

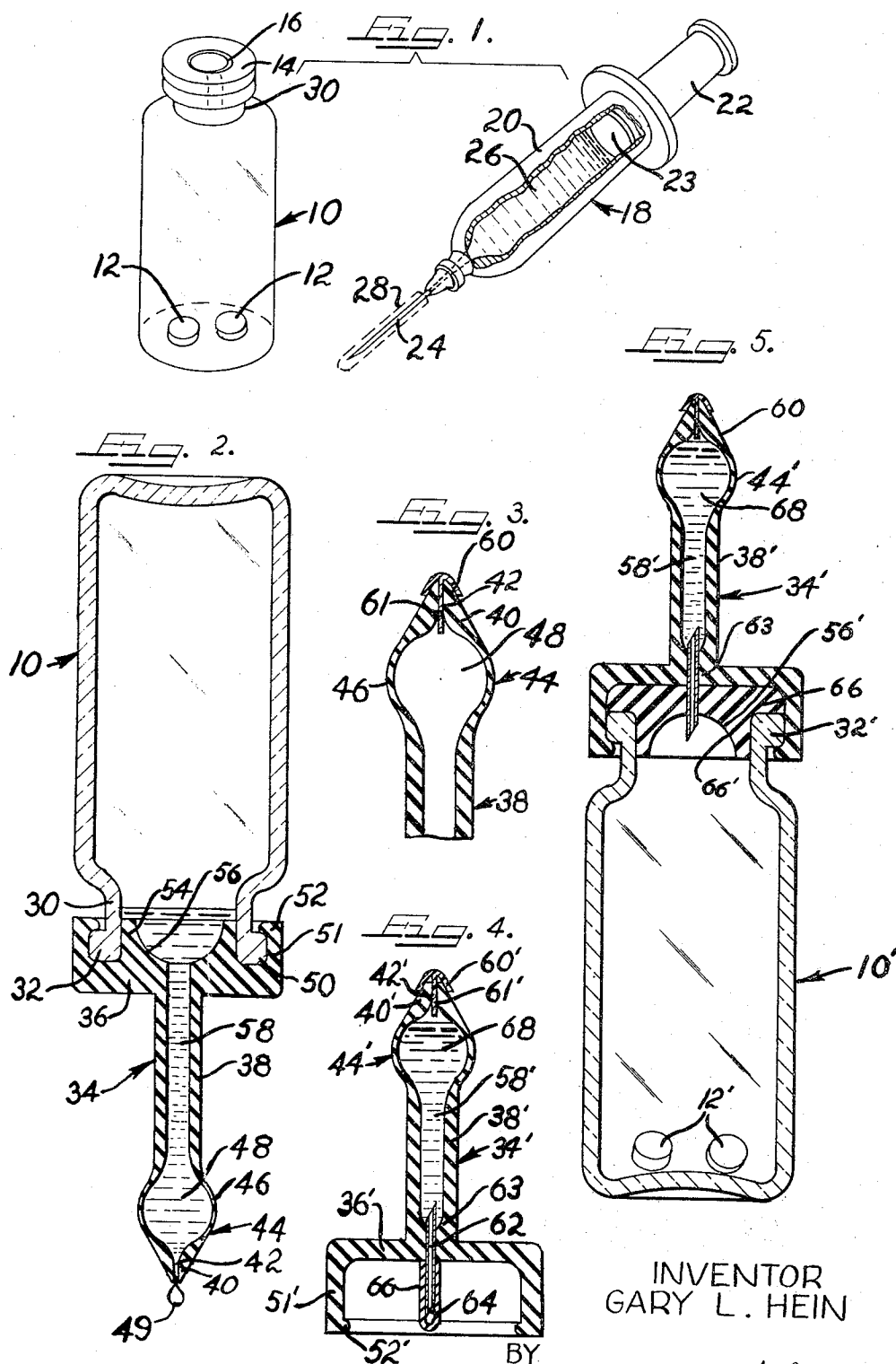
Feb. 20, 1968

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MEANS FOR RECONSTITUTING A DRY BIOLOGICAL AND FOR
CONTROLLED DISPENSING THEREOF

3,369,708

Filed Sept. 7, 1965

2 Sheets-Sheet 1



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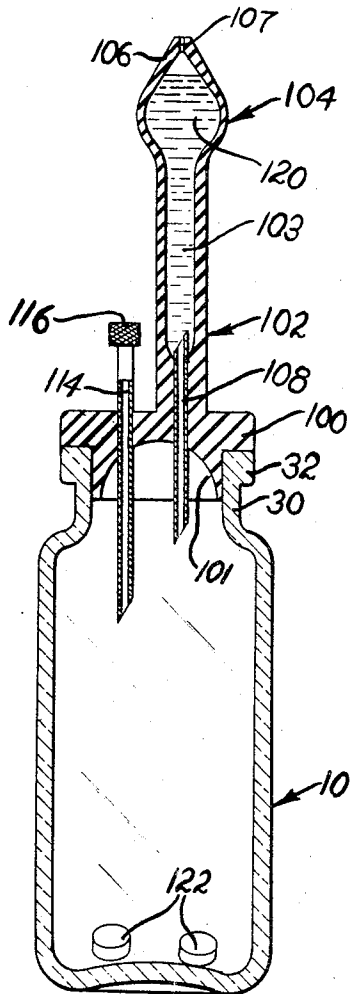


Fig. 7.

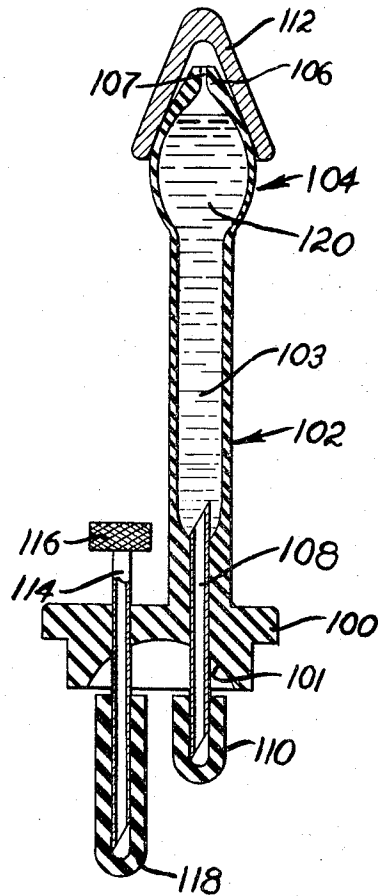


Fig. 6.

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3,369,708 MEANS FOR RECONSTITUTING A DRY BIOLOGICAL AND FOR CONTROLLED DISPENSING THEREOF

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Filed Sept. 7, 1965, Ser. No. 485,430
10 Claims. (Cl. 222-85)

This invention relates to an improved means for reconstituting a dry, or lyophilized, biological and for thereafter effecting controlled dispensing of the liquid biological as required.

The use of lyophilized biologicals, such as smallpox vaccine, has the appeal of an extended shelf life prior to being reconstituted. Present techniques dispose the dried biological in a glass vial under a reduced gas pressure maintained by a pierceable rubber seal or stopper. The reconstituting liquid is usually packaged in a syringe, or vial unit, having a sharp needle extending therefrom for piercing the seal on the container, after which the liquid is, in the case of a syringe, expressed through the needle into the container to reconstitute the dried biological, while in the case of a vial, the reduced gas pressure in the container operates to cause the fluid to move from the vial into the container. Thereafter, the liquid biological is either retained in the container, from which the stopper has been removed, so as to provide access to the liquid by dipping or the like, or the liquid is sucked back up through the needle into the syringe unit for dispensing therefrom as desired either through the needle or through some other tubular attachment. Both of said methods of storage of the liquid biological have drawbacks, since an open-topped container is subject to tipping and spillage therefrom, and the syringe unit requires skill in controlling limited expressing of liquid therefrom.

Thus, one object of this invention is to provide an improved means for both reconstituting a dried biological and for thereafter effecting simple controlled dispensing of the liquid biological as required.

Another object of this invention is to provide an improved selectively-controlled dispenser of liquid biologicals which obviates the drawbacks of existing systems and which is of simple but effective construction for achieving a more precise expressing of a very small amount of liquid therefrom as required.

Further objects and advantages of this invention will become apparent as the following description proceeds and the features of novelty which characterize this invention will be pointed out with particularity in the claims annexed to and forming part of this specification.

A preferred embodiment of the invention is shown in the accompanying drawings, in which:

FIG. 1 illustrates an existing system for reconstituting dried biological such as a vaccine including a container with a pierceable stopper and a syringe for introducing liquid into the container;

FIG. 2 illustrates a first form of dispenser that has been attached to the container of liquid biological;

FIG. 3 is an enlarged fragmentary cross-section view of the discharge end of the dispenser of FIG. 2, and showing its cooperation with a cap therefor;

FIG. 4 is a vertical cross-section view of a second form of dispenser wherein the dispenser prior to its use as such, also serves as the means for reconstituting the dried biological;

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FIG. 5 is a vertical cross-sectional view that illustrates how the device of FIG. 4 is connected to the container for dried biological prior to reconstituting the dried biological;

FIG. 6 is a vertical cross-sectional view of still another form of combination means for reconstituting dried biological and for thereafter dispensing liquid therefrom; and

FIG. 7 is a vertical cross-sectional view that illustrates how the device of FIG. 6 is connected to the container of dried biological prior to reconstituting the dried biological.

Referring now to the drawings, FIG. 1 illustrates an existing system for reconstituting a dry biological and for later using a portion thereof in the controlled dispensing of the liquid biological resulting from the process of reconstitution. Thus, in FIG. 1 there is shown a glass bottle generally indicated at 10 containing therein a preselected quantity of dry or lyophilized biological in the form of a plurality of tablets 12. The container 10 is typically known and is normally closed by a pierceable rubber stopper that is encircled by a sheet metal retainer 14 which is conveniently scored along various lines 16 so that upon rupture along such score lines the sheet metal retainer 14 may be entirely removed. Accompanying such a container 10 with dried biological therein, is a syringe device generally indicated at 18 and which comprises a barrel 20, a plunger 22 with a piston 23 at one end thereof located in barrel 20, and a sharpened hollow needle 24 at the opposite end of barrel 20. The interior of the barrel 20 is filled with a liquid operative to effect reconstitution of the dried biological when it has the pellets 12 immersed therein.

The manner of usage of this system to remove the protective sleeve 28 from the needle 24, then pierce the ordinary pierceable rubber stopper on container 10 with the needle 24, and then discharge the liquid contents 26 into the container 10, whereupon the dry biological 12 is immersed in a bath of liquid and becomes reconstituted. Then, in order to dispense the liquid biological in small amounts, in a controlled manner, the container 10 is inverted so that the liquid contacts needle 14, and the liquid biological is then sucked back up through needle 24 to the interior of the syringe device 18. Thereafter, the liquid biological may be dispensed either through the needle 24, or through some other tubular fitting that is substituted for the needle 24. What has thus far been described is well known in the art, and no novelty is ascribed to any of these features, except insofar as some of the same structural elements may be used to cooperate with the novel fittings hereinafter described.

Now, FIG. 2 illustrates the combination of the container 10 with one form of a novel discharge fitting at the end thereof. As earlier described, the container 10 is of glass and is, therefore, a rigid, mouthed storage container that defines a restricted neck 30 and an enlarged bead 32 at the discharge end of the container 10, which normally surrounds and defines the mouth of the container. The pierceable rubber stopper, which is normally provided for the container 10, has been removed and discarded, and there has been attached to the mouth of the container 10 a unitary dispensing device, generally indicated at 34, for selective controlled dispensing of the liquid biological that is within the container 10. The device 24 is molded of polyethylene, or rubber, or of some synthetic plastic material that is resilient enough to be manipulable in the manner as hereinafter described.

The dispensing device 34 is shaped to define an annular mounting base 36, whose center opening communicates

with one end of the bore of an elongated dispensing tube means 38. The distal end of the tube means 38, that is remote from the base 36, terminates in a dispensing tip 40 that is formed with a constricted orifice 42 there-through. There is also provided a flexible, bulged portion 44 intermediate the end of the tube means 38 and immediately adjacent the dispensing tip 40. The bulged portion 44 has its side walls thereof thinned down as at 46, relative to the thickness of the wall of the straight tubular portion of tube means 38, that extends between the base 36 and the bulged portion 46, and the side walls of portion 44 bulge outwardly of the exterior periphery of tube 38 to define an enlarged chamber, or well, 48 that is adapted to receive and hold a supply of liquid therein when the container 10 is inverted, in the manner as seen in FIG. 2. The well 48 is positioned immediately adjacent the dispensing tip 40 so as to locate a supply of the liquid to be dispensed immediately adjacent the dispensing tip.

The constricted dispensing orifice 42 is selected of such a size relative to the viscosity of the liquid that the liquid will not run out, under gravity forces, through orifice 42 when the container is merely inverted, but the flexible wall portions 46 of the dispensing tube means permits of manual manipulation so as to impose controlled dispensing forces onto the liquid within the reservoir 48, so that one is able to achieve a very accurately controlled dispensing of small amounts of liquid biological from the tip of the dispensing tube means. Such manual manipulation may be effected, for example, by pressing inwardly on thinned walls 46 of bulged portion 44, and as illustrated in FIG. 2 a small drop 49 is being dispensed from the dispensing tip of the device.

The mounting base of the dispensing device 34 is appropriately molded, or shaped, to provide an annular recess 50 surrounded by skirt 51 for receiving thereinto the enlarged bead 32 at the discharge end of the container 10. It is desirable to bulge the terminal end of the skirt 51 slightly inwardly at 52 to extend inwardly of the outermost portions of bead 32 and to provide that the device snap fits onto the container. The base 36 is also shaped to provide thereon a sleeve type insert element 54 which enters the mouth of the container and engages the inner wall of the restricted neck 30 to provide a good and preferably liquid-tight seal thereagainst. The portion of the base 36 which enters the mouth of the container is concavely recessed at 56 to provide a well, or funnel, that directs the liquid from the container 10 into the inlet end of the bore 58 of the tube means 38.

It will be understood that the device 34 that is shown attached to the container 10 in FIG. 2 is normally packaged in sterile condition in an envelope of cellophane or the like, and after the dry biological in the container 10 has been reconstituted, the envelope containing the dispensing device 34 is opened and the device is then mounted onto the mouth of the container 10. In order to provide a system that inhibits entry of air or other contaminants when the container is being stored under refrigeration, a closure cap 60 is provided, as best seen in FIG. 3, arranged for a frictional fit onto the discharge tip 40. If desired, the closure cap 60 may be molded to provide an obturator stem 61 which protrudes through orifice 42 to provide an excellent seal.

In the modified form of dispensing device as shown in FIG. 4, portions similar to those previously described are indicated by the same numeral, primed. The dispenser 34' of FIG. 4 is intended to cooperate with and overlie the pierceable rubber stopper 66 that is normally provided on the container 10. Furthermore, the device of FIGS. 4 and 5 utilizes the bore space 58' within the tubular means 38' and in the well 48' of the bulged portion 44' of the dispensing tube as a storage space for the reconstituting liquid. Thus, the discharge tip 40' of the device in FIG. 4 is provided thereon with a gas-tight cap or stopper 60' with obturator 61', for effecting a gas-

tight seal at the one end of the tubular interior of the device. At the opposite end of the bore, or canal, 58' through the tube, there is provided a hollow needle segment 62 which is held in assembled position by gas-tight frictional engagement thereof with the walls of the tubular part 38'. The needle 62 serves to communicate the interior of the storage container 10' with the entry end of the elongated dispensing tube means 38'. The outer beveled end 64 of needle 62 provides a piercing tip that extends below the mounting base 36' of the dispenser. The mounting base 36' and its depending skirt 51' serve as annular connector means for attachment to the mouth of the container 10'. The outer end of the needle 62 is normally sealed by means of a protective resilient cap 66 that is frictionally fitted over the needle.

In usage, the entire dispensing device, with a reconstituting liquid 68 therein is individually packaged, and when it is desired to reconstitute a dry biological such as at 12' in FIG. 5, the package is opened, and the sleeve, or cap, 66 is removed. Then the base 36' is snapped over the upper end of the container 10, as seen in FIG. 5, with the piercing portion 64 of the needle 62 held so that it pierces the rubber stopper 66 that is normally provided on container 10'. The reconstituting liquid 68 is then caused to enter the container 10' to reconstitute the dry biological 12' contained therein. After reconstitution, the container 10 may be inverted to effect selective discharge of liquid biological from dispensing tip 40' in the same manner as described in relation to FIG. 2.

The reconstituting liquid 68 may be caused to enter container 10 in a number of manners. If there is a vacuum in container 10', removal of cap 60 will cause the liquid 68 to be drawn into container 10' under the force from atmospheric pressure. If there is no vacuum in container 10 to draw the liquid 68 thereinto, the cap 60 is removed and manual squeezing of the tubular means 38' progressively from the tip 40' toward the base 36', operates to express, or milk, the liquid into the container 10'.

As to the mounting of needle 62, it will be seen that the base 36' and the portion of canal 58' adjacent base 36' is constricted to provide a relatively thickened and less resilient mounting sleeve portion 63 as part of the connector means that includes base 36' through which the shank of needle 62, that is located between the beveled ends of needle 62, is press fit so as to rigidly position needle 62 relative to base 36', and so as to maintain needle 62 in position relative to base 36'. The length of needle portion 64 which projects outwardly of base 36' is selected to be within the axial confines of skirt 51', and preferably of a length so that only the beveled terminus of needle 62 is exposed in the concave well 66', defined in stopper 66. This provides that almost all of the liquid in container 10' may enter needle 62 when the container is inverted to the position of FIG. 2.

In the modified form of device as shown in FIGS. 6 and 7, the dispensing tube means 102 is provided as part of a stopper-shaped base 100 that is intended to fit into and connect to the mouth of a container 10, to substitute for the stopper that is normally provided. The base 100 is provided with a concave well 101 on the inner side. The dispensing tube means 102 is laterally offset from the geometric center of the base 100, and a drain tube segment 108 is rigidly mounted on base 100, and partially extends into the canal 103 of tube means 102. A closure cap 110 slidably fits onto the projecting end of drain tube 108. The dispensing tube means 102 has a bulged portion 104 of thinned walls adjacent the dispensing tip 106 that has a constricted bore or orifice 107 therethrough. A sealing cap 112 seals off the discharge tip 106. The canal 103 of tube means 102 and the well 120 defined by bulged portion 104 carry therein a supply of reconstituting liquid for discharge into container 10, in the manner as described hereinabove in relation to the device of FIGS. 4 and 5.

The base 100 also carries a vent tube means 114 which extends through the base so that when mounted on container 10 one end of vent tube 114 is within container 10 and the other end is outside of the container. A filter 116 is carried on the outer end of vent tube 114, so that any air taken into vent tube 114 for passage into the container 10 must first pass through the filter 116. The filter element in filter 116 may be any appropriate means, such as gauze or cotton. A protective sleeve, or cap, 118 is provided on the extended inner end segment of vent tube 114. The tube 114 projects much further into container 10 than does tube 108, so that vent 114 is operable for venting even when the container is inverted.

In use, the caps 110 and 118 are first removed and the base 100 is mounted on the container, as seen in FIG. 7. Then cap 112 is removed so that the reconstituting liquid may be caused to enter container 10 to dissolve the dry biological 122, after which the combination container and dispenser of FIG. 7 may be used in the manner as disclosed in connection with the description of FIG. 2. The vent means 114 contributes to the ease in dispensing of liquid in controlled size of droplets and prevents air lock from interfering with the dispensing of biological from the tube means 102.

While there has been shown and described a particular embodiment of this invention, it will be obvious to those skilled in the art that various changes and modifications may be made therein without departing from the invention and, therefore, it is intended in the appended claims to cover all such changes and modifications as fall within the true spirit and scope of the invention.

What I claim as new, and desire to secure by Letters Patent of the United States, is:

1. A device for reconstituting a dried biological to liquid form and for effecting selective controlled dispensing of the reconstituted liquid biological, comprising, in combination: a storage container having therein a supply of biological in dried form, elongated tube means carrying a supply of liquid therein that is adapted to be selectively released to reconstitute the dried biological in the storage container, removable closure means at the ends of the tube means for maintaining the supply of liquid in the tube means prior to use, connector means at one end of said tube means for attaching the elongated tube means to the storage container, the other end of said tube means defining a dispensing tip thereat with a discharge orifice therethrough, means for causing the supply of liquid in the tube means to enter the storage container when the removable closure means at said one end of the tube means has been removed to reconstitute the dried biological, and said tube means providing a flexible portion therein adjacent the dispensing tip, which flexible portion is adapted to receive therein liquid from said container when the container is inverted so as to locate a supply of the reconstituted liquid biological within the tube means adjacent said other end when it is desired to dispense liquid therefrom, and said flexible portion being constructed to be flexed by manual digital pressure to effect controlled expressing of liquid biological from the dispensing tip when the removable closure means at said other end of the tube means is removed.

2. A device as set forth in claim 1 wherein said flexible portion of the tube means is bulged to form an enlarged reservoir for reconstituting liquid that is carried in said tube means, the discharge orifice of the tube means being constricted to prevent liquid from running out through said orifice under gravity forces, and the walls of said bulged portion being thinned relative to the remainder of the tube means to permit of manual manipulation thereof for achieving accurate pressurizing of the liquid in the enlarged reservoir to effect dispensing of small, precise amounts of liquid from said dispensing tip.

3. A device as set forth in claim 1 wherein a rigid hollow drain tube is provided extending outwardly from said one end of the tube means for communicating the

interior of the storage container with the interior of the tube means.

4. A device as set forth in claim 3 wherein the tube means and connector means are molded integrally of a resilient material and the connector means is formed to engage and relatively rigidly mount the hollow drain tube relative to said tube means, and the outwardly extending end of the drain tube being sharpened to provide a needle-like piercing point.

5. A device as set forth in claim 1 including venting means separate from said tube means and carried by said connector means for entering into the interior of the storage container to vent the container when the connector means connects the tube means to the storage container.

6. A device as set forth in claim 1 wherein the means for causing the supply of liquid in the tube means to enter the storage container includes the storage container with dried biological therein having a gas pressure therein reduced below atmospheric pressure.

7. A device for both reconstituting a dried biological within a storage container and for thereafter dispensing said reconstituted biological from said storage container through said device; said device comprising, in combination, elongated tube means carrying a supply of reconstituting liquid therein, an aperture means at each end of said tube means, a removable closure means for maintaining each aperture means closed prior to use of the device, connector means operatively associated with said tube means for selectively attaching one end of the tube means to a storage container after the removable closure means at the said one end of the tube means has been removed, the aperture means at one end of the tube means affording flow of the reconstituting liquid there-through from the tube means to the storage container, and the other end of the tube means defining a dispensing tip thereat through which liquid may be selectively expressed by manual digital pressure after the removable closure means at the other end of the tube means has been removed.

8. In a device for controlled dispensing of liquid such as a biological from a rigid, mouthed storage container for the liquid, the improvement comprising a body of resilient material shaped to define an elongated tube means surrounding an elongated bore one end of which is open and adapted to have liquid move freely there-through into and out of the bore of said tube means, the other end of said bore communicating with a constricted discharge orifice in a discharge tip on said body at one end of the tube means which prevents liquid from running through said orifice under gravity forces, a portion of the elongated tube means adjacent said discharge tip defining a bulged tube portion that is flexible relative to said discharge tip and which surrounds an enlarged section of the bore that serves as a liquid reservoir immediately adjacent the constricted discharge orifice, the reservoir having a cross-section dimension at the bulged tube portion that is greater than any other cross-section of the bore in said tube means, and said relatively flexible bulged tube portion permitting of digital pressure on liquid in said reservoir adjacent the discharge orifice to effect controlled expressing of a precise amount of liquid from said discharge tip.

9. A device as in claim 8 wherein the body of resilient material is shaped to define an annular resilient connector integral with the tube means adjacent said open one end of the bore, and a hollow piercing needle, separate from said body, is held by the resilient material of the body in said tube means in communication with said bore and projecting outwardly of the said open end of the bore.

10. A device as in claim 8 wherein the bore of the tube means carries a supply of liquid pre-assembled therein, and removable closure means are provided at the

ends of the tube means for maintaining the supply of
liquid in the tube means prior to use.

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