PCT WORLD INTELLECTUAL PROPERTY ORGANIZATION
International Bureau

INTERNATIONAL APPLICATION PUBLISHED UNDER THE PATENT COOPERATION TREATY (PCT)

(51) International Patent Classification 5 :		(11) International Publication Number:	WO 92/10147
A61C 15/00, A24F 47/00	A1	(43) International Publication Date:	25 June 1992 (25.06.92)

(21) International Application Number: PCT/US91/09363

(22) International Filing Date: 13 December 1991 (13.12.91)

(30) Priority data:

627,657	14 December 1990 (14.12.90)	US
674,710	25 March 1991 (25.03.91)	US

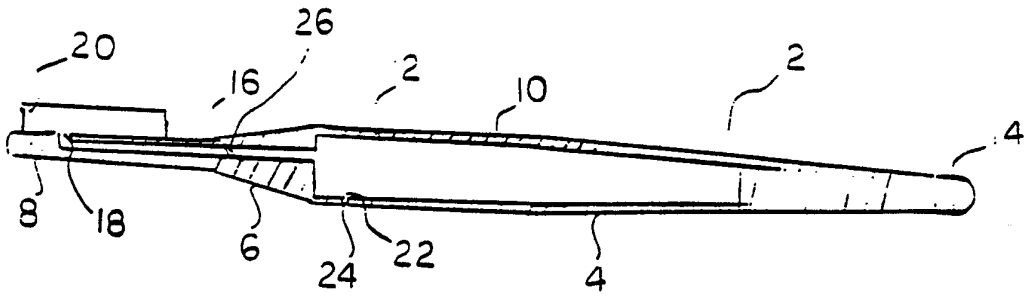
(71)(72) Applicant and Inventor: MONDRE, Steven, J. [US/US]; 136 East 57th Street, Suite 1604, New York, NY 10022 (US).

(74) Agent: ROUX, Philip, E.; Shea & Gould, 1251 Avenue of the Americas, New York, NY 10020-1193 (US).

(81) Designated States: AT (European patent), AU, BE (European patent), BR, CA, CH (European patent), DE (European patent), DK (European patent), ES (European patent), FI, FR (European patent), GB (European patent), GR (European patent), IT (European patent), JP, KP, KR, LU (European patent), MC (European patent), NL (European patent), NO, SE (European patent), SU+.

Published
With international search report.

(54) Title: NICOTINE-CONTAINING DENTAL FLOSS



(57) Abstract

Nicotine treated dental floss, oral hygiene composition and applicator (2) therefor, are disclosed which are useful in alleviating tobacco smokers' urges to smoke. The applicator (2) comprises a handle section (4) adapted for containing a nicotine-treatment fluid in a reservoir (12), a head section (8) and a neck section (6).

+ See back of page

+ DESIGNATIONS OF "SU"

Any designation of "SU" has effect in the Russian Federation. It is not yet known whether any such designation has effect in other States of the former Soviet Union.

FOR THE PURPOSES OF INFORMATION ONLY

Codes used to identify States party to the PCT on the front pages of pamphlets publishing international applications under the PCT.

AT	Austria
AU	Australia
BB	Barbados
BE	Belgium
BF	Burkina Faso
BG	Bulgaria
BJ	Benin
BR	Brazil
CA	Canada
CF	Central African Republic
CG	Congo
CH	Switzerland
CI	Côte d'Ivoire
CM	Cameroon
CS	Czechoslovakia
DE	Germany
DK	Denmark
ES	Spain
FI	Finland
FR	France
GA	Gabon
GB	United Kingdom
GN	Guinea
GR	Greece
HU	Hungary
IT	Italy
JP	Japan
KP	Democratic People's Republic of Korea
KR	Republic of Korea
LI	Liechtenstein
LK	Sri Lanka
LU	Luxembourg
MC	Monaco
MG	Madagascar
ML	Mali
MN	Mongolia
MR	Mauritania
MW	Malawi
NL	Netherlands
NO	Norway
PL	Poland
RO	Romania
SD	Sudan
SE	Sweden
SN	Senegal
SU+	Soviet Union
TD	Chad
TG	Togo
US	United States of America

NICOTINE-CONTAINING DENTAL FLOSS

The present application is a continuation-in-part of co-pending United States Patent Application Serial No. 07/627,657, filed December 14, 1990.

FIELD OF THE INVENTION

The present invention relates to dental floss, oral hygiene compositions and an applicator therefor. More particularly, the present invention relates to dental floss treated with a source of nicotine and, preferably, to nicotine-containing dental floss. The present invention also relates to oral hygiene compositions containing a source of nicotine and an applicator therefor. More particularly, the present invention relates to a novel dental floss combination, a novel oral hygiene composition and applicator therefor, and related methods for alleviating the urge to smoke tobacco while at the same time providing for the beneficial periodontal and oral hygiene effects resulting from frequent dental flossing, brushing, rinsing and/or gum massaging.

BACKGROUND OF THE INVENTION

Many persons who have acquired the habit of smoking tobacco are desirous of quitting. However, the addicting effects of tobacco smoking make it difficult for smokers to quit. Further, tobacco smoke is known to have deleterious effects to a person's teeth, gums and periodontal areas such as discoloration and gingivitis.

The health hazards from tobacco smoking are well established. Of the approximately 4,000 by-products of combustion found in cigarette smoke, many of which are known carcinogens, the three substances studied most have been tars, carbon monoxide and nicotine. Tars and carbon monoxide have been directly implicated in the production or exacerbation of numerous health disorders.

Thus, tars are the causative agents in cigarette smoke most implicated in the induction of cancers such as lung, larynx, oral cavity, esophageal, bladder, kidney, pancreatic, stomach and uterine and cervical cancers. Tars are also considered responsible for the induction of the hepatic microsomal enzyme systems which result in more rapid deactivation of a variety of drugs such as benzodiazepines as well as anti-depressants and analgesics. Tars are also responsible for the production of broncho-pulmonary diseases, including pulmonary emphysema, chronic bronchitis, and smoker's respiratory syndrome.

Carbon monoxide, a deadly gas, is an important health hazard even in minute quantities because it combines with the hemoglobin in the blood so that the hemoglobin can no longer carry sufficient oxygen to fully supply the tissues. Moreover, the stimulant effect of the nicotine in the smoke causes an increase in cardiac workload and oxygen demand, whereas the carbon monoxide effectly blocks the ability of the heart muscle to capture the needed oxygen. In other words, carbon monoxide and nicotine work together in a synergistically negative manner in a way which often results in muscular hypoxia or anoxia, and can ultimately result in cardiac damage. In addition, carbon monoxide has also been implicated as a causative agent in the development of such disorders as coronary artery disease and atherosclerosis.

Nicotine appears to be the most pharmacologically active substance in tobacco smoke, yet it appears to be not as significant from a health standpoint as the tars and carbon monoxide. However, nicotine is very important from another standpoint, i.e. it is the reinforcing substance in tobacco smoke which initiates and maintains the addiction. In this respect, a theme commonly heard among workers in the field of smoking research is: "People would be disinclined to smoke cigarettes if an alternate route of nicotine delivery could be devised."

Several such attempts have been made to administer nicotine in alternate ways, but with varying and generally ineffective results. For example, nicotine-containing pills have been studied; however, effective blood levels of nicotine are not achieved because drugs absorbed in the stomach pass through the liver first where, in this case, 80-90 percent of nicotine deactivation occurs. Similar findings have been demonstrated with nicotine chewing gum although it has been sufficiently successful to warrant its marketing.

There are other long established and traditional ways of absorbing nicotine through the mouth, including chewing tobacco, snuff and products which constitute diffusion bags of tobacco, all of such means relying on oral (or nasal) absorption of nicotine through the mucous membrane. However, because of the taste and other sensory effects of tobacco, such a manner of satisfying the nicotine habit is acceptable to only a very limited number of persons. Moreover, these habits still require the utilization of tobacco, and such use remains a problem especially for people with gum, mouth or throat problems as a result of long-term tobacco chewing or snuff "dipping" and who are unable to quit.

With regard to the nicotine gum referred to above, it has produced mouth ulcers in a number of individuals resulting in its rejection. In addition, the nicotine gum produces some gastric absorption with the resultant first pass through the liver and consequent rapid loss of activity. Moreover, people with artificial teeth have difficulty with gum in general; this is important as many people who experience the medical problems associated with years of smoking also tend to have generally poor dental hygiene and/or dental quality, and may also have artificial teeth.

Nicotine itself has been subjected to considerable study. Nicotine is a liquid alkaloid which is colorless, volatile and strongly alkaline. On exposure to air it turns brown. It is known to be very lipid soluble. The Merck

Index, 9th Edition, 1976, page 847, indicates that nicotine base is readily absorbed through mucous membrane and intact skin, but the salts are not. On the other hand, nicotine has no known therapeutic application (The Pharmacological Basis of Therapeutics, fifth edition, Goodman and Gilman, 1970, page 588) and has been primarily used in research as an experimental tool for investigating neural function.

It is known in the art to incorporate nicotine into lozenges and chewing gum so as to provide for a means of dispensing nicotine into a person's system so as to overcome the urge to smoke. However, such chewing gums and lozenges, such as described in published French Patent Application No. 2 608 156 can cause nausea in the person using such gums and/or lozenges due to the ingestion of nicotine into the stomach and other portions of the digestive tract.

It has been proposed that a nicotine-containing lozenge be compounded with lactose (or a lactose-containing substance), a known antidote to nicotine poisoning and the unpleasant nausea and discomforts associated with nicotine ingestion, such as described in published European Patent Application No. 0 251 642.

However, in all cases of nicotine-containing lozenges and/or chewing gums, it is believed that a large portion of the nicotine is not effectively absorbed into the blood stream, thereby reducing to a certain degree the beneficial effect of smoking urge suppression sought to be achieved. At the same time, the necessary carriers in lozenges and chewing gums, i.e. those comprised of sugars and like substances, have a tendency to promote dental decay in the nature of dental caries, particularly in the interproximal surfaces of the teeth.

In Etscorn, United States Patent No. 4,597,961, there is described a method of transcutaneous application of nicotine through the use of an occlusive pad so that the

nicotine is administered transdermally. The occlusive pad described therein is intended solely for external application.

None of the foregoing patents mention or suggest the application of nicotine to dental floss, nor the use of such nicotine-containing dental floss in the suppression of the urge to smoke.

Flossing of the teeth is known in the art to help remove plaque from the tooth surface. Further, it is known in the art to apply dentrifice medicaments to dental floss. For example, Lynch, United States Patent Nos. 4,632,937 and 4,627,975, discloses coating dental floss with a solution of a dentrifice formulation containing monoalkyl and dialkyl ethers of dianhydrohexitols, which is said to be effective in the treatment of oral surfaces and cavities to reduce irritation and plaque accumulation caused by the action of bacteria.

Similarly, Newman et al., United States Patent No. 4,548,219, disclose a fluoride-coated dental floss which has bactericidal activity; and Tarrson et al., United States Patent No. 4,162,688, disclose fluoride medicated dental floss and a dispenser for the wet application of fluoride to floss.

Cousse et al., United States Patent No. 4,098,879, disclose impregnating dental floss with fluoride salts of certain pyridine compounds, alone or in combination with ethyl-3-nicotinate hydrofluoride or Vitamin B, as inhibiting dental plaque.

However, none of the prior art relating to dental floss describe treating the floss with nicotine and the advantages of employing dental floss in aiding individuals to quit smoking.

Surprisingly, applicant has found that by providing a nicotine-treated dental floss there is provided an article of manufacture which produces both a beneficial periodontal effect and aids in alleviating an individual's urge to engage in tobacco smoking.

The use of oral hygiene compositions is known in the art to have a beneficial effect in the prophylaxis and treatment of inflammatory diseases of the periodontium.

Hofmann et al., United States Patent No. 3,992,519, describe an oral hygiene composition in toothpaste, mouthwash or chewing gum form comprising an antibacterial component, a vitamin component and a surfactant component.

However, none of the prior art teach an oral hygiene composition containing nicotine and the advantages of employing a nicotine-containing oral hygiene composition in aiding individuals to quit smoking.

Surprisingly, applicant has found that by providing a nicotine-containing oral hygiene composition there is provided a novel composition which produces both a beneficial periodontal effect and aids in alleviating an individual's urge to engage in tobacco smoking.

Also known in the art are a wide variety of toothbrushes having storage chambers for the retention of and, ultimately, for the application of, cleansing agents to the tooth surface.

For example, Muglia, United States Patent No. 3,592,551, discloses an aerosol charged toothbrush. Other disclosures of toothbrushes having storage chambers include, inter alia, Eguchi, United States Patent No. 4,963,046; Dahl et al., United States Patent No. 3,879,139; Broughton, United States Patent No. 3,937,235; Meyer et al., United States Patent No. 4,068,974; Rodriguez, United States Patent No. 4,332,497; and Green, United States Patent No. 4,522,524.

However, all of these disclosures are directed to the application of cleansing agents to the tooth surface with what can be accurately described as an abrasive-type mechanism through the use of a bristle head and do not teach the application of, nor are useful for (due to their abrasive nature) the application of a nicotine-containing oral hygiene composition to the gum surface.

Creed, United States Patent No. 4,863,380 describes a gum-treating method and device which allows an antibacterial treating solution to be injected into contact with the gums between the teeth by employing a device with a conical hollow rubber tipped head.

Surprisingly, applicant has found that by employing an applicator having a bristleless head, preferably in the nature of a pad, and more preferably also having a storage chamber, there is provided a novel article of manufacture which can be employed to apply a nicotine-containing oral hygiene composition to the gum surface which produces both a beneficial periodontal effect and aids in alleviating an individual's urge to engage in tobacco smoking. As used herein, the term "bristleless" refers to a head of the claimed toothbrush which is substantially free of bristles which are perpendicular, or substantially perpendicular, to the neck and/or handle of the toothbrush, and which have an aspect ratio (length to diameter) of greater than about 12.5. For example, a typical toothbrush contains bristles ranging from about .25 in. to about .50 in. in length and the bristles each have a diameter of about 0.02 in. giving an aspect ratio of about 12.5 to about 25. For example, the Butler 411 toothbrush has 42 bundles of 35 bristles, each bristle being .016 inches in diameter and 0.5 inches long giving an aspect ratio of 31.5.

SUMMARY OF THE INVENTION

It is, accordingly, an object of the present invention to overcome problems in the prior art, such as indicated above.

It is another object of the present invention to administer nicotine through the mouth using a delivery system comprised of nicotine-containing dental floss, a nicotine-containing oral hygiene composition, alone or in combination with or through the use of an applicator of the present invention, for the purpose of satisfying a nicotine habit

while minimizing or eliminating side effects caused by absorbing nicotine through the lungs along with products of combustion of tobacco, or through the digestive tract.

It is a further object of the present invention to provide a new method of assisting persons to break the habit of smoking tobacco or the use of any tobacco product, while at the same time providing for the beneficial effects of frequent dental flossing, toothbrushing, mouthwashing (rinsing) and/or gum massaging.

It is still another object of the present invention to provide a nicotine delivery system comprised of nicotine-containing dental floss, or a nicotine-containing oral hygiene composition, alone, or in combination with or through the use of an applicator of the present invention.

In one aspect of the present invention these and other objects of the invention are broadly achieved by providing a source of nicotine, i.e., nicotine, a nicotine derivative and/or a nicotine-containing compound, to a monofilament dental floss, multifilament dental floss or the like, whereby the source of nicotine is applied to the oral cavity, preferably to the periodontal areas, and permitted to enter the body.

In another aspect of the present invention, the objects of the invention are broadly achieved by providing an oral hygiene composition containing a source of nicotine, i.e., nicotine, a nicotine derivative and/or a nicotine-containing compound, such as a toothpaste, a tooth gel, a tooth powder, a mouthwash or the like, whereby the source of nicotine is applied to the oral cavity, preferably the periodontal areas, and permitted to enter the body.

In still another aspect of the present invention, the objects of the invention are broadly achieved by providing a nicotine-delivery system comprised of a nicotine-containing oral hygiene composition in combination with or through the use of an applicator.

Under such conditions of oral application as described above with respect to the present invention, the nicotine, being highly lipid soluble, is absorbed directly and rapidly through the oral tissues thereby satisfying the nicotine habit while minimizing or eliminating side effects which would otherwise be caused when absorbing nicotine through the lungs along with products of combustion, or through the digestive tract.

Such a delivery system, as mentioned below, can assist a person to quit smoking, and at the same time help to counter any possible deleterious dental effects, particularly deleterious periodontal effects, which often accompany long-term oral use of tobacco products.

A nicotine-containing dental floss, nicotine-containing oral hygiene composition, alone, or in combination with, or through the use of, an applicator of the present invention, may be used to supply the smoker with an alternate source of nicotine, for example, in the dose range of from 15 to 25 nanograms per liter of blood, so that the need for cigarettes is reduced or eliminated. Using such a mode of administration provides a number of beneficial results as follows:

1. An improved system becomes available to aid motivated smokers in eliminating their cigarette addiction. Numerous potent non-pharmacological factors which help maintain the cigarette addiction are the rituals involved with the act of smoking, including the sight of a pack of cigarettes, the smell, the taste, etc. These previously neutral cues acquire powerful reinforcing properties as a result of prolonged association with nicotine. Practice of the present system, however, assists in extinguishing these addiction-maintaining cues by supplying nicotine in the absence of such cues.

Indeed, a plurality of extinguishing techniques can be utilized in association with the present invention. Thus,

instead of completely substituting the technique of the instant invention for smoking, an interspersing regimen can be adopted wherein the nicotine-containing dental floss, oral hygiene composition and/or nicotine-delivering applicator according to the invention may be alternated with cigarettes to slowly extinguish the reinforcing properties of the non-pharmacological factors, and also reduce the severity of the initial termination of smoking as well as the incidence of relapse. As the non-pharmacological factors become reduced in importance, it then becomes easier to treat the nicotine addiction.

2. Patients with disorders such as emphysema, cardiac problems or lung cancer and who are unable to quit smoking thus exacerbating their medical problems, are able to satisfy their nicotine habit while sparing themselves further damage from the tars and carbon monoxides in tobacco smoke.

3. Nicotine absorbed through oral cavity, and particularly through the periodontal tissues, is not transported first through the liver where 80-90 percent of nicotine deactivation occurs, but goes directly and rapidly into systemic circulation with rapid rises in nicotine blood level. Thus, the nicotine habit can be satisfied while subjecting the body to far lesser quantities of nicotine.

Using the present system, blood levels of nicotine can be easily adjusted to acceptable and effective dosages for the suppression of craving by varying the amount and duration of nicotine delivery. This is difficult if not possible to accomplish with nicotine gums, or nicotine lozenges, because the person's rate of chewing is a major factor which manipulates dosage.

5. People with gum, mouth and throat problems, as a result of long-term tobacco chewing or snuff "dipping" and who are unable to quit, are aided in giving up their habits with the use of the nicotine-containing dental floss oral hygiene composition and/or nicotine-delivering applicator, and,

further, the regular use of floss, brushing, rinsing or gum massaging is known to alleviate or lessen many gum and/or periodontal problems.

6. Other advantages compared to nicotine-containing gum include obviating the problems of mouth ulcers in some individuals; reduction of nicotine taste as a secondary reinforcer; provision of a less conspicuous form of nicotine consumption (a short period of dental flossing, use of an oral hygiene composition and/or nicotine-delivering applicator is much less conspicuous than gum chewing); usability by those who reject gum on the basis of taste and some denture wearers who cannot chew gum; and provision of an alternate mode of nicotine administration. In this latter respect, even if the use of nicotine-containing dental floss or oral hygiene composition is only equal in effectiveness to nicotine gum for many persons, this will provide a further method of reducing smoking dependence, it being known in the field that different techniques work better for different individuals.

7. In the event that the subject of the instant invention becomes available over-the-counter (as are cigarettes, snuff, chewing tobacco, etc.), the instant invention will provide a means for those, unable or unwilling to quit smoking, to ingest nicotine without subjecting themselves and their environment to smoking with its attendant dangers of carbon monoxide and tars. As is now well-established, "second hand" smoke is recognized as a significant health hazard in our society, and may cost the economy hundreds of millions of dollars a year in lost productivity, medical costs and related expenses.

Use of the present invention would also allow ingestion of nicotine in places where smoking is prohibited, to avoid the consequences of performance decrements resulting from acute withdrawals. Moreover, for women unable to quit smoking during pregnancy, the use of nicotine-containing dental floss or oral hygiene composition would at least

eliminate carbon monoxide, thereby avoiding the deleterious effects of smoking on the fetus due to the blocking effects of carbon monoxide on oxygen absorption.

BRIEF DESCRIPTION OF THE DRAWING

FIG. 1 depicts a gingiva-massaging device useful in the practice of the present invention.

DETAILED DESCRIPTION OF THE PRESENT INVENTION

To attain the objects of the present invention, there is provided dental floss which is treated with, or an oral hygiene composition which contains a source of nicotine, e.g., nicotine (or 3-(1-methyl-2-pyrrolidinyl)pyridine), a pharmacologically active derivative thereof, or a nicotine or nicotine derivative-containing compound, alone or in combination with a pharmaceutically acceptable carrier, which is useful in the alleviation of an individual's urge to smoke tobacco and in the prophylaxis of periodontal disease.

Many methods of treating the dental floss are contemplated by the present invention. It is only necessary that the treatment method provide a substantially uniform dispersal of a source of nicotine, such as nicotine, nicotine derivative, or nicotine- or nicotine derivative-containing compound on the surface of, or impregnated into, the dental floss. The dental floss can be of varying configuration, including mono-filament and multi-filament design, according to end use. In this manner, it is believed, although the inventor does not wish to be bound by any particular theory, that while flossing the nicotine dispersed on the surface, or into the body, of the dental floss, is released into the mouth of the individual and subsequently is rapidly absorbed through the gums and into the bloodstream, thereby providing quick relief from the urge to smoke.

Dosage and duration of nicotine administration according to the present invention can be controlled in several ways separately and/or in combination.

In general, a carrier can be mixed with the nicotine which will either speed or slow its passage through the oral tissues and into the bloodstream. The thickness of the dental floss diameter of a monofilament dental floss, or the number of strands and/or thickness of the strands of multifilament dental floss can be varied to either increase or decrease the amount of nicotine available to be transferred from the dental floss to the oral tissues. The concentration of nicotine in the dental floss can be either decreased or increased in order to reduce or increase the duration or effect of treatment or the amount of dosing.

In general, no additive is necessary to assist in the administration of nicotine because nicotine base is very highly lipid soluble and is quickly and completely absorbed into the systemic circulation. However, should it be desirable to increase or decrease the rate of penetration, then the nicotine base can be carried by a suitable solvent such as propylene glycol, glycerin, mineral oil, polyethylene glycol, DMSO or alcohol. It may also be mixed with water in which the alkaloid is readily soluble, thereby forming a water soluble salt; such a salt, however, is less lipid soluble and penetrates the oral tissues more slowly than the alkaloid base.

It may be desirable to add a carrier which will slow absorption in view of the fact that nicotine is highly toxic. In this way, the nicotine may be diluted to reduce dangers of misuse; for example, the nicotine may be mixed with an oil such as indicated above. Other types of fillers may be utilized as well; for example, the nicotine may be retained in a gelatinous base.

Using nicotine-containing dental floss to effect nicotine delivery while varying the type of dental floss delivering the nicotine, varying the concentration of the nicotine, varying the carrier (if any) for the nicotine, varying the quantity of nicotine, and/or varying manner in

which the nicotine is retained, the dose and duration of nicotine administration are precisely controllable. Also, the total dosage and delivery rate can easily be adjusted to suit the needs of the particular patient, i.e. a different dose of nicotine will be desirable to reduce the craving of a one pack-a-day smoker versus a three pack-a-day smoker. According to the present invention, it is possible to mimic smoking in terms of the amount of nicotine delivered, thereby reducing or eliminating dependence on any form of tobacco.

In the practice of the present invention, the source of nicotine, e.g., nicotine, nicotine derivative or nicotine-containing compound, such as nicotine oil, available commercially, may be used alone, or is dissolved in an orally acceptable carrier to form a nicotine-containing mixture. The mixture is stirred to substantially uniformly disperse the nicotine, nicotine derivative or nicotine-containing compound throughout the mixture. Preferred orally acceptable carriers are selected from the group comprising water, alcohols such as ethanol, propylene glycol, waxes such as polyethylene glycol (sold under the trademark "CARBOWAX" by Challenge Products of Osage Beach, Mo.), glycerol, and sugar solutions.

It is further contemplated by the present invention to add effective amounts of anticariogenic fluoride compositions to the mixture. Suitable fluoride compositions are alkali or alkaline earth metal fluorides such as sodium fluoride, sodium monofluorophosphate, ammonium fluoride, n-alkyl-3-pyridinium methanol fluoride as described in United States Patent No. 4,098,879; and stannous fluoride as described in United States Patent No. 4,548,219.

To the mixture may also be added dyes and flavorings such as cherry or orange flavor and oil of wintergreen and the like. Other additives such as medicaments, astringents, detergents, polishing agents, sweeteners, gelling agents, thickeners, pigments and other antibacterial agents, such as those known to persons skilled in the art may be added to the

nicotine-mixture in amounts sufficient to impart their particular characteristic.

The string of floss, waxed or unwaxed, as commercially available, such as from John O. Butler Company of Chicago, IL is allowed to come into contact with the mixture containing the source of nicotine, such as by soaking or drawing the string through the solution using an apparatus designed for that purpose. The mixture containing the source of nicotine can be used as soaked or drawn, or is allowed to air dry and solidify in, or on the surface of, the floss. The preferred treated floss has a coating comprising from about 0.1 to about 0.8 mg of nicotine per inch of dental floss.

Many types of oral hygiene compositions are contemplated by the present invention. Preferred are toothpastes, tooth gels, toothpowders and mouthwashes. It is only necessary that the oral hygiene composition contains an effective amount of nicotine to satisfy the user's craving for nicotine. Dosage of nicotine administration may be controlled as described hereinabove with respect to dental floss.

In the case of a mouthwash, the liquid vehicle is preferably one in which nicotine is readily soluble. Suitable for this purpose include aqueous ethanol, aqueous isopropanol, aqueous n-propanol, aqueous sorbitol, aqueous glycerol, aqueous 1,2-propyleneglycol, aqueous 1,4-butanediol and mixtures of any of the foregoing. The liquid vehicle may further comprise flavoring agents, sweeteners, dyestuffs, thickeners, antioxidants, mixtures of any of the foregoing and the like. It is further contemplated that an orally acceptable antibacterial agent be included. These are well known to those skilled in the art and may comprise esters of p-hydroxybenzoic acid and/or o-hydroxybenzoic and such pharmaceutically acceptable as menthyl salicylate or phenyl salicylate.

Typical flavoring agents include peppermint oil, spearmint oil, wintergreen oil, aniseed oil, clove oil,

eucalyptus oil, cinnamon oil, geranium oil, coriander oil, menthol, anisol, anethole and mixtures of any of the foregoing. Preferred sweeteners are sodium saccharine, and sodium cyclamate and "NUTRASWEET".

In addition, the oral hygiene composition may include pharmaceutically effective amounts of anticariogenic fluoride components such as those known to those skilled in the art including alkali or alkaline earth metal (e.g. sodium or stannous) and ammonium fluorides and flourophosphates and n-alkyl-3-pyridinium methanol fluoride. Especially preferred are sodium monofluorophosphate and stannous fluoride.

In the case of a toothpaste, tooth powder or tooth gel, any pharmaceutically suitable paste, gel or powder carrier may be employed. These are well known to those skilled in the art. It is only necessary that the carrier contain an effective amount of a source of nicotine to satisfy the user's craving for nicotine.

Preferably the carrier also contains a cleansing agent such as a dentrifice which normally takes the form of a liquid, paste or powder. It is also known to those skilled in the art to employ a mild abrasive and various pharmaceutical ingredients conducive to cleaning teeth, as well as flavoring agents, sweeteners, dyestuffs, thickeners, antioxidants, mixtures of any of the foregoing and the like. These are described more fully hereinabove.

The present invention is further directed to a nicotine-delivering gingiva massaging article of manufacture. The device allows a nicotine-containing treatment fluid to come into contact with the gums. The device is a hand held unit having a handle, preferably with a reservoir contained therein, in communication with a neck, which is preferably hollow. Integral with the neck is a bristleless head of the device, as heretofore described, which may be in the form of a gingiva massaging pad attached to the surface of the head. The device also preferably further contains a check valve to

prevent fluid in the mouth from entering through the head and into the neck. Applying pressure by a pressure applying means to the reservoir expels the nicotine-containing treatment fluid from the reservoir through the neck, into the bristleless head, and into contact with the gums. The nicotine is thus absorbed into the body, as described hereinabove. In especially preferred embodiments, the device is provided in "single dose" configuration, i.e., in the nature of a disposable device which contains sufficient treatment solution to effect or mimic the dose of nicotine provided by a single cigarette, or in the nature of a non-disposable device in which the reservoir is refillable but can only contain an amount of treatment solution to effect or mimic the dose of nicotine provided by a single cigarette. This offers the advantages of reduced size, elimination of concerns regarding contamination of the treatment solution by mouth fluids and reduction or elimination of the possibility of misuse or overdosing.

In a preferred embodiment, referring to FIG. 1, the nicotine-delivering gingiva massaging device 2 comprises a handle section 4, a neck section 6 and a head section 8. The handle section 4 has contained therein a reservoir 12 adapted for containing a nicotine-treatment fluid. Preferably the sidewalls 10 of the reservoir 12 comprise a flexible resilient material. The user may squeeze the sidewalls 10 causing the reservoir 12 to contract to a contracted state of lesser volume, thereby forcing the nicotine-containing treatment fluid to be forced out of the reservoir 12 and eventually into gingiva massaging pad 20 as described more fully hereinbelow. When released, the resiliency of the sidewalls 10 returns them to their natural state, as shown in FIG. 1.

A check valve 22 is located covering a vent hole 24 that extends through the sidewall 10 near the top. The vent hole 24 allows air to flow into reservoir 12 when it is expanded back to its natural state. The check valve 22

prevents air or fluid from passing through the vent hole 24 when reservoir 12 is squeezed. The check valve 22 may be of various types known to those skilled in the art, and is shown in FIG. 1 as a flexible flap.

The handle section 4 also comprises a solid portion 14 which is joined to reservoir 12. The cross-section of solid portion 14 is sufficiently small so that it will fit into a conventional toothbrush holder. Further, the solid portion 14 is detachable from reservoir 12, thus enabling the user access to the reservoir 12 for refilling, cleaning or emptying purposes. Preferably, the solid portion 14 screws or snaps on to the reservoir forming a substantially air tight seal in a conventional manner as known to those skilled in the art.

The neck 6 is a rigid plastic member integrally attached to the handle 4 at the end opposite the solid handle portion 14. The neck has a narrow channel 16 contained therein in direct communication with reservoir 12. The neck 6 generally has a tapering cross-section which ends in the head 8. Further, a check valve 26 is located in the neck 6 at the base of the head 8. The check valve 26 allows fluid to flow out from the neck channel 16 into the head 8, but prevents any flow in the reverse direction. The check valve 26, similar to the check valve 22, is preferably a flexible flap.

The head 8 is a rigid plastic member integrally connected to the neck 6 and the channel 16 continues therethrough. The channel 16 is in direct communication with a duct 18 which opens into an absorbent gingiva massaging pad 20. The gingiva massaging pad 20 is generally comprised of a spongy porous material through which the nicotine-containing treatment fluid may pass, and which is suitable for gingiva massaging. Preferred is a foam rubber material, but the pad may similarly be, inter alia, an interwoven pad of elastomeric, e.g., polypropylene fibers, or comprised of

bristleless fibers, i.e. those which have an aspect ratio of less than about 10.

In a preferred mode of operation, the user detaches the solid portion 14 and fills the reservoir 12 with a "single dose" of nicotine-containing treatment fluid, and reattaches the solid portion 14. The user then places the gingiva-massaging pad 20 on the gums and gently massages the gums by moving the pad 20 back and forth while simultaneously applying pressure to the sidewalls 10. This expels treatment fluid out of the reservoir and into pad 20, whereby the treatment fluid comes into contact with the gums. The user continues massaging the gums until the user's craving for nicotine has subsided or until the "single dose" is used up.

Check valve 22 prevents any treatment fluid from flowing out vent hole 24 when the sidewalls 10 are squeezed. Further check valve 22 allows air to be drawn into the reservoir 12 when squeezing pressure is released to allow the sidewalls 10 to return to their normal shape. The check valve 26 prevents any suction created by the return of sidewalls 10 to their normal state from drawing any fluid back into the neck 6. This avoids contaminating or diluting any remaining fluid in the reservoir 12 with fluid from the mouth. The check valve 22 also reduces suction at the entrance of the duct 18 by admitting air to the reservoir 12 when the sidewalls 10 return to their natural state. If the reservoir 12 still contains treatment fluid after the user has treated the gums, the user may retain it in the reservoir 12 for later use.

The nicotine-containing treatment fluid may comprise any relatively low viscosity orally acceptable carrier solution containing a source of nicotine, such as nicotine, nicotine-containing compound or a nicotine-derivative. Preferred fluid carriers are the mouthwash or the dental floss solution described hereinabove.

It is further contemplated that a variety of other treatment fluid delivery means can be employed, such as an aerosol charged delivery system. These are describe in the literature and are well-known to those skilled in the art.

The dental floss, oral hygiene composition or treatment fluid of the present invention preferably comprises sufficient nicotine so that one flossing, brushing, rinsing or application is substantially equivalent to the amount of nicotine released into the bloodstream by smoking a single cigarette. Preferably, one flossing, brushing, rinsing or application comprises the release of from about 0.5 to about 2.0 mg nicotine, more preferably from about 0.7 to about 1.5 mg nicotine, and most preferably from about 1.0 to about 1.2 mg nicotine. Marlboro 100's, for example, are reported to contain 1.2 mg nicotine average per cigarette.

The individual desirous of quitting smoking need only floss, brush, rinse or apply the treating solution in a normal manner with the nicotine-treated dental floss, nicotine containing oral hygiene composition or nicotine-containing treatment fluid of the present invention to alleviate the urge to smoke. Preferably, the individual will floss, rinse, brush or apply the treatment fluid once each in the morning and evening and at times where pangs to smoke occur during the day. In a preferred method of treatment, the individual will gradually reduce the number of daily flossing, brushings, rinses or gingiva applications until the cravings disappear.

Additionally, the flossing, brushing, rinsing and gingiva applications have the beneficial effect of providing a prophylaxis of periodontal disease by aiding in the removal of plaque from the teeth and massaging of the gingiva. Thus, the present invention surprisingly succeeds in turning a bad habit, tobacco smoking, into the good habits of flossing, brushing, rinsing and gingiva massaging, which are likely to continue even when the individual has no more smoking cravings.

The above-mentioned patents are hereby incorporated by reference.

Many variations of the present invention will suggest themselves to those skilled in the art in light of the above-detailed description. For example, any nicotine-containing compound may be employed. Further, the floss employed may be of any type, waxed or unwaxed. All such obvious modifications are within the full intended scope of the appended claims.

CLAIMS:

1. An article of manufacture comprising dental floss having a substantially uniformly dispersed amount of nicotine, a nicotine derivative or nicotine-containing compound.

2. A process of manufacturing a nicotine-containing dental floss comprising:

(a) dissolving or suspending nicotine, a nicotine derivative or nicotine-containing compound in an orally acceptable carrier to form a nicotine-containing mixture; and

(b) applying the mixture obtained in (a) to dental floss.

3. A method of alleviating the urge to engage in tobacco smoking comprising flossing the teeth with an article of manufacture comprised of dental floss having a substantially uniformly dispersed amount of nicotine, a nicotine derivative or a nicotine-containing compound.

4. An oral hygiene composition comprising:

(a) an effective amount of a source of nicotine selected from the group consisting of nicotine, nicotine derivative or nicotine-containing compound; and

(b) an orally acceptable liquid, paste, gel, or powder carrier.

5. An oral hygiene composition as defined in Claim 4, wherein said component (b) comprises a mouthwash.

6. An oral hygiene composition as defined in Claim 5 wherein said mouthwash comprises a liquid vehicle selected from the group consisting of aqueous ethanol, aqueous isopropanol, aqueous n-propanol, aqueous sorbitol, aqueous glycerol, aqueous 1,2-propylene glycol, aqueous 1,4-butanediol and mixtures of any of the foregoing.

7. An oral hygiene composition as defined in Claim 5 wherein said mouthwash further comprises a flavoring agent.

8. An oral hygiene composition as defined in Claim 5 wherein said mouthwash further comprises a sweetener.

9. An oral hygiene composition as defined in Claim 5 which further comprises

(c) an effective amount of an anticariogenic fluoride compound.

10. An oral hygiene composition as defined in Claim 9 wherein said anticariogenic fluoride compound is selected from the group consisting of sodium monofluorophosphate, sodium fluoride and stannous fluoride.

11. An oral hygiene composition as defined in Claim 4 wherein said component (b) comprises a toothpaste, tooth gel, or tooth powder.

12. An oral hygiene composition as defined in Claim 11 wherein said component (b) further comprises an orally acceptable mild abrasive.

13. An oral hygiene composition as defined in Claim 11 wherein said component (b) further comprises a dentrifice cleansing agent.

14. An oral hygiene composition as defined in Claim 11 which further comprises:

(c) an effective amount of an anticariogenic fluoride compound.

15. An oral hygiene composition as defined in Claim 14 wherein said anticariogenic fluoride compound is selected from the group consisting of sodium monofluoro-phosphate, sodium fluoride and stannous fluoride.

16. An oral hygiene composition as defined in Claim 11 wherein said composition further comprises an additive selected from the group consisting of flavoring agents, sweeteners, dyestuffs, thickeners, antioxidants and mixtures of any of the foregoing.

17. A hand-held nicotine-delivering gingiva-massaging article comprising:

(a) a handle having a reservoir contained therein, said reservoir adapted for containing a nicotine-containing treatment solution;

(b) means for applying pressure to said reservoir;

(c) a neck having a narrow channel contained therein, said channel in communication with said reservoir; and

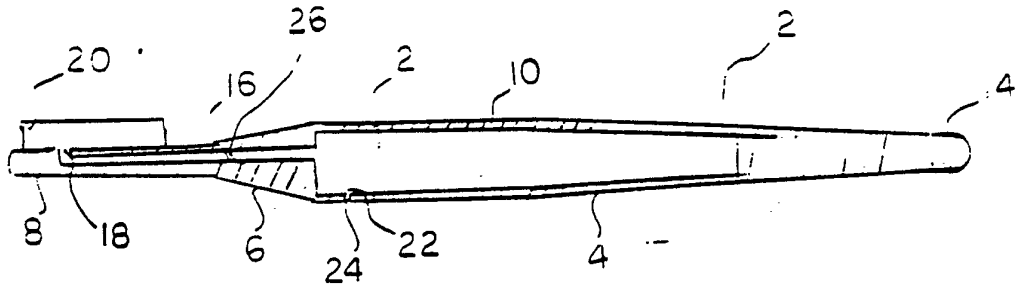
(d) a head comprising

(i) a narrow channel contained therein in communication with said neck channel;

(ii) a duct in direct communication with said head channel, leading to the surface of the head; and

(iii) a bristleless gingiva-massaging means integral with the head and in direct communication with said duct.

FIG. 1



INTERNATIONAL SEARCH REPORT

International Application No. PCT/US91/09363

I. CLASSIFICATION OF SUBJECT MATTER (if several classification symbols apply, indicate all) [6]

According to International Patent Classification (IPC) or to both National Classification and IPC

IPC(5): A61C 15/00, A24F 47/00

U.S. CL: 132/321, 329, 131/270

II. FIELDS SEARCHED

Minimum Documentation Searched [7]

Classification System	Classification Symbols
U. S.	131/270 132/321,329 514/813,343, 424/412

Documentation Searched other than Minimum Documentation to the Extent that such Documents are Included in the Fields Searched [8]

III. DOCUMENTS CONSIDERED TO BE RELEVANT [9]

Category *	Citation of Document, [11] with indication, where appropriate, of the relevant passages [12]	Relevant to Claim No. [13]
A	US, A, 4,971,079 (TALAPIN ET. AL.) 20 NOVEMBER 1990 See the entire document.	1-3
A	US, A, 4,867,181 (SMOLKO) 19 SEPTEMBER 1989 See the entire document.	1 & 3
A	US, A, 4,736,755 (OLDHAN ET. AL.) 12 APRIL 1988 See the entire document.	2
A	US, A, 4,638,823 (NEWMAN ET. AL.) 27 JANUARY 1987 See the entire document.	1-3
A	US, A, 4,276,890 (FISCHERA) 07 JULY 1981 See the entire document.	1-3
A	US, A, 3,699,979 (MUHLER ET. AL.) 24 OCTOBER 1972 See the entire document.	1-3
A	US, A, 656,479 (SCHELLENBACH) 21 AUGUST 1900 See the entire document.	1-3

* Special categories of cited documents: [10]

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

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

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

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

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

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

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

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

"&" document member of the same patent family

IV. CERTIFICATION

Date of the Actual Completion of the International Search

03 MARCH 1992

Date of Mailing of this International Search Report

08 APR 1992

International Searching Authority

ISA/US

Signature of Authorized Officer

CINDY A. CHERICHETTI

FURTHER INFORMATION CONTINUED FROM THE SECOND SHEET

A	US, A, 656,479 (SCHELLENBACH) 21 AUGUST 1990 See the entire document.	1-3

V. ☐ OBSERVATIONS WHERE CERTAIN CLAIMS WERE FOUND UNSEARCHABLE [1]

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

1. ☐ Claim numbers , because they relate to subject matter [2] not required to be searched by this Authority, namely:

2. ☐ Claim numbers , because they relate to parts of the international application that do not comply with the prescribed requirements to such an extent that no meaningful international search can be carried out [3], specifically:

3. ☐ Claim numbers_____, because they are dependent claims not drafted in accordance with the second and third sentences of PCT Rule 6.4(a).

VI. ☒ OBSERVATIONS WHERE UNITY OF INVENTION IS LACKING [4]

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

I. Claims 1-3 drawn to dental floss, method of making and method of use.
II. Claims 4-16 drawn to an oral hygiene composition.
III. Claim 17 drawn to a gingiva massaging articule.

1. ☐ As all required additional search fees were timely paid by the applicant, this international search report covers all searchable claims of the international application.

2. ☐ As only some of the required additional search fees were timely paid by the applicant, this international search report covers only those claims of the international application for which fees were paid, specifically claims:

3. ☒ No required additional search fees were timely paid by the applicant. Consequently, this international search report is restricted to the invention first mentioned in the claims; it is covered by claim numbers:

1-3

4. ☐ As all searchable claims could be searched without effort justifying an additional fee, the International Searching Authority did not invite payment of any additional fee.

Remark on Protest

☐ The additional search fees were accompanied by applicant's protest.

☐ No protest accompanied the payment of additional search fees.