be an advantage in dosage delivery compositions which can entrain a greater weight percentage of cannabinoid by comparison to conventional dosage delivery compositions while remaining formable for production of a dosage delivery film which
15 effectively delivers cannabinoids buccally or sublingually to increase bioavailability of the pharmaceutically active agent.

III. DISCLOSURE OF THE INVENTION

Accordingly, a broad object of the invention can be to provide one or more embodiments of a first or second carrier of a cannabinoid, the first carrier in the form of a micelle including a
20 hydrophobic core of about five to about fifty molecules of a cannabinoid disposed in a hydrophilic shell of a surfactant, the micelle having a diameter of between about 40 nm to about 100 nm ("cannabinoid micelle"), and the second carrier in the form of a cannabinoid-terpene-cyclodextrin complex ("CTC complex").

Another broad object of the invention can be to provide one or more embodiments of a
25 dosage delivery film composition into which a botanical drug substance can be introduced and thereafter formed into a dosage delivery film which bioerodes upon oral administration to buccally or sublingually deliver a dosage of the botanical drug substance, such as a cannabinoid, to the blood stream. The dosage delivery film composition including or consisting of: (i) one or more of a polymer, a plasticizer, a defoamer, or an antioxidant; and (ii) optionally, one or more
30 of: a taste mask, a vasodilator, or a lipophilic vehicle to transport the botanical drug substance across the mucous membrane.

Another broad object of the invention can be to provide one or more embodiments of a dosage delivery film formed from a dosage delivery film composition including an amount of a CTC complex or an amount of a cannabinoid-terpene-surfactant micelle, or combinations thereof, which bioerodes upon oral administration to buccally or sublingually deliver a dosage of a botanical drug substance, such as a cannabinoid, to the blood stream. The dosage delivery film including or consisting of: (i) one or more of a polymer, a plasticizer, a defoamer, or an antioxidant; (ii) a cannabinoid-cyclodextrin-terpene complex or a cannabinoid-terpene-surfactant micelle or combinations thereof; and (iii) optionally, one or more of: a taste mask, a vasodilator, or a lipophilic vehicle to transport the botanical drug substance across the mucous membrane.

Naturally, further objects of the invention are disclosed throughout other areas of the specification, drawings, photographs, and claims.

IV. MODE(S) FOR CARRYING OUT THE INVENTION

Generally, a dosage delivery film for oral delivery of a dosage of a botanical drug substance. Specifically, a dosage delivery film composition containing a botanical drug substance formable into a bioerodible dosage delivery film, the dosage delivery film composition including: (i) one or more of a polymer, a plasticizer, a defoamer, or an antioxidant; (ii) a cannabinoid-terpene-cyclodextrin complex or a cannabinoid-terpene-surfactant micelle (iii) optionally, one or more of: a taste mask, a vasodilator, or a lipophilic vehicle to facilitate transport of the botanical drug substance across the mucous membrane.

“A” or “an” entity means one or more of that entity; for example, “a polymer” refers to one or more polymers or at least one polymer. As such, the terms “a” or “an”, “one or more” and “at least one” can be used interchangeably herein. Furthermore, the language “selected from the group consisting of” refers to one or more of the elements in the list that follows, including combinations of two or more of the elements.

“About” means that ranges may be expressed as from "about" one particular value to "about" another particular value. When such a range is expressed, another embodiment includes from the one particular value to the other particular value. Similarly, when values are expressed as approximations, by use of the antecedent "about," it will be understood that the particular value forms another embodiment. In the context of such a numerical value or range “about” means plus or minus 10% of the numerical value or range recited or claimed unless otherwise specified, or the values within the range are incrementally divided into lesser percentage between ranges or values.

“Average molecular weight” for purposes of this invention means the number average molecular weight of all of the polymer chains in a polymer, calculated as $\sum N_i M_i / \sum N_i$, where N_i is the number of polymer chains having a particular mass, and M_i is the particular mass for those molecules.

5 “Bioerodible” for purposes of this invention means the ability of a material to break down within the physiological environment of the mouth by one or more physical, chemical, or cellular processes.

10 “Botanical drug substances” for the purposes of this invention means an extract which fulfils the definition of a “botanical drug substance” provided in the *Guidance for Industry Botanical Drug Products*, June 2004, US Department of Health and Human Services, Food and Drug Administration Centre for Drug Evaluation and Research of: “A drug substance derived from one or more plants, algae, or macroscopic fungi. It is prepared from botanical raw materials by one or more of the following processes: pulverization, decoction, expression, aqueous extraction, ethanolic extraction, or other similar processes.”

15 “Cannabinoid” for the purposes of this invention means a class of chemical compounds that act on cannabinoid receptors on cells that repress neurotransmitter release in the brain, the cannabinoid receptors including the endocannabinoids, phytocannabinoids, synthetic cannabinoids, and cannabidiol, or combinations thereof.

20 “Combination or combining” for the purposes of this invention means any method of putting two or more materials together. Such methods include, but are not limited to, mixing, blending, commingling, concocting, homogenizing, incorporating, intermingling, fusing, joining, shuffling, stirring, coalescing, integrating, confounding, joining, uniting, or the like.

“Complex” for the purposes of this invention means a molecular entity formed by chemical association involving two or more component molecular entities.

25 “Dosage delivery film” for the purposes of this invention means a film containing a botanical drug substance bioerodible upon oral administration to deliver the botanical drug substance to the mucous membrane of the oral cavity.

30 “Dosage delivery film composition” for purposes of this invention means a composition containing a botanical drug substance formable into dosage delivery film and without limitation to the breadth of the foregoing formable by manufacturing processes such as solvent casting,

semisolid casting, hot-melt extrusion, solid-dispersion extrusion, rolling, or other similar methods of manufacture.

“Equivalent” for the purposes of this invention means a drug or chemical containing similar amounts of the same ingredients as another drug or chemical or having similar chemical structures, properties or functions to another drug or chemical.

“Micelle” for the purposes of this invention means an aggregate of molecules having both polar or charged groups or molecules and nonpolar regions or molecules, where the polar or ionic groups or molecules form an outer shell in contact with a solution, and the nonpolar region or molecules are sequestered on the interior of the shell.

“Oral” for the purposes of this invention means the cavity of the mouth.

“Terpene” for the purposes of this invention means a hydrocarbon or derivative thereof, whether found as a natural product or biosynthesized by oligomerization of isoprene units. A terpene can be acyclic, monocyclic, bicyclic, or multicyclic.

Embodiments include a dosage delivery film which contains a dosage of a botanical drug substance which orally bioerodes for mucosal, buccal or sublingual delivery of the botanical drug substance. In particular embodiments, the botanical drug substance can be a cannabinoid associated with a carrier. A first carrier can be cyclodextrin which associates with the cannabinoid as cannabinoid-cyclodextrin complexes (“CB-CD complex”). In particular embodiments, the CB-CD complex can further include or consist of a terpene in a cannabinoid-cyclodextrin-terpene complex (“CTC complex”). A second carrier can be a surfactant which associates with the cannabinoid as a cannabinoid-terpene surfactant micelle (“cannabinoid micelle”). The CB-CD complex, the CTC complex, or the cannabinoid micelle can be discretely prepared or isolated and thereafter associated with the dosage delivery film composition, or as to particular embodiments, can be prepared as combinations of the CB-CD complex, the CTC complex, and the cannabinoid-terpene micelle, and such combination associated with the dosage delivery film composition which can be formed into the dosage delivery film.

Embodiments of the CTC complex, can include, consist essentially of or consist of a cannabinoid, a cyclodextrin, and a terpene. The CTC complex can be formed by combining an amount of a cannabinoid, an amount of a cyclodextrin, and an amount of one or more terpenes in a solvent. The solvent can, but need not necessarily, be ethanol or water. The CTC complex, upon formation and depending on the solvent(s), can remain in solution or precipitate out from

the solution as a solid and be collected by filtering or the solution can be lyophilized to yield the CTC complex as a solid.

The cannabinoid can be selected from the group including or consisting of: cannabinol, cannabinolic acid, $\Delta(9)$ -tetrahydrocannabinol, $\Delta(9)$ -tetrahydrocannabinolic acid, $\Delta(9)$ -cannabidiol, $\Delta(9)$ -tetrahydrocannabidiolic acid, $\Delta(8)$ -tetrahydrocannabinol, $\Delta(8)$ -tetrahydrocannabinolic acid, $\Delta(8)$ -tetrahydrocannabidiol, $\Delta(8)$ -tetrahydrocannabidiolic acid, $\Delta(9)$ -tetrahydrocannabivarin, cannabigerol, cannabidigerolic acid, cannabichromene, cannabichromenic acid, cannabicyclol, cannabicyclolic acid, cannabielsoin, cannabitrinol, nabilone, equivalents, or combinations thereof.

The cyclodextrin can be selected from the group including or consisting of: hydroxypropyl- β -cyclodextrin, sulfobutylether- β -cyclodextrin, maltosyl- β -cyclodextrin, dimethyl- β -cyclodextrin, trimethyl- β -cyclodextrin, randomly methylated- β -cyclodextrin, equivalents, or combinations thereof.

The terpene can be selected from the group including or consisting of: alpha-pinene, beta-pinene, myrcene, limonene, carophyllene, linalool, alpha bisabolol, delta 3 carene, borneol, eucalyptol, terpineol, camphene, nerolidol, terpinolene, valencene, humulene, geraniol, phellandrene, fenchol, phytol, sabinene, camphor, menthol, isoborneol, cedrane, guaiol, isopulegol, geranyl acetate, cymene, pulegon, citral, equivalents, or combinations thereof.

Now referring primarily to Table 1, particular embodiments of a CTC complex comprising, consisting essentially of, or consisting of a cannabinoid, a β -cyclodextrin and a terpene can be prepared as further described below.

TABLE 1. Cannabinoid- Terpene-Cyclodextrin Complex.

Ingredient	Percentage wt/wt
Cannabinoid	about 19% to about 50%
β -cyclodextrin	about 50% to about 80%
Terpene	about 0.1% to about 5%

As to particular embodiments of the CB-CD complex the ratio of cannabinoid associated with β -cyclodextrin weight to weight ("wt/wt") can be between about 1:1 to about 1:4 (about 20 percent by weight ("wt%") to about 50 wt%). As to particular embodiments of the CTC complex the ratio of cannabinoid associated with β -cyclodextrin weight to weight ("wt./wt.") can be between about 1:1 to about 1:4 (about 19 wt% to about 50 wt%) with the terpene being about 0.1

wt% to about 5 wt%. As to particular embodiments, the cannabinoid can be about 19 wt%, the β -cyclodextrin about 76 wt%, and the terpene about 5 wt%.

As to particular embodiments, the ratio of cannabinoid associated with β -cyclodextrin weight to weight can be selected from the group including or consisting of: about 1:1.5, about 1:2.0, about 1:2.5, about 1:3.0, and about 1:3.5, and combinations thereof.

As to particular embodiments, the amount of terpene, wt%, can be selected from the group consisting of: about 0.2% to about 2.0%, about 1.5% to about 2.5%, about 2.0% to about 3.0%, about 2.5% to about 3.5%, about 3.0% to about 4.0%, about 3.5% to about 4.5%, about 4.0% to about 4.9%. Because the cannabinoids or the terpenes can be isolated and purified and combined in pre-selected amounts, the amount of terpene or combinations of terpenes in the CTC complex can be adjusted in fine incremental gradation across the described ranges of the cannabinoid and terpene to adjust the pharmacological effect of the CTC complex.

In particular embodiments, the concentration of cannabinoid in solution, whether as a CB-CD complex or CTC complex can be about 10 milligrams per milliliter (mg/mL) to about 30 mg/mL. In other particular embodiments, the concentration of cannabinoid in solution can be selected from the group including or consisting of: about 10.5 mg/mL to about 15 mg/mL, about 12.5 mg/mL to about 17.5 mg/mL, about 15 mg/mL to about 20 mg/mL, about 17.5 mg/mL to about 22.5 mg/mL, about 20 mg/mL to about 25 mg/mL, about 22.5 mg/mL to about 27.5 mg/mL, and about 25 mg/mL to about 29.5 mg/mL, or combinations thereof.

Embodiments of the cannabinoid micelles can include, consist essentially of, or consist of a cannabinoid, a terpene and a surfactant, the cannabinoid and terpene being described above. The cannabinoid micelles can be formed by combining an amount of a cannabinoid, an amount of terpene, and an amount of a surfactant in a solvent. The solvent can, but need not necessarily, be an alcohol such as ethanol. The cannabinoid micelle, upon formation and depending on the solvent(s), can remain in solution or precipitate out from the solution as a solid for collection by filtering, or the solution can be lyophilized to yield the cannabinoid micelle as a solid.

The surfactant can be selected from the group including or consisting of: monoglycerides, diglycerides, polyethylene glycol sorbitan fatty acid esters; polyethylene glycol alkyl ethers, phospholipids, hydrophilic derivatives of phospholipids, ethoxylated castor oil (e.g., polyoxyethylene (40) castor oil, polyoxyethylene (60) castor oil) corn glycerides, vitamin E, polyoxyethylene alkyl ethers, polyethylene glycol glycerol fatty acid esters, polyoxyethylene sorbitan fatty acid esters, polyethylene glycol sorbitan monooleate (TWEEN[®] 80), polysorbate-

80, a nonionic surfactant, a cationic surfactant, an anionic surfactant, an amphoteric surfactant, equivalents, or combinations thereof.

Now referring primarily to Table 2, particular embodiments of a cannabinoid micelle comprising, consisting essentially of, or consisting of a cannabinoid, a surfactant, and a terpene
5 can be prepared as further described below.

TABLE 2. Cannabinoid Micelle Composition.

Ingredient	Percentage wt/wt
Cannabinoid	about 20% to about 45%
Surfactant	about 50% to about 80%
Terpene	about 0.1% to about 5%

The cannabinoid micelles can form as a hydrophobic core of about five to about fifty
10 molecules of a cannabinoid (whether homogenous or heterogeneous mixture thereof) along with the terpene (whether homogenous or heterogeneous mixture thereof) surrounded by a hydrophilic shell of the surfactant.

The diameter of each cannabinoid micelle depending on the type and number of molecules of cannabinoid and terpene included in the hydrophobic core can be about 40 nanometers (“nm”) to about 100 nm. In further embodiments, the diameter of the cannabinoid micelle can be selected
15 from the group including or consisting of about 41 nm to about 45 nm, about 42.5 nm to about 47.5 nm, about 45 nm to about 50 nm, about 47.5 nm to about 52.5 nm, about 50 nm to about 55 nm, about 52.5 nm to about 57.5 nm, about 55 nm to about 60 nm, about 57.5 nm to about 62.5 nm, about 60 nm to about 65 nm, about 62.5 nm to about 67.5 nm, about 65 nm to about 70 nm,
20 about 67.5 nm to about 72.5 nm, about 70 nm to about 75 nm, about 72.5 nm to about 77.5 nm, about 75 nm to about 80 nm, about 77.5 nm to about 82.5 nm, about 80 nm to about 85 nm, about 82.5 nm to about 87.5 nm, about 85 nm to about 90 nm, about 87.5 nm to about 92.5 nm, about 90 nm to about 95 nm, about 92.5 nm to about 97.5 nm, and about 95 nm to about 99 nm, or combinations thereof.

25 The relative weight percentages of the cannabinoid, terpene, and surfactant will vary depending upon the relative size of the cannabinoid-terpene micelles formed and the number of cannabinoid molecules and terpene molecules stationed within the hydrophobic core of the micelle. Accordingly, a finely graded series of weight percentages for each of the cannabinoid, terpene, and surfactant across the ranges of Table 2 can be achieved in the cannabinoid micelle.

In particular embodiments, the concentration of cannabinoid in solution, as a cannabinoid micelle, will vary depending on the relative size of the cannabinoid micelle and the number of cannabinoid molecules and terpene molecules stationed within the hydrophobic core. The concentration of cannabinoid can be about 10 milligrams per milliliter (mg/mL) to about 30 mg/mL. In other particular embodiments, the concentration of cannabinoid in solution can be selected from the group including or consisting of: about 10.5 mg/mL to about 15 mg/mL, about 12.5 mg/mL to about 17.5 mg/mL, about 15 mg/mL to about 20 mg/mL, about 17.5 mg/mL to about 22.5 mg/mL, about 20 mg/mL to about 25 mg/mL, about 22.5 mg/mL to about 27.5 mg/mL, and about 25 mg/mL to about 29.5 mg/mL, or combinations thereof.

As to particular embodiments, the CB-CD complex, CTC complex and the cannabinoid micelle can concurrently occur in solution. As to particular embodiments, the CB-CD complex or CTC complex can be further associated with the cannabinoid micelles to form larger complexes.

Now referring primarily to Tables 3 and 4, embodiments of a dosage delivery film composition can be formed into a dosage delivery film containing a botanical drug substance which can include one or more of: a polymer, a plasticizer, a defoamer, or an antioxidant, and water. In particular embodiments, the dosage delivery film composition can further include one or more of: a vasodilator, a lipophilic carrier, or a taste mask. Advantages of particular embodiments of the dosage delivery film composition can be that a greater weight percentage of cannabinoid can be admixed with the drug delivery film composition as compared to conventional dosage delivery film compositions while still maintaining composition properties or characteristics that allow the drug delivery film composition, including the admixed cannabinoid, to be formed into a dosage delivery film which may utilize conventional film forming equipment, as above described. As compared to conventional drug delivery film compositions per unit volume, a greater weight percent cannabinoid of about 5% to about 15% per unit volume can be achieved utilizing embodiments of the drug delivery film compositions from which a drug delivery film can be formed in substantial uniform thickness of about 50 micrometers (“ μm ”) to about 150 μm and cut to provide a dosage delivery film a few square centimeters in area, the area varying based on the dosage to be delivered. As to particular embodiments the greater weight percent cannabinoid contained in the dosage delivery film composition can be pre-selected in incremental fine gradation across the range of about 5% to about 15% to achieve particular pharmaceutical efficacy or effects in formed dosage delivery film. As to particular embodiments the greater weight percent can be selected from the group

including or consisting of: about 5.5% to about 7.5%, about 6.25% to about 8.75%, about 7.5% to about 10%, about 8.75% to about 11.25%, about 10% to about 12.5%, about 11.25% to about 13.75%, and about 12.5% to about 14.5%, or combinations thereof.

5 Polymers are macromolecules having a molecular chain of a number of monomers chemically linked together. The sequence of monomers can be a series of more than one type of monomer (also referred to as “a block copolymer”). The polymer can be a heteropolymer, branched polymer, or charged polymer. The polymers in accordance with embodiments of the dosage delivery film composition can be digestible, non-toxic polymers. Various characteristics can be imparted to the dosage delivery film depending upon the polymer(s) utilized in preparation
10 of the dosage delivery film composition, whether utilizing one type or molecular structure of polymer, or combining a plurality of polymers of different types or molecular structures. The characteristics that can be imparted or altered in the drug delivery film can be drug release profiles, plasticity, mechanical strength such as Young’s modulus, percent elongations, tensile strength, tear resistance, texture, viscosity, mucoadhesive properties, and other like properties.

15 Illustrative examples of the polymer(s) suitable for use in embodiments of the dosage delivery film composition can include or consist of: polyethylene oxide, pullulan, hydroxypropylmethyl cellulose, hydroxyethyl cellulose, hydroxypropyl cellulose, polyvinyl pyrrolidone, carboxymethyl cellulose, polyvinyl alcohol, sodium alginate, polyethylene glycol, xanthan gum, tragacanth gum, guar gum, acacia gum, arabic gum, polyacrylic acid,
20 methylmethacrylate copolymer, carboxyvinyl copolymers, starch, gelatin, ethyl cellulose, hydroxypropyl ethyl cellulose, cellulose acetate phthalate, hydroxypropyl methyl cellulose phthalate, biodegradable polymers, copolymers, block polymers, poly(glycolic acid) (PGA), poly(lactic acid) (PLA), polydioxanones, polyoxalates, poly(α -esters), polyanhydrides, polyacetates, polycaprolactones, poly(orthoesters), polyamino acids, polyaminocarbonates,
25 polyurethanes, polycarbonates, polyamides, poly(alkyl cyanoacrylates), stereopolymers of L- and D-lactic acid, copolymers of bis(p-carboxyphenoxy) propane acid and sebacic acid, sebacic acid copolymers, copolymers of caprolactone, poly(lactic acid)/poly(glycolic acid)/polyethyleneglycol copolymers, copolymers of polyurethane and poly(lactic acid), copolymers of polyurethane and poly(lactic acid), copolymers of α -amino acids, copolymers of
30 α -amino acids and caproic acid, copolymers of α -benzyl glutamate and polyethylene glycol, copolymers of succinate and poly(glycols), polyphosphazene, polyhydroxy-alkanoates, cellulose ethers, polymethacrylates, poloxamers, extrudable carbohydrates, acrylates, cellulose acetate butyrate, poly(ethylene-co-vinyl acetate), polyvinyl acetate, poly(methylvinyl ether/maleic

anhydride) co-polymer, cellulose acetate phthalate, acrylic polymers, vinylacetate, sodium sulphonated polyesters, carboxylated acrylics, trimethylpentanediol/adipic acid/glycerin cross polymer, polyglycerol-2-diisostearate/IPDI copolymer, carboxylated vinyl acetate copolymer, vinylpyrrolidone/vinyl acetate/alkylaminoacrylate polymers, vinylpyrrolidone/vinyl acetate copolymer, equivalents, or combinations thereof.

Plasticizer(s) can be included in embodiments to produce or promote plasticity and flexibility and to reduce brittleness of the dosage delivery film. Illustrative examples of the plasticizer(s) suitable for use in embodiments of the dosage delivery film composition can be selected from the group including or consisting of: glycerol, glycerol monoacetate, diacetate, triacetate, triacetin, cetyl alcohol, propylene glycol, sorbitol, sodium diethylsulfosuccinate, triethyl citrate, tributyl citrate, glycerin triacetate, equivalents, or combinations thereof.

An anti-foam agent or defoamer can be included in embodiments of the dosage delivery film composition to reduce or hinder the formation of foam during production of intermediate chemical entities or during forming of the production of the dosage delivery film from the dosage delivery film composition. As illustrative examples, defoamer(s) suitable for use in embodiment of the dosage delivery film composition can be selected from the group including or consisting of: simethicone, polydimethylsiloxane, polyethylene glycol, fatty alcohols, fatty acid soaps, fatty acid esters, BREVIOL[®] equivalents, or combinations thereof.

Antioxidants can be included in embodiments of the dosage delivery film composition to reduce or hinder oxidation during production of intermediate chemical entities or products in the production dosage delivery film. As illustrative examples, antioxidants suitable for use in embodiments of the dosage delivery film composition can be selected from the group including or consisting of: citric acid, butylated hydroxytoluene, ascorbic acid, malonic acid, succinic acid, fumaric acid, maleic acid, adipic acid, lactic acid, levulinic acid, glutamic acid, aspartic acid, oleic acid, glutaric acid, taratic acid, malic acid, sorbic acid, glutathione, retinol, α -tocopherol, β -carotene, α -carotene, γ -tocopherol, ubiquinone, butylated hydroxyanisole, ethylenediaminetetraacetic acid, selenium, zinc, lignin, uric acid, lipoic acid, and N-acetylcysteine, equivalents, or combinations thereof.

Taste masks can, but need not necessarily, be included in embodiments of the dosage delivery film composition to mask taste of the dosage delivery film produced from the dosage delivery film composition. As illustrative examples, the taste mask can, but need not necessarily, be selected from the group of sweeteners including or consisting of: monosaccharides,

disaccharides, polysaccharides, xylose, ribose, glucose, mannose, galactose, fructose, sucrose, high fructose corn syrup, maltose, corn syrup solids, dihydrochalcones, ASPARTAME[®], SLENDA[®], SUCRALOSE[®], Thauratin I, Thauratin II, Lo Han Kuo, STEVIA[®], steviosides, monellin, glycyrrhizin, a water-soluble sweetening agent, a water-soluble artificial sweetener, a dipeptide-based sweetener, a protein-based sweetener, equivalents, or combinations thereof.

A vasodilator can, but need not necessarily, be included in embodiments of the dosage delivery film composition. As illustrative examples, a vasodilator suitable for use in embodiments of the dosage delivery composition can, but need not necessarily, be menthol, whether synthetic or obtained by processing corn mint, peppermint, or other mint oils, equivalents, or combinations thereof.

A lipophilic carrier can, but need not necessarily, be included in embodiments of the dosage delivery film composition. As illustrative examples, a lipophilic carrier suitable for use in embodiments of the dosage delivery composition can, but need not necessarily, be menthol, whether synthetic or obtained by processing corn mint, peppermint, or other mint oils, equivalents, or combinations thereof.

Now referring primarily to Table 3, particular embodiments of the dosage delivery film composition comprising, consisting essentially of, or consisting of: a polymer, plasticizer, defoamer, antioxidant and water can be prepared as further described below.

TABLE 3. Dosage Delivery Film Composition.

20

Ingredient	Percentage (wt/wt)
Polymer	20-50%
Plasticizer	0-5%
Defoamer	0-0.5%
Antioxidant	0-3%
Water	30-60%

As to particular embodiments, the dosage delivery film composition can include only a polymer and water, or comprise, consist essentially of, or consist of a polymer, water, and one or more of: a plasticizer, a defoamer and an antioxidant.

Now referring primarily to Table 4, another particular embodiment of a dosage delivery film composition can comprise, consist essentially of, or consist of combinations of ingredients of Table 3, which can further include a taste mask or a vasodilator.

TABLE 4. Dosage Delivery Film Composition

Ingredient	Percentage (wt/wt)
Polymer	20-45%
Plasticizer	0-5%
Defoamer	0-0.5%
Antioxidant	0-3%
Water	30-60%
Vasodilator	0-5%
Taste Mask	0-5%

As to particular embodiments, the dosage delivery film composition can comprise, consist essentially of, or consist of: a polymer, water, and one or more of: a plasticizer, a defoamer, an antioxidant, a vasodilator, and a taste mask.

Additional embodiments of the dosage delivery film composition as above described or as set forth in Table 3 or Table 4 can further include a cannabinoid dosage either as a CTC complex as above described or set forth in Table 1 or a cannabinoid micelle as above described or as set forth in Table 2 or as a combination of CTC complexes and cannabinoid micelles.

Accordingly, a particular embodiment of the dosage delivery film composition including a cannabinoid dosage in the form of a CTC complex can comprise, consist essentially of, or consist of the combinations of ingredients of Table 5.

TABLE 5. Dosage Delivery Film Composition Including a Cannabinoid Dosage.

Ingredient	Percentage (wt/wt)
Polymer	20-50%
Plasticizer	0-5%
Defoamer	0-0.5%
Water	25-60%
Antioxidant	0-0.5%
β -cyclodextrin	5-50%
Cannabinoid	5-10%
Terpene	0.1-1.0%

As to particular embodiments, the dosage delivery film composition can comprise, consist essentially of, or consist of a polymer, water, β -cyclodextrin, cannabinoid, and terpene. Additional embodiments of the dosage delivery system film composition can comprise, consist

essentially of, or consist of: a polymer, water, β -cyclodextrin, cannabinoid, terpene, and one or more of: a plasticizer, a defoamer and an antioxidant.

A particular embodiment of the dosage delivery film composition including a cannabinoid dosage in the form of a cannabinoid micelle can comprise, consist essentially of, or consist of the combinations of ingredients of Table 6.

TABLE 6. Dosage Delivery Film Composition Including a Cannabinoid Dosage.

Ingredient	Percentage (wt/wt)
Polymer	20-50%
Plasticizer	0-5%
Defoamer	0-0.5%
Water	25-60%
Antioxidant	0-0.5%
Surfactant	1-25%
Cannabinoid	5-18%
Terpene	0.1-1.0%

As to particular embodiments, the dosage delivery film composition can comprise, consist essentially of, or consist of: a polymer, water, a surfactant, a cannabinoid, and a terpene. Additional embodiments of the dosage delivery film composition can comprise, consist essentially of, or consist of a polymer, water, a surfactant, a cannabinoid, terpene, and one or more of: a plasticizer, a defoamer, and an antioxidant.

A particular embodiment of the dosage delivery film composition including a cannabinoid dosage in the form of a CTC complex and a cannabinoid micelle can comprise, consist essentially of, or consist of the combinations of ingredients of Table 7.

TABLE 7. Dosage Delivery Film Composition Including A Cannabinoid Dosage.

Ingredient	Percentage (wt/wt)
Polymer	14-60.5 %
Plasticizer	0-5%
Defoamer	0-0.5%
Surfactant	1-10%
Water	25-60%
Antioxidant	0.02-0.2%
Cannabinoid	1-10%
β -cyclodextrin	4-40%
Terpene	0.1-5%

In particular embodiments, the dosage delivery film composition can comprise, consist essentially of, or consist of a polymer, water, β -cyclodextrin, an antioxidant, a surfactant, a cannabinoid, and a terpene. Additional embodiments of the dosage delivery film composition can comprise, consist essentially of, or consist of a polymer, water, β -cyclodextrin, an antioxidant, a surfactant, a cannabinoid, a terpene, and one or more of: a plasticizer and a defoamer.

In particular embodiments, the dosage delivery film composition including a cannabinoid dosage as described above and set forth in either Tables 5, 6, or 7, can further comprise, consist essentially of, or consist of an amount of: a taste mask in the form of a sweetener in an amount of about 3% to about 6%, or an amount of vasodilator in the form of menthol of about 0.1 % to about 5%, or both.

Accordingly, a particular embodiment of the dosage delivery film composition including a cannabinoid dosage in the form of a combination of a CTC complex and a cannabinoid micelle and further including a taste mask in the form of an amount of sweetener and optionally a vasodilator in the form of an amount of menthol, or both, can comprise, consist essentially of, or consist of the combinations of ingredients of Table 8.

TABLE 8. Dosage Delivery Film Composition Including a Cannabinoid Dosage.

Ingredient	Percentage (wt/wt)
Polymer	14-60.5 %
Plasticizer	2-8%
Taste Mask (Sweetener)	3-6%
Defoamer	0.01-0.2%
Surfactant	1-10%
Water	25-60%
Antioxidant	0.02-0.2%
Vasodilator	0-5%
Cannabinoid	5-40%
β -cyclodextrin	5-20%
Terpene	0.1-1.0%

A particular embodiment of the dosage delivery film composition including a cannabinoid dosage in the form of a combination of a CTC complex and a cannabinoid micelle, and further including a task mask in the form of an amount of sweetener and optionally a vasodilator in the form of an amount of menthol can comprise, consist essentially of, or consist of the combination of ingredients of Table 9.

TABLE 9. Dosage Delivery Film Composition Including a Cannabinoid Dosage.

Ingredient	Percentage (wt/wt)
Polyethylene Glycol	0-15%
Hydroxypropylmethyl cellulose	0-0.5%
Polyvinyl Alcohol	5-50%
Glycerol	2-8%
Taste Mask (sucrose)	3-6%
Polydimethoxysilane	0.01-0.2%
Polyethylene glycol sorbitan monooleate	1-10%
Water	25-60%
Beta-carotene	0.02-0.2%
Vasodilator (Menthol)	0-5%
Polyvinylpyrrolidone	0-20%
Cannabinoid	5-40%
β -cyclodextrin	5-20%
Terpene	0.1-1.0%

In particular embodiments, the polyvinyl alcohol can be hydrolyzed between about 84%
5 to about 89%. Further, the average molecular weight of the polyvinyl alcohol can be between
about 25,000 Daltons (Da) and about 78,000 Da. The average molecular weight of the polyvinyl
alcohol can be selected from the group including or consisting of: about 26,000 Da to about
30,000 Da, about 27,500 Da to about 28,250 Da, about 30,000 Da to about 35,000 Da, about
32,500 Da to about 37,500 Da, about 35,000 Da to about 40,000 Da, about 37,500 Da to about
10 42,500 Da, about 40,000 Da to about 45,000 Da, about 42,500 Da to about 47,500 Da, about
45,000 Da to about 50,000 Da, about 47,500 Da to about 52,500 Da, about 50,000 Da to about
55,000 Da, about 52,500 Da to about 57,500 Da, about 55,000 Da to about 60,000 Da, about
57,500 Da to about 62,500 Da, about 60,000 Da to about 65,000 Da, about 62,500 Da to about
67,500 Da, about 65,000 Da to about 70,000 Da, about 67,500 Da to about 72,500 Da, about
15 70,000 Da to about 75,000 Da, and about 72,500 Da to about 77,000 Da, or combinations thereof.

In particular embodiments, the polyethylene glycol can have an average molecular weight
of about 1000 Da to about 1600 Da. The average molecular weight of the polyethylene glycol
can be selected from the group including or consisting of: about 1025 Da to about 1075 Da, about
1050 Da to about 1100 Da, about 1075 Da to about 1125 Da, about 1100 Da to about 1150 Da,
20 about 1125 Da to about 1175 Da, about 1150 Da to about 1200 Da, about 1175 Da to about 1225
Da, about 1200 Da to about 1250 Da, about 1225 Da to about 1275 Da, about 1250 Da to about
1300 Da, about 1275 Da to about 1325 Da, about 1300 Da to about 1350 Da, about 1325 Da to

about 1375 Da, about 1350 Da to about 1400 Da, about 1375 Da to about 1425 Da, about 1400 Da to about 1450 Da, about 1425 Da to about 1475 Da, about 1450 Da to about 1500 Da, about 1475 Da to about 1525 Da, about 1500 Da to about 1550 Da, and about 1525 Da to about 1575 Da, or combinations thereof.

5 In particular embodiments, the polyvinylpyrrolidone can have an average molecular weight between about 20,000 Da and about 40,000 Da. The average molecular weight of the polyvinylpyrrolidone can be selected from the group including or consisting of: about 21,000 Da to about 23,000 Da, about 22,000 Da to about 24,000 Da, about 23,000 Da to about 25,000 Da, about 24,000 Da to about 26,000 Da, about 25,000 Da to about 27,000 Da, about 26,000 Da to
10 about 28,000 Da, about 27,000 Da to about 29,000 Da, about 28,000 Da to about 30,000 Da, about 29,000 Da to about 31,000 Da, about 30,000 Da to about 32,000 Da, about 31,000 Da to about 33,000 Da, about 32,000 Da to about 34,000 Da, about 33,000 Da to about 35,000 Da, about 34,000 Da to about 36,000 Da, about 35,000 Da to about 37,000 Da, about 36,000 Da to about 38,000 Da, and about 37,000 Da to about 39,000 Da, or combinations thereof.

15 The following working examples are intended to illustrate a method of making the dosage delivery film composition containing a dosage of cannabinoid carried by the first or second carriers, as above described.

EXAMPLE 1. Preparation of cannabinoid micelles.

20 A cannabinoid micelle in accordance with embodiments can be prepared by combining in the weight percentages above described in Table 2 of cannabinoid and terpene in ethanol, and further combining this solution with the surfactant in water. The combination of ingredients incubated at about 20°C to about 25°C for a period of about 1 hour to about 4 hours to produce cannabinoid micelles.

EXAMPLE 2. Preparation of CTC complexes.

25 A CTC complex in accordance with embodiments can be prepared by combining in the weight percentages above described in Table 1 of cannabinoid and terpene in ethanol, and further combining this solution with β -cyclodextrin in water. The combination of ingredients is incubated at about 20°C to about 25°C for a period of about 1 hour to about 4 hours to produce the CTC complex. As to particular embodiments, the CTC complex can be rendered as a solid
30 by lyophilization. As to particular embodiments, the CTC complex may form a precipitate which can be captured by filtration of the solution.

EXAMPLE 3. Preparation of CTC complexes and cannabinoid micelles.

A CTC complex in accordance with embodiments and a cannabinoid micelle in accordance with embodiments can be prepared by combining cannabinoid and terpene in ethanol, and further combining the solution with β -cyclodextrin and surfactant in water in the weight percentages or ratios of weight percentages described above. The combination of ingredients
5 incubated at about 20°C to about 25°C for a period of about 1 hour to about 4 hours. The solution will contain a mixture of CTC complexes and cannabinoid micelles which can remain discrete in solution or can associate in solution to form CTC complex-cannabinoid micelle complexes.

EXAMPLE 4. Preparation of the Dosage Delivery Film Composition.

Dosage delivery film compositions in accordance with embodiments can be prepared by combining in the weight percentages above described in Table 3 or Table 4, a polymer (such as polyethylene glycol, hydroxypropylmethylcellulose or polyvinylpyrrolidone), a plasticizer (such as glycerol), optionally a taste mask (such as sucrose), in a portion of the water (such as deionized or distilled water). The ingredients are mixed at 80°C until all ingredients have dissolved. A
15 second solution can be prepared by combining in the weight percentages above described in Table 3 or Table 4, a polymer (such as polyvinyl alcohol), and defoamer (such as polydimethylsiloxane) in a portion of the water (such as deionized or distilled). The ingredients are mixed at 60°C until all the ingredients have dissolved. The first solution can be mixed with the second solution at a temperature of about 60°C for about 15 to about 30 minutes.

EXAMPLE 5. Preparation of the Dosage Delivery Film Composition Including a Cannabinoid Dosage.

A dosage delivery film composition in accordance with embodiments including, but not limited to, the compositions of Table 5 through 9 can be prepared by combining in the weight percentages above described in a first solution polyethylene glycol, hydroxypropylmethylcellulose, polyvinylpyrrolidone, glycerol (each a polymer), and optionally
25 sucrose (a taste mask) in a portion of the water. The ingredients are mixed at 80°C until all ingredients have dissolved. A second solution can be prepared by combining in the weight percentages above described polyvinyl alcohol (a polymer), and polydimethylsiloxane (a defoamer), in a portion of the water. The ingredients are mixed at 60°C until all the ingredients
30 have dissolved. A third solution can be prepared by combining in the weight percentages above described polyethylene glycol sorbitan monooleate (a surfactant), cannabinoid, β -cyclodextrin, beta-carotene (an antioxidant), menthol (a vasodilator or lipophilic vehicle), terpene (an anesthetic,

sedative, or aromatic or combinations thereof), and polyvinylpyrrolidone (a polymer). The ingredients are mixed at about 20°C to about 25°C until all ingredients are dissolved. The ethanol can be evaporated from the solution using a rotary evaporator with a bath temperature of about 50°C.

5 The first solution can be mixed with the second solution at a temperature of about 60°C for about 15 minutes to about 30 minutes. The third solution can then be added to the first and second solution with vigorous mixing at 60°C for about 15 minutes to about 35 minutes. In some circumstances, the resulting combined mixture of the first, second, and third solutions can further undergo rotary evaporation to remove excess ethanol.

10 As can be easily understood from the foregoing, the basic concepts of the present invention may be embodied in a variety of ways. The invention involves numerous and varied embodiments of a dosage delivery film and methods for making and using such dosage delivery films including the best mode.

 As such, the particular embodiments or elements of the invention disclosed by the
15 description or shown in the figures or tables accompanying this application are not intended to be limiting, but rather exemplary of the numerous and varied embodiments generically encompassed by the invention or equivalents encompassed with respect to any particular element thereof. In addition, the specific description of a single embodiment or element of the invention
20 may not explicitly describe all embodiments or elements possible; many alternatives are implicitly disclosed by the description and figures.

 It should be understood that each element of an apparatus or each step of a method may be described by an apparatus term or method term. Such terms can be substituted where desired to make explicit the implicitly broad coverage to which this invention is entitled. As but one
25 example, it should be understood that all steps of a method may be disclosed as an action, a means for taking that action, or as an element which causes that action. Similarly, each element of an apparatus may be disclosed as the physical element or the action which that physical element facilitates. As but one example, the disclosure of a “dosage” should be understood to encompass
30 disclosure of the act of “dosing” -- whether explicitly discussed or not -- and, conversely, were there effectively disclosure of the act of “dosing”, such a disclosure should be understood to encompass disclosure of a “dosage” and even a “means for dosing.” Such alternative terms for each element or step are to be understood to be explicitly included in the description.

In addition, as to each term used it should be understood that unless its utilization in this application is inconsistent with such interpretation, common dictionary definitions should be understood to be included in the description for each term as contained in the Random House Webster's Unabridged Dictionary, second edition, each definition hereby incorporated by
5 reference.

All numeric values herein are assumed to be modified by the term "about", whether or not explicitly indicated. For the purposes of the present invention, ranges may be expressed as from "about" one particular value to "about" another particular value. When such a range is expressed, another embodiment includes from the one particular value to the other particular
10 value. The recitation of numerical ranges by endpoints includes all the numeric values subsumed within that range. A numerical range of one to five includes for example the numeric values 1, 1.5, 2, 2.75, 3, 3.80, 4, 5, and so forth. It will be further understood that the endpoints of each of the ranges are significant both in relation to the other endpoint, and independently of the other endpoint. When a value is expressed as an approximation by use of the antecedent "about," it
15 will be understood that the particular value forms another embodiment. The term "about" generally refers to a range of numeric values that one of skill in the art would consider equivalent to the recited numeric value or having the same function or result. Similarly, the antecedent "substantially" means largely, but not wholly, the same form, manner or degree and the particular element will have a range of configurations as a person of ordinary skill in the art would consider
20 as having the same function or result. When a particular element is expressed as an approximation by use of the antecedent "substantially," it will be understood that the particular element forms another embodiment.

Moreover, for the purposes of the present invention, the term "a" or "an" entity refers to one or more of that entity unless otherwise limited. As such, the terms "a" or "an", "one or more"
25 and "at least one" can be used interchangeably herein.

Thus, the applicant(s) should be understood to claim at least: i) each of the dosage delivery films herein disclosed and described, ii) the related methods disclosed and described, iii) similar, equivalent, and even implicit variations of each of these devices and methods, iv) those alternative embodiments which accomplish each of the functions shown, disclosed, or described, v) those
30 alternative designs and methods which accomplish each of the functions shown as are implicit to accomplish that which is disclosed and described, vi) each feature, component, and step shown as separate and independent inventions, vii) the applications enhanced by the various systems or components disclosed, viii) the resulting products produced by such systems or components, ix)

methods and apparatuses substantially as described hereinbefore and with reference to any of the accompanying examples, x) the various combinations and permutations of each of the previous elements disclosed.

5 The background section of this patent application provides a statement of the field of endeavor to which the invention pertains. This section may also incorporate or contain paraphrasing of certain United States patents, patent applications, publications, or subject matter of the claimed invention useful in relating information, problems, or concerns about the state of technology to which the invention is drawn toward. It is not intended that any United States patent, patent application, publication, statement or other information cited or incorporated herein
10 be interpreted, construed or deemed to be admitted as prior art with respect to the invention.

The claims set forth in this specification, if any, are hereby incorporated by reference as part of this description of the invention, and the applicant expressly reserves the right to use all of or a portion of such incorporated content of such claims as additional description to support any of or all of the claims or any element or component thereof, and the applicant further
15 expressly reserves the right to move any portion of or all of the incorporated content of such claims or any element or component thereof from the description into the claims or vice-versa as necessary to define the matter for which protection is sought by this application or by any subsequent application or continuation, division, or continuation-in-part application thereof, or to obtain any benefit of, reduction in fees pursuant to, or to comply with the patent laws, rules, or
20 regulations of any country or treaty, and such content incorporated by reference shall survive during the entire pendency of this application including any subsequent continuation, division, or continuation-in-part application thereof or any reissue or extension thereon.

Additionally, the claims set forth in this specification, if any, are further intended to describe the metes and bounds of a limited number of the preferred embodiments of the invention
25 and are not to be construed as the broadest embodiment of the invention or a complete listing of embodiments of the invention that may be claimed. The applicant does not waive any right to develop further claims based upon the description set forth above as a part of any continuation, division, or continuation-in-part, or similar application.

With respect to the formulations provided in this description, it should be understood that
30 different formulations can contain the same raw materials, but can be distinguished by the difference in the weight percent of each of the raw materials. Specific difference in weight percent of each raw material between formulations can impart different functional characteristics

or property to the dosage delivery film. Accordingly, it will be understood that each particular weight percent value for a raw material can form another embodiment of the dosage delivery film.

Also, it is to be understood that the ranges established by the differences of the particular weight percent values for each raw material can include the outliers in the normal variation of each particular value necessary to achieve one or more particular functional characteristics or can be the variation inherent to the manufacturing process of a particular formulation. Accordingly, a value range can describe either a single embodiment having a formulation that can vary as to any particular raw material between the particular weight percent values, or two different liquid cleaners differentiated by the extremes of the weight percent values of each raw material, each extreme having the normal degree of variation based on manufacturing practices, or a plurality of different embodiments, each having a discrete formulation which includes a weight percent value of each raw material which falls in the range of weight percent values established by the difference in weight percent values (with normal variation in weight percent due to the manufacturing process). Additionally, each particular value listed is not intended to be interpreted solely as an absolute value but is also intended to include in the alternative an embodiment which includes the term "about" for the particular value, as that term is described above.

Generally, as to each of the formulation set out herein, each particular weight percent value shall not be interpreted solely as an absolute value and each particular weight percent value as to each raw material will be interpreted as having a range between a first particular weight percent value and second particular weight percent value based upon normal variation in the manufacturing process of the formulation, these ranges may be expressed herein as from "about" one particular value to "about" another particular value. When such a range is expressed, another embodiment includes from the particular value to the other particular value. Similarly, when values are expressed as approximations, by use of the antecedent "about," it will be understood that the particular value forms another embodiment. It will further be understood that the endpoints of each of the ranges are significant both in relation to the other endpoint, and independently of the other endpoint.

30

V. CLAIMS

I claim:

1. A composition, comprising:
polymer of about 20% to about 50%;
5 plasticizer of about 0% to about 5%;
defoamer of about 0% to 0.5%;
antioxidant of about 0% to about 3%; and
water of about 30% to about 60%.
2. The composition of claim 1, wherein said defoamer comprised of polydimethoxysilane or
10 BREVIOL[®].
3. The composition of claim 1, wherein said plasticizer comprised of glycerol or glycerin triacetate.
4. The composition of claim 1, wherein said antioxidant comprised of beta-carotene, tocopherol, or vitamin E.
- 15 5. A composition, comprising:
polymer of about 20% to about 45%;
plasticizer of about 0% to about 5%;
defoamer of about 0% to 0.5%;
antioxidant of about 0% to about 3%;
20 water of about 30% to about 60%;
vasodilator of about 0% to about 5%; and
taste mask of about 0% to about 5%.
6. The composition of claim 5, wherein said defoamer comprised of polydimethoxysilane or
BREVIOL[®].
- 25 7. The composition of claim 5, wherein said plasticizer comprised of glycerol or glycerin triacetate.
8. The composition of claim 5, wherein said antioxidant comprised of beta-carotene, tocopherol, or vitamin E.
9. The composition of claim 5, wherein said vasodilator comprises menthol.

10. The composition of claim 5, wherein said taste mask comprises glucose or maltose.

11. A composition, comprising:

polyethylene glycol of about 0% to about 15%;

hydroxypropyl methylcellulose of about 0% to about 0.5%;

5 polyvinyl alcohol of about 5% to about 50%;

plasticizer of about 2% to about 8%;

taste mask of about 3% to about 6%;

defoamer of about 0.01% to about 0.2%;

surfactant of about 1% to about 10%;

10 water of about 25% to about 60%;

antioxidant of about 0.02% to about 0.2%;

vasodilator of about 0% to about 5%;

polyvinylpyrrolidone of about 0% to about 20%;

cannabinoid of about 5% to about 40%;

15 beta-cyclodextrin of about 5% to about 20%; and

terpenes of about 0.1% to about 1%;

wherein a first portion of said cannabinoid associated with β -cyclodextrin have a wt/wt ratio of between about 1:1 to about 1:4;

20 wherein a second portion of said cannabinoid configured as a micelle having a hydrophobic core of between about five to about fifty molecules of a cannabinoid and a hydrophilic shell of a surfactant, wherein said micelle has a diameter of between about 40 nm to about 100 nm.

12. The composition of claim 11, wherein said cannabinoid selected from the group consisting of: cannabitol, cannabitolic acid, $\Delta(9)$ -tetrahydrocannabitol, $\Delta(9)$ -tetrahydrocannabitolic acid, $\Delta(9)$ -cannabidiol, $\Delta(9)$ -tetrahydrocannabidiolic acid, $\Delta(8)$ -tetrahydrocannabitol, $\Delta(8)$ -tetrahydrocannabitolic acid, $\Delta(8)$ -tetrahydrocannabidiol, $\Delta(8)$ -tetrahydrocannabidiolic acid, $\Delta(9)$ -tetrahydrocannabivarin, cannabigerol, cannabidigerolic acid, cannabichromene, cannabichromenic acid, cannabicyclol, cannabicyclolic acid, cannabielsoin, cannabitol, Nabilone, or combinations thereof.

30 13. The composition of claim 11, wherein said surfactant selected from the group consisting of: monoglycerides, diglycerides, polyethylene glycol sorbitan fatty acid esters, polyethylene glycol alkyl ethers, phospholipids, hydrophilic derivatives of phospholipids, PEG-40 castor oil, PEG-60 corn glycerides, vitamin E, TWEEN[®] 80, polyoxyethylene alkyl ethers, polyethylene

glycol glycerol fatty acid esters, polyoxyethylene sorbitan fatty acid esters, or combinations thereof.

14. The composition of claim 11, wherein said diameter of said micelle selected from the group consisting of: about 41 nm to about 45 nm, about 42.5 nm to about 47.5 nm, about 45 nm
5 to about 50 nm, about 47.5 nm to about 52.5 nm, about 50 nm to about 55 nm, about 52.5 nm to about 57.5 nm, about 55 nm to about 60 nm, about 57.5 nm to about 62.5 nm, about 60 nm to about 65 nm, about 62.5 nm to about 67.5 nm, about 65 nm to about 70 nm, about 67.5 nm to about 72.5 nm, about 70 nm to about 75 nm, about 72.5 nm to about 77.5 nm, about 75 nm to about 80 nm, about 77.5 nm to about 82.5 nm, about 80 nm to about 85 nm, about 82.5 nm to
10 about 87.5 nm, about 85 nm to about 90 nm, about 87.5 nm to about 92.5 nm, about 90 nm to about 95 nm, about 92.5 nm to about 97.5 nm, and about 95 nm to about 99 nm, or combinations thereof.

15. The composition of claim 11, wherein said β -cyclodextrin selected from the group consisting of: hydroxypropyl- β -cyclodextrin, sulfobutylether- β -cyclodextrin, maltosyl- β -
15 cyclodextrin, dimethyl- β -cyclodextrin, trimethyl- β -cyclodextrin, randomly methylated- β -cyclodextrin, or combinations thereof.

16. The composition of claim 11, wherein said β -cyclodextrin consists of randomly-methylated β -cyclodextrin or hydroxypropyl- β -cyclodextrin.

17. The composition of claim 11, wherein said terpene selected from the group consisting of:
20 alpha-pinene, beta-pinene, myrcene, limonene, carophyllene, linalool, alpha bisabolol, delta 3 carene, borneol, eucalyptol, terpineol, camphene, nerolidol, terpinolene, valencene, humulene, geraniol, phellandrene, fenchol, phytol, sabinene, camphor, menthol, isborneol, cedrane, guaiol, isopulegol, geranyl acetate, cymene, pulegon, citral, or combinations thereof.

18. The composition of claim 11, wherein said taste mask comprises glucose or maltose.

25 19. The composition of claim 11, wherein a molecular weight of said polyethylene glycol between about 1,000 Da and about 1,600 Da.

20. The composition of claim 19, wherein said molecular weight of said polyethylene glycol selected from the group consisting of: about 1025 Da to about 1075 Da, about 1050 Da to about 1100 Da, about 1075 Da to about 1125 Da, about 1100 Da to about 1150 Da, about 1125 Da to
30 about 1175 Da, about 1150 Da to about 1200 Da, about 1175 Da to about 1225 Da, about 1200

Da to about 1250 Da, about 1225 Da to about 1275 Da, about 1250 Da to about 1300 Da, about 1275 Da to about 1325 Da, about 1300 Da to about 1350 Da, about 1325 Da to about 1375 Da, about 1350 Da to about 1400 Da, about 1375 Da to about 1425 Da, about 1400 Da to about 1450 Da, about 1425 Da to about 1475 Da, about 1450 Da to about 1500 Da, about 1475 Da to about 1525 Da, about 1500 Da to about 1550 Da, and about 1525 Da to about 1575 Da, or combinations thereof.

21. The composition of claim 11, wherein a molecular weight of said polyvinyl alcohol between about 25,000 Da to about 78,000 Da.

22. The composition of claim 21, wherein said molecular weight of said polyvinyl alcohol selected from the group consisting of: about 26,000 Da to about 30,000 Da, about 27,500 Da to about 32,500 Da, about 30,000 Da to about 35,000 Da, about 32,500 Da to about 37,500 Da, about 35,000 Da to about 40,000 Da, about 37,500 Da to about 42,500 Da, about 40,000 Da to about 45,000 Da, about 42,500 Da to about 47,500 Da, about 45,000 Da to about 50,000 Da, about 47,500 Da to about 52,500 Da, about 50,000 Da to about 55,000 Da, about 52,500 Da to about 57,500 Da, about 55,000 Da to about 60,000 Da, about 57,500 Da to about 62,500 Da, about 60,000 Da to about 65,000 Da, about 62,500 Da to about 67,500 Da, about 65,000 Da to about 70,000 Da, about 67,500 Da to about 72,500 Da, about 70,000 Da to about 75,000 Da, and about 72,500 Da to about 77,000 Da, or combinations thereof.

23. The composition of claim 11, wherein said defoamer comprised of polydimethoxysilane or BREVIOL[®].

24. The composition of claim 11, wherein said surfactant comprised of TWEEN[®] 80 or polysorbat-80.

25. The composition of claim 11, wherein said plasticizer comprised of glycerol or glycerin triacetate.

26. The composition of claim 11, wherein said antioxidant comprised of beta-carotene, tocopherol, or vitamin E.

27. The composition of claim 11, wherein a molecular weight of said polyvinylpyrrolidone between about 20,000 Da and about 40,000 Da.

28. The composition of claim 27, wherein said molecular weight of said polyvinylpyrrolidone selected from the group consisting of: about 21,000 Da to about 23,000 Da, about 22,000 Da to

about 24,000 Da, about 23,000 Da to about 25,000 Da, about 24,000 Da to about 26,000 Da, about 25,000 Da to about 27,000 Da, about 26,000 Da to about 28,000 Da, about 27,000 Da to about 29,000 Da, about 28,000 Da to about 30,000 Da, about 29,000 Da to about 31,000 Da, about 30,000 Da to about 32,000 Da, about 31,000 Da to about 33,000 Da, about 32,000 Da to about 34,000 Da, about 33,000 Da to about 35,000 Da, about 34,000 Da to about 36,000 Da, about 35,000 Da to about 37,000 Da, about 36,000 Da to about 38,000 Da, and about 37,000 Da to about 39,000 Da, or combinations thereof.

29. A composition, consisting of:

polyethylene glycol of about 0% to about 15%;

10 hydroxypropylmethylcellulose of about 0% to about 0.5%;

polyvinyl alcohol of about 5% to about 50%;

plasticizer of about 2% to about 8%;

taste mask of about 3% to about 6%;

defoamer of about 0.01% to about 0.2%;

15 surfactant of about 1% to about 10%;

water of about 25% to about 60%;

antioxidant of about 0.02% to about 0.2%;

vasodilator of about 0% to about 5%;

polyvinylpyrrolidone of about 0% to about 20%;

20 cannabinoid of about 5% to about 40%;

beta-cyclodextrin of about 5% to about 20%; and

terpenes of about 0.1% to about 1%;

wherein a first portion of said amount of cannabinoid associated with β -cyclodextrin have a wt/wt ratio of between about 1:1 to about 1:4;

25 wherein a second portion of said amount of cannabinoid configured as a micelle having a hydrophobic core of between about five to about fifty molecules of a cannabinoid and a hydrophilic shell of a surfactant, wherein said micelle has a diameter of between about 40 nm to about 100 nm.

30 30. The composition of claim 29, wherein said cannabinoid selected from the group consisting of: cannabitol, cannabitolic acid, $\Delta(9)$ -tetrahydrocannabitol, $\Delta(9)$ -tetrahydrocannabitolic acid, $\Delta(9)$ -cannabidiol, $\Delta(9)$ -tetrahydrocannabidiolic acid, $\Delta(8)$ -tetrahydrocannabitol, $\Delta(8)$ -tetrahydrocannabitolic acid, $\Delta(8)$ -tetrahydrocannabidiol, $\Delta(8)$ -tetrahydrocannabidiolic acid, $\Delta(9)$ -tetrahydrocannabivarin, cannabigerol, cannabidigerolic acid,

cannabichromene, cannabichromenic acid, cannabicyclol, cannabicyclolic acid, cannabielsoin, cannabitol, Nabilone, or combinations thereof.

31. The composition of claim 29, wherein said surfactant selected from the group consisting of: monoglycerides, diglycerides, polyethylene glycol sorbitan fatty acid esters; polyethylene glycol alkyl ethers, phospholipids, hydrophilic derivatives of phospholipids, PEG-40 castor oil, PEG-60 corn glycerides, vitamin E, TWEEN[®] 80, polyoxyethylene alkyl ethers, polyethylene glycol glycerol fatty acid esters, polyoxyethylene sorbitan fatty acid esters, or combinations thereof.

32. The composition of claim 29, wherein said surfactant comprised of TWEEN[®] 80 or polysorbate-80.

33. The composition of claim 29, wherein said diameter of said micelle selected from the group consisting of: about 41 nm to about 45 nm, about 42.5 nm to about 47.5 nm, about 45 nm to about 50 nm, about 47.5 nm to about 52.5 nm, about 50 nm to about 55 nm, about 52.5 nm to about 57.5 nm, about 55 nm to about 60 nm, about 57.5 nm to about 62.5 nm, about 60 nm to about 65 nm, about 62.5 nm to about 67.5 nm, about 65 nm to about 70 nm, about 67.5 nm to about 72.5 nm, about 70 nm to about 75 nm, about 72.5 nm to about 77.5 nm, about 75 nm to about 80 nm, about 77.5 nm to about 82.5 nm, about 80 nm to about 85 nm, about 82.5 nm to about 87.5 nm, about 85 nm to about 90 nm, about 87.5 nm to about 92.5 nm, about 90 nm to about 95 nm, about 92.5 nm to about 97.5 nm, and about 95 nm to about 99 nm, or combinations thereof.

34. The composition of claim 29, wherein said β -cyclodextrin selected from the group consisting of: hydroxypropyl- β -cyclodextrin, sulfobutylether- β -cyclodextrin, maltosyl- β -cyclodextrin, dimethyl- β -cyclodextrin, trimethyl- β -cyclodextrin, randomly methylated- β -cyclodextrin, or combinations thereof.

35. The composition of claim 29, wherein said β -cyclodextrin consists of randomly-methylated β -cyclodextrin or hydroxypropyl- β -cyclodextrin.

36. The composition of claim 29, wherein said terpene selected from the group consisting of: alpha-pinene, beta-pinene, myrcene, limonene, carophyllene, linalool, alpha bisabolol, delta 3 carene, borneol, eucalyptol, terpineol, camphene, nerolidol, terpinolene, valencene, humulene, geraniol, phellandrene, fenchol, phytol, sabinene, camphor, menthol, isborneol, cedrane, guaiol, isopulegol, geranyl acetate, cymene, pulegon, citral, or combinations thereof.

37. The composition of claim 29, wherein said taste mask comprises glucose or maltose.

38. The composition of claim 29, wherein a molecular weight of said polyethylene glycol between about 1,000 Da and about 1,600 Da.

39. The composition of claim 38, wherein said molecular weight of said polyethylene glycol
5 selected from the group consisting of: about 1025 Da to about 1075 Da, about 1050 Da to about 1100 Da, about 1075 Da to about 1125 Da, about 1100 Da to about 1150 Da, about 1125 Da to about 1175 Da, about 1150 Da to about 1200 Da, about 1175 Da to about 1225 Da, about 1200 Da to about 1250 Da, about 1225 Da to about 1275 Da, about 1250 Da to about 1300 Da, about 1275 Da to about 1325 Da, about 1300 Da to about 1350 Da, about 1325 Da to about 1375 Da,
10 about 1350 Da to about 1400 Da, about 1375 Da to about 1425 Da, about 1400 Da to about 1450 Da, about 1425 Da to about 1475 Da, about 1450 Da to about 1500 Da, about 1475 Da to about 1525 Da, about 1500 Da to about 1550 Da, and about 1525 Da to about 1575 Da, or combinations thereof.

40. The composition of claim 29, wherein a molecular weight of said polyvinyl alcohol
15 between about 25,000 Da to about 78,000 Da.

41. The composition of claim 40, wherein said molecular weight of said polyvinyl alcohol selected from the group consisting of: about 26,000 Da to about 30,000 Da, about 27,500 Da to about 32,500 Da, about 30,000 Da to about 35,000 Da, about 32,500 Da to about 37,500 Da, about 35,000 Da to about 40,000 Da, about 37,500 Da to about 42,500 Da, about 40,000 Da to
20 about 45,000 Da, about 42,500 Da to about 47,500 Da, about 45,000 Da to about 50,000 Da, about 47,500 Da to about 52,500 Da, about 50,000 Da to about 55,000 Da, about 52,500 Da to about 57,500 Da, about 55,000 Da to about 60,000 Da, about 57,500 Da to about 62,500 Da, about 60,000 Da to about 65,000 Da, about 62,500 Da to about 67,500 Da, about 65,000 Da to about 70,000 Da, about 67,500 Da to about 72,500 Da, about 70,000 Da to about 75,000 Da, and
25 about 72,500 Da to about 77,000 Da, or combinations thereof.

42. The composition of claim 29, wherein said defoamer comprised of polydimethoxysilane or BREVIOL[®].

43. The composition of claim 29, wherein said plasticizer comprised of glycerol or glycerin triacetate.

44. The composition of claim 29, wherein said antioxidant comprised of beta-carotene, tocopherol, or vitamin E.

45. The composition of claim 29, wherein a molecular weight of said polyvinylpyrrolidone between about 20,000 Da and about 40,000 Da.

5 46. The composition of claim 45, wherein said molecular weight of said polyvinylpyrrolidone selected from the group consisting of: about 21,000 Da to about 23,000 Da, about 22,000 Da to about 24,000 Da, about 23,000 Da to about 25,000 Da, about 24,000 Da to about 26,000 Da, about 25,000 Da to about 27,000 Da, about 26,000 Da to about 28,000 Da, about 27,000 Da to about 29,000 Da, about 28,000 Da to about 30,000 Da, about 29,000 Da to about 31,000 Da, 10 about 30,000 Da to about 32,000 Da, about 31,000 Da to about 33,000 Da, about 32,000 Da to about 34,000 Da, about 33,000 Da to about 35,000 Da, about 34,000 Da to about 36,000 Da, about 35,000 Da to about 37,000 Da, about 36,000 Da to about 38,000 Da, and about 37,000 Da to about 39,000 Da, or combinations thereof.

47. A composition, comprising:

15 a micelle having a hydrophobic core of between about five to about fifty molecules of a cannabinoid and a hydrophilic shell of a surfactant, wherein said micelle has a diameter of between about 40 nm to about 100 nm.

48. The composition of claim 47, wherein said cannabinoid selected from the group consisting of: cannabinol, cannabinolic acid, $\Delta(9)$ -tetrahydrocannabinol, $\Delta(9)$ -tetrahydrocannabinolic acid, $\Delta(9)$ -cannabidiol, $\Delta(9)$ -tetrahydrocannabidiolic acid, $\Delta(8)$ -tetrahydrocannabinol, $\Delta(8)$ -tetrahydrocannabinolic acid, $\Delta(8)$ -tetrahydrocannabidiol, $\Delta(8)$, 20 tetrahydrocannabidiolic acid, $\Delta(9)$ -tetrahydrocannabivarin, cannabigerol, cannabidigerolic acid, cannabichromene, cannabichromenic acid, cannabicyclol, cannabicyclolic acid, cannabielsoin, cannabitrinol, Nabilone, or combinations thereof.

25 49. The composition of claim 47, wherein said surfactant selected from the group consisting of: monoglycerides, diglycerides, polyethylene glycol sorbitan fatty acid esters; polyethylene glycol alkyl ethers, phospholipids, hydrophilic derivatives of phospholipids, PEG-40 castor oil, PEG-60 corn glycerides, vitamin E, TWEEN[®] 80, polyoxyethylene alkyl ethers, polyethylene glycol glycerol fatty acid esters, polyoxyethylene sorbitan fatty acid esters, or combinations 30 thereof.

50. The composition of claim 47, wherein said diameter of said micelle selected from the group consisting of: about 41 nm to about 45 nm, about 42.5 nm to about 47.5 nm, about 45 nm to about 50 nm, about 47.5 nm to about 52.5 nm, about 50 nm to about 55 nm, about 52.5 nm to about 57.5 nm, about 55 nm to about 60 nm, about 57.5 nm to about 62.5 nm, about 60 nm to about 65 nm, about 62.5 nm to about 67.5 nm, about 65 nm to about 70 nm, about 67.5 nm to about 72.5 nm, about 70 nm to about 75 nm, about 72.5 nm to about 77.5 nm, about 75 nm to about 80 nm, about 77.5 nm to about 82.5 nm, about 80 nm to about 85 nm, about 82.5 nm to about 87.5 nm, about 85 nm to about 90 nm, about 87.5 nm to about 92.5 nm, about 90 nm to about 95 nm, about 92.5 nm to about 97.5 nm, and about 95 nm to about 99 nm, or combinations thereof.

51. A composition, comprising:
an amount of cannabinoid;
an amount of β -cyclodextrin; and
an amount of at least one terpene;
wherein said cannabinoid and said β -cyclodextrin have a wt/wt ratio of between about 1:1 to about 1:4.

52. The composition of claim 51, wherein said cannabinoid selected from the group consisting of: cannabitol, cannabitolic acid, $\Delta(9)$ -tetrahydrocannabinol, $\Delta(9)$ -tetrahydrocannabinolic acid, $\Delta(9)$ -cannabidiol, $\Delta(9)$ -tetrahydrocannabidiolic acid, $\Delta(8)$ -tetrahydrocannabinol, $\Delta(8)$ -tetrahydrocannabinolic acid, $\Delta(8)$ -tetrahydrocannabidiol, $\Delta(8)$, tetrahydrocannabidiolic acid, $\Delta(9)$ -tetrahydrocannabivarin, cannabigerol, cannabidigerolic acid, cannabichromene, cannabichromenic acid, cannabicyclol, cannabicyclolic acid, cannabielsoin, cannabitol, Nabilone, or combinations thereof.

53. The composition of claim 51, wherein said β -cyclodextrin selected from the group consisting of: hydroxypropyl- β -cyclodextrin, sulfobutylether- β -cyclodextrin, maltosyl- β -cyclodextrin, dimethyl- β -cyclodextrin, trimethyl- β -cyclodextrin, randomly methylated- β -cyclodextrin, or combinations thereof.

54. The composition of claim 51, wherein said β -cyclodextrin consists of randomly-methylated β -cyclodextrin or hydroxypropyl- β -cyclodextrin.

55. The composition of claim 51, wherein said terpene selected from the group consisting of: alpha-pinene, beta-pinene, myrcene, limonene, carophyllene, linalool, alpha bisabolol, delta 3 carene, borneol, eucalyptol, terpineol, camphene, nerolidol, terpinolene, valencene, humulene,

geraniol, phellandrene, fenchol, phytol, sabinene, camphor, menthol, isoborneol, cedrane, guaiol, isopulegol, geranyl acetate, cymene, pulegon, citral, or combinations thereof.

56. A composition, comprising:

an amount of cannabinoid;

5 an amount of β -cyclodextrin;

at least one or more terpene;

an amount of surfactant; and

a solvent;

10 wherein a first portion of said amount of cannabinoid associates with said amount of β -cyclodextrin as a complex in said solvent, said complex having a wt/wt ratio of about 1:1 to about 1:4; and

15 wherein a second portion of said amount of cannabinoid forms a micelle in said solvent, said micelle having a hydrophobic core of between about five to about fifty molecules of a cannabinoid and a hydrophilic shell of said amount of surfactant, wherein said micelle has a diameter of about 40 nm to about 100 nm.

57. The composition of claim 56, wherein said cannabinoid selected from the group consisting of: cannabitol, cannabitolic acid, $\Delta(9)$ -tetrahydrocannabinol, $\Delta(9)$ -tetrahydrocannabinolic acid, $\Delta(9)$ -cannabidiol, $\Delta(9)$ -tetrahydrocannabidiolic acid, $\Delta(8)$ -tetrahydrocannabinol, $\Delta(8)$ -tetrahydrocannabinolic acid, $\Delta(8)$ -tetrahydrocannabidiol, $\Delta(8)$,
20 tetrahydrocannabidiolic acid, $\Delta(9)$ -tetrahydrocannabivarin, cannabigerol, cannabidigerolic acid, cannabichromene, cannabichromenic acid, cannabicyclol, cannabicyclolic acid, cannabielsoin, cannabitol, Nabilone, or combinations thereof.

58. The composition of claim 56, wherein said surfactant selected from the group consisting of: monoglycerides, diglycerides, polyethylene glycol sorbitan fatty acid esters; polyethylene
25 glycol alkyl ethers, phospholipids, hydrophilic derivatives of phospholipids, PEG-40 castor oil, PEG-60 corn glycerides, vitamin E, TWEEN[®] 80, polyoxyethylene alkyl ethers, polyethylene glycol glycerol fatty acid esters, polyoxyethylene sorbitan fatty acid esters, or combinations thereof.

59. The composition of claim 56, wherein said diameter of said micelle selected from the
30 group consisting of: about 41 nm to about 45 nm, about 42.5 nm to about 47.5 nm, about 45 nm to about 50 nm, about 47.5 nm to about 52.5 nm, about 50 nm to about 55 nm, about 52.5 nm to about 57.5 nm, about 55 nm to about 60 nm, about 57.5 nm to about 62.5 nm, about 60 nm to

about 65 nm, about 62.5 nm to about 67.5 nm, about 65 nm to about 70 nm, about 67.5 nm to about 72.5 nm, about 70 nm to about 75 nm, about 72.5 nm to about 77.5 nm, about 75 nm to about 80 nm, about 77.5 nm to about 82.5 nm, about 80 nm to about 85 nm, about 82.5 nm to about 87.5 nm, about 85 nm to about 90 nm, about 87.5 nm to about 92.5 nm, about 90 nm to
5 about 95 nm, about 92.5 nm to about 97.5 nm, and about 95 nm to about 99 nm, or combinations thereof.

60. The composition of claim 56, wherein said β -cyclodextrin selected from the group consisting of: hydroxypropyl- β -cyclodextrin, sulfobutylether- β -cyclodextrin, maltosyl- β -cyclodextrin, dimethyl- β -cyclodextrin, trimethyl- β -cyclodextrin, randomly methylated- β -
10 cyclodextrin, or combinations thereof.

61. The composition of claim 56, wherein said β -cyclodextrin consists of randomly-methylated β -cyclodextrin or hydroxypropyl- β -cyclodextrin.

62. The composition of claim 61, wherein said terpene selected from the group consisting of: alpha-pinene, beta-pinene, myrcene, limonene, carophyllene, linalool, alpha bisabolol, delta 3
15 carene, borneol, eucalyptol, terpineol, camphene, nerolidol, terpinolene, valencene, humulene, geraniol, phellandrene, fenchol, phytol, sabinene, camphor, menthol, isoborneol, cedrane, guaiol, isopulegol, geranyl acetate, cymene, pulegon, citral, or combinations thereof.

AMENDED CLAIMS

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V. CLAIMS

I claim:

1. A composition, comprising:
5 polymer of about 20% to about 50%;
plasticizer of about 6% to about 9%;
defoamer of about 0.2% to about 0.5%;
antioxidant of about 0% to about 3%; and
water of about 30% to about 60%.
- 10 2. The composition of claim 1, wherein said defoamer comprises simethicone, polydimethylsiloxane, polyethylene glycol, fatty alcohols, fatty acid soaps, fatty acid esters, or combinations thereof.
3. The composition of claim 1, wherein said plasticizer comprises glycerol or glycerin triacetate.
- 15 4. The composition of claim 1, wherein said antioxidant comprises beta-carotene, tocopherol, or vitamin E.
5. A composition, comprising:
polymer of about 20% to about 45%;
plasticizer of about 6% to about 9%;
20 defoamer of about 0.2% to 0.5%;
antioxidant of about 0% to about 3%;
water of about 30% to about 60%;
vasodilator of about 0% to about 5%; and
taste mask of about 0% to about 5%.
- 25 6. The composition of claim 5, wherein said defoamer comprises simethicone, polydimethylsiloxane, polyethylene glycol, fatty alcohols, fatty acid soaps, fatty acid esters, or combinations thereof.
7. The composition of claim 5, wherein said plasticizer comprises glycerol or glycerin triacetate.

8. The composition of claim 5, wherein said antioxidant comprises beta-carotene, tocopherol, or vitamin E.

9. The composition of claim 5, wherein said vasodilator comprises menthol.

10. The composition of claim 5, wherein said taste mask comprises glucose or maltose.

5 11. A composition, comprising:

polyethylene glycol of about 0% to about 15%;

hydroxypropyl methylcellulose of about 0% to about 0.5%;

polyvinyl alcohol of about 5% to about 50%;

plasticizer of about 2% to about 8%;

10 taste mask of about 3% to about 6%;

defoamer of about 0.01% to about 0.2%;

surfactant of about 1% to about 10%;

water of about 25% to about 60%;

antioxidant of about 0.02% to about 0.2%;

15 vasodilator of about 0% to about 5%;

polyvinylpyrrolidone of about 0% to about 20%;

cannabinoid of about 5% to about 40%;

beta-cyclodextrin of about 5% to about 20%; and

terpenes of about 0.1% to about 1%;

20 wherein a first portion of said cannabinoid associated with β -cyclodextrin have a wt/wt ratio of between about 1:1 to about 1:4;

wherein a second portion of said cannabinoid configured as a micelle having a hydrophobic core of between about five to about fifty molecules of a cannabinoid and a hydrophilic shell of a surfactant, wherein said micelle has a diameter of between about 40 nm
25 to about 100 nm.

12. The composition of claim 11, wherein said cannabinoid selected from the group consisting of: cannabiol, cannabinolic acid, $\Delta(9)$ -tetrahydrocannabinol, $\Delta(9)$ -tetrahydrocannabinolic acid, $\Delta(9)$ -cannabidiol, $\Delta(9)$ -tetrahydrocannabidiolic acid, $\Delta(8)$ -tetrahydrocannabinol, $\Delta(8)$ -tetrahydrocannabinolic acid, $\Delta(8)$ -tetrahydrocannabidiol, $\Delta(8)$,
30 tetrahydrocannabidiolic acid, $\Delta(9)$ -tetrahydrocannabivarin, cannabigerol, cannabidigerolic

acid, cannabichromene, cannabichromenic acid, cannabicyclol, cannabicyclolic acid, cannabielsoin, cannabitrinol, Nabilone, or combinations thereof.

13. The composition of claim 11, wherein said surfactant selected from the group consisting of: monoglycerides, diglycerides, polyethylene glycol sorbitan fatty acid esters, polyethylene glycol alkyl ethers, phospholipids, hydrophilic derivatives of phospholipids, PEG-40 castor oil, PEG-60 corn glycerides, vitamin E, polysorbate 80, polyoxyethylene alkyl ethers, polyethylene glycol glycerol fatty acid esters, polyoxyethylene sorbitan fatty acid esters, or combinations thereof.

14. The composition of claim 11, wherein said diameter of said micelle selected from the group consisting of: about 41 nm to about 45 nm, about 42.5 nm to about 47.5 nm, about 45 nm to about 50 nm, about 47.5 nm to about 52.5 nm, about 50 nm to about 55 nm, about 52.5 nm to about 57.5 nm, about 55 nm to about 60 nm, about 57.5 nm to about 62.5 nm, about 60 nm to about 65 nm, about 62.5 nm to about 67.5 nm, about 65 nm to about 70 nm, about 67.5 nm to about 72.5 nm, about 70 nm to about 75 nm, about 72.5 nm to about 77.5 nm, about 75 nm to about 80 nm, about 77.5 nm to about 82.5 nm, about 80 nm to about 85 nm, about 82.5 nm to about 87.5 nm, about 85 nm to about 90 nm, about 87.5 nm to about 92.5 nm, about 90 nm to about 95 nm, about 92.5 nm to about 97.5 nm, and about 95 nm to about 99 nm, or combinations thereof.

15. The composition of claim 11, wherein said β -cyclodextrin selected from the group consisting of: hydroxypropyl- β -cyclodextrin, sulfobutylether- β -cyclodextrin, maltosyl- β -cyclodextrin, dimethyl- β -cyclodextrin, trimethyl- β -cyclodextrin, randomly methylated- β -cyclodextrin, or combinations thereof.

16. The composition of claim 11, wherein said β -cyclodextrin consists of randomly-methylated β -cyclodextrin or hydroxypropyl- β -cyclodextrin.

17. The composition of claim 11, wherein said terpene selected from the group consisting of: alpha-pinene, beta-pinene, myrcene, limonene, carophyllene, linalool, alpha bisabolol, delta 3 carene, borneol, eucalyptol, terpineol, camphene, nerolidol, terpinolene, valencene, humulene, geraniol, phellandrene, fenchol, phytol, sabinene, camphor, menthol, isoborneol, cedrane, guaiol, isopulegol, geranyl acetate, cymene, pulegon, citral, or combinations thereof.

18. The composition of claim 11, wherein said taste mask comprises glucose or maltose.

19. The composition of claim 11, wherein a molecular weight of said polyethylene glycol between about 1,000 Da and about 1,600 Da.

20. The composition of claim 19, wherein said molecular weight of said polyethylene glycol selected from the group consisting of: about 1025 Da to about 1075 Da, about 1050 Da to about 1100 Da, about 1075 Da to about 1125 Da, about 1100 Da to about 1150 Da, about 1125 Da to about 1175 Da, about 1150 Da to about 1200 Da, about 1175 Da to about 1225 Da, about 1200 Da to about 1250 Da, about 1225 Da to about 1275 Da, about 1250 Da to about 1300 Da, about 1275 Da to about 1325 Da, about 1300 Da to about 1350 Da, about 1325 Da to about 1375 Da, about 1350 Da to about 1400 Da, about 1375 Da to about 1425 Da, about 1400 Da to about 1450 Da, about 1425 Da to about 1475 Da, about 1450 Da to about 1500 Da, about 1475 Da to about 1525 Da, about 1500 Da to about 1550 Da, and about 1525 Da to about 1575 Da, or combinations thereof.

21. The composition of claim 11, wherein a molecular weight of said polyvinyl alcohol between about 25,000 Da to about 78,000 Da.

22. The composition of claim 21, wherein said molecular weight of said polyvinyl alcohol selected from the group consisting of: about 26,000 Da to about 30,000 Da, about 27,500 Da to about 32,500 Da, about 30,000 Da to about 35,000 Da, about 32,500 Da to about 37,500 Da, about 35,000 Da to about 40,000 Da, about 37,500 Da to about 42,500 Da, about 40,000 Da to about 45,000 Da, about 42,500 Da to about 47,500 Da, about 45,000 Da to about 50,000 Da, about 47,500 Da to about 52,500 Da, about 50,000 Da to about 55,000 Da, about 52,500 Da to about 57,500 Da, about 55,000 Da to about 60,000 Da, about 57,500 Da to about 62,500 Da, about 60,000 Da to about 65,000 Da, about 62,500 Da to about 67,500 Da, about 65,000 Da to about 70,000 Da, about 67,500 Da to about 72,500 Da, about 70,000 Da to about 75,000 Da, and about 72,500 Da to about 77,000 Da, or combinations thereof.

23. The composition of claim 11, wherein said defoamer comprised of simethicone, polydimethylsiloxane, polyethylene glycol, fatty alcohols, fatty acid soaps, fatty acid esters, or combinations thereof.

24. The composition of claim 11, wherein said surfactant comprised of polysorbate 80.

25. The composition of claim 11, wherein said plasticizer comprised of glycerol or glycerin triacetate.

26. The composition of claim 11, wherein said antioxidant comprised of beta-carotene, tocopherol, or vitamin E.

27. The composition of claim 11, wherein a molecular weight of said polyvinylpyrrolidone between about 20,000 Da and about 40,000 Da.

5 28. The composition of claim 27, wherein said molecular weight of said polyvinylpyrrolidone selected from the group consisting of: about 21,000 Da to about 23,000 Da, about 22,000 Da to about 24,000 Da, about 23,000 Da to about 25,000 Da, about 24,000 Da to about 26,000 Da, about 25,000 Da to about 27,000 Da, about 26,000 Da to about 28,000 Da, about 27,000 Da to about 29,000 Da, about 28,000 Da to about 30,000 Da, about 29,000
10 Da to about 31,000 Da, about 30,000 Da to about 32,000 Da, about 31,000 Da to about 33,000 Da, about 32,000 Da to about 34,000 Da, about 33,000 Da to about 35,000 Da, about 34,000 Da to about 36,000 Da, about 35,000 Da to about 37,000 Da, about 36,000 Da to about 38,000 Da, and about 37,000 Da to about 39,000 Da, or combinations thereof.

29. A composition, consisting of:

15 polyethylene glycol of about 0% to about 15%;

hydroxypropylmethylcellulose of about 0% to about 0.5%;

polyvinyl alcohol of about 5% to about 50%;

plasticizer of about 2% to about 8%;

taste mask of about 3% to about 6%;

20 defoamer of about 0.01% to about 0.2%;

surfactant of about 1% to about 10%;

water of about 25% to about 60%;

antioxidant of about 0.02% to about 0.2%;

vasodilator of about 0% to about 5%;

25 polyvinylpyrrolidone of about 0% to about 20%;

cannabinoid of about 5% to about 40%;

beta-cyclodextrin of about 5% to about 20%; and

terpenes of about 0.1% to about 1%;

30 wherein a first portion of said amount of cannabinoid associated with β -cyclodextrin have a wt/wt ratio of between about 1:1 to about 1:4;

wherein a second portion of said amount of cannabinoid configured as a micelle having a hydrophobic core of between about five to about fifty molecules of a cannabinoid and a

hydrophilic shell of a surfactant, wherein said micelle has a diameter of between about 40 nm to about 100 nm.

30. The composition of claim 29, wherein said cannabinoid selected from the group consisting of: cannabinol, cannabinolic acid, $\Delta(9)$ -tetrahydrocannabinol, $\Delta(9)$ -tetrahydrocannabinolic acid, $\Delta(9)$ -cannabidiol, $\Delta(9)$ -tetrahydrocannabidiolic acid, $\Delta(8)$ -tetrahydrocannabinol, $\Delta(8)$ -tetrahydrocannabinolic acid, $\Delta(8)$ -tetrahydrocannabidiol, $\Delta(8)$ -tetrahydrocannabidiolic acid, $\Delta(9)$ -tetrahydrocannabivarin, cannabigerol, cannabidigerolic acid, cannabichromene, cannabichromenic acid, cannabicyclol, cannabicyclolic acid, cannabielsoin, cannabitrinol, Nabilone, or combinations thereof.

10 31. The composition of claim 29, wherein said surfactant selected from the group consisting of: monoglycerides, diglycerides, polyethylene glycol sorbitan fatty acid esters; polyethylene glycol alkyl ethers, phospholipids, hydrophilic derivatives of phospholipids, PEG-40 castor oil, PEG-60 corn glycerides, vitamin E, polysorbate 80, polyoxyethylene alkyl ethers, polyethylene glycol glycerol fatty acid esters, polyoxyethylene sorbitan fatty acid esters, or combinations
15 thereof.

32. The composition of claim 29, wherein said surfactant comprised of polysorbate 80.

33. The composition of claim 29, wherein said diameter of said micelle selected from the group consisting of: about 41 nm to about 45 nm, about 42.5 nm to about 47.5 nm, about 45 nm to about 50 nm, about 47.5 nm to about 52.5 nm, about 50 nm to about 55 nm, about 52.5 nm to about 57.5 nm, about 55 nm to about 60 nm, about 57.5 nm to about 62.5 nm, about 60 nm to about 65 nm, about 62.5 nm to about 67.5 nm, about 65 nm to about 70 nm, about 67.5 nm to about 72.5 nm, about 70 nm to about 75 nm, about 72.5 nm to about 77.5 nm, about 75 nm to about 80 nm, about 77.5 nm to about 82.5 nm, about 80 nm to about 85 nm, about 82.5 nm to about 87.5 nm, about 85 nm to about 90 nm, about 87.5 nm to about 92.5 nm, about 90 nm to about 95 nm, about 92.5 nm to about 97.5 nm, and about 95 nm to about 99 nm, or
20 combinations thereof.

34. The composition of claim 29, wherein said β -cyclodextrin selected from the group consisting of: hydroxypropyl- β -cyclodextrin, sulfobutylether- β -cyclodextrin, maltosyl- β -cyclodextrin, dimethyl- β -cyclodextrin, trimethyl- β -cyclodextrin, randomly methylated- β -
30 cyclodextrin, or combinations thereof.

35. The composition of claim 29, wherein said β -cyclodextrin consists of randomly-methylated β -cyclodextrin or hydroxypropyl- β -cyclodextrin.

36. The composition of claim 29, wherein said terpene selected from the group consisting of: alpha-pinene, beta-pinene, myrcene, limonene, carophyllene, linalool, alpha bisabolol, delta
5 3 carene, borneol, eucalyptol, terpineol, camphene, nerolidol, terpinolene, valencene, humulene, geraniol, phellandrene, fenchol, phytol, sabinene, camphor, menthol, isoborneol, cedrane, guaiol, isopulegol, geranyl acetate, cymene, pulegon, citral, or combinations thereof.

37. The composition of claim 29, wherein said taste mask comprises glucose or maltose.

38. The composition of claim 29, wherein a molecular weight of said polyethylene glycol
10 between about 1,000 Da and about 1,600 Da.

39. The composition of claim 38, wherein said molecular weight of said polyethylene glycol selected from the group consisting of: about 1025 Da to about 1075 Da, about 1050 Da to about 1100 Da, about 1075 Da to about 1125 Da, about 1100 Da to about 1150 Da, about 1125 Da to about 1175 Da, about 1150 Da to about 1200 Da, about 1175 Da to about 1225 Da,
15 about 1200 Da to about 1250 Da, about 1225 Da to about 1275 Da, about 1250 Da to about 1300 Da, about 1275 Da to about 1325 Da, about 1300 Da to about 1350 Da, about 1325 Da to about 1375 Da, about 1350 Da to about 1400 Da, about 1375 Da to about 1425 Da, about 1400 Da to about 1450 Da, about 1425 Da to about 1475 Da, about 1450 Da to about 1500 Da, about 1475 Da to about 1525 Da, about 1500 Da to about 1550 Da, and about 1525 Da to about 1575
20 Da, or combinations thereof.

40. The composition of claim 29, wherein a molecular weight of said polyvinyl alcohol between about 25,000 Da to about 78,000 Da.

41. The composition of claim 40, wherein said molecular weight of said polyvinyl alcohol selected from the group consisting of: about 26,000 Da to about 30,000 Da, about 27,500 Da
25 to about 32,500 Da, about 30,000 Da to about 35,000 Da, about 32,500 Da to about 37,500 Da, about 35,000 Da to about 40,000 Da, about 37,500 Da to about 42,500 Da, about 40,000 Da to about 45,000 Da, about 42,500 Da to about 47,500 Da, about 45,000 Da to about 50,000 Da, about 47,500 Da to about 52,500 Da, about 50,000 Da to about 55,000 Da, about 52,500 Da to about 57,500 Da, about 55,000 Da to about 60,000 Da, about 57,500 Da to about 62,500 Da,
30 about 60,000 Da to about 65,000 Da, about 62,500 Da to about 67,500 Da, about 65,000 Da to

about 70,000 Da, about 67,500 Da to about 72,500 Da, about 70,000 Da to about 75,000 Da, and about 72,500 Da to about 77,000 Da, or combinations thereof.

42. The composition of claim 29, wherein said defoamer comprised of simethicone, polydimethylsiloxane, polyethylene glycol, fatty alcohols, fatty acid soaps, fatty acid esters, or combinations thereof.

43. The composition of claim 29, wherein said plasticizer comprised of glycerol or glycerin triacetate.

44. The composition of claim 29, wherein said antioxidant comprised of beta-carotene, tocopherol, or vitamin E.

45. The composition of claim 29, wherein a molecular weight of said polyvinylpyrrolidone between about 20,000 Da and about 40,000 Da.

46. The composition of claim 45, wherein said molecular weight of said polyvinylpyrrolidone selected from the group consisting of: about 21,000 Da to about 23,000 Da, about 22,000 Da to about 24,000 Da, about 23,000 Da to about 25,000 Da, about 24,000 Da to about 26,000 Da, about 25,000 Da to about 27,000 Da, about 26,000 Da to about 28,000 Da, about 27,000 Da to about 29,000 Da, about 28,000 Da to about 30,000 Da, about 29,000 Da to about 31,000 Da, about 30,000 Da to about 32,000 Da, about 31,000 Da to about 33,000 Da, about 32,000 Da to about 34,000 Da, about 33,000 Da to about 35,000 Da, about 34,000 Da to about 36,000 Da, about 35,000 Da to about 37,000 Da, about 36,000 Da to about 38,000 Da, and about 37,000 Da to about 39,000 Da, or combinations thereof.

47. A composition, comprising:

a micelle having a hydrophobic core of between about five to about fifty molecules of a cannabinoid and a hydrophilic shell of a surfactant, wherein said micelle has a diameter of between about 40 nm to about 100 nm.

48. The composition of claim 47, wherein said cannabinoid selected from the group consisting of: cannabitol, cannabinoic acid, $\Delta(9)$ -tetrahydrocannabinol, $\Delta(9)$ -tetrahydrocannabinolic acid, $\Delta(9)$ -cannabidiol, $\Delta(9)$ -tetrahydrocannabidiolic acid, $\Delta(8)$ -tetrahydrocannabinol, $\Delta(8)$ -tetrahydrocannabinolic acid, $\Delta(8)$ -tetrahydrocannabidiol, $\Delta(8)$ -tetrahydrocannabidiolic acid, $\Delta(9)$ -tetrahydrocannabivarin, cannabigerol, cannabidigerolic

acid, cannabichromene, cannabichromenic acid, cannabicyclol, cannabicyclolic acid, cannabielsoin, cannabitriol, Nabilone, or combinations thereof.

49. The composition of claim 47, wherein said surfactant selected from the group consisting of: monoglycerides, diglycerides, polyethylene glycol sorbitan fatty acid esters; polyethylene glycol alkyl ethers, phospholipids, hydrophilic derivatives of phospholipids, PEG-40 castor oil, PEG-60 corn glycerides, vitamin E, polysorbate 80, polyoxyethylene alkyl ethers, polyethylene glycol glycerol fatty acid esters, polyoxyethylene sorbitan fatty acid esters, or combinations thereof.

50. The composition of claim 47, wherein said diameter of said micelle selected from the group consisting of: about 41 nm to about 45 nm, about 42.5 nm to about 47.5 nm, about 45 nm to about 50 nm, about 47.5 nm to about 52.5 nm, about 50 nm to about 55 nm, about 52.5 nm to about 57.5 nm, about 55 nm to about 60 nm, about 57.5 nm to about 62.5 nm, about 60 nm to about 65 nm, about 62.5 nm to about 67.5 nm, about 65 nm to about 70 nm, about 67.5 nm to about 72.5 nm, about 70 nm to about 75 nm, about 72.5 nm to about 77.5 nm, about 75 nm to about 80 nm, about 77.5 nm to about 82.5 nm, about 80 nm to about 85 nm, about 82.5 nm to about 87.5 nm, about 85 nm to about 90 nm, about 87.5 nm to about 92.5 nm, about 90 nm to about 95 nm, about 92.5 nm to about 97.5 nm, and about 95 nm to about 99 nm, or combinations thereof.

51. A composition, comprising:
an amount of cannabinoid;
an amount of β -cyclodextrin; and
an amount of at least one terpene;
wherein said cannabinoid and said β -cyclodextrin have a wt/wt ratio of between about 1:1 to about 1:4.

52. The composition of claim 51, wherein said cannabinoid selected from the group consisting of: cannabinol, cannabinolic acid, $\Delta(9)$ -tetrahydrocannabinol, $\Delta(9)$ -tetrahydrocannabinolic acid, $\Delta(9)$ -cannabidiol, $\Delta(9)$ -tetrahydrocannabidiolic acid, $\Delta(8)$ -tetrahydrocannabinol, $\Delta(8)$ -tetrahydrocannabinolic acid, $\Delta(8)$ -tetrahydrocannabidiol, $\Delta(8)$ -tetrahydrocannabidiolic acid, $\Delta(9)$ -tetrahydrocannabivarin, cannabigerol, cannabidigerolic acid, cannabichromene, cannabichromenic acid, cannabicyclol, cannabicyclolic acid, cannabielsoin, cannabitriol, Nabilone, or combinations thereof.

53. The composition of claim 51, wherein said β -cyclodextrin selected from the group consisting of: hydroxypropyl- β -cyclodextrin, sulfobutylether- β -cyclodextrin, maltosyl- β -cyclodextrin, dimethyl- β -cyclodextrin, trimethyl- β -cyclodextrin, randomly methylated- β -cyclodextrin, or combinations thereof.

5 54. The composition of claim 51, wherein said β -cyclodextrin consists of randomly-methylated β -cyclodextrin or hydroxypropyl- β -cyclodextrin.

55. The composition of claim 51, wherein said terpene selected from the group consisting of: alpha-pinene, beta-pinene, myrcene, limonene, carophyllene, linalool, alpha bisabolol, delta 3 carene, borneol, eucalyptol, terpineol, camphene, nerolidol, terpinolene, valencene,
10 humulene, geraniol, phellandrene, fenchol, phytol, sabinene, camphor, menthol, isoborneol, cedrane, guaiol, isopulegol, geranyl acetate, cymene, pulegon, citral, or combinations thereof.

56. A composition, comprising:
an amount of cannabinoid;
an amount of β -cyclodextrin;
15 at least one or more terpene;
an amount of surfactant; and
a solvent;

wherein a first portion of said amount of cannabinoid associates with said amount of β -cyclodextrin as a complex in said solvent, said complex having a wt/wt ratio of about 1:1 to
20 about 1:4; and

wherein a second portion of said amount of cannabinoid forms a micelle in said solvent, said micelle having a hydrophobic core of between about five to about fifty molecules of a cannabinoid and a hydrophilic shell of said amount of surfactant, wherein said micelle has a diameter of about 40 nm to about 100 nm.

25 57. The composition of claim 56, wherein said cannabinoid selected from the group consisting of: cannabinol, cannabinolic acid, $\Delta(9)$ -tetrahydrocannabinol, $\Delta(9)$ -tetrahydrocannabinolic acid, $\Delta(9)$ -cannabidiol, $\Delta(9)$ -tetrahydrocannabidiolic acid, $\Delta(8)$ -tetrahydrocannabinol, $\Delta(8)$ -tetrahydrocannabinolic acid, $\Delta(8)$ -tetrahydrocannabidiol, $\Delta(8)$,
30 tetrahydrocannabidiolic acid, $\Delta(9)$ -tetrahydrocannabivarin, cannabigerol, cannabidigerolic acid, cannabichromene, cannabichromenic acid, cannabicyclol, cannabicyclolic acid, cannabielsoin, cannabitriol, Nabilone, or combinations thereof.

58. The composition of claim 56, wherein said surfactant selected from the group consisting of: monoglycerides, diglycerides, polyethylene glycol sorbitan fatty acid esters; polyethylene glycol alkyl ethers, phospholipids, hydrophilic derivatives of phospholipids, PEG-40 castor oil, PEG-60 corn glycerides, vitamin E, polysorbate 80, polyoxyethylene alkyl ethers, polyethylene glycol glycerol fatty acid esters, polyoxyethylene sorbitan fatty acid esters, or combinations thereof.

59. The composition of claim 56, wherein said diameter of said micelle selected from the group consisting of: about 41 nm to about 45 nm, about 42.5 nm to about 47.5 nm, about 45 nm to about 50 nm, about 47.5 nm to about 52.5 nm, about 50 nm to about 55 nm, about 52.5 nm to about 57.5 nm, about 55 nm to about 60 nm, about 57.5 nm to about 62.5 nm, about 60 nm to about 65 nm, about 62.5 nm to about 67.5 nm, about 65 nm to about 70 nm, about 67.5 nm to about 72.5 nm, about 70 nm to about 75 nm, about 72.5 nm to about 77.5 nm, about 75 nm to about 80 nm, about 77.5 nm to about 82.5 nm, about 80 nm to about 85 nm, about 82.5 nm to about 87.5 nm, about 85 nm to about 90 nm, about 87.5 nm to about 92.5 nm, about 90 nm to about 95 nm, about 92.5 nm to about 97.5 nm, and about 95 nm to about 99 nm, or combinations thereof.

60. The composition of claim 56, wherein said β -cyclodextrin selected from the group consisting of: hydroxypropyl- β -cyclodextrin, sulfobutylether- β -cyclodextrin, maltosyl- β -cyclodextrin, dimethyl- β -cyclodextrin, trimethyl- β -cyclodextrin, randomly methylated- β -cyclodextrin, or combinations thereof.

61. The composition of claim 56, wherein said β -cyclodextrin consists of randomly-methylated β -cyclodextrin or hydroxypropyl- β -cyclodextrin.

62. The composition of claim 61, wherein said terpene selected from the group consisting of: alpha-pinene, beta-pinene, myrcene, limonene, carophyllene, linalool, alpha bisabolol, delta 3 carene, borneol, eucalyptol, terpineol, camphene, nerolidol, terpinolene, valencene, humulene, geraniol, phellandrene, fenchol, phytol, sabinene, camphor, menthol, isoborneol, cedrane, guaiol, isopulegol, geranyl acetate, cymene, pulegon, citral, or combinations thereof.

63. A composition, comprising:
polymer of about 8% to about 50%;
plasticizer of about 0.1% to about 5%;

defoamer of about 0% to about 0.2%;
water of about 40% to about 90%; and
taste mask of about 0.1% to about 1.0%.

5 64. The composition of claim 63, further comprising antioxidant of about 0% to about 3%.

65. The composition of claim 64, further comprising vasodilator of about 0% to about 5%.

10 66. The composition of claim 63, wherein said defoamer comprises simethicone, polydimethylsiloxane, polyethylene glycol, fatty alcohols, fatty acid soaps, fatty acid esters, or combinations thereof.

67. The composition of claim 63, wherein said plasticizer comprises glycerol or glycerin triacetate.

68. The composition of claim 64, wherein said antioxidant comprises beta-carotene, tocopherol, or vitamin E.

15 69. The composition of claim 65, wherein said vasodilator comprises menthol.

70. The composition of claim 63, wherein said taste mask comprises glucose or maltose.

20 71. A composition, consisting of:
polymer of about 8% to about 50%;
plasticizer of about 0.1% to about 5%;
defoamer of about 0% to about 0.2%;
water of about 40% to about 90%; and
taste mask of about 0.1% to about 1.0%.

72. The composition of claim 71, further consisting of antioxidant of about 0% to about 3%.

25 73. The composition of claim 72, further consisting of vasodilator of about 0% to about 5%.

74. The composition of claim 71, wherein said defoamer is selected from the group consisting of: simethicone, polydimethylsiloxane, polyethylene glycol, fatty alcohols, fatty acid soaps, fatty acid esters, or combinations thereof.

75. The composition of claim 71, wherein said plasticizer is selected from the group
5 consisting of: glycerol and glycerin triacetate.

76. The composition of claim 72, wherein said antioxidant is selected from the group consisting of beta-carotene, tocopherol, and vitamin E.

77. The composition of claim 73, wherein said vasodilator consists of menthol.

78. The composition of claim 71, wherein said taste mask is selected from the group
10 consisting of: glucose and maltose.

INTERNATIONAL SEARCH REPORT

International application No.

PCT/US18/31398

A. CLASSIFICATION OF SUBJECT MATTER

IPC - A23L 29/10; A61K 47/32, 47/36, 31/00, 47/10, 31/355, 9/00 (2018.01)

CPC - A23L 29/10; A61K 8/678, 47/32, 9/5015, 47/36, 31/00, 9/0056, 47/10, 31/355, 9/00; C11D 3/0026

According to International Patent Classification (IPC) or to both national classification and IPC

B. FIELDS SEARCHED

Minimum documentation searched (classification system followed by classification symbols)

See Search History document

Documentation searched other than minimum documentation to the extent that such documents are included in the fields searched

See Search History document

Electronic data base consulted during the international search (name of data base and, where practicable, search terms used)

See Search History document

C. DOCUMENTS CONSIDERED TO BE RELEVANT

Category*	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.
X --- Y	US 4,719,239 A (MULLER, BWW et al.) 12 January 1988; column 3, lines 41-49; column 6, lines 3-15; column 7 table	1, 5 --- 2-4, 6-10
Y	WO 2014/000803 A1 (OPTIMAGS DR. ZIMMERMANN GMBH) 03 January 2014; see English translation; third page, ninth paragraph; fourth page, table	2, 6
Y	US 5,374,304 A (FRISCHE, R et al.) 20 December 1994; column 4, lines 35-39; column 7, lines 5-6	3, 7
Y	US 6,194,379 B1 (MCEWEN, JW et al.) 27 February 2001; column 15, lines 5-10	4, 8
Y	US 2004/0047930 A1 (WEBBE, JH et al.) 11 March 2004; paragraph [0006]; claim 8	9
Y	GB 2 355 405 A (AZN BIOTECH LIMITED) 25 April 2001; abstract; claims 3, 5	10

 Further documents are listed in the continuation of Box C. See patent family annex.

* Special categories of cited documents:

"A" document defining the general state of the art which is not considered to be of particular relevance

"E" earlier application or patent but published on or after the international filing date

"L" document which may throw doubts on priority claim(s) or which is cited to establish the publication date of another citation or other special reason (as specified)

"O" document referring to an oral disclosure, use, exhibition or other means

"P" document published prior to the international filing date but later than the priority date claimed

"T" later document published after the international filing date or priority date and not in conflict with the application but cited to understand the principle or theory underlying the invention

"X" document of particular relevance; the claimed invention cannot be considered novel or cannot be considered to involve an inventive step when the document is taken alone

"Y" document of particular relevance; the claimed invention cannot be considered to involve an inventive step when the document is combined with one or more other such documents, such combination being obvious to a person skilled in the art

"&" document member of the same patent family

Date of the actual completion of the international search

09 July 2018 (09.07.2018)

Date of mailing of the international search report

14 SEP 2018

Name and mailing address of the ISA/

Mail Stop PCT, Attn: ISA/US, Commissioner for Patents
P.O. Box 1450, Alexandria, Virginia 22313-1450

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PCT OSP: 571-272-7774

INTERNATIONAL SEARCH REPORT

International application No.

PCT/US18/31398

Box No. II Observations where certain claims were found unsearchable (Continuation of item 2 of first sheet)

This international search report has not been established in respect of certain claims under Article 17(2)(a) for the following reasons:

1. Claims Nos.:
because they relate to subject matter not required to be searched by this Authority, namely:

2. Claims Nos.:
because they relate to parts of the international application that do not comply with the prescribed requirements to such an extent that no meaningful international search can be carried out, specifically:

3. Claims Nos.:
because they are dependent claims and are not drafted in accordance with the second and third sentences of Rule 6.4(a).

Box No. III Observations where unity of invention is lacking (Continuation of item 3 of first sheet)

This International Searching Authority found multiple inventions in this international application, as follows:

This application contains the following inventions or groups of inventions which are not so linked as to form a single general inventive concept under PCT Rule 13.1. In order for all inventions to be examined, the appropriate additional examination fees must be paid.

Group I: Claims 1-10 are directed toward a composition, comprising: polymer of about 20% to about 45%; plasticizer of about 0% to about 5%; defoamer of about 0% to 0.5%; antioxidant of about 0% to about 3%; water of about 30% to about 60%; vasodilator of about 0% to about 5%; and taste mask of about 0% to about 5%, wherein said vasodilator comprises menthol.

-Continued Within the Next Supplemental Box-

1. As all required additional search fees were timely paid by the applicant, this international search report covers all searchable claims.
2. As all searchable claims could be searched without effort justifying additional fees, this Authority did not invite payment of additional fees.
3. As only some of the required additional search fees were timely paid by the applicant, this international search report covers only those claims for which fees were paid, specifically claims Nos.:

4. No required additional search fees were timely paid by the applicant. Consequently, this international search report is restricted to the invention first mentioned in the claims; it is covered by claims Nos.:
1-10

Remark on Protest

- The additional search fees were accompanied by the applicant's protest and, where applicable, the payment of a protest fee.
- The additional search fees were accompanied by the applicant's protest but the applicable protest fee was not paid within the time limit specified in the invitation.
- No protest accompanied the payment of additional search fees.

INTERNATIONAL SEARCH REPORT

International application No.

PCT/US18/31398

-***-Continued from Box No. III Observations where unity of invention is lacking-***-

Group II: Claims 11-55 are directed toward a composition, consisting of: polyethylene glycol of about 0% to about 15%; hydroxypropylmethylcellulose of about 0% to about 0.5%; polyvinyl alcohol of about 5% to about 50%; plasticizer of about 2% to about 8%; taste mask of about 3% to about 6%; defoamer of about 0.01% to about 0.2%; surfactant of about 1% to about 10%; water of about 25% to about 60%; antioxidant of about 0.02% to about 0.2%; vasodilator of about 0% to about 5%; polyvinylpyrrolidone of about 0% to about 20%; cannabinoid of about 5% to about 40%; beta-cyclodextrin of about 5% to about 20%; and terpenes of about 0.1% to about 1%; wherein a first portion of said amount of cannabinoid associated with beta-cyclodextrin have a wt/wt ratio of between about 1:1 to about 1:4; wherein a second portion of said amount of cannabinoid configured as a micelle having a hydrophobic core of between about five to about fifty molecules of a cannabinoid and a hydrophilic shell of a surfactant, wherein said micelle has a diameter of between about 40 nm to about 100 nm.

Group III: Claims 56-62 are directed toward a composition, comprising: an amount of cannabinoid; an amount of beta-cyclodextrin; at least one or more terpene; an amount of surfactant; and a solvent; wherein a first portion of said amount of cannabinoid associates with said amount of beta-cyclodextrin as a complex in said solvent, said complex having a wt/wt ratio of about 1:1 to about 1:4; and wherein a second portion of said amount of cannabinoid forms a micelle in said solvent, said micelle having a hydrophobic core of between about five to about fifty molecules of a cannabinoid and a hydrophilic shell of said amount of surfactant, wherein said micelle has a diameter of about 40 nm to about 100 nm.

The inventions listed as Groups I-III do not relate to a single general inventive concept under PCT Rule 13.1 because, under PCT Rule 13.2, they lack the same or corresponding special technical features for the following reasons:

the special technical features of Group I include a composition, comprising: polymer of about 20% to about 45%; plasticizer of about 0% to about 5%; defoamer of about 0% to 0.5%; antioxidant of about 0% to about 3%; water of about 30% to about 60%; vasodilator of about 0% to about 5%; and taste mask of about 0% to about 5%, wherein said vasodilator comprises menthol, which are not present in Groups II-III;

the special technical features of Group II include a composition, consisting of: polyethylene glycol of about 0% to about 15%; hydroxypropylmethylcellulose of about 0% to about 0.5%; polyvinyl alcohol of about 5% to about 50%; plasticizer of about 2% to about 8%; taste mask of about 3% to about 6%; defoamer of about 0.01% to about 0.2%; surfactant of about 1% to about 10%; water of about 25% to about 60%; antioxidant of about 0.02% to about 0.2%; vasodilator of about 0% to about 5%; polyvinylpyrrolidone of about 0% to about 20%; cannabinoid of about 5% to about 40%; beta-cyclodextrin of about 5% to about 20%; and terpenes of about 0.1% to about 1%; wherein a first portion of said amount of cannabinoid associated with beta-cyclodextrin have a wt/wt ratio of between about 1:1 to about 1:4, which are not present in Groups I and III;

the special technical features of Group III include a composition, comprising: an amount of cannabinoid; an amount of beta-cyclodextrin; at least one or more terpene; an amount of surfactant; and a solvent; wherein a first portion of said amount of cannabinoid associates with said amount of beta-cyclodextrin as a complex in said solvent, said complex having a wt/wt ratio of about 1:1 to about 1:4, which are not present in Groups I-and III;

The common technical features of Groups I-III is a composition, comprising an amount of solvent.

This common technical feature is disclosed by US 2016/0279073 A1 to FULL SPECTRUM LABORATORIES, LTD. (hereinafter 'Spectrum'). Spectrum discloses a composition, comprising an amount of solvent (formulations of terpenes, hemp oil and cannabinoids in a solvent such as water; paragraph [0038]).

Since the common technical feature is previously disclosed by Spectrum, this common feature is not special and so Groups I-III lack unity.