US009387168B2

(12) **United States Patent**
Barreca et al.

(10) **Patent No.: US 9,387,168 B2**
(45) **Date of Patent: *Jul. 12, 2016**

(54) **CHEWING GUM WITH TOMATIDINE**

(71) Applicants: **Jack Barreca**, Highlands Ranch, CO (US); **Joseph E. Kovarik**, Englewood, CO (US)

(72) Inventors: **Jack Barreca**, Highlands Ranch, CO (US); **Joseph E. Kovarik**, Englewood, CO (US)

(*) Notice: Subject to any disclaimer, the term of this patent is extended or adjusted under 35 U.S.C. 154(b) by 0 days.

This patent is subject to a terminal disclaimer.

(21) Appl. No.: **14/283,459**

(22) Filed: **May 21, 2014**

(65) **Prior Publication Data**

US 2014/0294915 A1 Oct. 2, 2014

Related U.S. Application Data

(63) Continuation-in-part of application No. 14/220,224, filed on Mar. 20, 2014, which is a continuation-in-part of application No. 12/052,054, filed on Mar. 20, 2008, now Pat. No. 8,679,522, which is a continuation of application No. 11/084,707, filed on Mar. 17, 2005, now Pat. No. 7,351,425, which is a continuation of application No. 10/646,503, filed on Aug. 21, 2003, now Pat. No. 6,869,614, which is a continuation of application No. 10/316,700, filed on Dec. 10, 2002, now Pat. No. 6,652,839, which is a continuation of application No. 09/664,630, filed on Sep. 19, 2000, now Pat. No. 6,491,540.

(60) Provisional application No. 60/154,972, filed on Sep. 20, 1999.

(51) **Int. Cl.**

A61Q 11/00	(2006.01)
A61K 9/68	(2006.01)
A23G 4/12	(2006.01)
A23G 3/36	(2006.01)
A23G 3/48	(2006.01)
A23G 3/54	(2006.01)
A23G 4/06	(2006.01)
A23G 4/20	(2006.01)
A61K 36/258	(2006.01)
A61K 36/82	(2006.01)

(52) **U.S. Cl.**

CPC ***A61K 9/0058*** (2013.01); ***A23G 3/362*** (2013.01); ***A23G 3/368*** (2013.01); ***A23G 3/48*** (2013.01); ***A23G 3/54*** (2013.01); ***A23G 3/545*** (2013.01); ***A23G 4/064*** (2013.01); ***A23G 4/068*** (2013.01); ***A23G 4/126*** (2013.01); ***A23G 4/20*** (2013.01); ***A23G 4/205*** (2013.01); ***A61K 36/258*** (2013.01); ***A61K 36/82*** (2013.01); *A23V 2002/00* (2013.01); *A61Q 11/00* (2013.01); *Y10S 514/909* (2013.01)

(58) **Field of Classification Search**

None

See application file for complete search history.

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Primary Examiner — Susan Tran

(74) *Attorney, Agent, or Firm* — Sheridan Ross P.C.

(57) **ABSTRACT**

A chewing gum with a liquid-fill composition and a surrounding gum region, with one or both containing active ingredients, such as herbal, medicinal and/or mineral elements or combinations thereof, present in an amount of at least about 0.05 mg.

5 Claims, 2 Drawing Sheets

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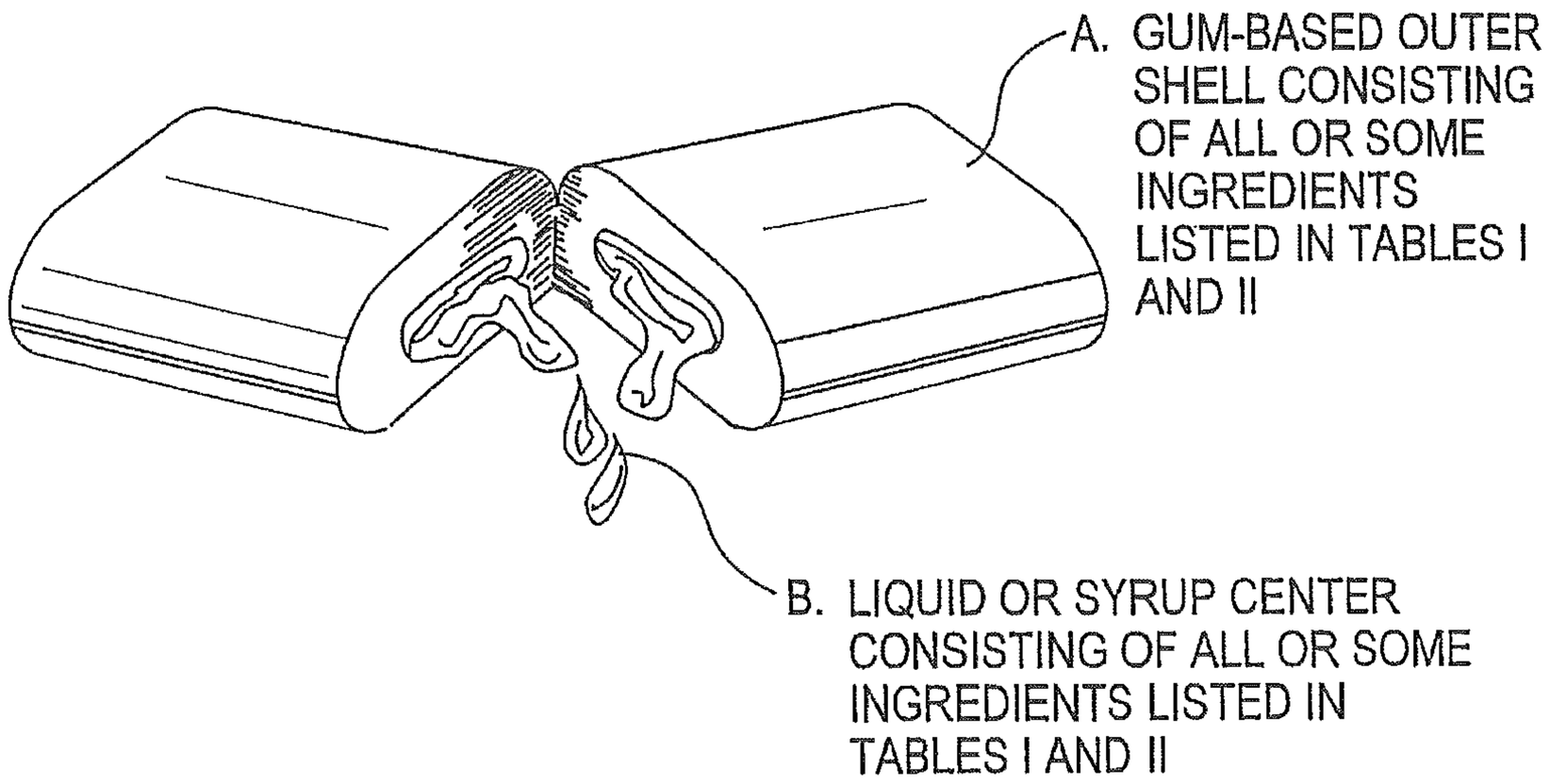

A. GUM-BASED OUTER SHELL CONSISTING OF ALL OR SOME INGREDIENTS LISTED IN TABLES I AND II
B. LIQUID OR SYRUP CENTER CONSISTING OF ALL OR SOME INGREDIENTS LISTED IN TABLES I AND II

FIG. 1

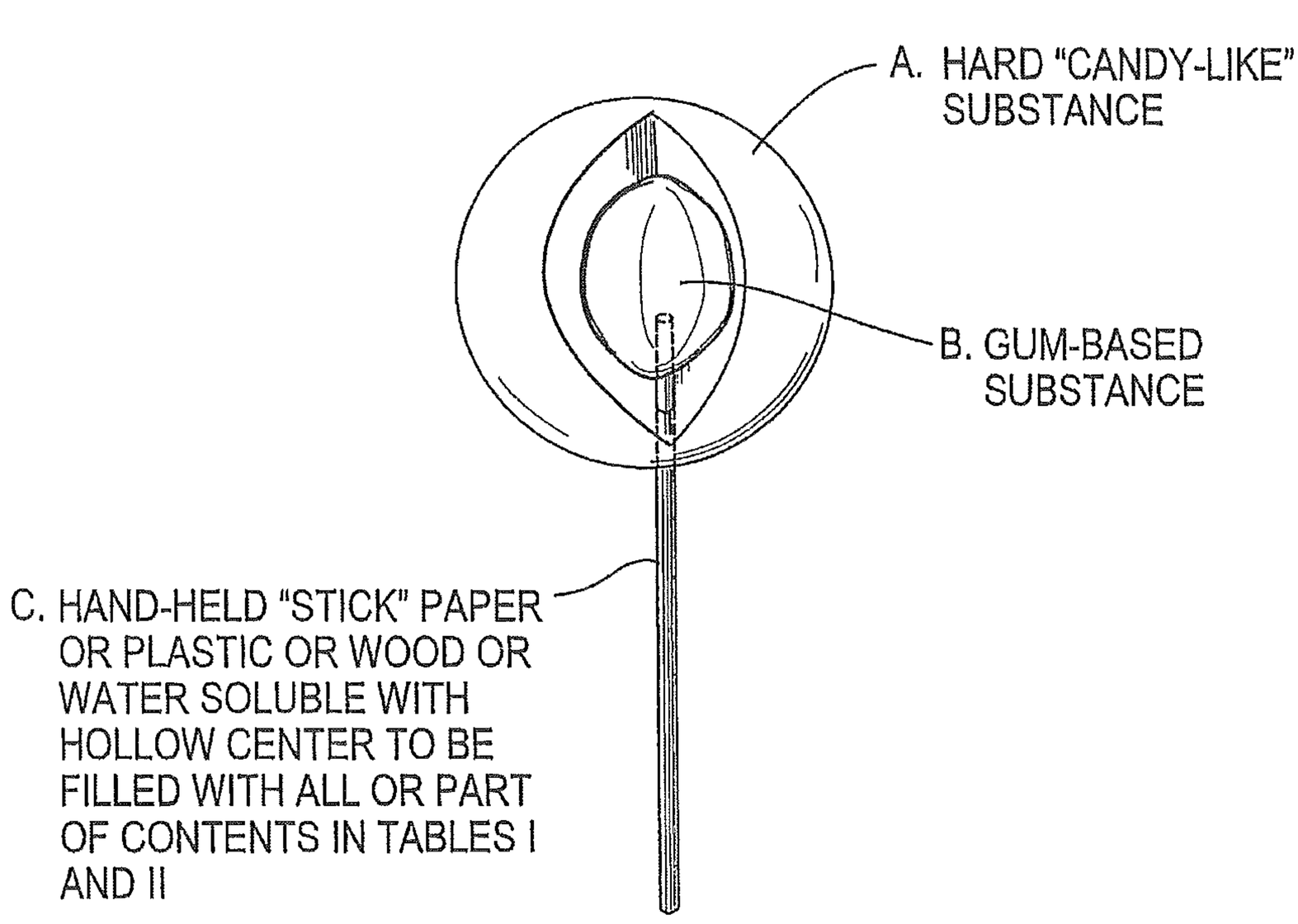

A. HARD "CANDY-LIKE" SUBSTANCE
B. GUM-BASED SUBSTANCE
C. HAND-HELD "STICK" PAPER OR PLASTIC OR WOOD OR WATER SOLUBLE WITH HOLLOW CENTER TO BE FILLED WITH ALL OR PART OF CONTENTS IN TABLES I AND II

FIG. 2

CHEWING GUM WITH TOMATIDINE

CROSS REFERENCE TO RELATED APPLICATIONS

This is a continuation-in-part application of pending prior application Ser. No. 14/220,224 filed on Mar. 20, 2014, which is a continuation-in-part of application Ser. No. 12/052,054 filed on Mar. 20, 2008 (now U.S. Pat. No. 8,679,522), which is a continuation of application Ser. No. 11/084,707 filed on Mar. 17, 2005 (now U.S. Pat. No. 7,351,425), which is a continuation of prior application Ser. No. 10/646,503 filed on Aug. 21, 2003 (now U.S. Pat. No. 6,869,614), which is a continuation of application Ser. No. 10/316,700 filed on Dec. 10, 2002 (now U.S. Pat. No. 6,652,839), which is a continuation of application Ser. No. 09/664,630 filed on Sep. 19, 2000 (now U.S. Pat. No. 6,491,540) and claims priority from U.S. Provisional Patent Application No. 60/154,972 filed on Sep. 20, 1999. The entire disclosure of the prior applications are considered to be part of the disclosure of the accompanying application and are hereby incorporated by reference.

FIELD OF THE INVENTION

The present invention is directed to functional gums, suckers (e.g., lollipops) and lozenges, and more particularly, to a gum and/or sucker and/or lozenge that has at least an exterior and an interior component, having distinct metabolic and functional characteristics that correspond with the ingredients contained therein.

BACKGROUND OF THE INVENTION

Throughout the ages, human beings have attempted to attain and maintain particular body morphologies, and in particular, have attempted to control their weight so as to conform with then-fashionable mores. During the recent past, a preference for less massive morphologies has been in vogue and a populous genetically ill-equipped to conform with such weight characteristics is bombarded with images of svelte figures in both male and female forms.

The desire of individuals to lose weight and specifically, to lose fatty tissue, has become nearly an obsession in the United States and many other countries. Any simple and safe method toward achieving a slim figure is in great demand. Methods for losing weight include hundreds of advised diets, machines and methods for exercise, various psychiatric techniques involving alteration in mental attitudes, and a variety of surgical techniques. Liposuction has created an entirely new surgical cosmetic industry, but carries a small but significant risk and often leaves the patient with an unsightly cosmetic result due to the inflammatory reaction surrounding where the fatty tissue has been removed by a technique which produces a severe tissue reaction.

Obesity is a serious public health hazard, second in importance only to tobacco. Approximately ⅓ of Americans are seriously overweight according to life insurance data. In approximately 12 million Americans, obesity significantly contributes toward the cause and complications of serious disease. Such conditions include heart and lung disease, many types of cancer, diabetes, high blood pressure, and peripheral arterial disease. This is in addition to how obesity becomes a cosmetic problem. Being overly fat limits both length of life and its quality.

A multi-billion dollar industry has developed in an effort to control weight. The many varied and expensive techniques employed speak to the relative ineffectiveness of the many techniques that have been tried to get rid of excess fat.

Obesity has recently been recognized as a public health hazard of epidemic proportions by the World Health Organization. One of three Americans between the ages of 20-74 are obese (Body Mass Index>30 Kg/m^2 body surface). This amounts to 58 million people. The number of obese adults has increased dramatically. In 1980 25% of US adults were obese. The equivalent figure was 33% in 1990. In Europe the equivalent figure is about 40%.

Obesity significantly contributes to the dangers of other diseases in approximately half of those who exceed the threshold description of obesity. For example, 19% of the cost of management of heart disease can be ascribed to obesity. Obesity is also recognized as a co-morbid factor for obese patients suffering from degenerative arthritis, peripheral vascular disease, and many forms of pulmonary disease such as emphysema. The expenditure for products, goods, and services in the management of obesity is estimated to be $33 billion per year. This is 3%-4% of total health care expenditure per year and exceeds that expended for AIDS and cancer.

Obesity is such a prevalent, important and distressing problem that its many methods for suggested management are too well known to deserve more than listing. They include diets that exclude fats and high caloric elements, food supplements, appetite suppressants, exercise machines and regimes, biofeedback and other psychotherapeutic techniques, and a variety of operative techniques. Operations include a number of methods for decreasing the capacity the stomach, gastric by-pass operations, methods to shorten the small intestinal absorption surface, excision of the unwanted fat (lipectomy) and techniques of liposuction. Liposuction is performed approximately 51,000 times each year in the US. The maximum amount of fat that can safely be removed is approximately 2 Kg. Being an operative technique for removing fat, in this case by suction, it inevitably excites an inflammatory response at the operative site, which results not only in post operative inflammation but in subsequent uneven and unsightly scarring beneath the skin where the fat has been removed.

Incorporated by reference in its entirety are the following U.S. patents directed generally to chewing gum compositions, methods and apparatus for making chewing gum, and in particular, methods for enabling one of skill in the art to produce soft-centered chewing gums as contemplated by the present invention. The novelty of the present invention, however, should be understood as being distinguished from such prior art references and such incorporation by reference is only provided for enabling support of the numerous ways in which the particular novel product can be manufactured. The U.S. patents incorporated by reference are as follows: U.S. Pat. Nos. 5,922,347; 5,916,606; 5,912,030; 5,900,230; 5,885,630; 5,866,179; 5,858,423; 5,846,557; 5,834,002; 5,827,526; 5,824,291; 5,736,175; 4,156,740; 5,498,429; 4,466,983; 4,157,402; 5,569,477; 5,125,819; 5,248,508; 4,975,288; 4,792,453; 4,980,178; 4,683,138; 5,087,460; 4,292,329; 4,642,235; 4,316,915; 4,513,012; 4,250,196; 5,431,929; and 4,647,450.

Weight control systems and methods have improved over the years. Indeed, the ancient Romans believed that the vomitorium was penance for their uncontrollable feasting and drinking during long celebrations for their various deities. Modern methods of weight control including arduous and sometimes bizarre workout routines and machines are no less peculiar in modern times. Moreover, with the advent of liposuction, stomach stapling, etc., there appears to be no bounds beyond which humans will go to attain desired physical char-

acteristics as such relate to their weight. The effect of such weight norms has created a $60 billion a year market for diet and weight control products. It is estimated that nearly half of all American women, and a quarter of all men, are on a diet at any given time. As is well known, however, most diets, studies have shown, do not work for nine out of ten people who, after suffering through such diets, quickly regain their weight and often exceed their previous body mass. Such an unfortunate volley of feasting and dieting leads not only to physical harm due to increased rates of diabetes, arterial sclerosis, and other physical health problems, but also to an often devastating decreased estimation of a person's self-worth.

There is thus a long felt but unsolved need for an effective, inexpensive and easy way in which to provide health conscious individuals with diet products to assist in achieving desired weight loss.

SUMMARY OF THE INVENTION

In one embodiment, the present invention is directed to a method and product which provides functional components such as, herbal, medicinal and/or vitamin substances for various applications (e.g., weight control substances) to an individual other than through the consumption of pills, suppositories, diet beverages and/or tasteless and low caloric foodstuffs. In one embodiment, the present invention is directed to a particular gum product having at its center a composition different from the surrounding gum and having distinct functional and metabolic characteristics. For example, various metabolism increasing components can be provided in the interior of a gum in a liquid or semi-liquid form while the gum itself can be of a traditional gum composition and/or may incorporate various other desirable metabolic increasing components to supplement and/or coact with components contained in the liquid center of the gum. Indeed, in one particular embodiment of the present invention, time release capsules may be provided suspended in a liquid medium inside a gum enclosure.

The present discussion pertains principally to a diet control gum/lozenge/lollipop, but the present invention is not so limited and includes one or more combinations of ingredients as set forth, for example, in Tables I and II below, which may be useful in numerous and varied applications. For illustration purposes only, however, the following discusses weight loss applications of the present invention. In one embodiment, chewing of the gum-based product releases the interior liquid substance, thus providing a product and a method desirable by weight conscious individuals who do not wish to publicly announce or disclose their dietary desires. In a preferred embodiment, the substance contained within the gum (e.g. the interior liquid substance) would have as a principal characteristic the capability of increasing a user's caloric burn rate (e.g. by increasing a person's metabolism, adjusting/regulating hormonal activity in an individual, providing fiber to increase a person's feelings of satiety).

In a particular embodiment of the present invention, a gum is utilized having liquid interior components surrounded by the dense gum, for example, the interior having a density less than 10% as dense as the exterior gum, more preferably at least about 15% less dense, and more preferably, at least about 35% less dense than the surrounding gum. The interior liquid components can be herbal, organic, natural, chemical and/or hormonal in nature, and may be selected dependent upon their individual and synergistic characteristics, with the objective being to increase a person's metabolism in order to achieve a higher caloric burn rate and/or to decrease the desire for additional food (e.g. generate a feeling of satiety or fullness).

It is within the scope of the present invention to incorporate various known diet control substances in either the gum material itself and/or in the liquid interior material encompassed by the gum material. In a preferred embodiment, however, the surrounding gum material is comprised of traditional gum flavors and compositions and the interior liquid and/or semi-liquid (e.g. gel) components of the present invention comprise diet regulating substances.

Yet another embodiment of the present invention relates to a hard candy substance (e.g. primarily comprising a natural sugar and corn syrup base) often referred to as a "sucker" or "lollipop." The interior of the sucker or lollipop, however, contains a less rigid, soft and/or liquid or semi-liquid component. The enclosed material of the lollipop includes metabolic enhancers for weight and caloric control.

In still another embodiment, a lozenge can be manufactured having a denser exterior and a less dense interior, where either the interior or exterior of the lozenge, or both, contain diet controlling substances. Preferably, diet controlling substances are positioned within the interior of such lozenges so as to facilitate the enjoyment by an individual of consuming the lozenge without the possible unpleasant and/or undesirable taste characteristics of various dietary components within the center of the lozenge.

It will be understood that one purpose of certain embodiments of the present invention is to increase metabolic efficiency and to burn calories in an individual. Herbal additives may be incorporated into such products to aid in the body's ability to digest food and/or to block absorption of fat molecules into the system. For example, chitosan compositions can be utilized either in the interior and/or exterior of the gum, lollipop and lozenge embodiments desired above and hereafter. In addition to chitosan, other fiber-like components, vitamins and minerals (e.g., especially calcium compositions to treat osteoporosis) can be incorporated into the present invention to provide desired feelings of satiety or fullness to an individual using such products and/or to treat various vitamin and/or mineral deficiencies.

While the present invention is primarily directed to administering diet control substances to individuals, it should be understood that other medicinal and/or nutritional and/or biological components can be administered to animals in general (companion pets, livestock, etc.) but preferably humans. Indeed, the present inventor believes that the administration of medicinal compounds to young children can be greatly facilitated by use of the present invention given that children are more apt to take medicine in the form of a lollipop, lozenge or gum, particularly if the taste and flavor and textural characteristics of such candy products are preserved and effective amounts of desired components are delivered to such individuals when consuming such products.

Muscle atrophy, or wasting, is caused by aging and a variety of illnesses and injuries, including cancer, heart failure, and orthopedic injuries. It makes people weak and fatigued, impairs physical activity and quality of life, and predisposes people to falls and fractures. The condition affects more than 50 million Americans annually, including 30 million people over age 60, and often forces people into nursing homes or rehabilitation facilities. Skeletal muscle atrophy is a common and debilitating condition that lacks an effective therapy. Although skeletal muscle atrophy has broad clinical impact, current treatment recommendations (e.g. physical rehabilitation, nutritional optimization, and treatment of underlying disease) are often ineffective and/or unfeasible. Moreover, a pharmacologic therapy does not exist. Thus, skeletal muscle atrophy represents a very large unmet medical need.

A natural small molecule from tomato plants, tomatidine, is believed to cause cell growth, especially in skeletal muscle tissue. Properly administered, such as via the methods and systems set forth herein, tomatidine is an effective agent to treat muscle atrophy and to further increase strength and exercise capacity. Tomatidine is an inhibitor of muscle atrophy and thus has a use as a therapeutic agent for skeletal muscle atrophy. Tomatidine is a steroidal alkaloid and the aglycone of α-tomatine, an abundant glycoalkaloid in tomato plants that mediates plant defense against fungi, bacteria, viruses and predatory insects. When consumed by animals, α-tomatine is hydrolyzed by stomach acid and intestinal bacteria to tomatidine, which is absorbed by the gut. Tomatidine's effects on skeletal muscle are unknown. However, the finding that the mRNA expression signature of tomatidine negatively correlated to signatures of muscle atrophy suggest that tomatidine has an anti-atrophic (anabolic) effect in skeletal muscle.

In one embodiment, a person having from one, preferably two, and more preferably three pieces of center-filled chewing gum in a 24 hour period of time, such gum containing tomatidine, is able to achieve the stimulation of skeletal muscle anabolism, leading to muscle hypertrophy, increased strength and improved exercise capacity. In still other embodiments, especially those including one or more of the agents as set forth in Tables I and II, and especially at least one metabolic enhancer, tomatidine provided in at least a 1 mg per piece of gum, is believed to result in two major effects on body composition, namely, increased skeletal muscle and decreased fat. Tomatidine is believed to limit the progression of skeletal muscle atrophy during fasting and muscle disuse, and enhances the recovery from disuse skeletal muscle atrophy. Tomatidine and/or α-tomatine are also important components in various embodiments of the present invention directed to inclusion into so-called functional foods and nutraceuticals designed to maintain muscle mass and function in persons without muscle atrophy. In addition to having potential utility in its own right, tomatidine supports the concept that systems-based methods can be used to discover small molecules that improve skeletal muscle mass, function and metabolism. Such compounds could potentially have several beneficial uses for patients and society in general.

Studies have shown that tomatidine fed mice had larger muscles, but their overall body weight did not change due to a corresponding loss of fat. Thus, another aspect of the present invention directed to treating obesity, is further enhanced by providing certain amounts of tomatidine as an effective compound in the treatment of obesity. Tomatidine is a natural compound derived from tomatoes and is produced when alpha-tomatine, which is found in green tomatoes, is digested in the gut. Tomatidine is significantly more potent than ursolic acid in building muscle tissue and has a different mechanism of action. One application of the present invention is to provide a center-filled chewing gum lollipop or lozenge that contains tomatidine, as well as other select agents (set forth herein) in a manner that is effective to preserve muscle mass and function during the aging process. Preferably, the compositions included in the gum center-fill or in the gum base material contain tomatidine without any ursolic acid.

As set forth in Tables I and II below, certain embodiments of the present invention are directed to a center-filled gum, lozenge or lollipop that includes particular combinations of active ingredients, including calcium, vitamin E and a chemotherapeutic agent and/or Herbal component, which in certain embodiments consists of tomatidine. Incorporated herein by this reference are the following US patent publications, which further demonstrate that tomatidine falls into such classifications set forth in Tables I and II herein, i.e. US Patent Publication Nos. 20140030332 to Baron, et. al., and 20070123448 to Kaplan et al.

BRIEF DESCRIPTION OF THE DRAWINGS

FIG. **1** represents one embodiment of the invention depicting both a gum-based outer shell and a liquid or syrup center, both consisting of all or some ingredients listed in Table I or Table II.

FIG. **2** represents another embodiment of the present invention in a lollipop form.

DETAILED DESCRIPTION OF THE PREFERRED EMBODIMENT

The following table contains a list of possible components that may be incorporated into the center of the gum, lollipop and lozenge aspects of the present invention:

TABLE I

Dexatrim	Diuretics
Chitosan	Antacids
Oatmeal fiber	Antibiotics
Vitamins	Herbal components
Mineral supplements	Stimulants
Medicinal components	Metabolic enhancers
Lipid substances (HDLs)	
Chemotherapeutic agents	

The following U.S. issued patents are also incorporated herein by reference: U.S. Pat. No. 5,474,989 by Hasimoto et al., U.S. Pat. No. 5,747,475 by Norquist et al., U.S. Pat. No. 5,830,883 by Block et al., U.S. Pat. No. 5,880,109 by Nakamura et al., U.S. Pat. No. 4,963,367 by Ecanow, U.S. Pat. No. 4,738,850 by Thakur et al., U.S. Pat. No. 5,846,952 by Vournakis et al., and U.S. Pat. No. 4,223,023 by Furda. It will therefore be appreciated by one of skill in the art that various compositions, formulations, masking agents (e.g., to "mask" unpleasant flavors and/or textures and/or mouth feel characteristics of vitamins, medicinal compounds, minerals, etc.) and binders can be combined with the present structure of the present invention to achieve various desired purposes. For example, controlled release formulations are encompassed by the present invention as are the preparation and use of various different carrier vehicles useful for medicinally administering compositions to animals, time release formulations, compositions having desirable solubility and dissolution rates, and the incorporation into the present invention of food additives such as vitamins, pharmaceutical preparations and other compounds, specifically those that reduce the absorption of lipids such a chitosan.

Both the gum with liquid-type fillers and the sucker with a gum-based center can be comprised of one or more of the following: xanthan, guar, locust bean gum, karaya, gum tragacanth, carrageenans, alginates, gum arabic, corn syrup, sugar, starches, gum bases. While multiple recipes exist, most candy substances can also be made from natural and herbal substitutes listed in Table II. The cavities that are extruded in both the gum and the lollipop can be made with one or more cavities that can be filled with multiple bio-enhancing and weight management substances, compiling all or some of the properties in Table II. The combination of them will achieve various results. Example: Guarana and malluang and chitosan will create energy and a feeling of "fullness" for the con-

sumer; chromium picolinate (RE. 33, 988) and ginseng and ginger will allow the user to burn calories more efficiently).

TABLE II

Siberian Ginseng	Vitamin E
Green Tea	Zinc
Casgara Sagrada	Mahuang
Apple Pectin	*Astragalus*
Dandelion	Guarana
Chickweek	Bee Pollen
Gymnema Sylvestre	Chromium Picolinate
Licorice	Bluegreen Algae
Bladderwrack	Royal Jelly
Ginger	Damiana
Magnesium	Lecithin
Sarsaparilla	Gotu Kola
Golden Seal	Nettles
Chitosan	

The amounts of all or some of these ingredients can vary, preferably being present in an amount between no less than about 0.05 mg. The size of the gum exterior can be made of a size less than 4.5 grams to more than 18.4 grams with the cavity center being able to accommodate a volume between 0.5 mg to more than 5 grams. The lollipop can be a total size of less than 0.65 oz. with the cavity center being a volume of no more than 0.42 oz. and no less than 4.5 grams, to a size larger than 1.35 oz. with a cavity center being of at least 19 grams.

In one particular embodiment, the invention is directed to a beverage, so-called a Bloody Mary beverage, that includes the following: in a 12 fluid once serving: up to but not exceeding 9.9% alcohol (by volume); no fat; up to 1200 mg of sodium; 3 grams of protein; Vitamin C, Vitamin A, calcium, potassium and iron. In a preferred embodiment the beverage includes water, tomato concentrate, natural grain spirits, high fructose corn syrup, aloe vera juice, sodium chloride, vinegar, citric acid, taurine, pectin, ascorbic acid, and citrus aurantium extract. In still other embodiments, the beverage includes the following: fresh horseradish, tomato juice, Tabasco, Worcestershire sauce, celery salt, and one of amontillado; cream sherry, and pure cane sugar. In yet another embodiment, the present invention includes a beverage consisting of: water; a tomato concentrate having a tomato soluble solids content of about 24% to about 36% by weight, ethyl alcohol, Vitamin C, Vitamin A, calcium, potassium, iron, water, high fructose corn syrup, aloe vera juice, sodium chloride, vinegar, citric acid, taurine, pectin, ascorbic acid, and citrus aurantium extract, horseradish, Worcestershire sauce, and celery salt. Certain other embodiments are directed to a Bloody Mary beverage that has the benefits of an energy drink, and include at least the following: tomato juice containing lycopene, Ginger, Honey, taurine and caffeine. By way of providing additional background, context, and to further satisfy the written description requirements of 35 U.S.C. §112, the following references are incorporated by reference in their entireties: U.S. Patent Publication No. 20130115329 to Savant, et al. and U.S. Pat. No. 8,202,561 to Livaich. One of skill in the art will further appreciate that the beverage ingredients of the above can also be incorporated into the chewing gum and lollipop embodiments as further described herein.

While various embodiments of the present invention have been described in detail, it is apparent that further modifications and adaptations of the invention will occur to those skilled in the art. However, it is to be expressly understood that such modifications and adaptations are within the spirit and scope of the present invention.

What claimed is:

1. A chewing gum product consisting essentially of a first substance configured so as to have at least one cavity capable of retaining a liquid or semi-liquid substance as a second substance, wherein at least said second substance has an active ingredient consisting essentially of a chemotherapeutic agent and at least one ingredient selected from the group consisting of calcium, zinc, chromium picolinate, magnesium, a metabolic enhancer and combinations thereof, said active ingredient present in an amount of at least about 0.05 mg, wherein said active ingredient is present in the form of a controlled release formulation, and wherein said controlled release formulation comprises time release capsules.

2. A chewing gum product consisting essentially of a first substance configured so as to have at least one cavity capable of retaining a liquid or semi-liquid substance as a second substance, wherein at least said second substance has an active ingredient consisting essentially of a chemotherapeutic agent and at least one ingredient selected from the group consisting of a metabolic enhancer, green tea, zinc, chromium picolinate and magnesium, said active ingredient present in an amount of at least about 0.05 mg, wherein said active ingredient is present in the form of a controlled release formulation, and wherein said controlled release formulation comprises time release capsules.

3. A chewing gum product consisting essentially of a first substance configured so as to have at least one cavity capable of retaining a liquid or semi-liquid substance as a second substance, wherein at least said second substance has an active ingredient consisting essentially of a chemotherapeutic agent, calcium, zinc and magnesium, said active ingredient present in an amount of at least about 0.05 mg, wherein said active ingredient is present in the form of a controlled release formulation, and wherein said controlled release formulation comprises time release capsules.

4. The chewing gum of claim **1** wherein said active ingredient is present in an amount of more than 30 mg.

5. A chewing gum as act forth in claim **1**, wherein said controlled release formulation has desirable solubility and dissolution rates.

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