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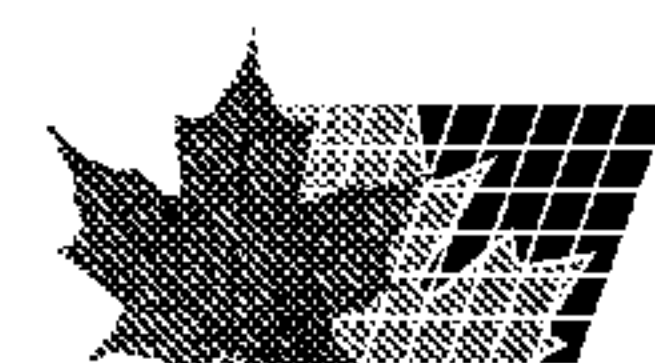
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(54) **Titre :** COMPOSITION SALINE OXYGENEE PULVERISABLE ET SON UTILISATION

(54) **Title:** SPRAYABLE OXYGENATED SALINE COMPOSITION AND USE THEREOF

(57) **Abrégé/Abstract:**

A sprayable product provides oxygen delivery to the body and benefits to physiological processes. In one embodiment the invention relates to an oxygenated saline composition comprising stabilized oxygen, sodium chloride (aqueous saline solution), and one or more plant minerals. The stabilized oxygen can include quad-atomic oxygen. The plant minerals can include humic and fulvic acids, homeopathic components, and other elemental minerals or salts thereof. Also provided is use of an oxygenated saline composition comprising stabilized oxygen, aqueous saline solution, and one or more plant minerals, for use in the case of nasal and/or sinus congestion, allergy, or dryness, wherein the nutritional composition is administered by intranasal spraying.



ABSTRACT

A sprayable product provides oxygen delivery to the body and benefits to physiological processes. In one embodiment the invention relates to an oxygenated saline composition comprising stabilized oxygen, sodium chloride (aqueous saline solution), and one or more plant minerals. The stabilized oxygen can include quad-atomic oxygen. The plant minerals can include humic and fulvic acids, homeopathic components, and other elemental minerals or salts thereof. Also provided is use of an oxygenated saline composition comprising stabilized oxygen, aqueous saline solution, and one or more plant minerals, for use in the case of nasal and/or sinus congestion, allergy, or dryness, wherein the nutritional composition is administered by intranasal spraying.

SPRAYABLE OXYGENATED SALINE COMPOSITION AND USE THEREOF

FIELD OF THE INVENTION

[0001] A sprayable product relates to oxygen delivery to the body and benefits to physiological processes. In particular, a sprayable oxygenated saline composition supplements oxygen and other helpful nutrients to the body in the most effective, economic, non-invasive manner.

BACKGROUND

[0002] When the body is in a depleted state from fighting off infection and allergen-created histamines, it is assisted by the delivery of supplemental oxygen. This in turn requires the body to work less to extract oxygen from the allergen-polluted atmosphere or fight to inhale through swollen and/or infected nasal tissues. By not having to work as hard to bring oxygen into the system, the greater residual energy can be dedicated to the body's detoxification and healing processes. The bottom line is that oxygen supplementation in a depleted physiological state may enable a human subject to feel better and recover more quickly.

[0003] The administration of oxygen via nasal structures has significant advantages over the intravenous, oral, or transdermal routes. For example, compared to an injection, nasal devices eliminate the pain and the fear associated with the needle. Delivery via the nose also has the following benefits: enhanced patient compliance; decreased needle injury occurrences; no requirement for trained personnel for administration; and decreased the total cost of the treatment; among other advantages described herein.

[0004] When compared to the oral route of delivery, nasal devices and delivery systems have other advantages: elimination of gastric and hepatic medication degradation; lower dosage requirements; and importantly, faster onset of action.

[0005] Remedies in the cold and allergy market fall into two general categories: over-the-counter (OTC) medications and saline sprays/flushes. OTC products can often create a negative "rebound" congestion caused by overuse. This can create a vicious cycle of overuse and dependence that feels like an addiction.

[0006] Rhinitis medicamentosa (RM) is a condition of rebound nasal congestion, brought on by extended use of topical decongestants (e.g., oxymetazoline, phenylephrine, xylometazoline, and naphazoline nasal sprays), that work by constricting blood vessels in the lining of the nose. In as little as 5 days of continued OTC use, onset of RM can begin. Alongside chronic

congestion, other symptoms can include regular nose bleeds, headaches, and even a loss of smell and taste. Some habituated or addicted patients also complain of feeling jittery, irritable and thirsty, especially as their medication dose wears off. In very severe cases, oral steroids or nasal surgery may be necessary.

[0007] Some saline spray products are spray versus mist and therefore use more product per treatment. The known saline-based products can use as much as 10 ml per treatment. Lesser amounts, i.e. volume is desired for spray treatments administered by the nasal route.

[0008] Therefore, if a way could be found to provide an oxygenated saline spray in an efficient manner, this would represent a contribution to the medical and nutraceutical arts. It would also be advantageous to provide an all-natural pH-balanced oxygenated saline spray or mist, optionally containing other beneficial nutrients or minerals, that could be administered as often as desired without any of the adverse effects as discussed.

[0009] In view of the above, there is a need and a desire for a stabilized oxygen saline nasal spray in a readily bioavailable formulation.

SUMMARY OF THE INVENTION

[0010] In one embodiment, the invention relates to an oxygenated saline composition comprising stabilized oxygen, sodium chloride (aqueous saline solution), and one or more plant minerals. The stabilized oxygen can include quad-atomic oxygen. The plant minerals can include humic and fulvic acids, and other elemental minerals and salts thereof.

[0011] In another embodiment, an oxygenated saline composition made by a process of: adding sodium chloride to distilled water; adding oxygen (in quad-atomic form) to provide the stabilized oxygen solution; adding plant or phyto-ionic minerals to the stabilized oxygen solution; and diluting with water to give the sprayable oxygenated saline composition, is provided.

[0012] Also provided is a method for treating, reducing or preventing nasal and/or sinus congestion, allergy, or dryness, comprising administering to an individual in need thereof an effective amount of an oxygenated saline composition comprising stabilized oxygen, aqueous saline solution, and one or more plant minerals, wherein the nutritional composition is administered by intranasal spraying.

BRIEF DESCRIPTION OF THE DRAWINGS

[0013] FIG. 1 depicts removal by hand of a lid from atop a spray bottle having a spraying apparatus in one embodiment of the present invention, in which a sprayable oxygenated saline containing composition is provided in a reservoir of the spray bottle.

[0014] FIG. 2 depicts insertion of a tip of the spraying apparatus of the spray bottle of FIG. 1 by hand into a nasal cavity of a human subject in an embodiment of the present invention.

[0015] FIG. 3 depicts an application of the sprayable oxygenated saline containing composition to the nasal mucosa and/or sinus passages of the nasal cavity by pump compression of the spraying apparatus of FIG. 1 by hand to produce a fine mist or cloud of droplets of/from the composition whereby the composition is efficiently delivered to the target tissues of the subject, i.e., in this instance the nasal cavity.

DETAILED DESCRIPTION

[0016] In one aspect, an aqueous composition containing stabilized oxygen solution, sodium chloride (aqueous saline solution), and one or more plant minerals is described. The stabilized oxygen can include quad-atomic oxygen. The plant minerals can include humic and fulvic acids, and other elemental minerals and salts thereof.

[0017] This oxygen molecular form makes it very stable and bio-available. Further, due to the intra-nasal delivery system, the oxygenated aqueous composition immediately raises the level of circulating blood oxygen to help increase energy levels and enhance detoxification. Its natural anti-bacterial properties enable the immune system. The intranasal delivery system makes it ideal for fighting cold/flu, allergy, and general nasal congestion and irritation symptoms.

[0018] In an embodiment, the aqueous composition contains from about 20-25% by weight stabilized oxygen solution, about 1-6% by weight plant minerals in aqueous solution, and the balance water (about 70-74%).

[0019] In a preferred embodiment, the aqueous composition contains from about 23.5% by weight stabilized oxygen solution, about 5.8% by weight plant minerals in aqueous solution, and the balance water (about 70.6%).

[0020] Various phyto-ionic or plant minerals are useful in the aqueous compositions. In one embodiment plant minerals comprise an aqueous solution containing humic and fulvic acids in a range up to about 57,300 ppm. In another embodiment, humic and fulvic acids can range from

about 25,000 to about 75,000 ppm. In yet another embodiment, humic and fulvic acids can range from about 25,000 to about 57,300 ppm.

[0021] In a further embodiment plant minerals comprise an aqueous solution containing humic and fulvic acids, and further containing elemental minerals, metals, or salts thereof. The following is a list of representative elemental minerals, one or more of which may be used in the aqueous plant minerals, as shown in Table 1.

TABLE 1

Element	Analytical measurement	Per Unit	Test Method
Aluminum	4,626	ppm	ICP-OES USP <730>
Antimony	<0.5	ppm	ICP-OES USP <730>
Barium	<0.5	ppm	ICP-OES USP <730>
Beryllium	14.80	ppm	ICP-OES USP <730>
Bismuth	5.354	ppm	ICP-OES USP <730>
Boron	60.13	ppm	ICP-OES USP <730>
Calcium	550.8	ppm	ICP-OES USP <730>
Carbon	180	ppm	LECO
Cerium	50.614	ppm	ICP-MS USP <730>
Cesium	0.005	ppm	ICP-MS USP <730>
Chloride	0.868	mg/ml	USP <221> Titration
Chromium	6.262	ppm	ICP-OES USP <730>
Cobalt	19.83	ppm	ICP-OES USP <730>
Copper	2.633	ppm	ICP-OES USP <730>
Dysprosium	4.687	ppm	ICP-MS USP <730>
Erbium	2.525	ppm	ICP-MS USP <730>
Europium	1.322	ppm	ICP-MS USP <730>
Fluoride	0.016	mg/ml	AOAC 939.11
Gadolinium	6.615	ppm	ICP-MS USP <730>
Gallium	<0.001	ppm	ICP-MS USP <730>
Germanium	0.088	ppm	ICP-MS USP <730>
Gold	<0.5	ppm	ICP-MS USP <730>
Hafnium	0.063	ppm	ICP-MS USP <730>
Holmium	0.908	ppm	ICP-MS USP <730>
Indium	<0.001	ppm	ICP-MS USP <730>
Iodine	0.094	mg/ml	ICP-MS USP <730>
Iridium	0.001	ppm	ICP-MS USP <730>

Iron	20,580	ppm	ICP-OES USP <730>
Lanthanum	28.19	ppm	ICP-OES USP <730>
Lithium	4.317	ppm	ICP-OES USP <730>
Lutetium	0.311	ppm	ICP-MS USP <730>
Magnesium	2,237	ppm	ICP-OES USP <730>
Manganese	119.1	ppm	ICP-OES USP <730>
Molybdenum	0.974	ppm	ICP-OES USP <730>
Neodymium	30.286	ppm	ICP-MS USP <730>
Nickel	26.95	ppm	ICP-OES USP <730>
Niobium	<0.5	ppm	ICP-OES USP <730>
Osmium	0.006	ppm	ICP-MS USP <730>
Palladium	0.167	ppm	ICP-MS USP <730>
Phosphorus	691.4	ppm	ICP-OES USP <730>
Platinum	<0.001	ppm	ICP-MS USP <730>
Potassium	8.200	ppm	ICP-OES USP <730>
Praseodymium	7.796	ppm	ICP-MS USP <730>
Rhenium	0.006	ppm	ICP-MS USP <730>
Rhodium	0.001	ppm	ICP-MS USP <730>
Rubidium	0.009	ppm	ICP-MS USP <730>
Ruthenium	<0.001	ppm	ICP-MS USP <730>
Samarium	6.404	ppm	ICP-MS USP <730>
Scandium	4.877	ppm	ICP-MS USP <730>
Selenium	<0.5	ppm	ICP-OES USP <730>
Silicon	77.51	ppm	ICP-OES USP <730>
Silver	<0.5	ppm	ICP-OES USP <730>
Sodium	7.165	ppm	ICP-OES USP <730>
Strontium	5.524	ppm	ICP-OES USP <730>
Sulfur	29,925	ppm	ICP-OES USP <730>
Tantalum	0.012	ppm	ICP-MS USP <730>
Tellurium	<0.5	ppm	ICP-OES USP <730>
Terbium	0.538	ppm	ICP-MS USP <730>
Thallium	<0.5	ppm	ICP-OES USP <730>
Thorium	1.963	ppm	ICP-OES USP <730>
Thulium	0.322	ppm	ICP-MS USP <730>
Tin	<0.5	ppm	ICP-OES USP <730>
Titanium	0.732	ppm	ICP-OES USP <730>

Tungsten	4.819	ppm	ICP-OES USP <730>
Vanadium	<0.5	ppm	ICP-OES USP <730>
Ytterbium	2.057	ppm	ICP-MS USP <730>
Yttrium	25.61	ppm	ICP-OES USP <730>
Zinc	94.15	ppm	ICP-OES USP <730>
Zirconium	2.405	ppm	ICP-OES USP <730>
Mercury	0.001	ppm	ICP-MS USP <730>
Lead	0.396	ppm	ICP-MS USP <730>
Arsenic	3.028	ppm	ICP-MS USP <730>
Cadmium	0.670	ppm	ICP-MS USP <730>
Nitrogen	<0.2	%	AOAC 990.03
Total Dissolved Solids	115,729	ppm	AOAC 920.193

pH : 1.40

[0022] In Table 1, the total dissolved solids comprise the elemental minerals and humic and fulvic acids measured at 57,300 ppm.

[0023] A sprayable oxygenated saline composition has been discovered. In one embodiment, the composition contains stabilized oxygen solution containing sodium chloride, and one or more plant minerals.

[0024] One useful stabilized oxygen solution is Maximum Performance (Aquagen International, Lindon, Utah), of composition: purified water (99.8% by weight), molecules of dissolved oxygen (0.1877%), and sodium chloride (0.00757%); pH 7.5 (av.). The stabilized oxygen solution's active ingredient is a quad-atomic oxygen molecule in a saline suspension. Without being bound by theory, it is believed that the oxygen contained in the stabilized oxygen solution is from a relatively newly identified oxygen molecule known as O₄, i.e., quad-atomic oxygen or "stabilized oxygen." Cacace, F., et al., *Angew. Chem. Intl. Ed.* (2001) 40: 4062-4065. The quad-atomic oxygen molecule is safe, stable, and readily absorbed by the body.

[0025] In an embodiment, the stabilized oxygen is suspended in a saline solution that is further enriched by a blend of pure plant minerals that enhance the overall health benefits of the product. Useful plant minerals can include natural phyto-ionic materials of other phytonutrients, such as, for example, humic and fulvic acids. Other useful minerals include elemental metals, or salts thereof. Other plant minerals can include, but are not limited to, certain homeopathic components that are useful for treatment of allergy/hay fever, sore throat, earache, and the like.

[0026] Representative homeopathic components can include, but are not limited to, the following. Homeopathic dilutions are intended to be exemplary and non-limiting.

[0027] For allergy/hay fever, homeopathic components useful for exemplary symptoms in parentheses: Allium Cepa, 6X HPUS (hay fever, watery eyes); Natrum Muriaticum, 6X HPUS (sneezing, itchy eyes); Histaminum Hydrochloricum, 12X HPUS (sinus pain); Luffa Operculata, 12X HPUS (sneezing, runny nose); and Nux Vomica, 6X HPUS (itchy nose & throat).

[0028] For sore throat, homeopathic components useful for relief of exemplary symptoms in parentheses: Arnica Montana, 3C HPUS (relieves hoarseness due to overexertion of the vocal cords); Arum triphyllum, 3C HPUS (relieves vocal cord fatigue in speakers and singers); Belladonna, 3C HPUS, containing less than 6-10 mg alkaloids per dose (relieves red and sore throat); Bromium, 3C HPUS (relieves swollen and painful tonsils); Bryonia alba, 3C HPUS (relieves sore throat with intense thirst); Mercurius solubilis, 3C HPUS (relieves sore throat with intense salivation); Pulsatilla, 3C HPUS (relieves raw sore throat); Phytolacca decandra, 3C HPUS (relieves sore throat with pain spreading to the ears); and Spongia tosta, 3C HPUS (relieves hoarseness with dry throat).

[0029] For earache, homeopathic components useful for exemplary symptoms in parentheses: Pulsatilla, 30C HPUS (ear pain, worse at night); Chamomilla, 30C HPUS (restlessness or irritability); Sulphur, 30C HPUS (ear pain with burning sensation); Calcarea Carbonica, 30C HPUS (throbbing, pulsing pain in ears); Belladonna, 30C HPUS (3 X 10-60% alkaloids) – (fever and inflammation); and Lycopodium, 30C HPUS (pain and congestion in ears).

[0030] An exemplary sprayable oxygenated saline composition is Oxy Bump Saline Oxygen Nasal Spray, available from Oxy Bump Corporation, Miami, Florida; pH 7-7.4.

[0031] The pain of the consumer or patient is the need to find physical relief balanced against the risks of OTC medications or the mess of saline nasal flushing. The sprayable oxygenated saline composition, enriched with plant-based phyto-ionic minerals, provides the solution. In a preferred embodiment, the composition promotes clean, fast relief that can be sprayed into the nose to contact the nasal and sinus tissues.

[0032] When taken or applied by spraying, the sprayable oxygenated saline composition helps to clean the nasal and sinus passages of infectious and irritating materials (both microscopic and larger contaminants). These allergens can remain in the nasal cavities for

extended periods of time unless cleared. The spraying of the oxygenated saline composition helps to dislodge them and also can reduce the inflammation caused by these allergens as well.

[0033] While most medicated products cause the temporary drying of nasal membranes, the sprayable oxygenated saline composition not only moisturizes, but can help to heal irritated nasal passageways. By facilitating the delivery of an essential life element (namely, oxygen), which enhances the detoxifying release of carbon dioxide, it empowers all of the body's metabolic functions to leave more residual energy to fight off infection. The sprayable oxygenated saline composition accelerates the mending of delicate sinus tissues to create a lasting benefit rather than simple short-term dehydration of these passages.\

[0034] By enhancing the delivery of oxygen to the body, cellular respiration and all other physiological processes are stimulated. It is believed that when the oxygenated saline composition is inhaled, the highly bioavailable stabilized oxygen (quad-atomic oxygen) is quickly absorbed from the respiratory system and delivered to the circulatory system. Next, the amount of circulating blood oxygen immediately rises to be delivered on a cellular level.

[0035] The use of the sprayable oxygenated saline composition (e.g., Oxy Bump Saline Oxygen Nasal Spray) provides greater relief and healing properties than saline alone and costs less per treatment. Moreover, it is non-medicated, non-addictive, pH balanced and 100% all-natural, and most importantly, has none of the harmful effects of the OTCs.

[0036] One important advantage of the sprayable oxygenated saline composition is delivering highly bio-available, pH neutral oxygen solution via the fastest biological delivery system with little degradation of the active ingredient, or discomfort to the consumer, as compared to other methodology.

[0037] Now turning to the figures, a bottle lid (20) is removed by hand from a spray bottle (10) having an appropriate spraying apparatus which contains a sprayable oxygenated saline containing composition (30) provided in a reservoir of the spray bottle, as shown in Figure 1. Figure 2 depicts the insertion of a tip of the spraying apparatus of the spray bottle (10) by hand into a nasal cavity of the nose (120) of a human subject (100) in an embodiment of the present invention. Figure 3 depicts an application of the sprayable oxygenated saline containing composition to the nasal mucosa and/or sinus passages of the nasal cavity (130) by pump compression of the spraying apparatus of the spray bottle (10) by hand directly into the nose (120) to produce a fine mist or cloud of droplets (30a) of/from the composition whereby the

composition is efficiently delivered to the target tissues of the subject (130), i.e., in this instance the nasal cavity.

[0038] Delivery system

[0039] Intranasal administration is preferred. Useful delivery systems include, but are not limited to, oral or nasal sprays or inhalers, and the like.

[0040] Solutions or suspensions are applied directly to the nasal cavity by conventional means, for example with a dropper, pipette or spray. The compositions may be provided in single or multi-dose form. In compositions intended for administration to the respiratory tract, including intranasal compositions, the compound will generally have a small particle size for example of the order of 5 microns or less. Such a particle size may be obtained by means known in the art, for example by micronization, or nebulizer technology.

[0041] Also contemplated are moistened towelettes, wipes, wet naps, swabs, and the like, wherein the oxygenated saline composition may be applied by hand. In such a system, the oxygenated saline composition can be provided within a woven or nonwoven cloth or fiber matrix, for example. Administration can be achieved by applying gentle pressure and/or a generally circular wiping motion in order to apply the composition to the skin or other target tissue of a human subject.

[0042] The components of the invention, together with a conventional adjuvant, carrier, or diluent, may thus be placed into the form of pharmaceutical compositions and unit dosages thereof. Such forms include solids, and in particular tablets, filled capsules, powder and pellet forms, and liquids, in particular aqueous or non-aqueous solutions, suspensions, emulsions, elixirs, and capsules filled with the same, all for oral use, suppositories for rectal administration, and sterile injectable solutions for parenteral use. Such pharmaceutical compositions and unit dosage forms thereof many comprise conventional ingredients in conventional proportions, with or without additional active compounds or principles, and such unit dosage forms may contain any suitable effective amount of the active ingredient commensurate with the intended daily dosage range to be employed.

[0043] The components of the present invention can be administered in a wide variety of oral and parenteral dosage forms. It will be obvious to those skilled in the art that the following dosage forms may comprise, as the active component, either a chemical compound of the invention or a pharmaceutically acceptable salt of a chemical compound of the invention.

[0044] Liquid preparations include solutions, suspensions, and emulsions, for example, water or water-propylene glycol solutions. For example, parenteral injection liquid preparations can be formulated as solutions in aqueous polyethylene glycol solution. The chemical compound according to the present invention may thus be formulated for parenteral administration (e.g. by injection, for example bolus injection or continuous infusion) and may be presented in unit dose for in ampoules, pre-filled syringes, small volume infusion or in multi-dose containers with an added preservative. The compositions may take such forms as suspensions, solutions, or emulsions in oily or aqueous vehicles, and may contain formulation agents such as suspending, stabilising and/or dispersing agents. Alternatively, the active ingredient may be in powder form, obtained by aseptic isolation of sterile solid or by lyophilization from solution, for constitution with a suitable vehicle, e.g. sterile, pyrogen-free water, before use.

[0045] Aqueous solutions suitable for oral use can be prepared by dissolving the active component in water and adding suitable colorants, flavors, stabilizing and thickening agents, as desired. Aqueous suspensions suitable for oral use can be made by dispersing the finely divided active component in water with viscous material, such as natural or synthetic gums, resins, methylcellulose, sodium carboxymethylcellulose, or other well known suspending agents.

[0046] Compositions suitable for topical administration in the mouth includes lozenges comprising the active agent in a flavored base, usually sucrose and acacia or tragacanth; pastilles comprising the active ingredient in an inert base such as gelatin and glycerine or sucrose and acacia; and mouthwashes comprising the active ingredient in suitable liquid carrier.

[0047] The pharmaceutical preparations are preferably in unit dosage forms. In such form, the preparation is subdivided into unit doses containing appropriate quantities of the active component. The unit dosage form can be a packaged preparation, the package containing discrete quantities of preparation, such as packaged tablets, capsules, and powders in vials or ampoules. Also, the unit dosage form can be a capsule, tablet, cachet, or lozenges itself, or it can be the appropriate number of any of these in packaged form.

[0048] Tablets, capsules and lozenges for oral administration and liquids for oral use are preferred compositions. Solutions or suspensions for application to the nasal cavity or to the respiratory tract are preferred compositions. Transdermal patches for topical administration to the epidermis are preferred.

[0049] Further details on techniques for formulation and administration may be found in the latest edition of Remington's Pharmaceutical Sciences (Mack Publishing Co., Easton, PA).

[0050] Liquid nutritional compositions for oral administration in connection with a method for preventing and/or treating inflammation, colds and/or flu can be prepared in water or other aqueous vehicles. In addition to the above enumerated ingredients or compounds, liquid nutritional compositions can include suspending agents such as, for example, methylcellulose, alginates, tragacanth, pectin, kelgin, carrageenan, acacia, polyvinylpyrrolidone, polyvinyl alcohol, and the like. The liquid nutritional compositions can be in the form of a solution, emulsion, syrup, gel, or elixir including or containing, together with the above enumerated ingredients or compounds, wetting agents, sweeteners, and coloring and flavoring agents. Various liquid and powder nutritional compositions can be prepared by conventional methods. Various ready-to-drink formulations (RTD's) are contemplated.

[0051] The nutraceutical compositions of the present invention may be administered in combination with a nutraceutically acceptable carrier. The active ingredients in such formulations may comprise from 1% by weight to 99% by weight, or alternatively, 0.1% by weight to 99.9% by weight. "Nutraceutically acceptable carrier" means any carrier, diluent or excipient that is compatible with the other ingredients of the formulation and not deleterious to the user. In accordance with one embodiment, suitable nutraceutically acceptable carriers can include ethanol, aqueous ethanol mixtures, water, fruit and/or vegetable juices, and combinations thereof.

[0052] The pharmaceutical compositions of the present invention may be administered in combination with a pharmaceutically acceptable carrier. The active ingredients in such formulations may comprise from 1% by weight to 99% by weight, or alternatively, 0.1% by weight to 99.9% by weight. "Pharmaceutically acceptable carrier" means any carrier, diluent or excipient that is compatible with the other ingredients of the formulation and not deleterious to the user.

[0053] Routes of Administration

[0054] The compositions may be administered by any suitable route, including but not limited to oral, sublingual, buccal, ocular, pulmonary, rectal, and parenteral administration, or as an oral or nasal spray (e.g. inhalation of nebulized vapors, droplets, or solid particles). Parenteral administration includes, for example, intravenous, intramuscular, intraarterial, intraperitoneal,

intranasal, intravaginal, intravesical (e.g., to the bladder), intradermal, transdermal, topical, or subcutaneous administration. Also contemplated within the scope of the invention is the instillation of a pharmaceutical composition in the body of the patient in a controlled formulation, with systemic or local release of the drug to occur at a later time. For example, the drug may be localized in a depot for controlled release to the circulation, or for release to a local site.

[0055] Pharmaceutical compositions of the invention may be those suitable for oral, rectal, bronchial, nasal, pulmonal, topical (including buccal and sub-lingual), transdermal, vaginal or parenteral (including cutaneous, subcutaneous, intramuscular, intraperitoneal, intravenous, intraarterial, intracerebral, intraocular injection or infusion) administration, or those in a form suitable for administration by inhalation or insufflations, including powders and liquid aerosol administration, or by sustained release systems. Suitable examples of sustained release systems include semipermeable matrices of solid hydrophobic polymers containing the compound of the invention, which matrices may be in form of shaped articles, e.g. films or microcapsules.

[0056] The unique selling property of the sprayable oxygenated saline composition (e.g., Oxy Bump Saline Oxygen Nasal Spray) is the fast delivery of stabilized oxygen via a small, economic, and easy-to-use nasal spray. Due to the intra-nasal delivery system, the sprayable oxygenated saline composition immediately raises the level of circulating blood oxygen to help increase energy levels and enhance detoxification. Also, the sprayable oxygenated saline composition's natural anti-bacterial/antiviral properties can stimulate the immune system. The nasal application makes it ideal for fighting cold/flu, allergy, and general nasal congestion and irritation symptoms. In one embodiment, a small ergonomic bottle can make it easy-to-use and transport so that it can be used anywhere without messy application.

[0057] Without limitation, the sprayable oxygenated saline composition can be used to treat, prevent, or help with: healing nasal passages; reducing inflammation, fighting infection, sinus congestion, dry or runny nose, stuffy or swollen nose, cleansing & moisturizing, dry climate relief, headaches, migraines, nasal irritation from foreign matter like dust or pollen, nasal dryness from chronic oxygen gas use, nose bleeds, reduce muscle cramps, poor sleep or insomnia, jetlag, altitude sickness, hangover symptoms, and the like. The sprayable oxygenated saline composition can also be used to promote or help with: breathing easier, providing more energy

without jitters, metabolic enhancement, immune boosting, increase mental acuity and brain function, detoxification, enhanced carbon dioxide and toxin release, restoring pH balance, enhance physical performance and endurance, speed recovery from exertion, and the like.

[0058] Consequently the use of intranasal delivery in the invention makes a vital difference in the product's effectiveness. Intranasal use of the oxygenated saline composition provides rapid delivery of the active ingredients to the bloodstream and rapid onset of beneficial effects to the user. The ease of use and speed of onset through intranasal delivery provides value to the user and an unexpected synergistic effect. Suitable methods of administration include, but are not limited to, sublingual, buccal, oral, intranasal, inhalational, and the like.

[0059] Other types of products containing the oxygenated saline composition and/or uses can include, but are not limited to, throat spray, wound spray, face/skin spray or mist; topical cream ointment, cleansing rinse, eye drops, ear drops, oral rinse, sports nutrition beverages such as waters or ready-to-drink (RTDs), and the like.

[0060] In accordance with one embodiment, a method for treatment of nasal congestion is provided, comprising administering to an individual in need thereof a nutraceutically effective amount of an oxygenated saline composition.

[0061] In accordance with another embodiment, a method for treatment of allergy or allergic inflammation, or other allergic symptoms is provided, comprising administering to an individual in need thereof a nutraceutically effective amount of an oxygenated saline composition.

[0062] In accordance with one embodiment, an oxygenated saline composition can be made by a process as follows: adding sodium chloride to distilled water; adding oxygen (in quad-atomic form) to provide the stabilized oxygen solution; adding plant or phyto-ionic minerals to the stabilized oxygen solution; and diluting with water to give the sprayable oxygenated saline composition.

[0063] In accordance with other embodiments, a method for increasing muscle performance or endurance, or increasing energy and stamina during sports exertion or other strenuous physical activities is provided, comprising administering to an individual in need thereof a nutraceutically effective amount of an oxygenated saline composition.

[0064] The aqueous composition and methods described above may be further understood in connection with the following Examples. In addition, the following non-limiting examples are provided to illustrate the invention.

EXAMPLE 1A

[0065] Sprayable Oxygenated Saline Formulation

[0066] A representative solution of Oxygenated Saline Formulation may include or consist of the following ingredients of Table 2.

TABLE 2

Ingredient	Weight %
Stabilized Oxygen saline solution (AQUAGEN Maximum Performance)	23.5
Plant minerals, aq. soln. containing humic/fulvic acids*	5.8
Water	70.6

* Optionally including one or more components of Table 1, as discussed above.

pH 7.0-7.4.

EXAMPLE 1B

[0067] Process for Preparation

[0068] In accordance with one embodiment, food grade sodium chloride is added to distilled water and oxygen is added in to form the stabilized oxygen solution. Plant or phyto-ionic minerals are added as above. The final solution is diluted to the specified volume as in Table 2 for use as a nasal spray formulation.

EXAMPLE 2

[0069] Method for treatment of nasal congestion or allergy

[0070] In accordance with an embodiment, it is expected that an individual human subject using the oxygenated saline composition of Example 1B by using a dosage of 1-3 sprays into one or both nasal passages, at a dosage per spray of 0.3 mm osculum, 0.1 ml/T, will attain a marked, measurable relief from congestion or stuffiness, within a period of about 10 seconds to about 30 minutes. In a variation, it is expected that an individual will attain a marked, measurable relief from inflammation or other symptoms produced by allergy, within a period of about 10 seconds to about 30 minutes.

[0071] While in the foregoing specification this invention has been described in relation to certain embodiments thereof, and many details have been put forth for the purpose of illustration,

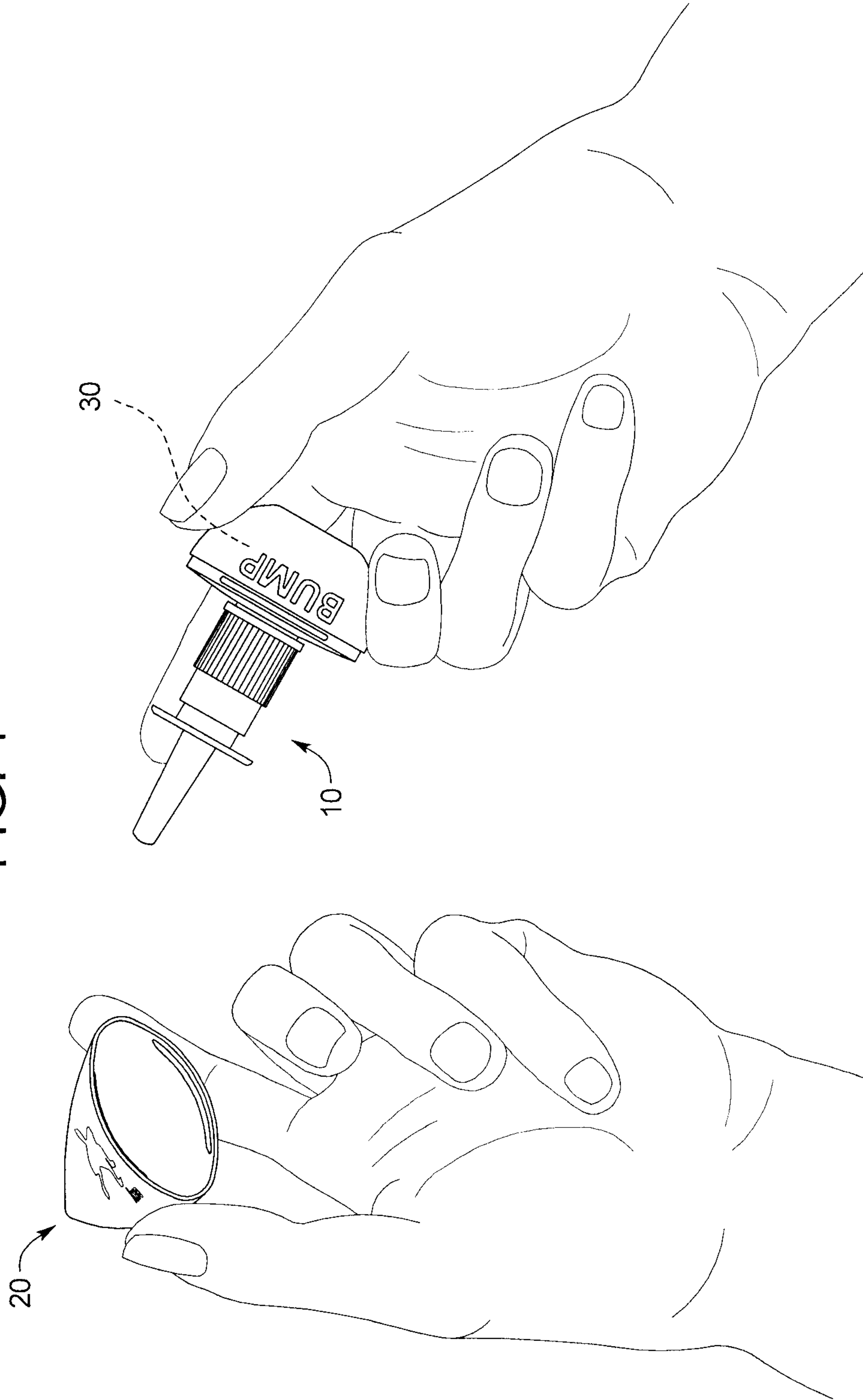
it will be apparent to those skilled in the art that the invention is susceptible to additional embodiments and that certain of the details described herein can be varied considerably without departing from the basic principles of the invention.

[0072] All references cited herein are incorporated by reference in their entirety. The present invention may be embodied in other specific forms without departing from the spirit or essential attributes thereof and, accordingly, reference should be made to the appended claims, rather than to the foregoing specification, as indicating the scope of the invention.

THE EMBODIMENTS OF THE INVENTION IN WHICH AN EXCLUSIVE PROPERTY OR PRIVILEGE IS CLAIMED ARE DEFINED AS FOLLOWS:

1. An oxygenated saline composition comprising stabilized oxygen, aqueous saline solution, and one or more plant minerals.
2. The composition wherein the stabilized oxygen includes quad-atomic oxygen.
3. The composition wherein the one or more plant minerals include humic and fulvic acids.

FIG. 1



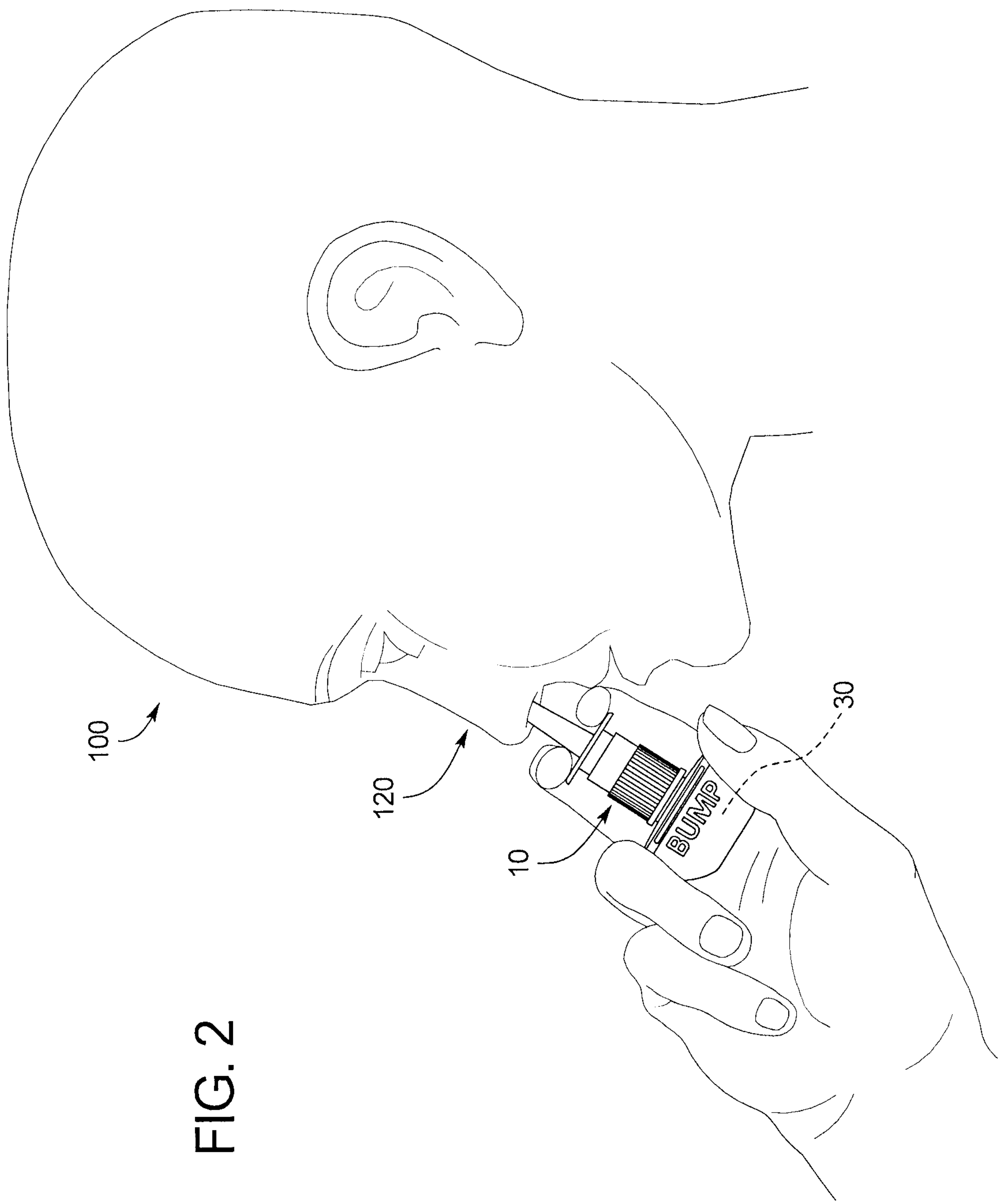


FIG. 2

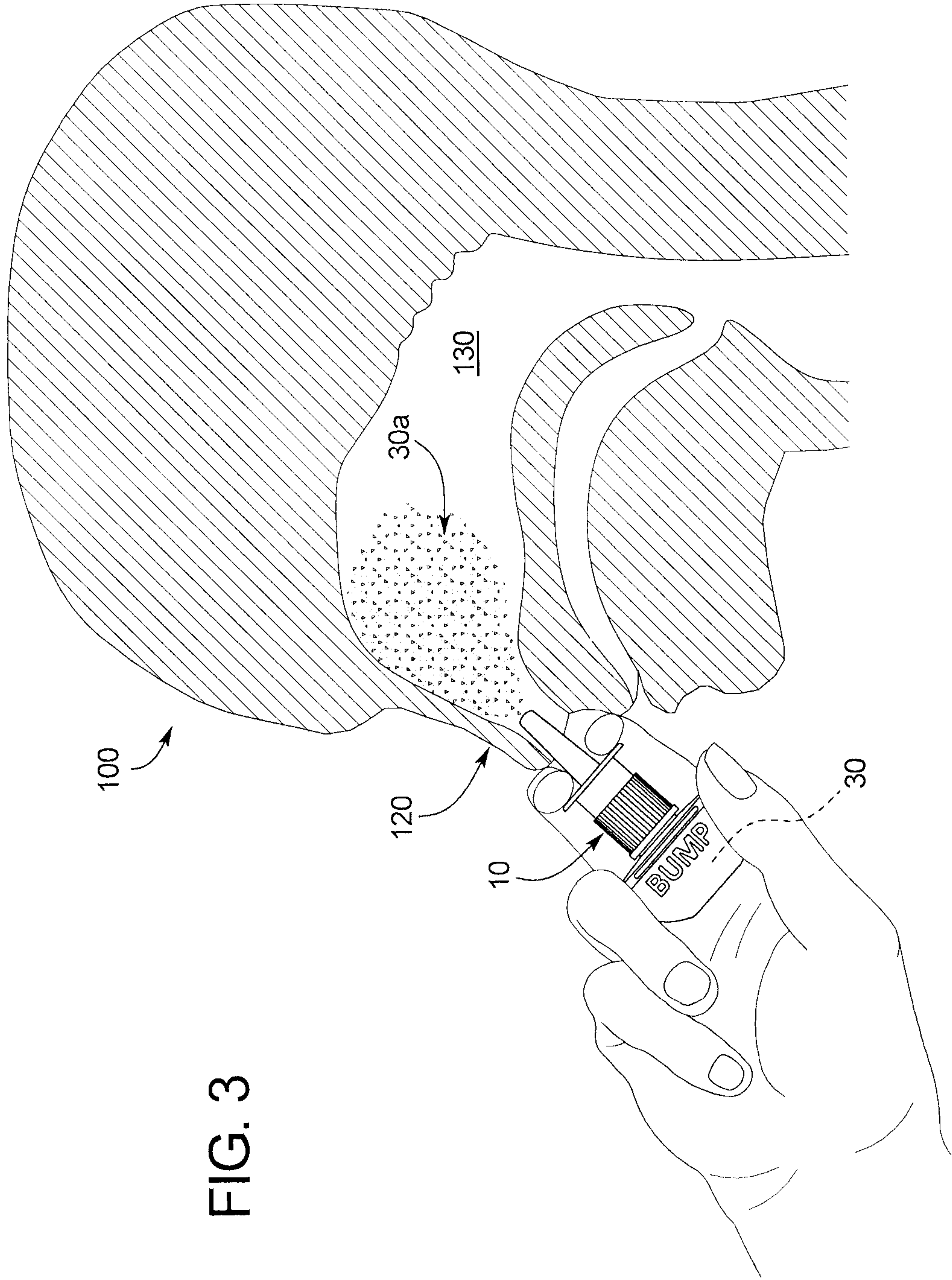


FIG. 3