ORAL COMPOSITION AND METHOD FOR STRESS REDUCTION ASSOCIATED WITH SMOKING CESSION

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ABSTRACT
A confectionary composition is used in a method of reducing stress and the urge to smoke in abstaining tobacco users. The confectionary composition includes at least one of a sugar or a sugar alcohol and an effective amount of stress-reducing flavoring agent. Where the confectionary composition is a chewing gum, the composition includes a water soluble bulk portion and a water insoluble base portion. The stress-reducing flavoring agent can be one or more of peppermint flavor, vanilla flavor, or peach flavor. The stress-reducing flavoring agent reduces an abstaining tobacco user’s urge to smoke and can reduce the level of salivary Cortisol in the abstaining tobacco user. The method reduces stress in tobacco users who must temporarily abstain from tobacco use and can reduce consumption of tobacco by tobacco users by increasing the interval between consumption events.
ORAL COMPOSITION AND METHOD FOR STRESS REDUCTION ASSOCIATED WITH SMOKING cessation

RELATED APPLICATION DATA

TECHNICAL FIELD
[0002] The invention relates generally to aids for treating tobacco or nicotine habits and, more particularly, to oral compositions, such as chewing gum and confectionary compounds, formulated to relieve psychological and physiological stress associated with smoking cessation.

BACKGROUND
[0003] There are about 1.1 billion tobacco smokers worldwide. In the U.S., about 30% of the population smokes cigarettes, of these, about 36-40% are 18-25 years old. Direct and passive exposure to smoking, and particularly cigarette smoking, is recognized as a substantial health factor, and a major risk factor in a variety of diseases, including coronary artery disease and a wide range of cancers. It is also recognized that nicotine, a constituent of tobacco, is highly addictive, making decreasing or ceasing to smoke tobacco-related products very difficult for a significant percentage of tobacco users. As governments worldwide increase restrictions on tobacco use in public, there is a need for methods to assist smokers, and especially young adults, with the stress of smoking cessation. Many products now in use to reduce the urge to smoke may also directly or indirectly lower stress levels associated with smoking cessation.

[0004] At present there are several consumer products that attempt to help people overcome their addiction to nicotine found in all tobacco related products. One type of product includes a transdermal patch, which allows the person's body to slowly absorb a prescribed amount of nicotine over a given period. Little by little the dosage of nicotine in the patches is decreased until the person is no longer addicted. Once the physical addiction to nicotine is overcome, the person can more easily fight the psychological stress associated with smoking cessation.

[0005] Another type of product is sold in the form of a chewing gum containing nicotine. Thus, whenever a smoker has the urge to smoke, the smoker will chew the gum instead. However, the smoker still has to restrict the use of the gum in a manner that will eventually overcome the addiction.

[0006] There are substantial limitations and drawbacks to the various methods of nicotine-replacement therapy in current use. Orally ingested materials containing nicotine have a bad taste, may lead to mouth ulcers, heartburn and other adverse consequences, and are highly dependent of the user following a specific regime. Other forms of oral administration can result in nausea, unpredictable nicotine blood levels and the like. Patches, including transdermal patches, and other topical applications of nicotine can cause skin irritation, and patches containing nicotine are known to cause pruritus.

[0007] Devices and methods involving nicotine therapy all necessarily depend on the use of nicotine, the substance causing addiction, to control nicotine craving or desire. This approach is thus susceptible to abuse, and users are known to become addicted to the use of gum, patches or the like, and not to decrease nicotine intake as instructed. In addition, users are known to concurrently use both tobacco, as in cigarettes, and nicotine therapy aids, such as gum or patches, thereby increasing the total intake of nicotine. Further, in such instances acute adverse medical consequences mayresult, including increased heart rate, increased blood pressure and other conditions associated with nicotine administration. Accordingly, the use of nicotine therapy may actually increase the stress associated with smoking cessation.

[0008] There are certain herbal preparations that are known to have been used as smoking materials, including use in non-tobacco cigarettes. For example, nicotine-free herbal compositions, have been used either as a substitute for or in combination with tobacco. This smoking composition may include Laurus nobilis and Nelumbo garein. Also, herbs such as Plantago major, Piper methysticum, and Hypericum perforatum have been used in herbal preparations for aid in cessation of tobacco.

[0009] Several non-nicotine chewing gum and confectionary smoking cessation aids have been developed. For example, citrus leaf powder, oat extract, and tea extracts have been used in an anti-smoking chewing gum. Other non-nicotine confections have been formulated containing sugar substitutes. For example, sugar alcohols, maltitol and lactitol, and menthol or mint flavor have been used in smoking control confections.

BRIEF SUMMARY
[0010] In one aspect of the invention, a confectionary composition is formulated to reduce stress and the urge to smoke in abstaining tobacco users. The composition includes at least one of a sugar or a sugar alcohol and an effective amount of a stress-reducing flavoring agent sufficient to substantially reduce the urge to consume tobacco products.

[0011] In another aspect of the invention, a chewing gum composition is formulated to reduce stress and the urge to smoke in abstaining tobacco users. The composition includes a water soluble bulk portion, a water insoluble base portion, and at least one stress-reducing flavoring agent sufficient to substantially reduce the urge to smoke.

[0012] In yet another aspect of the invention, a method of reducing the urge to smoke in abstaining tobacco users includes orally administering a confectionary composition having an amount of stress-reducing flavoring agent effective to substantially reduce the urge to smoke during periods of smoking abstinence.

[0013] In a further aspect of the invention, a method of reducing stress in tobacco users who must temporarily abstain from tobacco use includes orally administering a confectionary composition having an amount of stress-reducing flavoring agent effective to substantially reduce the urge to smoke during periods of smoking abstinence.

[0014] In a still further aspect of the invention, a method of reducing consumption of tobacco by a tobacco user by increasing the interval between consumption events com-
prising orally administering a confectionary composition having an amount of stress-reducing flavoring agent effective to substantially reduce the urge to smoke during periods of smoking abstinence.

[0015] The stress-reducing flavoring agent can be one or more of peppermint flavor, vanilla flavor, or fruit flavors, such as peach flavor.

Detailed Description

[0016] The present invention will now be further described. In the following passages, different aspects of the invention are defined in more detail. Each aspect so defined may be combined with any other aspect or aspects unless clearly indicated to the contrary. In particular, any feature indicated as being preferred or advantageous may be combined with any other feature or features indicated as being preferred or advantageous.

[0017] Confectionary compositions can be used as vehicles for delivering components to the oral cavity which provide benefits such as breath freshening and antibacterial properties. Such systems have the advantage of providing a consumer with a convenient and inexpensive method for maintaining oral health and fresh breath throughout the course of the day. Chewing gums and confections such as hard and soft candies also provide the user with certain psychological benefits. The action of chewing a gum or sucking on a candy can provide a form of relaxation and provide relief of stress and tension in the body.

[0018] The cessation of smoking or other forms of tobacco use in tobacco users is usually accompanied by increased stress levels. The human stress hormone Cortisol is secreted in response to stressful or threatening situations, such as during periods when a person has the urge to smoke, but cannot because of either environmental restrictions or attempting to break the smoking habit. Saliva Cortisol is released in the oral cavity during times of mental stress or increased body tension. (J. Smyth, et al. “Stressors And Mood Measured On A Momentary Basis Are Associated With Salivary Cortisol Secretion” Psychoneuroendocrinology 1998; 23:353-370).

[0019] In accordance with an embodiment of the invention, an oral delivery vehicle, preferably a confectionary product such as a chewing gum or the like, containing an effective amount of a stress-reducing flavoring agent, is masticated by an abstaining tobacco user. Suitable confectionary products include tablets, lozenges, hard and soft candies, pressed mints, and the like. The term “masticated” as used herein includes operations by which a chewing gum or candy is partially or wholly consumed while it is being held in the mouth, such as by chewing, sucking, or dissolving. Holding the product in the mouth for longer periods of time is expected to be associated with greater levels of stress reduction in an abstaining tobacco user.

[0020] The present invention provides a confectionary that reduces the anxiety in tobacco users when they cannot smoke. For example, during travel on commercial airlines, while at meetings, while in non-smoking restaurants, and the like. These are situations in which tobacco users must temporarily abstain from tobacco use. Accordingly, the present invention contemplates a method in which a confection containing a stress-reducing flavoring agent is used to relieve stress in tobacco users who must temporarily abstain from tobacco use.

[0021] The present invention also provides a confectionary that, when used, effectively increases the time period between tobacco use episodes by reducing the urge to smoke or otherwise use or consume tobacco products. By relieving the stress associated with abstaining from tobacco use, the overall consumption of tobacco products can be reduced in individuals desiring to permanently abstain from tobacco use. In this aspect, the invention provides a method of assisting tobacco users in overcoming a tobacco use habit.

[0022] The present invention incorporates flavoring agents in a confectionary composition that have been discovered to reduce stress generally, and stress related to tobacco abstinence as well as the urge to smoke. In accordance with one embodiment of the invention, an oral composition includes an effective amount of a flavoring agent such as peppermint or vanilla or both. In other embodiments, an oral composition includes an effective amount of a fruit flavoring agent, such as peach. These flavoring agents have been found effective in reducing the urge to smoke in both men and women over an extended period after smoking cessation. In particular, chewing gums containing peppermint or vanilla flavors were found to reduce saliva Cortisol levels in test subjects in a three-day trial following cessation of cigarette smoking.

[0023] Studies conducted to determine the effects of peppermint and vanilla flavored chewing gums have shown an alleviation of withdrawal symptoms and a reduction in the urge to smoke in cigarette smokers. In a double-blind, randomized cross-over study, the withdrawal symptoms, urge to smoke, and salivary Cortisol levels were measured in 10 subjects over a three-day trial following cessation of smoking. In the study, the salivary cortisol levels in 5 women and 5 men were measured at several intervals on the third day of the abstinence test period. Both the urge to smoke and the overall withdrawal symptoms were measured on the third day of the abstinence.

[0024] In the study, the subjects had their last cigarette before going to bed on Sunday. They did not smoke on Monday, the first day of abstinence, but answered questions relating to symptoms and urge to smoke at about 10 am. This was designated as zero hour. The “48 hour” tests were run at about 10:00 am on Wednesday, the third day of abstinence. Saliva samples were taken throughout Wednesday. Thus, by the time the last saliva sample was taken on Wednesday night, the subjects had gone 72 hours since their last cigarette. Abstinence was enforced by testing for carbon monoxide in the breath—a clear indicator of cigarette smoking.

[0025] Table 1 below shows scale values relating to the urge to smoke for the overall study as a group, and for the women and the men within the group.

| TABLE 1 |
|-----------------|--------|--------|
|                | Total  | Women  | Men    |
| Peppermint Gum | 73.9   | 83.6   | 64.2   |
| Vanilla Gum    | 64.3   | 61.2   | 67.4   |
| No Gum         | 85.1   | 88.8   | 81.4   |
The values shown in Table 1 are Visual Analog Scale Values in which the subjects indicated on a 100 mm line scale the degree of their subjective urge to smoke. The scale values ranged from 0 (no urge to smoke) to 100 (maximum urge to smoke).

Overall, both peppermint and vanilla flavored chewing gums substantially reduced the urge to smoke in comparison with no chewing gum. Further, the study showed that, overall, vanilla flavored chewing gum had a more pronounced effect on the urge to smoke than peppermint flavored chewing gum. The vanilla flavored chewing gum reduced the urge to smoke by about 24% compared with no chewing gum.

Within the group, vanilla flavored chewing gum reduced the urge to smoke in the female subjects by about 31%, while the peppermint chewing gum had a much less pronounced reduction. In men, the peppermint flavored chewing gum reduced the urge to smoke by about 21%, while the vanilla flavored chewing gum had a slightly less effect on the urge to smoke.

The total withdrawal systems in the test subjects are shown in Table 2 below.

| TABLE 2 |
| Total Withdrawal Symptoms At A 48 Hour Interval After Cessation Of Smoking (Average scale values of self-reported symptom severity) |
| Total | Women | Men |
| Peppermint Gum | 11.6 | 12.8 | 10.4 |
| Vanilla Gum | 13.5 | 14.2 | 12.8 |
| No Gum | 16.5 | 18.6 | 14.4 |

The values listed in Table 2 are the average of the subject’s self-reported severity of eleven smoking cessation-related symptoms. The values for each symptom are provided on a four-point scale. The values for each symptom range from 0 (not present) to 3 (severe). Thus, in the averages listed above in Table 2, the maximum possible score when all eleven symptoms are at their highest level for any one subject is 33.

In the overall study group, both peppermint flavored chewing gum and vanilla flavored chewing gum substantially reduced the total withdrawal symptoms. The peppermint and vanilla flavored chewing gums reduced the total withdrawal symptoms by 30% and 18%, respectively. In the female subjects, peppermint flavored chewing gum reduced the total withdrawal symptoms by about 30%, while the vanilla flavored chewing gum reduced the total withdrawal symptoms by about 24%. In the male subjects, the peppermint flavored chewing gum reduced the total withdrawal symptoms by about 28%, while the vanilla flavored chewing gum showed much less effect.

During the third day of abstinence, the saliva samples were taken at six intervals throughout the day: upon waking (A), 45 minutes later (A+45), at noon (12), at 6:00 pm (6), between 8:00 and 9:00 pm (8-9), and at bed time (B). Cortisol levels are known to peak shortly after rising in the morning and then decline throughout the day. Using the peak Cortisol level as a baseline, the reduction in salivary Cortisol levels was determined for the control and experimental treatments.

Table 3 shows the relative salivary Cortisol levels taken from the test subjects at the various time intervals on the third day following cessation of smoking. The values shown in the table are nanomoles of Cortisol per milliliter of saliva.

| TABLE 3 |
| Saliva Cortisol Levels On The Third Day After Cessation Of Smoking (nanomoles/ml) |
| A | A + 45 | 12 | 6 | 8-9 | B |
| Peppermint Gum | 0.53 | 0.50 | 0.32 | 0.12 | 0.18 | 0.20 |
| Vanilla Gum | 0.40 | 0.59 | 0.25 | 0.10 | 0.09 | 0.12 |
| No Gum | 0.34 | 0.42 | 0.29 | 0.22 | 0.20 | 0.11 |

The results are shown for subjects that were allowed to chew peppermint flavored chewing gum, vanilla flavored chewing gum, and no chewing gum. As shown above in Table 3, peak salivary Cortisol levels were measured in the test subjects at the time of awakening (A) and shortly after arising (A+45), then declined over the remainder of the day. The subjects chewing either the peppermint flavored chewing gum or the vanilla flavored chewing gum showed greater reductions from peak levels than did the subjects who chewed no gum. This indicates that the experimental gums were effective in substantially reducing stress in smokers on the third day of abstinence.

As illustrated in the foregoing description, the stress associated with abstaining from the use of tobacco products can be substantially reduced by consuming a confectionery composition having a stress-reducing flavoring agent.

The following examples illustrate various embodiments of the invention for oral compositions including stress-reducing flavoring agents.

**Chewing Gum**

Pursuant to the present invention, a flavor such as peppermint, vanilla, peach flavor or other stress-reducing flavoring agents can be used to formulate a chewing gum. In this regard, the present invention also provides a chewing gum comprising a water insoluble base portion, a water soluble base portion, and a stress-relieving flavoring agent. The water soluble portion dissipates with a portion of the flavor over a period of time during chewing. The gum base portion is retained in the mouth throughout the chew. The chewing gum may be any of a variety of different chewing gums, including low or high moisture, sugar or sugarless, wax-containing or wax-free, low calorie and/or a chewing gum that includes dental health agents.

The insoluble gum base generally comprises elastomers, resins, fats and oils, softeners, and inorganic fillers. The gum base may or may not include wax. The insoluble gum base can constitute about 5 to about 95 percent, by weight, of the chewing gum, more commonly, the gum base comprises about 10 to about 50 percent of the gum, and in some preferred embodiments, about 20 to about 35 percent, by weight, of the chewing gum.

In one formulation, the chewing gum base contains about 20 to about 60 weight percent synthetic elastomer, about 0 to about 30 weight percent natural elastomer, about
5 to about 55 weight percent elastomer plasticizer, about 4 to about 35 weight percent filler, about 5 to about 35 weight percent softener, and optional minor amounts (about one percent or less) of miscellaneous ingredients such as colorants, antioxidants, and the like.

[0040] Synthetic elastomers may include, but are not limited to, polyisobutylene with a GPC weight average molecular weight of about 10,000 to about 95,000, isobutylene-isoprene copolymer (butyl elastomer), styrene-butadiene copolymers having styrene-butadiene ratios of about 1:3 to about 3:1, polyvinyl acetate having a GPC weight average molecular weight of about 2,000 to about 90,000, polyisoprene, polyethylene, vinyl acetate-vinyl laureate copolymer having vinyl laureate content of about 5 to about 50 percent by weight of the copolymer, and combinations thereof.

[0041] Preferred ranges are, for polyisobutylene, about 50,000 to about 80,000 GPC weight average molecular weight, for styrene-butadiene, 1:1 to 1:3 bound styrene-butadiene, for polyvinyl acetate, 10,000 to 65,000 GPC weight average molecular weight with the higher molecular weight polyvinyl acetates typically used in bubble gum base, and for vinyl acetate-vinyl laureate, vinyl laureate content of about 10 to about 45 percent.

[0042] Natural elastomers may include natural rubber such as smoked or liquid latex and guayule as well as natural gums such as jelutong, lechi caspi, perillo, sorva, massaranduba balata, massaranduba chocolate, nispero, rosindinha, chicle, gutta hang kang, and combinations thereof. The preferred synthetic elastomer and natural elastomer concentrations vary depending on whether the chewing gum in which the base is used is adhesive or conventional, bubble gum or regular gum, as discussed below. Preferred natural elastomers include jelutong, chicle, sorva and massaranduba balata.

[0043] Elastomer plasticizers may include, but are not limited to, natural rosin esters such as glycerol esters of partially hydrogenated rosin, glycerol esters polymerized rosin, glycerol esters of partially dimerized rosin, glycerol esters of rosin, pentacyrtiaryl esters of partially hydrogenated rosin, methyl and partially hydrogenated methyl esters of rosin, pentacyrtiaryl esters of rosin; synthetics, such as terpene resins derived from alpha-pinene, beta-pinene, and/or d-limonene; and any suitable combinations of the foregoing, the preferred elastomer plasticizers will also vary depending on the specific application, and on the type of elastomer which is used.

[0044] Fillers/texturizers may include magnesium and calcium carbonate, ground limestone, silicate types such as magnesium and aluminum silicate, clay, alumina, talc, titanium oxide, mono-, di- and tri-calcium phosphate, cellulose polymers, such as wood, and combinations thereof.

[0045] Water insoluble softeners and emulsifiers are typically incorporated into the gum base at levels between 5 and 50%. These may include fats such as tallow, hydrogenated tallow, hydrogenated and partially hydrogenated vegetable oils, cocoa butter; fatty ingredients such as glycerol monostearate and other mono- and diglycerides, glycerol tristearate, lecithin, acetylated mono- and diglycerides, fatty acids (e.g. stearic, palmitic, oleic and linoleic acids), waxes such as paraffin and microcrystalline waxes and combinations thereof.

[0046] Colorants and whiteners may include FD&C-type dyes and lakes, fruit and vegetable extracts, titanium dioxide, and combinations thereof.

[0047] The gum base may or may not include wax. An example of a wax-free gum base is disclosed in U.S. Pat. No. 5,286,500, the disclosure of which is incorporated herein by reference.

[0048] In addition to a water insoluble gum base portion, a typical chewing gum composition includes a water soluble bulk portion and one or more flavoring agents. The water soluble portion can include bulk sweeteners, high intensity sweeteners, flavoring agents, softeners, emulsifiers, colors, acidulants, fillers, antioxidants, and other components that provide desired attributes.

[0049] Bulk sweeteners include both sugar and sugarless components. Bulk sweeteners typically constitute about 5 to about 15% by weight of the chewing gum, more typically, about 20 to about 80% by weight, and more commonly, about 30 to about 60% by weight of the gum.

[0050] Sugar sweeteners generally include saccharide-containing components commonly known in the chewing gum art, including, but not limited to, sucrose, dextrose, maltose, dextrin, dried invert sugar, fructose, levulose, galactose, corn syrup solids, and the like, alone or in combination.

[0051] Sugarless sweeteners include, but are not limited to, sugar alcohols such as sorbitol, mannitol, xylitol, hydrogenated starch hydrolysates, maltitol, and the like, alone or in combination, and polymeric sucrose replacers including maltooltrins, polydextrose, and hydrogenated starch hydrolysate (HSH).

[0052] High intensity artificial sweeteners can also be used, alone or in combination with the above. Preferred sweeteners include, but are not limited to sucralose, aspartame, Neotame, salts of acesulfame, such as the synthetic sweetener 3,6-dihydro-6-methyl-1,1,2,3,4-oxathiazin-4-one-2,2-dioxide, particularly the potassium substituted sweetener (Acesulfame-K), alitame, saccharin and its salts, cyclamic acid and its salts, glycyrrhizin, dihydrochalcones, thaumatin, monellin, and the like, alone or in combination. In order to provide longer lasting sweetness and flavor perception, it may be desirable to encapsulate or otherwise control the release of at least a portion of the artificial sweetener. Such techniques as wet granulation, wax granulation, spray drying, spray chilling, fluid bed coating, coating, and fiber extension may be used to achieve the desired release characteristics.

[0053] Usage level of the artificial sweetener will vary greatly and will depend on such factors as potency of the sweetener, rate of release, desired sweetness of the product, level and type of flavor used and cost considerations. Thus, the active level of artificial sweetener may vary from about 0.02 to about 8%. When carriers used for encapsulation are included, the usage level of the encapsulated sweetener will be proportionately higher.

[0054] Encapsulated sweeteners can also be incorporated into the gum formulation. The encapsulation techniques that can be used can give varying degrees of coating from partial to full coating depending on the coating composition used in the process. Also the coating compositions may be suscep-
tible to water permeating to various degrees. Generally, compositions that have high organic solubility, good film forming properties, and low water solubility, provide a better encapsulation of aspartame. Such compositions include acrylic polymers and copolymers, carboxyvinyl polymers, polyamides, poly(styrene), polyvinyl acetate, polyvinyl acetate phthalate, polyvinyl pyrrolidone, and waxes.

[0055] Although all of the above materials are possible for the encapsulation of aspartame, only food grade materials should be used. Two standard food grade coating materials that are good formers, but not water soluble, are shellac and Zein. Others which are more water soluble, but also good film formers, are materials such as agar, alginites, a wide range of cellulose derivative like ethyl cellulose and hydroxypropylmethyl cellulose, dextrin, gelatin and modified starches. Other encapsulants like acacia or maltodextrin can also be used to encapsulate the aspartame.

[0056] Generally, the higher the level of coating and the lower the amount of aspartame, the higher the stability of aspartame. To obtain the desired encapsulation, the encapsulant should be preferably at least about 20% of the coated product. More preferably, the encapsulant should be at least about 30% of the coated product, and most preferably should be at least about 40% of the coated product. Depending on the coating material, a higher or lower amount of coating material may be needed to provide the desired encapsulation.

[0057] Another method of partial encapsulation is agglomeration with an agglomerating agent, which partially coats aspartame. This method includes the step of mixing the aspartame and agglomerating agent with a small amount of water or solvent. The mixture is prepared in such a way as to have individual wet particles in contact with each other so a partial coating can be applied. After the water or solvent is removed, the mixture is ground and used as a powdered coated encapsulated aspartame.

[0058] Materials that can be used as the agglomerating agent are the same as those used in the encapsulation previously mentioned. However, since the coating is only a partial encapsulation, some agglomerating agents are more effective than others. Some of the better agglomerating agents are organic polymers such as acrylic polymer and copolymers, polyvinyl acetate, polyvinyl pyrrolidone, waxes, shellac and Zein. Other agglomerating agents may not be as effective as are the polymers, waxes, shellac and Zein. These other agglomerating agents include, but are not limited to, agar, alginites, a wide range of cellulose derivatives, dextrin, gelatin, modified starches, and vegetable gums such as guar gums, locust bean gum, and carrageenan.

[0059] Even though the agglomerated aspartame is only partially coated, when the quantity of coating is increased compared to the quantity of aspartame, improved aspartame stability is obtained. The level of coating used in the agglomerated product should be at about 5%. Preferably the coating level should be at least about 15%, and more preferably about 20%.

[0060] Aspartame may be coated in a two-step process or multiple step process. Aspartame may be encapsulated with any of the materials previously described and then the encapsulated material can be agglomerated as previously described to obtain an encapsulated/agglomerated product that could be used in chewing gum to improve stability.

[0061] Combinations of sugar and/or sugarless sweeteners may be used in chewing gum. Additionally, the softener may also provide additional sweetness such as with aqueous sugar or alditol solutions.

[0062] If a low caloric gum is desired, a low caloric bulking agent can be used. Examples of low caloric bulking agents include: polydextrose; Raffitolose; Raffitin; Fructooligosaccharides (NutraFlora); Palatinose oligosaccharide; Guar Gum Hydrolysate (Sun Fiber); or indigestible dextrin (Fibersol). However, other low caloric bulking agents can be used.

[0063] Softeners are added to the chewing gum in order to optimize the chewability and mouth feel of the gum. Softeners, also known in the art as plasticizers or plasticizing agents, generally constitute between about 0.5% to about 15% of the chewing gum. These include glycerin, propylene glycol and aqueous sweetener solutions such as those containing sorbitol. Hydrogenated starch hydrolysate and corn or other starch hydrolysate syrups (sometimes called glucose syrups) and combinations thereof are particularly preferred as they also function as binders to improve the flexibility and other physical properties of the gum.

[0064] In addition to the stress-reducing flavoring agents described above, a variety of additional flavoring agents can be used. The flavor can be used in amounts of approximately about 0.1 to about 10 weight percent of the gum, and preferably, about 0.3 to 2%. Flavoring agents may include essential oils, synthetic flavors or mixtures thereof including, but not limited to, oils derived from plants and fruits. In addition to peppermint oil, vanilla, and peach, other mint oils including spearmint oil, can be added. Artificial flavoring agents and components may also be used. Natural and artificial flavoring agents may be combined in any sensorially acceptable fashion.

[0065] The stress-reducing flavoring agent can be in the form of a spray-dried flavor. Spray-drying of the flavor oils, such as peppermint oil, can be accomplished by conventional spray-drying techniques whereby a carrier solution or mixture containing the flavor oil is fed through a pressure nozzle and atomized. Generally, the spray-dried flavor is present in the carrier mixture in amounts of about 15 to about 20% by weight of the total carrier and flavor. In the case of spray-dried mint flavors which are to be used in sugar-containing chewing gum compositions, the carrier solution can be a sucrose solution. In sugarless formulations, the carrier solution can be an aqueous gum arabic solution.

[0066] The oral composition of the invention can also contain cooling agents and cooling flavors, such as those disclosed in U.S. Pat. No. 6,627,233, the disclosure of which is incorporated by reference herein. Cooling agents and flavors are used in chewing gum to improve the “cool” sensation perceived upon chewing the gum and to extend the duration of the “cool” sensation. In chewing gums, adding a cooling agent provides the chewing gum with an unexpected, high-flavor impact. This is particularly valuable for sugarless chewing gum where the harsh notes of an added flavor are not masked by sugar. Several different known cooling agents can be used including menthol succinate, acrylic carboxamide; menthol lactate; 3-1-menthoylpropane-1,2-diol; N-substituted p-menthane carboxamide; menthone glycerol ketals and mixtures thereof.

[0067] In an additional aspect, a cooling agent or combinations of cooling agents can be treated to have a modified-
release. The controlled release combination of physiological cooling agents is obtained by modifying the cooling agents by encapsulation, partial encapsulation or partial coating, entrapment or absorption with water-soluble materials or water-insoluble materials. The procedures for modifying the physiological cooling agents include spray drying, spray chilling, fluid-bed coating, coacervation, extrusion, and other agglomerating and standard encapsulating techniques. The cooling agents may also be absorbed onto an inert or water-insoluble material. The cooling agents may be modified in a multiple step process comprising any of the processes noted.

[0068] In general, the chewing gum is manufactured by sequentially adding the various chewing gum ingredients to a commercially available mixer known in the art. After the ingredients have been thoroughly mixed, the gum mass is discharged from the mixer and shaped into the desired form, such as rolling into sheets and cut into sticks or tabs, extruding into chunks or casting into pellets, which are then coated or panned.

[0069] Generally, the ingredients are mixed by first melting the gum base and adding it to the running mixer. The base may also be melted in the mixer itself. Color or emulsifiers may also be added at this time. The softener may also be added at this time, along with syrup and a portion of the bulking agent. Further parts of the bulking agent are added to the mixer. Flavoring agents, such as the stress-reducing flavoring agent described above, are added with the final portion of the bulking agent. Other optional ingredients are added to the batch in a typical fashion, well known to those of ordinary skill in the art.

[0070] The entire mixing procedure typically takes from five to fifteen minutes, but longer mixing times may sometimes be required. Those skilled in the art will recognize that many variations of the above described procedure may be followed.

[0071] After the ingredients are mixed, the gum mass is either sheeted or formed into pellets or balls. Pellet or ball gum is prepared as conventional chewing gum but formed into pellets that are pillow shaped, or into balls.

[0072] If a coated chewing gum is desired, the pellets/balls can be used as cores for a coated chewing gum product having a core. The cores can be sugar or polyol coated or panned by conventional panning techniques to make a coated pellet gum. The weight of the coating may be about 20% to about 50% of the weight of the finished product, but may be as much as 75% of the total gum product.

[0073] Conventional panning procedures generally coat with sucrose, but recent advances in panning have allowed use of other carbohydrate materials to be used in place of sucrose. Some of these coating materials include, but are not limited to, sugars such as dextrose, maltose, isomaltulose, and tagatose, or sugarless bulk sweeteners such as xylitol, sorbitol, lactitol, hydrogenated isomaltulose, erythritol, maltitol, and other new polyols (also referred to as alditols) or combinations thereof. A preferred coating comprises about 30% to about 75% maltitol. These materials may be blended with panning modifiers including, but not limited to, gum arabic, gum tragacanth, maltodextrins, corn syrup, gelatin, cellulose type materials like carboxymethyl cellulose or hydroxyethyl cellulose, starch and modified starches, vegetables like alginites, locust bean gum, guar gum, and gum tragacanth. Antistick agents may also be added as panning modifiers, which allow the use of a variety of carbohydrates and sugar alcohols. Flavors, such as the stress-reducing flavoring agents described above, may also be added with the sugar or sugarless coating to yield unique product characteristics.

[0074] Table 4 below provides two exemplary chewing gum formulations in accordance with aspects of the invention.

<table>
<thead>
<tr>
<th>TABLE 4</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Ingrediant</strong></td>
</tr>
<tr>
<td>Gum Base</td>
</tr>
<tr>
<td>Alditol/Glycerin Syrup</td>
</tr>
<tr>
<td>Sorbitol</td>
</tr>
<tr>
<td>Encapsulated Acesulfame K</td>
</tr>
<tr>
<td>Encapsulated Aspartame</td>
</tr>
<tr>
<td>Acesulfame K</td>
</tr>
<tr>
<td>Leucine</td>
</tr>
<tr>
<td>Salt Solution (10%)</td>
</tr>
<tr>
<td>Water</td>
</tr>
<tr>
<td>Vanilla Flavor</td>
</tr>
<tr>
<td>Peppermint Flavor</td>
</tr>
<tr>
<td>Spray Dried Peppermint</td>
</tr>
<tr>
<td>Spray Dried Cooling Agent</td>
</tr>
<tr>
<td>Cocoa Glycerin Dispersion</td>
</tr>
<tr>
<td>Total</td>
</tr>
</tbody>
</table>

[0075] The Alditol/Glycerin Syrup listed above is a blend of sorbitol solution, hydrogenated starch hydrolysate syrup, and glycerin co-evaporated to about 3% moisture. The composition of the Alditol/Glycerin Syrup composition is given below in Table 5.

<table>
<thead>
<tr>
<th>TABLE 5</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Alditol/Glycerin Syrup Composition</strong></td>
</tr>
<tr>
<td>Glycerin</td>
</tr>
<tr>
<td>Mannitol</td>
</tr>
<tr>
<td>ESH solids</td>
</tr>
<tr>
<td>Sorbitol</td>
</tr>
<tr>
<td>Water</td>
</tr>
<tr>
<td>Total</td>
</tr>
</tbody>
</table>

Candy

[0076] In another aspect of the invention, confectionery compositions or products containing stress-reducing flavoring agents can include, for example, hard candies, chewy candies, coated chewy center candies, and tabletted candies. By way of example, the hard candy is primarily comprised of corn syrup and sugar, and derives its name from the fact that it contains only 1% and 4% moisture. In appearance, these types of candies are solid, but they are actually supercooled liquids, which are far below their melting points. There are different types of hard candies. Glass types are usually clear or made opaque with dyes. Grained types of hard candies are always opaque.

[0077] Another aspect of the present invention contemplates the incorporation of the stress reducing flavoring
agents into solid oral carriers such as slow dissolving tablets or lozenges manufactured by conventional techniques. The solid carrier is sugar or a water soluble polyhydric alcohol (polyol) such as mannitol, xylitol, sorbitol, maltitol, a hydrogenated starch hydrolysate ("Tycsin"), hydrogenated glucose, hydrogenated disaccharides, and/or hydrogenated polysaccharides, as the major ingredient, in an amount of about 85-98% by weight of the total carrier. Solid salts such as sodium bicarbonate, sodium chloride, potassium bicarbonate or potassium chloride may totally or partially replace the polyol carrier.

[0078] Tableting lubricants, in minor amounts of about 0.1 to 5% by weight, may be incorporated into the tablet or lozenge formulation to facilitate the preparation of both the tablets and the lozenges. Suitable lubricants include vegetable oil such as coconut oil, magnesium stearate, aluminum stearate, teci, starch and Carboswax.

[0079] Lozenge formulations may contain about 2% hydrocolloid as a barrier agent to provide a shiny surface as opposed to a tablet which has a smooth finish. The lozenge or tablet may optionally be coated with a coating material such as waxes, shellacs, carboxymethyl cellulose, polyethylene/maleic anhydride copolymer or Kappa-carrageenan, to further increase the time it takes the tablet or lozenge to dissolve in the mouth. The coated tablet or lozenge should be slowly dissolving, providing a sustained release rate of the active ingredients over the period of about 3 to about 15 minutes.

[0080] The stress-reducing flavoring agents of the present invention are incorporated into a lozenge or tablet by conventional mixing and tableting techniques known in this field.

[0081] The present embodiment of the invention further contemplates the optional inclusion of a sweetener, flavorant, or colorant component into the tablets or lozenges containing stress-reducing flavoring agents.

[0082] The sweetener component comprises any one or more sweeteners known in the art, including both natural and artificial sweeteners. The sweetener may be chosen from a wide range of materials, including water-soluble sweeteners, water-soluble artificial sweeteners, dipeptide based sweeteners, and mixtures thereof. Thus, sweeteners may be chosen from the following non-limiting list, which includes sugars such as sucrose, glucose, corn syrup, dextrose, invert sugar, fructose and mixtures thereof; saccharine and its various salts such as the sodium or calcium salt; cyclamic acid and its various salts such as the sodium salt; free aspartame; dihydrochalcone sweetening compounds; glycyrrhizin; stevioside; monellin; thaumatin; sucralose; isomaltitol; neosugar; lactitol; polydextrose; tagatose; maltitol; and sugar alcohols such as sorbitol, sorbitol syrup, mannitol, xylitol, and the like. Also contemplated as a sweetener is the nonfermentable sugar substitute hydrogenated starch hydrolysate (also known as Lycasin). Also contemplated is the synthetic sweetener 3,6-dihydro-6-methyl-1,2,3-oxathiazin-4-one-2,2-dioxide, particularly potassium (Acetulfame-K), sodium and calcium salts thereof. Sorbitol is the preferred sweetening and bulking agent. The amount of sweetener included is an amount effective to provide the desired degree of sweetness and bulk, generally 0.001 to 70 weight % of the tablet or lozenge.

[0083] High intensity artificial sweeteners can also be used, alone or in combination, with the above. Preferred sweeteners include, but are not limited to, sucralose, aspartame, APM derivatives such as neotame, salts of acesulfame, alitame, saccharin and its salts, cyclamic acid and its salts, glycyrrhizinate, dihydrochalcones, thaumatin, monellin, and the like, alone or in combination. In order to provide longer lasting sweetness and flavor perception, it may be desirable to encapsulate or otherwise control the release of at least a portion of the artificial sweetener. Such techniques as wet granulation, wax granulation, spray drying, spray chilling, fluid bed coating, conevaporation, and fiber extension may be used to achieve the desired release characteristics.

[0084] In addition to the stress-reducing flavoring agents, additional flavorants may be included. Suitable additional flavorants include natural and artificial flavors, such as menthol, oil of spearmint, oil of cinnamon, oil of wintergreen (methyl salicylate), and various fruit flavors, including but not limited to lemon oil, orange oil, grape flavor, lime oil, grapefruit oil, apple, apricot essence, and combinations thereof. As described above, particularly preferred flavors are stress-reducing flavoring agents, such as peppermint, vanilla, and peach. The flavorings are generally utilized in amounts that will vary depending upon the individual flavor, and may, for example, range in amounts of about 0.5% to about 3% by weight of the tablet or lozenge.

[0085] Colorants can be present in the tablets or lozenges of the present invention. Examples include pigments such as titanium dioxide, natural food colorants such as beta carotenes, betanin, turmeric, and other dyes suitable for food, drug and cosmetic applications known as F.D. & C. dyes, and the like. The materials may be incorporated in amounts of up to about 1% by weight, preferably up to about 6% by weight of the tablet or lozenge.

[0086] The stress-reducing flavoring agents may be incorporated into an otherwise conventional pressed tablet formulation. The pressed tablet into which the stress-reducing flavoring agents are incorporated may be prepared by wet granulation, dry granulation, and direct compression methods. These methods involve conventional procedures well known to the ordinary skilled artisan. In general, wet granulation involves mixing milled powders, preparing a wet mass by blending the milled powders with a binder solution, coarse screening the wet mass and drying the moist granules, screening the granules through a 14 to 20 mesh screen, mixing the screened granules with lubricants and disintegrating agents and finally tablet compressing the mass. In contrast, dry granulation generally involves milling of powders, compression into large hard tablets to make slugs, screening of slugs, mixing with lubricants and disintegrating agents and finally tablet compression. In the direct compression method, the milled ingredients are mixed and then merely tabletted by compression.

[0087] The pressed tablet ingredients used in the invention are selected from those materials routinely used. Such ingredients primarily include sweeteners, lubricants, and optional coloring agents, binders and fillers.

[0088] Sweetening agents may be selected from a wide range of materials such as water-soluble sweetening agents, water-soluble artificial sweeteners, and dipeptide based sweeteners, including mixtures thereof. Without being limited to particular sweeteners, representative illustrations encompass: 1) Water-soluble sweetenings agents such as monosaccharides, disaccharides and polysaccharides such
as xylose, ribose, glucose, mannose, galactose, lactose, fructose, dextrose, sucrose, sugar, maltose, partially hydrolyzed starch, or corn syrup solids and sugar alcohols such as sorbitol, xylitol, mannitol and mixtures thereof; 2) Water-soluble artificial sweeteners such as the soluble saccharin salts, i.e. sodium or calcium saccharin salts, cyclamate salts and the like, and the free acid form of saccharin; 3) Dipeptide based sweeteners include L-aspartyl-L-phenylalanine methyl ester and related compounds.

[0089] In general, the amount of sweetener will vary with the desired amount of sweetener selected. This amount will normally be about 0.001% to about 98% by weight when using an easily extractable sweetener. The water-soluble sweeteners are preferably used in amounts of about 75% to about 98% by weight, and most preferably about 80% to about 95% by weight of the final tablet composition. In contrast, the artificial sweeteners are used in amounts of about 0.01% to about 5.0% and most preferably about 0.05% to about 0.25% by weight of the final tablet composition. These amounts are necessary to achieve a desired level of sweetness independent from the flavor level achieved from the flavor oil.

[0090] Lubricants are used in the tablet formulations in order to ease the ejection of the tablet from the die, to prevent sticking of the tablets to the punches and to limit wear on dies and punches. Tableting lubricants may be selected from a wide range of materials such as magnesium stearate, calcium stearate, zine stearate, hydrogenated vegetable oils, tule, light mineral oil, sodium benzoate, sodium laurel sulfite, magnesium lauryl sulfite and mixtures thereof. Magnesium stearate is the preferred lubricant in view of its ready availability and efficient lubrication properties.

[0091] The lubricants should be in as fine a state of subdivision as possible since the smaller the particle size the greater the efficiency in the granulation. Preferred sizes are those that pass through an 80 or 100 mesh screen and most preferred through a 200 mesh screen before use. The amount of lubricant will vary broadly and is preferably from about 0.1% to about 5% by weight of the total composition.

[0092] Colorants should be selected from materials that are unaffected by higher temperatures and are considered optional ingredients in the tablet formulations. Such materials when used are employed in amounts of 0 to about 0.03% by weight of the total formulation.

[0093] Binders that are used when a wet granulation process is employed include starch, pregelatinized starch, gelatin, free polyvinylpyrrolidone, methylcellulose, sodium carboxymethylcellulose, polyvinylalcohols and so forth. Binders when used can be employed in amounts up to about 25% and preferably about 5 to about 15% by weight. Conventional fillers may also be present such as calcium sulfate, dicalcium phosphate, tricalcium phosphate, starch, microcrystalline cellulose and so forth in amounts up to about 50% by weight with preferred amounts from about 5 to 20% by weight of the final formulation.

[0094] The pressed tablet formulations can be prepared by conventional means using standard techniques and equipment known to those skilled in the art. In one method, stress-reducing flavoring agents are blended with the tablet formulation ingredients. Once incorporated, mixing is continued until a uniform mixture is obtained and thereafter the mixture is formed into suitable shapes by subjected the formulation to a tableting operation. Compression pressures on the order up to 65 megapascals (approximately 12 tons per square inch) are normally employed.

[0095] In the event that the oral composition is in the form of a lozenge or a pressed tablet, a barrier agent is usually present, preferably in a concentration of up to about 2 weight %. The barrier agent provides a shiny surface as opposed to a tablet which, although having a smooth finish, is usually not shiny. In a preferred embodiment, the barrier agent is a hydrocolloid.

[0096] Where the oral composition is a lozenge, a tablet, or a pressed tablet, these products may be coated with a coating material. Among the coating materials suitable for use in this application are waxes, shellacs, carboxymethyl cellulose, ethylene-maleic anhydride copolymers and carrageenan. A coating material is used to increase the time it takes for the tablet or lozenge to dissolve in the mouth. A coated tablet or lozenge is slow dissolving, providing sustained release of the active ingredients over a longer period of time, for example 3 to 15 minutes, or sometimes even longer.

[0097] It should be understood that various changes and modifications to the presently preferred embodiments described herein will be apparent to those skilled in the art. For example, other comestibles which may be formed from the components discussed above are within the contemplation of the present invention. Such changes and modifications can be made without departing from the spirit and scope of the present invention and without diminishing its intended advantages. It is therefore intended that such changes and modifications are within the scope of the appended claims and equivalents thereof.

1. A confectionary composition, formulated to reduce stress and the urge to smoke in abstaining tobacco users, the composition comprising:

(a) at least one of a sugar or a sugar alcohol; and

(b) an effective amount of a stress-reducing flavoring agent sufficient to substantially reduce the urge to consume tobacco products.

2. The composition of claim 1 wherein the stress-reducing flavoring agent comprises peppermint flavor.

3. The composition of claim 1 wherein the stress-reducing flavoring agent comprises vanilla flavor.

4. The composition of claim 1 wherein the stress-reducing flavoring agent comprises a combination of peppermint flavor and vanilla flavor.

5. The composition of claim 1 wherein the stress-reducing flavoring agent comprises peach flavor.

6. The composition of claim 1 wherein the composition comprises a chewing gum.

7. The composition of claim 1 wherein the composition comprises a hard candy.

8. The composition of claim 1 wherein the composition comprises a soft candy.

9. The composition of claim 1 wherein the composition further comprises an artificial sweetener.

10. The composition of claim 1 wherein the stress-reducing flavoring agent reduces the level of salivary Cortisol in the abstaining tobacco users.
11. A chewing gum composition formulated to reduce stress and the urge to smoke in abstaining tobacco users, the composition comprising:

(a) a water soluble bulk portion;
(b) a water insoluble base portion; and
(c) an effective amount of at least one stress-reducing flavoring agent sufficient to substantially reduce the urge to smoke.

12. The chewing gum composition of claim 11 wherein the water soluble bulk portion comprises one or more sweeteners, high intensity sweeteners, flavoring agents, softeners, emulsifiers, colors, acidulants, fillers, and antioxidants.

13. The chewing gum composition of claim 11 wherein the water insoluble base portion comprises one or more of elastomers, resins, fats and oils, softeners, and inorganic fillers.

14. The chewing gum of claim 11 wherein the stress-reducing flavoring agent comprises peppermint flavor.

15. The chewing gum of claim 14 wherein the peppermint flavor comprises spray dried peppermint flavor.

16. The chewing gum of claim 11 wherein the stress-reducing flavoring agent comprises vanilla flavor.

17. The chewing gum of claim 11 wherein the stress-reducing flavoring agent comprises a combination of peppermint flavor and vanilla flavor.

18. The chewing gum of claim 11 wherein the stress-reducing flavoring agent comprises peach flavor.

19. The chewing gum of claim 11 wherein the water soluble bulk portion comprises a water soluble polyhydric alcohol and artificial sweeteners.

20. A coated chewing gum product comprising the composition of claim 11.

21. A method of reducing the urge to smoke in abstaining tobacco users comprising orally administering a confectionary composition having an amount of stress-reducing flavoring agent effective to substantially reduce the urge to smoke during periods of smoking abstinence.

22. The method of claim 21 wherein the oral administration of the confectionary composition reduces psychological anxiety during periods of smoking abstinence.

23. The method of claim 21 wherein the oral administration of the confectionary composition increases the time period between tobacco use sessions in a habitual tobacco user.

24. A method of reducing stress in tobacco users who must temporarily abstain from tobacco use comprising orally administering a confectionary composition having an amount of stress-reducing flavoring agent effective to substantially reduce the urge to smoke during periods of smoking abstinence.

25. A method of reducing consumption of tobacco by a tobacco user by increasing the interval between consumption events comprising orally administering a confectionary composition having an amount of stress-reducing flavoring agent effective to substantially reduce the urge to smoke during periods of smoking abstinence.

* * * * *