

**CONTINUOUSLY SEALING ONE WAY VALVE ASSEMBLY AND FLUID
DELIVERY SYSTEM AND FORMULATIONS FOR USE THEREIN**

CROSS-REFERENCE TO RELATED APPLICATIONS

This application claims priority to U.S. Patent Application Serial No. 11/267,868, filed November 3, 2005, and U.S. Provisional Patent Application Serial No. 60/823,462, filed August 24, 2006, each of which are incorporated by reference herein in their entirety.

FIELD OF THE INVENTION

The present invention is directed to a dispensing and delivery system including a continuously sealing one way valve assembly for dispensing a sterile flowable substance, which can include preservatives or be preservative free, while preventing a backflow of contaminants into the source of the flowable substance. The dispensing and delivery system includes, for example, a valve assembly enclosed by a pressure displaceable flexible member or elastomeric member for effecting the passage of the flowable substance to a controllable outlet, while preventing any backflow to the source of the flowable substance after dispensing individual portions or doses of the flowable substance.

BACKGROUND INFORMATION

In the past, to maintain the flowable substance free of contaminants, preservatives have been mixed in with the flowable substance in the reservoir from which it is to be dispensed. The use of preservatives tends to be detrimental to users and often limits the effectiveness of the flowable substance, particularly when the flowable substance is a pharmaceutical such as an eye care solution, an intranasal drug, cosmetic treatment or skin treatment product. This group of prescription and nonprescription medications are often formulated with preservatives in multi-dose formats. The flowable substance may also be a food stuff, a beverage, a nutraceutical or cosmeceutical product.

Another consideration is the ability of the valve assembly to deliver a selected amount of the flowable substance to the outlet without causing any damage to the user, such as when applying an eye care solution directly into the eye.

In the past, flexible membranes have been used to control the flow of the flowable substance to the valve assembly outlet while preventing any backflow to the source of the flowable substance. However such valves, such as the valve described in U.S. Patent No. RE34,243, which is incorporated by reference herein in its entirety, describe the use of O-rings in conjunction with a uniformly thick flexible membrane to effect a seal. Other valve assemblies also used cylindrical parts which required, for example, sliding the pretensioned flexible membrane over the straight sided core during assembly, preventing automated high speed assembly. Therefore, an effectively designed valve assembly which was able to be manufactured, for example via high speed automated production, and limited the costs of manufacture by reducing component parts and allowing the use of high speed automated production, was not provided in the past.

SUMMARY OF THE INVENTION

According to an exemplary embodiment of the present invention, a dispensing and delivery system conveys a flowable substance from a closed source, such as a collapsible reservoir, while preventing any backflow of oxygen or other contaminants from the ambient atmosphere through the valve assembly and into the source of the flowable substance after a portion of the substance has been dispensed.

The collapsible reservoir can be, for example, a bellows type reservoir, a collapsible tube, an internal bag or other type of suitable reservoir designed to dispense practically all of its contents. According to an exemplary embodiment of the present invention, the dispensing delivery system has a normally closed controllable outlet orifice for dispensing a controlled amount of the flowable substance out of the valve assembly. The

reservoir is in sealed contact with the valve assembly so that its contents do not receive any contaminants when the flowable substance is dispensed.

Dispensation of the flowable substance is effected by applying pressure to a reservoir directly or through a pump so that its contents flow to and through the valve assembly. The contents may be, for example, a pharmaceutical, such as an eye care solution or other substance which is to be kept free of contaminants during dispensing. According to an exemplary embodiment of the present invention, a multiple number of dispensed amounts can be provided while keeping the undispensed flowable substance preservative-free. Other flowable substances which are preservative-free can be food stuffs, juices or beverages, cosmetics, or other flowable substances intended to be maintained free of preservatives and contaminants, notwithstanding multiple uses of the dispenser delivery system. The flowable substance reservoir is protected by a housing so that pressure is not accidentally applied.

The valve assembly includes, for example, an axially extending structure open to the dispenser or reservoir of the flowable substance. The valve assembly can be formed of an axially extending inner core open to the reservoir and formed of a rigid plastic component. The interior of the core can have a passageway for receiving the flowable substance from the reservoir. At least one port extending from the passageway can be provided and affords an opening for conveying the flow substance out of the inner core. The inner core can be designed with a substantially tapered or substantially conical shape.

An axially extending flexible membrane tightly encloses the inner core and covers the outlet end of the port through the inner core. The flexible membrane moves outwardly from the inner core when the flowable substance is pressurized and passes through the port and flows toward the outlet end of the flexible membrane. The flexible membrane is structured such that it is, for example, thicker at the end closest to the valve opening, e.g. the flexible membrane is not uniformly thick along its length. This thickness allows the valve to

seal at the thicker end first. Alternatively, even if the membrane was of uniform thickness, the elasticity of the membrane can be varied so that the portion of the membrane closest to the valve opening is less elastic, resulting in the portion of the membrane closest to the valve opening closing first.

In exemplary embodiments, the flexible membrane and, as described above, the inner core, are of a substantially tapered or substantially conical shape, allowing for the rapid assembly and natural resting of the flexible membrane over the inner core.

A valve cover located laterally outwardly from the flexible membrane ends at the controllable outlet orifice. The pressurized flowable substance travels between the radially outwardly extended flexible membrane and the outer surface of the inner core and flows to the controllable outlet orifice. The outlet orifice provides for controlled amounts of the flowable substance to be dispensed. An over cap covers the exterior of the valve cover to protect the valve assembly during storage. A collar can join the valve assembly to the reservoir and afford a sealed arrangement preventing any flow of contaminants into the reservoir. The collar and the neck area of the reservoir are designed with locking features that permit the override of the collar during assembly but subsequently prevent the unscrewing and disassembly of the collar and the opening of and likely contamination of the system.

The various features of novelty which characterize the present invention are pointed out with particularity in the claims annexed to and forming a part of this disclosure. For a better understanding of the present invention, its operation, advantages and specific objects attained by its use, reference should be had to the accompanying drawings and descriptive matter in which preferred embodiments of the invention are illustrated and described.

BRIEF DESCRIPTION OF THE DRAWINGS:

Fig. 1 is an axially extending view of a dispensing and delivery system according to an exemplary embodiment of the present invention.

Fig. 2A is an exploded view of a dispensing and delivery system such as that shown in Fig 1 according to an exemplary embodiment of the present invention.

Fig. 2B is an exploded view of a dispensing and delivery system such as that shown in Fig 1 according to an exemplary embodiment of the present invention which includes a pump for dispensing flowable substance.

Fig. 3 is an exploded view of the soft cover and its controllable outlet orifice according to an exemplary embodiment of the present invention wherein the controllable outlet orifice is a cross slit.

Fig. 4A is an enlarged axially extending partial view of the continuously sealing one way valve assembly with a flat topped soft cover according to an exemplary embodiment of the present invention.

Fig. 4B is an enlarged axially extending partial view of the continuously sealing one way valve assembly with a rounded soft cover according to an exemplary embodiment of the present invention wherein the continuously sealing one way valve assembly is in the rest position.

Fig. 4C is an enlarged axially extending partial view of the continuously sealing one way valve assembly with a rounded soft cover according to an exemplary embodiment of the present invention wherein the continuously sealing one way valve assembly is in the dispensing position.

Fig. 4D is an enlarged axially extending partial view of the continuously sealing one way valve assembly where the opening in the soft cover contains a portion of the flexible membrane and inner core of the valve assembly according to an exemplary embodiment of the present invention.

Fig. 5 is an enlarged partial axially extending view of the continuously sealing one way valve assembly shown in Figs. 4B and 4C according to an exemplary embodiment of the present invention.

Fig. 6A is an axially extending partial view of the continuously sealing one way valve assembly with one port and an outlet port according to an exemplary embodiment of the present invention.

Fig. 6B is an enlarged axially extending partial view of the continuously sealing one way valve assembly with one port and an outlet port according to an exemplary embodiment of the present invention.

DETAILED DESCRIPTION OF THE INVENTION

As shown in Figs. 1, 2A and 2B, dispensing and delivery system 1 according to exemplary embodiments of the present invention is comprised of a bellows reservoir or source 2 located within a housing 6. The housing 6 and holds reservoir 2 of flowable substance, preferably a sterile or pure flowable substance, a valve assembly 3 (shown in detail in Figs. 2A, 2B and 4A-D) for conveying the flowable substance from the reservoir 2 to an outlet when pressure is applied to the reservoir 2 or to an actuator 2a connected to the reservoir 2. An over cap 15 covers the valve assembly 3 to prevent contamination from entering the valve assembly 3 during storage. The housing 6 has surfaces 6a for holding the assembly. A collar 8 connects the valve assembly 3 to the reservoir 2 affording a sealed connection so that ambient contaminants cannot pass into the reservoir 2.

Referring again to Figs. 1, 2A and 2B, the bellows reservoir 2 is sufficiently large to allow for multiple doses to be dispensed from the reservoir and collapses when pressure is applied to the reservoir. Other suitable reservoirs may be used, such as a collapsible tube or an internal bag in a reservoir that permit multi-dose dispensation of the flowable substance. The valve assembly 3 and collar 8 preferably prevents air or other contamination from entering the reservoir following the dispensing procedure.

Referring yet again to Figs. 1, 2A and 2B, the bellows reservoir or source 2 is laterally enclosed, for example, by an axially extending housing 6 to prevent the accidental application of pressure to the reservoir. A slot 6b extending axially in the housing 6 permits a user to gain access to an actuator 2a of the reservoir as the flowable substance is pressed out. The housing 6 has surfaces 6a for holding the housing when the flowable substance is being dispensed.

Referring now to Figs. 2A and 2B, the valve assembly 3 has valve cover 14 which encircles the flexible membrane 13. The valve assembly 3 is comprised of an inner core 10, an axially extending blind passageway 11, ports 12, a flexible membrane 13, a valve cover 14 with a flange 14a, and a soft cover 7 with a controllable outlet orifice 7a (all of which are described in greater detail below in connection with the descriptions of Figs. 4A-D). While the flexible membrane 13 is hollow so as to accommodate the inner core 10, it is understood that when assembled with the device, it is filled with the inner core 10 such that no gap remains when the valve assembly is at rest.

The end of the valve cover 14 adjacent the reservoir 2 has a radially outwardly extending flange 14a bearing against the flange at the end of the flexible membrane effecting the seal for the valve assembly at the opening from the reservoir 2. The opening or neck area of reservoir 2 seals against flange 14a, for example, by way of a screw thread which mates with the collar 8. Alternatively, or in addition, the collar 8 and the opening or neck area of

the reservoir 2 are designed with locking features that permit the override of the collar 8 during assembly but subsequently prevent the unscrewing and disassembly of the collar 8 and the opening of the system. This prevents any unintended contamination by the consumer and also eliminates the possibility of refilling the system.

Referring now especially to Fig. 2B, in an embodiment suitable for pumping flowable substance, a pump assembly 16 is joined to a valve assembly 3a and to a reservoir 2 and bottle 6b. The collar 8 surrounds the connection between the pump assembly 16 and valve assembly 3a. The pump assembly 16 is connected to the bottle 6 by screw threads. The opening or neck area of bottle 6 seals against pump assembly 16, for example, by way of a screw thread which mates with the pump assembly 16 sealing flange 2c of reservoir 2 between the bottle 6 and the pump assembly 16. Alternatively, or in addition, the collar 8 and the opening or neck area of the reservoir 2 are designed with locking features that permit the override of the pump assembly 16 during assembly but subsequently prevent the unscrewing and disassembly of the pump assembly 16 and the opening of the system. This prevents any unintended contamination by the consumer and also eliminates the possibility of refilling the system.

The pump assembly 16 is thus connected to a valve assembly 3a having an actuator 17, an inner core 10, an axially extending blind passageway 11, ports 12, a flexible membrane 13, a valve cover 14 with a flange 14a, and a soft cover 7 with a controllable outlet orifice 7a (further described below in connection with the descriptions of Figs. 4A-D). Optionally, the actuator 17 may be connected to or include an atomizer. In operation the actuator 17 serves to transfer force via a check valve of the pump assembly 16 to draw flowable substance from the reservoir 2, thus providing the force necessary to dispense flowable substance. For example, conventional pumps may be utilized in this manner.

Furthermore, the reservoir 2 can be disposed within a bottle 6 whose open end is sealed by a plug 2c. Plug 2c serves to protect the reservoir 2 from damage, rupture or inadvertent application of force on the reservoir 2.

Referring now to Fig. 3, the controllable outlet orifice 7a is a cross-slit enabling substantially dripless dispensing of the flowable substance. The cross-slit causes the controllable outlet orifice 7a to self close on itself after pressure is released.

The controllable outlet orifice 7a can be formed as desired to provide a spray or a stream of the flowable substance. Alternatively, by selectively dimensioning the controllable outlet orifice 7a, a drop-like amount of the flowable substance can be dispensed, for example if an eye care solution is being dispensed. If a greater amount of the flowable substance is to be dispensed, the controllable outlet orifice 7a can be formed for dispensing a larger quantity of the flowable substance, for example, a eye or nasal solution and/or gel.

Referring now to Figs. 4A-D, the valve assembly 3 preferably has an inner core 10, an axially extending blind passageway 11, ports 12, a flexible membrane 13, a valve cover 14 with a flange 14a, and a soft cover 7 with a controllable outlet orifice 7a. An over cap 15 is placed over the valve assembly 3 when it is not in use, protecting it from contact with ambient contaminants.

In the valve assembly 3, an axially extending inner core 10 bears against the opening of the reservoir 2 so that flow from the reservoir enters into an axially extending blind passageway 11 in the inner core. The passageway 11 extends for a major portion of the axial length of the inner core. At approximately half the length of the passageway 11, the inner core has a pair of ports 12 extending transversely of the passageway axis from the surface of the passageway to the outer surface of the inner core 10. The inner core 10 is formed of, for example, a rigid plastic material and terminates inwardly of the outlet end of the valve assembly. Furthermore, in exemplary embodiments, upon assembly and filling of

the assembly no air is present inside the passageway 11 and the ports 12. It should be noted that additional ports 12 may be located through the inner core 10.

Furthermore, in exemplary embodiments the inner core 10 and the flexible membrane 13 are constructed such that they fit tightly together, for example having very close tolerances which allow for an air-tight seal to be formed between the flexible membrane 13 and the inner core 10. In further exemplary embodiments the molding process for the flexible membrane 13 and the inner core 10, as well as other components described above as sealing against one another is an asymmetric molding process which creates a surface substantially free of defects or seam lines at the areas of contact where sealing occurs. Accordingly, in an exemplary embodiment, very close tolerances between the parts, for example the inner core 10 and flexible membrane 13 and the other parts, are used to provide an optimal seal and operation of the valve assembly.

A flexible membrane 13, such as an elastomeric member, is fitted tightly over the outer surface of the inner core and extends from the opening in the reservoir 2 to the opposite end of the inner core 10. As can be noted in Figs. 4A-D, the thickness of the membrane is preferably variable along its axial length. In the region of the outlet end of the inner core has, for example, an axially extending continuous uninterrupted end considerably thicker than the remainder of the flexible membrane 13. That is, the band is not separated in the axial direction by axially extending cuts. The thicker end ensures that after the valve has dispensed fluid, as further described below, the valve closes at the end closest to the opening 7a first, therefore preventing any backflow. This is effected by the heavy wall thickness which provides for greater tension. As a result, the flexible membrane 13 exhibits non-uniform tension.

In a further example, in yet other embodiments, the thickness of the membrane may be variable along its axial length and the region surrounding the outlet end of the inner

core has, for example, an axially extending continuous uninterrupted annular band considerably thicker than the remainder of the flexible membrane 13. Furthermore, in certain embodiments, the band is not separated in the axial direction by axially extending cuts. Alternatively, the elasticity or durometer of the end of the flexible membrane closest to the valve opening may be varied, for example it may be reduced, such that the end closest to the valve opening seals first when pressure is relieved.

In a further embodiment, flexible membrane 13 and inner core 10 are substantially tapered or substantially conical at the ends closest to the controllable outlet orifice 7a such that the inner core 10 nest into the flexible membrane 13 one another when being assembled by high speed automated production equipment.

At its end adjacent to the opening of the reservoir 2, the flexible membrane 13 has an outwardly extending flange bearing against a flange on the inner core located at the opening from the reservoir.

An axially extending valve cover 14 encircles the flexible membrane 13 and, as shown in the rest position in Fig. 2a, is spaced radially outwardly from the outer surface of the flexible membrane. The end of the valve cover 14 adjacent the reservoir 2 has a radially outwardly extending flange 14a bearing against the flange at the end of the flexible membrane effecting the seal for the valve assembly at the opening from the reservoir 2.

The valve cover 14 is formed, for example, of an inner layer of an elastomeric material extending axially from its flange 14a to and over the outlet end of the valve assembly 3. Elastomeric material forms a soft cover 7 over the outlet end of the valve cover 14 which is particularly advantageous when the valve assembly is used for dispensing an eye care solution. Such a soft cover 7 prevents, for example, any likelihood of harm to the delicate outer surfaces of the eye or surrounding tissue. The soft cover 7 has a controllable outlet orifice 7a for dispensing the flowable substance. The outlet orifice is closed in the rest

position of the continuously sealing one way valve assembly and open in the dispensing position.

Referring yet again to Figs. 4A-D and to Fig. 5, various embodiments of the valve assembly 3 are depicted having variations in the structure of the soft cover 7 as described below.

Referring now especially to Fig. 4A, a valve assembly having a flat topped soft cover 7 is provided. The soft cover 7 has a flattened top, which allows for less flowable substance to adhere to the controllable outlet orifice 7a because the flattened top results in a shorter controllable outlet orifice 7a. The soft cover 7 has a controllable outlet orifice 7a which can be formed as desired to provide a spray or a stream of the flowable substance. Furthermore, the controllable outlet orifice 7a can be a cross-slit as shown in Fig. 3. Alternatively, by selectively dimensioning the controllable outlet orifice 7a, a drop-like amount of the flowable substance can be dispensed, for example if an eye care solution or other solution typically delivered in droplet form, is being dispensed. If a greater amount of the flowable substance is to be dispensed, the controllable outlet orifice 7a can be formed for dispensing a larger quantity of the flowable substance, for example by having a larger diameter opening.

Referring now especially to Figs. 4B-C, a valve assembly having a rounded soft cover 7 is provided. The soft cover 7 has a rounded top useful for dispensing flowable substance into the outer surfaces of the eye and surrounding tissue or other sensitive body areas. Because the rounded tip lacks sharp edges, damage to the eye or other sensitive tissues is avoided or reduced if incidental contact occurs during administration of the flowable substance. The soft cover 7 has a controllable outlet orifice 7a which can be formed as desired to provide a spray or a stream of the flowable substance. Furthermore, the controllable outlet orifice 7a can be a cross-slit as shown in Fig. 3. Alternatively, by

selectively dimensioning the controllable outlet orifice 7a, a drop-like amount of the flowable substance can be dispensed, for example if an eye care solution or other solution typically delivered in droplet form, is being dispensed. If a greater amount of the flowable substance is to be dispensed, the controllable outlet orifice 7a can be formed for dispensing a larger quantity of the flowable substance, for example by having a larger diameter opening.

Referring now especially to Fig. 4D, a valve assembly having a flat cover 7 which has an enlarged version of controllable outlet orifice 7a is provided. The enlarged version of controllable outlet orifice 7a is able to accommodate the inner core 10 and flexible membrane 13 and is suitable for dispensing viscous flowable substances such as lotions, creams and emollients, but may also be used for any flowable substance. The enlarged version of controllable outlet orifice 7a allows flowable substance to be dispensed without having to move through two openings - namely the opening at the end of the flexible elastomer 13 and the controllable outlet orifice 7a, since these are now flush.

Referring now to Fig. 5 the gap formed between inner core 10 and the flexible membrane 13 by the pressurized fluid flowing out of ports 12 can more easily be seen. The controllable outlet orifice 7a in soft cover 7 can also be seen and may for example be a substantially uniform circular bore through the material of soft cover 7 or may be suitably dimensioned as described in the preceding paragraphs.

Referring now to Figs. 6A-B, in another embodiment, flowable substance flows through a single port 12 in inner core 10 and expands the flexible membrane 13, swirling around the exterior of inner core 10, and exiting via an outlet port 12a as shown in Figs. 6A and 6B. This results in the need for less cracking pressure to dispense flowable substance and is particularly advantageous for use with, though not limited to, flowable substances having higher viscosities such as lotions, creams and emollients. It should be noted that additional ports 12 may be located through the inner core 10.

In exemplary operation, when the flowable substance is to be dispensed, the over cap 15 is removed and pressure is applied to the actuator 2a of the reservoir 2 so that an amount of the flowable substance passes out of the reservoir into the passageway 11 in the inner core 10. The substance flows through the ports 12 and expands the flexible membrane 13 radially outwardly and flows toward the outlet end of the flexible membrane where it exits from the flexible membrane radially inwardly into the controllable outlet orifice 7a in the cover and is dispensed.

When the flowable substance is being dispensed and exits the outlet end of the flexible membrane, it flows radially inward to the controllable outlet orifice 7a which then opens allowing the substance to flow out of the valve assembly. When the flowable substance is dispensed and pressure on the source is withdrawn the controllable outlet orifice 7a closes blocking any backflow into the valve assembly. An over cap 15 is placed over the valve assembly 3 when it is not in use, protecting it from contact with ambient contaminants.

In another embodiment, as depicted in Figs. 6A and 6B for example, flowable substance flows through a single port 12 in inner core 10 and expands the flexible membrane 13, swirling around the exterior of inner core 10, and exiting via an outlet port 12a as shown in Figs. 6A and 6B. This results in the need for less cracking pressure to dispense flowable substance and is particularly advantageous for use with, though not limited to, flowable substances having higher viscosities such as creams and emollients.

By releasing the pressure on the actuator 2a of the reservoir, the dispensing operation is terminated and the flexible membrane 13 returns inwardly into contact with the outer surface of the inner core 10. The inward movement of the flexible membrane starts at its outlet end because of its increased thickness and affords gradual contact with the outer surface of the inner core, returning any flowable substance through the ports back into the reservoir whereby contaminants cannot enter the reservoir. Dispensing individual portions of

the flowable substance can be continued until the reservoir is almost completely emptied. As a result of the structure and operation of the valve assembly, the valve assembly according to an exemplary embodiment of the present invention provides uniform pressure on the valve components via the pressurization of the flowable substance.

In still another exemplary embodiment, for example a spray pump such as that depicted in Fig 2B, an actuator 17 serves to transfer force to the pump assembly 16 when it is depressed. This in turn compresses the reservoir 2, thus providing the force necessary to open the valve assembly and in certain embodiments described above, controllable outlet port 7a, to dispense flowable substance.

Elastomers suitable to form the soft cover 7, the flexible membrane 13 and the valve cover 14 in exemplary embodiments of the present invention include thermoplastic elastomers such as Dynaflex manufactured by GLS Corp., C-Flex manufactured by CPT Inc., or Santoprene manufactured by Advanced Elastomer Systems, Inc. The elastomers, and the materials comprising any of the other components of the device may have integrated, impregnated, otherwise placed within them anti-microbial ingredients such as silver ions contained within a ceramic carrier, such as those supplied by AgION, or sustained-release ionic silver compounds, such as those supplied by Westlake Plastic Technologies which are known to be used in the making of anti-microbial plastics. Furthermore, other anti-microbial suitable for compounding with or coating plastics may be used. Furthermore, the soft cover 7 or the flexible membrane 13 or both could, for example, be positively charged to repel residual flowable substance, coated in for example, Teflon type-plastics, have increased surface tension or be anti-wetting, or any combination of the above so as to repel flowable substance.

In yet other embodiments, including those described above, the durometer of the elastomers can be varied in relation to the viscosity of the flowable substance. For

example, assemblies containing substances with comparatively higher viscosities would utilize softer, *i.e.* lower durometer elastomers, in order to reduce the cracking force needed to dispense flowable substance, whereas lower viscosity flowable substances would utilized harder, *i.e.* higher durometer elastomers to maintain a strong seal. Likewise, flowable substances containing lubricants would also utilize harder, *i.e.* higher durometer elastomers to maintain a strong seal.

As described above, the parts of the dispensing and delivery device, including the valve assembly may be manufactured to close tolerances such that they form airtight seals and are close fitting ensuring optimal seals and operation of the device.

A variety of pharmaceuticals, cosmetics, food stuffs and other flowable materials can be dispensed where it is important to maintain them free of contaminants from the ambient atmosphere. The flowable characteristics of the material being dispensed determines or at least may affect the type and dimension of the valve assembly.

According to exemplary embodiments of the present invention, the material forming the controllable outlet orifice 7a does not absorb the flowable substance. As a result, any substance entering the outlet orifice 7 is ejected from the dispenser and does not return into the space between the inner core and the flexible membrane, thereby maintaining the purity or sterility of the product remaining in the reservoir.

It should be understood that the various embodiments of the valve assembly described above can each be used in the various embodiments of the continuously sealing one way valve assembly device.

As mentioned, the flowable substance may be a pharmaceutical cosmeceutical, or nutraceutical, an eye care solution, other ophthalmological product, otorhinolarygology product, dermatological product, gynecological product, or product for treating or preventing anorectal, dermatological or pulmonary disorders or any formulation administered to the

body through the mucus membranes; a food stuff, such as dairy products, beverages or juices; a cosmetic, such as a skin care solution or toiletries; and liquid vitamins, all of which are intended to be maintained free of contaminants from the ambient atmosphere and of preservatives during storage within the reservoir 2.

According to exemplary embodiments of the present invention, many existing commercial products that contain preservatives can be reformulated into preservative free versions and provided for multiple dose dispensing with the valve assembly and delivery system of the present invention. For example, conventional creams, emollients, eye drops, nasal sprays, cosmetic creams that currently require preservatives, notably parabens and benzalkonium chloride that have proved to be deleterious to tissue, may be reformulated in a preservative free form and are amenable to storage and dispensing from reservoirs using the continuously sealing one way valve assembly and delivery system of the present invention. This can be accomplished by, for example, formulating the product according to its original formulation, but without the preservative, or by readjusting the formulation of the product, for example by changing the excipients or the amount of the excipients or both. Thus, these preservative free products are amenable to storage and dispensing from reservoirs using the continuously sealing one way valve assembly and delivery system of the present invention because they are preservative free formulations.

The following examples provide embodiments describing categories of medical products which are amenable to storage and dispensing from reservoirs using the continuously sealing one way valve assembly and delivery system of the present invention. Preservative-free storage and delivery of formulations also can be accomplished by providing, for example, multi-dose metered, high barrier and for preservative-free systems as described in U.S. Patent No. RE 34,243, incorporated by reference above and U.S. Patent

Nos. 5,092,855; 5,305,783; 5,279,447; 5,305,786; and 5,353,961 all of which are hereby incorporated by reference in their entirety.

Examples

Example 1

In an exemplary embodiment, preservative free ophthalmological products are amenable to storage and dispensing from reservoirs using the continuously sealing one way valve assembly and delivery system of the present invention. For example, eye drops, and preferably those eye drops involved in chronic care, for example, dry eye, glaucoma, allergies and NSAIDs, and also those eye drops intended for acute care, for example during ocular surgery, are amenable to storage and dispensing from reservoirs using the continuously sealing one way valve assembly and delivery system of the present invention. As a further example, those eye drops used to relieve eye fatigue, those eye drops used to relieve dry eye, those eye drops used relieve dry eye due to computer use, television use, or fatigue due to prolonged awake periods are amenable to storage and dispensing from reservoirs using the continuously sealing one way valve assembly and delivery system of the present invention.

Examples of dry eye products can include dry eye products comprising methycellulose, hyaluronic acid, polyethelene glycol 400 0.4%, propylene glycol 0.3%, glycerin, and mineral oils. Examples of glaucoma products include glaucoma products comprising timolol 0.25%/0.50%, brimonidine tartrate 0.1%, bimatoprost 0.03% and travaprost 0.004%. Examples of allergy products include allergy products comprising olopatadine HCL 0.1% and predisalone acetate 1%. Examples of NSAID products include NSAID products comprising ketorolac 0.5% and diclofenac 0.1%.

Example 2

In an exemplary embodiment, preservative-free otorhinolarygological products are amenable to storage and dispensing from reservoirs using the continuously

sealing one way valve assembly and delivery system of the present invention. For example, nasal medicines, and preferably nasal sprays, external ear creams, ear drops, steroid ear drops, antibiotic ear drops, nose drops, and nose drops comprising phenylephrine 0.25% and pseudoephedrine 30mg, are amenable to storage and dispensing from reservoirs using the continuously sealing one way valve assembly and delivery system of the present invention.

Example 3

In an exemplary embodiment, preservative free dermatological products are amenable to storage and dispensing from reservoirs using the continuously sealing one way valve assembly and delivery system of the present invention. For example, preservative free skin preparations; scalp preparations; corticosteroid creams, lotions and ointments; topical antibiotics and topical anti-fungal agents are amenable to storage and dispensing from reservoirs using the continuously sealing one way valve assembly and delivery system of the present invention. Thus, these preservative free dermatological products are amenable to storage and dispensing from reservoirs using the continuously sealing one way valve assembly and delivery system of the present invention because they are preservative free formulations.

Example 4

In an exemplary embodiment, preservative free products for the treatment or prevention of dermatologic disorders are amenable to storage and dispensing from reservoirs using the continuously sealing one way valve assembly and delivery system of the present invention. For example, preservative free skin preparations; scalp preparations; corticosteroid creams, lotions and ointments; topical antibiotics; topical anti-fungal agents; therapeutic skin creams including anti-bacterial, anti-fungal/parasitic, allergic and non-specific dermatitis creams and emollients and all cosmetic dermatologic compounds used for

dermatologic disorders are amendable to storage and dispensing from reservoirs using the continuously sealing one way valve assembly and delivery system of the present invention.

Example 5

In an exemplary embodiment, products for the treatment or prevention of anorectal disorders are amenable to storage and dispensing from reservoirs using the continuously sealing one way valve assembly and delivery system of the present invention. For example, preservative free creams, topical anaesthetics, lubricating jellies and jelly or other preparations for hemorrhoid treatment, prevention or management, are amenable to storage and dispensing from reservoirs using the continuously sealing one way valve assembly and delivery system of the present invention.

Example 6

In an exemplary embodiment, preservative free products for the treatment or prevention of pulmonary disorders are amenable to storage and dispensing from reservoirs using the continuously sealing one way valve assembly and delivery system of the present invention. For example preservative free formulations of products for chronic obstruction disorder, for example, aerosol nebulizers using B-adrenergic, anticholinergic, corticosteroid and theophylline derivatives requiring multi-dose application are amenable to storage and dispensing from reservoirs using the continuously sealing one way valve assembly and delivery system of the present invention.

Example 7

In an exemplary embodiment, preservative free gynecological products are amenable to storage and dispensing from reservoirs using the continuously sealing one way valve assembly and delivery system of the present invention. For example, vulvovaginal treatment medicines, such as medicines for contact irritant or allergic vulvitis, chemical irritation, bacterial vaginosis, Candidal vaginitis therapy including all azoles and nystatins,

butoconazole, butoconazole 2%, clotrimazole, clotrimazole 1%, metronidazole and trichomonas treatments are amenable to storage and dispensing from reservoirs using the continuously sealing one way valve assembly and delivery system of the present invention.

Example 8

In an exemplary embodiment, preservative free lens care products are amenable to storage and dispensing from reservoirs using the continuously sealing one way valve assembly described herein. For example, contact lens rinsing, cleaning disinfecting and storage solutions, or a multi-purpose solution encompassing contact lens rinsing, cleaning disinfecting and storage are amenable to storage and dispensing from reservoirs using the continuously sealing one way valve assembly and delivery system of the present invention.

Example 9

In an exemplary embodiment, preservative free eye wash products (*e.g.* irrigation solutions) are amenable to storage and dispensing from reservoirs using the continuously sealing one way valve assembly described herein. For example, eye wash products used to clear the eye of environmental contamination are amenable to storage and dispensing from reservoirs using the continuously sealing one way valve assembly described herein. As a further example, eye wash products used to clear the eye of environmental contamination such as pollen or dirt are amenable to storage and dispensing from reservoirs using the continuously sealing one way valve assembly and delivery system of the present invention.

Although the system is designed for use with various preservative free formulations it may also be used with formulations which are not preservative free.

In the claims:

1. A continuously sealing one way valve assembly and delivery system for dispensing a flowable substance, comprising:

a source for storage of the flowable substance, the source having an opening;
a valve assembly coupled to the opening of the source, said valve assembly including

- (i) an inner core having an inlet opening for receiving the flowable substance into a passageway and at least one port opening from the passageway,
- (ii) a hollow flexible membrane having a first end and a second end, the first end being thicker than the second end, wherein the hollow flexible membrane is fitted over an outer surface of the inner core and when the flowable substance is placed under pressure the flowable substance exits through the at least one port opening and expands said membrane outwardly from said outer surface of said inner core;

a cover enclosing the flexible membrane and having an outlet orifice for dispensing the flowable substance from the valve assembly when pressure is applied to the flowable substance and

wherein when the pressure on the flowable substance is released, the first end of the hollow flexible membrane moves back into tightly fitting contact with the outer surface of the inner core before the remainder of the hollow flexible membrane moves back into tightly fitting contact with the outer surface of said inner core.

2. A continuously sealing one way valve assembly and delivery system as set forth in claim 1, wherein the hollow flexible membrane has an axially extending

uninterrupted continuous band at the first end of the hollow flexible membrane adjacent the outlet orifice in the cover and completely encircling the core.

3. A continuously sealing one way valve assembly and delivery system as set forth in claim 1, wherein said membrane has a radially outwardly extending flange at the second end thereof adjacent to the passageway of the inner core, and the cover also has a radially outwardly extending flange pressing the flange on the membrane into fluid tight contact with a radially outwardly extending flange at the passageway opening into the inner core.

4. A continuously sealing one way valve assembly and delivery system as set forth in claim 3, wherein a collar and connector member on the source secure the valve assembly to the source.

5. A continuously sealing one way valve assembly and delivery system as set forth in claim 4 wherein the connector member is a threaded screw which mates to the collar.

6. A continuously sealing one way valve assembly and delivery system as set forth in claim 4 wherein a collar and connector member on the source secure the valve assembly to the source and effect a positive lock preventing opening of the source.

7. A continuously sealing one way valve assembly and delivery system as set forth in claim 1, wherein the outlet orifice in the cover is arranged so that it can dispense a selected quantity of the flowable substance.

8. A continuously sealing one way valve assembly and delivery system as set forth in claim 1, wherein the outlet orifice in the cover is formed of a soft material.

9. A continuously sealing one way valve assembly and delivery system as set forth in claim 1, wherein the outlet orifice in the cover is formed of a flexible material.

10. A continuously sealing one way valve assembly and delivery system as set forth in claim 1, wherein the cover is formed of an inner axially extending flexible member laterally enclosed by an axially extending rigid plastic shell.

11. A continuously sealing one way valve assembly and delivery system as set forth in claim 1, wherein an overcap is arranged to fit over and form a seal with said valve assembly sufficient to prevent external contamination from coming in contact with the valve assembly during storage.

12. A continuously sealing one way valve assembly and delivery system as set forth in claim 1, wherein at least two ports extend from the passageway through the inner core and to the inner surface of the flexible membrane.

13. A continuously sealing one way valve assembly and delivery system as set forth in claim 1, wherein the source comprises a collapsible reservoir reducible in volume in proportion as the flowable substance is dispensed from of the collapsible reservoir.

14. A continuously sealing one way valve assembly and delivery system as set forth in claim 13, wherein said collapsible reservoir is one of a bellows, a tube and an internal bag.

15. A continuously sealing one way valve assembly and delivery system as set forth in claim 1, wherein an axially extending housing laterally encloses the source.

16. A continuously sealing one way valve assembly and delivery system as set forth in claim 15, wherein the housing has a slot extending in the axial direction for applying dispensing pressure to an actuator of the collapsible reservoir.

17. A continuously sealing one way valve assembly and delivery system as set forth in claim 1, wherein the cover has a closed outlet orifice which opens for dispensing the flowable substance from the cover when dispensing pressure is applied to the source.

18. A continuously sealing one way valve assembly and delivery system, as set forth in claim 17, wherein the outlet orifice in the cover is impervious to the flowable substance and does not retain the flowable substance inwardly of the outlet orifice.

19. A continuously sealing one way valve assembly and delivery system as set forth in claim 1 wherein the inner core is connected to a pump assembly and to an actuator such that flowable substance is dispensed from the outlet orifice when the actuator is depressed.

20. A one-way valve assembly and delivery system of claim 1, wherein the source is filled with a preservative free product.

21. A one-way valve assembly and delivery system of claim 20 wherein said preservative-free product is selected from one of ophthalmological products, otorhinolaryngological products, dermatological products, gynecological products, and products for the treatment or prevention of anorectal disorders, dermatological disorders, pulmonary disorders or any product which can be administered to the body through mucus membranes.

22. A one-way valve assembly and delivery system of claim 20 wherein said preservative-free product comprises a product selected from one of methycellulose, hyaluronic acid, polyethelene glycol 400 0.4%, propylene glycol 0.3%, glycerin, and mineral oils.

23. A one-way valve assembly and delivery system of claim 20 wherein said preservative-free product comprises a product selected from one of timolol 0.25%/0.50%, brimonidine tartrate 0.1%, bimatoprost 0.03% and travaprost 0.004%.

24. A one-way valve assembly and delivery system of claim 20 wherein said preservative-free product comprises a product selected from one of olopatadine HCL 0.1% and prednisolone acetate 1%.

25. A one-way valve assembly and delivery system of claim 20 wherein said preservative-free product comprises a product selected from one of ketorolac 0.5% and diclofenac 0.1%.

26. A one-way valve assembly and delivery system of claim 20 wherein said preservative-free product comprises a product selected from one of phenylephrine 0.25% and pseudoephedrine 30mg.

27. A one-way valve assembly and delivery system of claim 20 wherein said preservative-free product comprises a product selected from one of skin preparations; scalp preparations; corticosteroid creams, lotions and ointments; topical antibiotics and topical anti-fungal agents.

28. A one-way valve assembly and delivery system of claim 20 wherein said preservative-free product comprises a product selected from one of skin preparations; scalp preparations; corticosteroid creams, lotions and ointments; topical antibiotics; topical anti-fungal agents; therapeutic skin creams including anti-bacterial, anti-fungal/parasitic, allergic and non-specific dermatitis creams and emollients and cosmetic dermatologic compounds used for dermatologic disorders

29. A one-way valve assembly and delivery system of claim 20 wherein said preservative-free product comprises a product selected from one of creams, topical anaesthetics, lubricating jellies and other preparations for hemorrhoid treatment, prevention or management.

30. A one-way valve assembly and delivery system of claim 20 wherein said preservative-free product comprises a product selected from one of B-adrenergic, anticholinergic, corticosteroid and theophylline derivatives.

31. A one-way valve assembly and delivery system of claim 20 wherein said preservative-free product comprises a product selected from one of azoles, nystatins,

butoconazole, butoconazole 2%, clotrimazole, clotrimazole 1%, metronidazole and trichomonas treatments.

32. A one-way valve assembly and delivery system of claim 19, wherein said product is a contact lens care product.

33. A one-way valve assembly and delivery system of claim 19, wherein said product is selected from one of: herbal, cosmetic, eye wash or skin care products.

34. A continuously sealing one way valve assembly and delivery system as set forth in claim 1, wherein the continuously sealing one way valve assembly and delivery system can dispense multiple doses of preservative-free product.

35. A continuously sealing one way valve assembly and delivery system for dispensing a preservative-free flowable substance, comprising:

a source for storage of the preservative-free flowable substance, the source having an opening;

a valve assembly coupled to the opening of the source, said valve assembly including

- (i) an inner core having an inlet opening for receiving the preservative-free flowable substance into a passageway and at least one port opening from the passageway,
- (ii) a hollow flexible membrane having a first end and a second end, the first end being thicker than the second end, wherein the hollow flexible membrane is fitted over an outer surface of the inner core and when the preservative-free flowable substance is placed under pressure the preservative-free flowable substance exits through the at least one port opening and expands said membrane outwardly from said outer surface of said inner core;

a cover enclosing the flexible membrane and having an outlet orifice for dispensing the preservative-free flowable substance from the valve assembly when pressure is applied to the preservative-free flowable substance and

wherein when the pressure on the preservative-free flowable substance is released, the first end of the hollow flexible membrane moves back into tightly fitting contact with the outer surface of the inner core before the remainder of the hollow flexible membrane moves back into tightly fitting contact with the outer surface of said inner core.

36. A continuously sealing one way valve assembly and delivery system for dispensing multiple doses of a preservative-free flowable substance, comprising:

a source for storage of the preservative-free flowable substance, the source having an opening;

a valve assembly coupled to the opening of the source, said valve assembly including

- (i) an inner core having an inlet opening for receiving the preservative-free flowable substance into a passageway and at least one port opening from the passageway,
- (ii) a hollow flexible membrane having a first end and a second end, the first end being thicker than the second end, wherein the hollow flexible membrane is fitted over an outer surface of the inner core and when the preservative-free flowable substance is placed under pressure the preservative-free flowable substance exits through the at least one port opening and expands said membrane outwardly from said outer surface of said inner core;

a cover enclosing the flexible membrane and having an outlet orifice for dispensing the preservative-free flowable substance from the valve assembly when pressure is applied to the preservative-free flowable substance and

wherein when the pressure on the preservative-free flowable substance is released, the first end of the hollow flexible membrane moves back into tightly fitting contact with the outer surface of the inner core before the remainder of the hollow flexible membrane moves back into tightly fitting contact with the outer surface of said inner core.

37. A delivery system comprising:

a source for storage of the flowable substance, the source having an opening;
a valve assembly coupled to the opening of the source, said valve assembly including

- (i) an inner core having an inlet opening for receiving the flowable substance into a passageway and at least one port opening from the passageway,
- (ii) a hollow flexible membrane having a first end and a second end, the first end being thicker than the second end, wherein the hollow flexible membrane is fitted over an outer surface of the inner core and when the flowable substance is placed under pressure the flowable substance exits through the at least one port opening and expands said membrane outwardly from said outer surface of said inner core;

a cover enclosing the flexible membrane and having an outlet orifice for dispensing the flowable substance from the valve assembly when pressure is applied to the flowable substance and

wherein when the pressure on the flowable substance is released, the first end of the hollow flexible membrane moves back into tightly fitting contact with the outer surface

of the inner core before the remainder of the hollow flexible membrane moves back into tightly fitting contact with the outer surface of said inner core.