United States Patent

Meierhoefer

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[54] DISPENSER FOR POWDERED MEDICAMENTS

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[73] Assignee: **American Home Products Corporation,** New York, N.Y.

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[52] **U.S. Cl.**.....**222/564,** 128/272

[51] **Int. Cl.**.....**B67d 3/00**

[58] **Field of Search** 222/563, 564, 569, 80; 128/272; 138/42; 141/330

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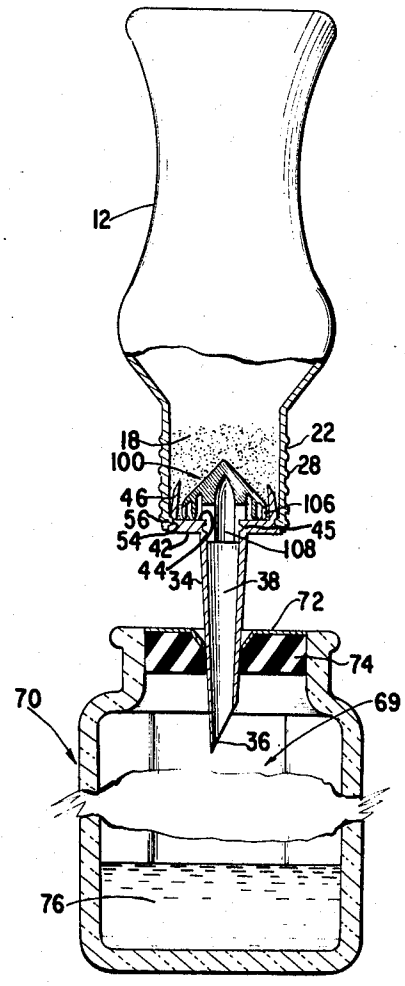
[57] **ABSTRACT**

The disclosure is directed to an improvement in a dispensing package for adding a supplemental medicine to a parenteral solution container which is characterized by a plug disposed between the medicament reservoir and the discharge conduit. The plug has a labyrinth through which solid medicament must pass on discharge. The function of the labyrinth is to prevent the additive powder from being spilled or misdistributed out of the package as the package is being brought into functional engagement with an intravenous solution bottle.

6 Claims, 4 Drawing Figures



Patented May 16, 1972

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2 Sheets-Sheet 1

FIG. 1

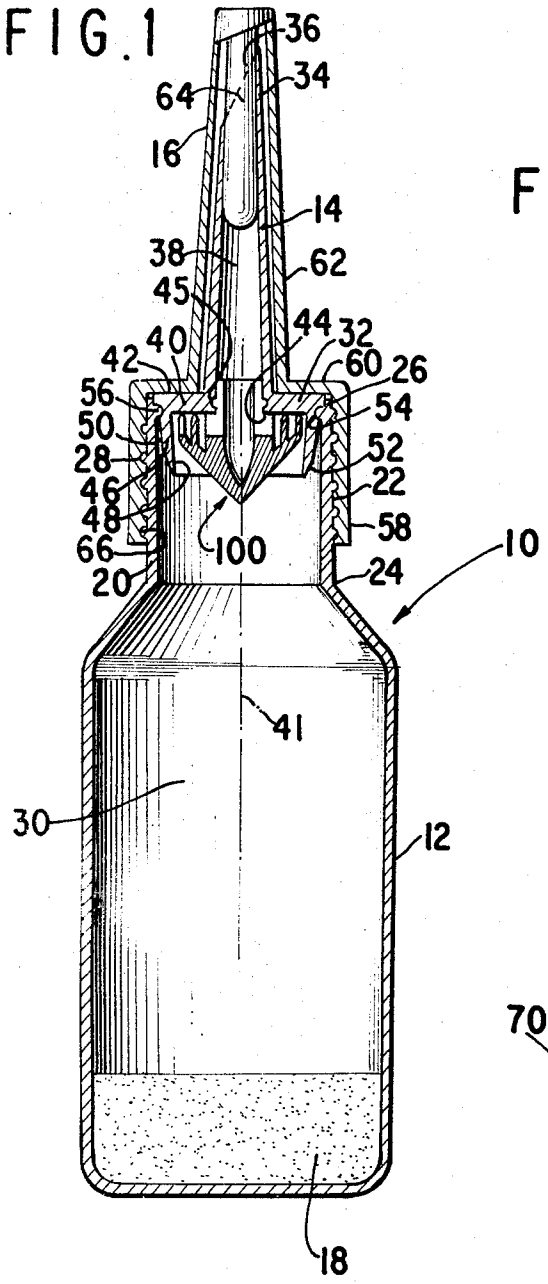


FIG. 2

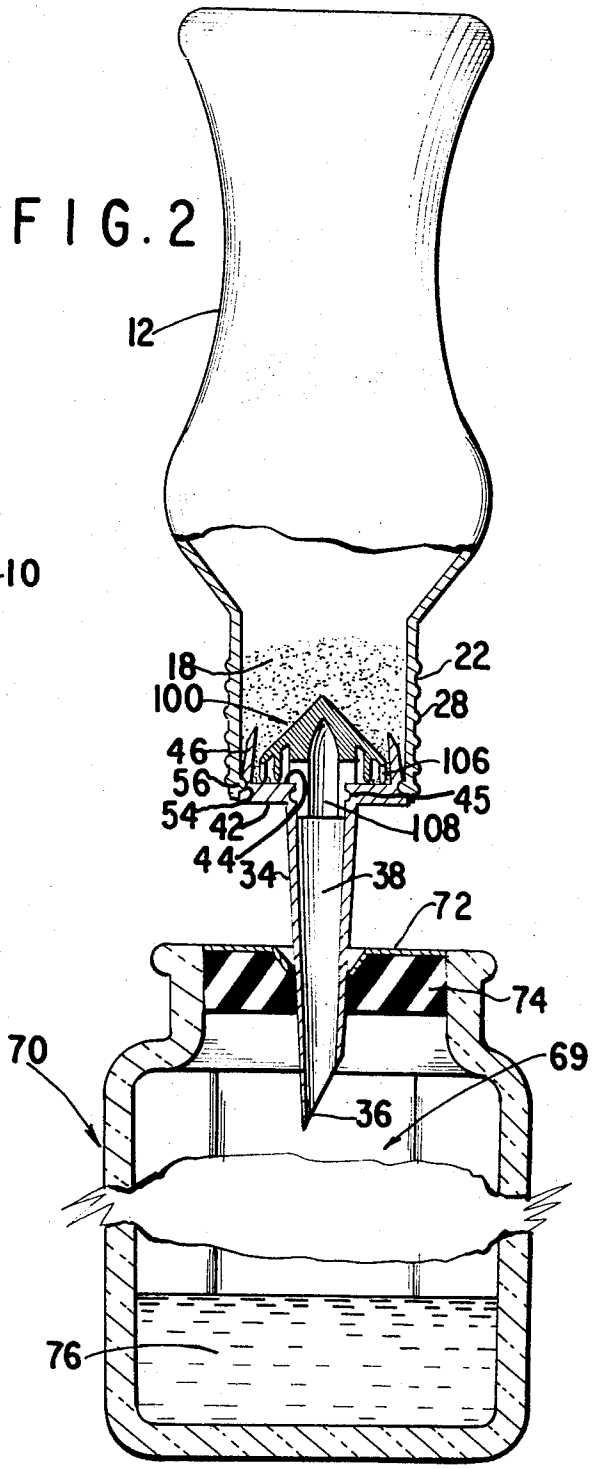
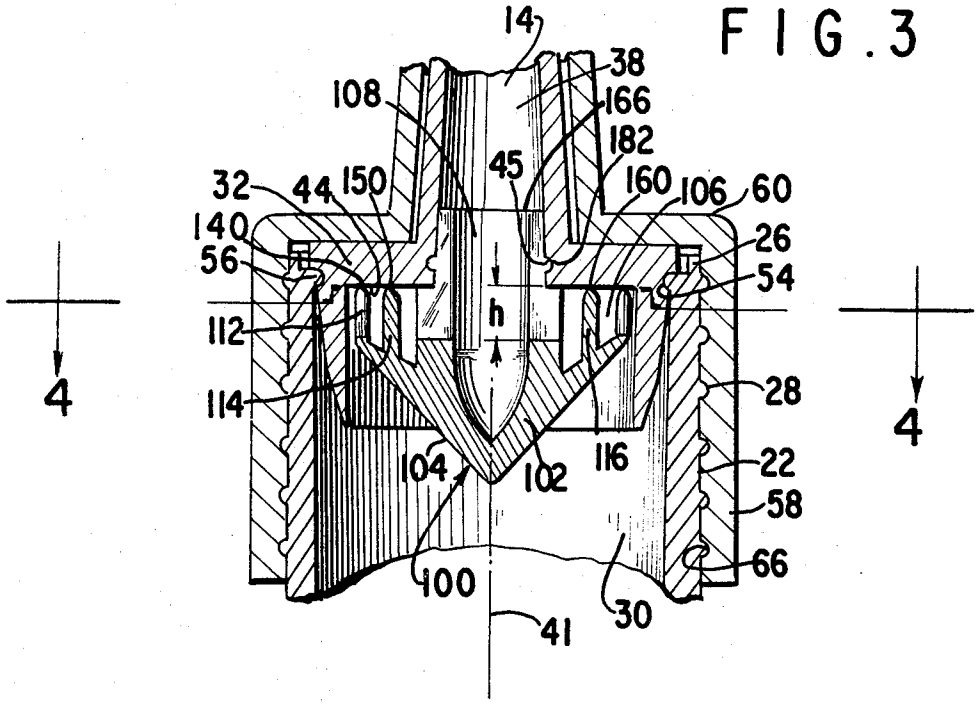


FIG. 3


14
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28
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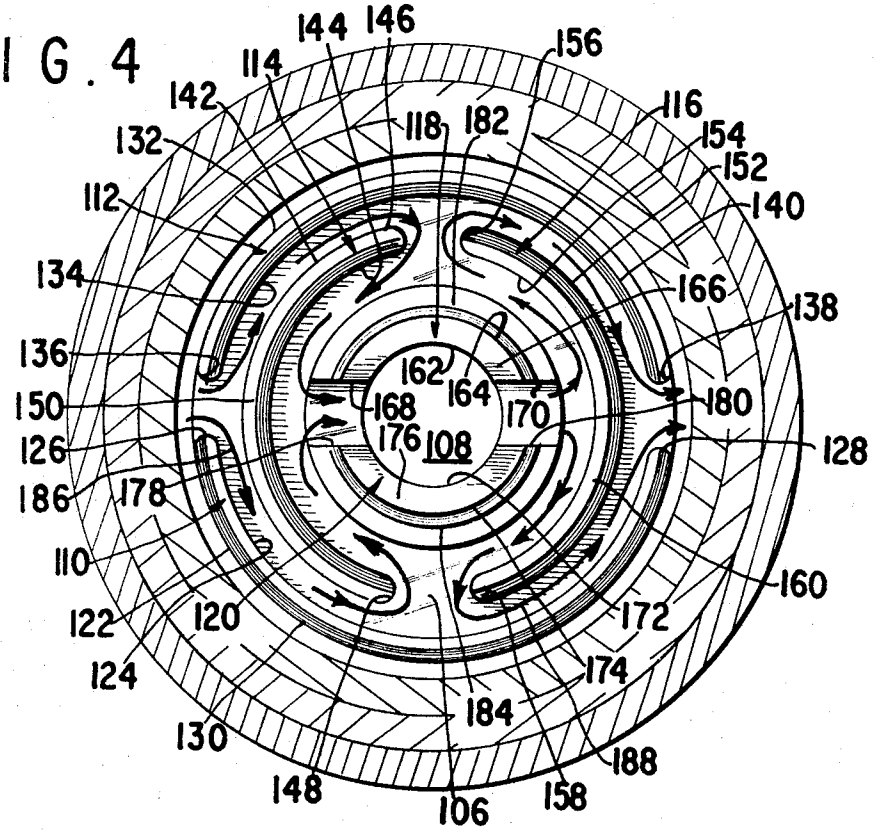
FIG. 4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A DISPENSER FOR POWDERED MEDICAMENTS

This invention is directed to an improvement in dispensing packages for parenteral medicaments which are to be added to an intravenous solution bottle prior to administration to a patient. The improvement is characterized by the interposition of a labyrinth between a powdered medicament contained in a reservoir portion of the medicament package and a conduit used to introduce the medicament into a parenteral solution bottle. Typically the conduit is a hollow "spike." The labyrinth is a series of intricate passageways defined in a "powder plug." The powder plug and its inherent labyrinth prevent the powdered medicament from being spilled or misdistributed out of the conduit as the package is being brought into functional engagement with the parenteral solution bottle.

The package is an improvement on the package described in United States patent application Ser. No. 742,872, filed July 5, 1968, by Howard J. Levin. The improvement comprises, in part, the substitution in the Levin package of a powder plug for the membrane filter described by Levin.

BACKGROUND OF THE INVENTION

Medicaments are frequently added to bottles of parenteral solution for intravenous administration to a patient. Numerous additives are available in powdered form and must be reconstituted by mixing the parenteral solution and the powdered medicament. The powdered medicament may be added directly to the parenteral solution or may be reconstituted and then added back into the parenteral solution bottle for administration to the patient.

Currently two parenteral solution systems are offered: an "open" system and a "closed" system. In either system it is desirable and preferable to invert the medicament package and bring it into sealed engagement with an aperture in the parenteral solution bottle so as to transfer into the additive bottle a quantity of solution for reconstitution of the additive powder. It is undesirable to spill or lose powdered medicament during the act of bringing the medicament package and the parenteral solution bottle into sealed engagement. A problem in the art has been that devices used to prevent inadvertent discharge of the powder have required special provision to assure an adequate flow of solution from the parenteral solution bottle into the medicament package to dissolve the powder. Likewise, a flow path of adequate size is required to transfer the liquid containing the dissolved medicament out of the medicament package back into the parenteral solution bottle.

It is an object of the present invention to provide improved apparatus for the addition of medicaments to both open and closed system parenteral solution bottles.

It is another object of this invention to provide a universal dispensing package for powdered medicaments to be added to intravenous parenteral solution bottles which utilizes a labyrinth to prevent spillage of the medicament.

Other and further objects of the present invention will be apparent to those skilled in the art from reading the following descriptions taken in conjunction with the drawings, in which:

FIG. 1 is a sectional view of a dispensing package embodying the features of the present invention;

FIG. 2 is a partial sectional view showing the embodiment of FIG. 1 in use in conjunction with a closed system intravenous container;

FIG. 3 is a partial sectional view of the package of FIG. 1 particularly showing the details of construction of the powder plug of the present invention; and

FIG. 4 is a sectional view taken generally along lines 4—4 of FIG. 3 showing details of construction of the powder plug of the present invention.

The objects of the present invention may be achieved with a medicament dispensing package which is made up of a reservoir adapted to contain a medicament, a conduit adapted to connect to the reservoir and to convey the medicament from the reservoir to a parenteral solution container, and a powder plug defining a labyrinth which is disposed between the reservoir and the conduit.

A preferred embodiment of the present invention is shown in FIG. 1. A universal dispensing package **10** is made up of a container **12**, a conduit **14**, and an outer cover **16**, and contains a medicament **18**. A powder plug **100** characterizes the invention and is connected at the proximal end of the conduit **14** and is interposed between the medicament **18** and the conduit **14**.

The container **12** has a shank **20**. The outer surface **22** of the shank **20** tapers from a proximal periphery **24** to a distal periphery **26** and generally defines a truncated cone, as shown. The outer surface **22** may have a mechanical thread **28** defined on it to adapt it better to cooperate with the outer cover **16**. The container **12** has a large reservoir **30** defined within it.

The conduit **14** is made up of an annular mounting support **32** and a piercing device **34** tapering from the mounting support to the distal, or discharge end **36**. The annular mounting support **32** and the piercing device **34** are hollow and together define an internal passage **38**. The annular mounting support **32** further comprises a planar portion **40** having a distal surface **42** and a proximal surface **44** which is substantially planar. An annular groove **45** cooperates with the powder plug **100** as further described below to connect the powder plug **100** and the conduit **14** disengageably together. An annular wall **46** is connected to the periphery of the planar portion **40** and tapers toward the axis **41**. The wall **46** has an inner surface **48**, an outer surface **50** and a second outer surface **52** which tapers toward the inner surface **48**. The effect of the tapering of walls **50** and **52** is to provide for fast machine assembly of the conduit **14** to the container **12**. Also defined on the outer surface **50** is an annular groove **54** which cooperates with an annular ridge **56** on the shank **20** which serves to hold the conduit **14** to the container **12**.

As is shown in FIG. 1, the outer cover **16** surrounds the entire conduit **14** and shank **20**. The outer cover **16** is made up of a proximal portion **58**, a shoulder portion **60**, a conical portion **62** and a plug portion **64**. The it portion **58** has internal female threads **66** defined on its which engage the male threads **28** of the container **12** and serve to hold the cover to the container. The plug **64** extends down into the spike **34** filling the distal portion of the passage **38** and preventing discharge of the contents **18** of the container.

In the preferred embodiment, best shown in FIG. 3, the powder plug **100** is composed of a barrier portion **102** and a plurality of arcuate septa connected to the barrier portion **102**. The barrier portion **102** is preferably conical having its apex on the side **104** facing the reservoir **30**. The pitch of the cone is such as to exceed the angle of repose of the powdered medicament **18**. Thus, in the inverted position, the powdered medicament will not build up on the cone but will fall towards the conduit. The arcuate septa define a passageway **106** connecting the interior of the reservoir with an internal passage **108** leading to the internal passage **38**.

In a preferred embodiment, the passageway **106** is defined by the septa **110, 112, 114, 116, 118** and **120**. As may be seen in FIG. 4, septa **110** and **112** are arcuate and concentric about the axis and are mirror images of each other. Septum **100** is made up of surfaces **122** and **124** which are vertical during discharge, have end portions **126** and **128**, and a distal surface **130** which contacts the proximal surface **44** of the conduit support **32**. Similarly, septum **112** has surfaces **132** and **134**, end portions **136, 138** and a distal surface **140**.

Septa **114** and **116** are concentric about the axis **41** and are also mirror images of each other. Septum **114** has surfaces **142** and **144**, end portions **146** and **148**, and a distal surface **150**. Similarly, septum **116** has surfaces **152** and **154**, end portions **156** and **158**, and distal surface **160**.

The innermost septa **118** and **120** are mirror images of each other, are arcuate, concentric about the axis **41**, define interior passage **108** and extend into conduit **14**. Septum **118** has an inner surface **162**, an outer surface **164**, a distal surface **166** and end surfaces **168** and **170**. Similarly, septum **120** is made up of an inner surface **172**, an outer surface **174**, a distal surface **176** and end surfaces **178** and **180**. An arcuate ridge **182**

is defined on the outer surface **164** and an arcuate ridge **184** is defined on outer surface **174**. As shown in FIG. **3**, ridges **182** and **184** cooperate with the groove **45** in the conduit **14** to connect the powder plug **100** and the conduit **14** together and to hold the distal surfaces of the septa in contact with the proximal surface **44** of the conduit support **32**. Thus, the distal surfaces **130, 140, 150, 160, 166** and **176** contact the surface **44** when the powder plug is in place in order to define the passageway **106**.

The medicament may take a number of paths through the powder plug when passing from the reservoir into the conduit as will be apparent from inspection of the drawings. A typical path is shown by the arrow **186** in FIG. **4**. The passageway or channel is defined between septa **110, 114**, between septa **114** and **116**, between septa **114** and **120** and between septa **118** and **120** into passage **108** leading to passage **38**.

A typical entry path for fluid is shown by arrow **188**.

The powder plug **100** which characterizes the invention is substantially comprised of a solid material, such as polyethylene, polypropylene, or the like. As described above, the powder plug **100** is substantially coextensive with the interior surface of that portion of the reservoir which is immediately adjacent to the conduit, has a connector portion attached to it and is adapted to cooperate with the interior surface of the conduit to hold the plug in a predetermined fixed position with relation to the conduit and the reservoir.

The preferred embodiment as shown in the figures utilizes a connector portion which is substantially concentric with a circular solid portion. It is to be understood that the plug portion may be other than circular in shape, if desired, or if dictated by the internal surface of the container. It is to be further understood that the connector portion may be eccentrically placed on the plug where preferred or where dictated by the arrangement of the conduit with regard to the reservoir.

The plug may be formed from one solid piece by diecasting or by machining from a solid stock.

The container **12** is preferably made of polyethylene, but may be made of a similar elastically recoverable material, if desired. The conduit **14** is preferably made of a rigid polyethylene but may be made of any other suitable plastic or metal. The piercing device **34** is typically made of the same material as the remainder of the conduit **14**, but if desired may be made of a different material such as metal or alloy. The outer cover **16** is typically made of a water impermeable plastic, such as heavy gauge polyethylene, but may be made of rubber or other suitable water impermeable material, such as drawn aluminum.

The minimum height *h* of the passageway **106** is shown in FIG. **3**. To prevent the powdered medicament **18** from falling out of the package **10** when inverted, the ratio of the height *h* to the length of the passageway may be less than the tangent of the angle of repose of the powdered medicament. Preferably the minimum length of the passageway **106** is at least five times the minimum height *h* of the passageway **106**.

In use, the outer cover **16** is removed. This may be accomplished by pulling on a pull-tab, not shown, where provided, which propagates a tear along the base of the proximal portion **58** in well known fashion. When used with a closed system intravenous container **70**, as is shown in FIG. **2**, the piercing device **34** is inserted through a sealing member **72** and a rubber stopper **74** of the closed system intravenous container **70**. The passage **38** provides communication between the interior **69** of the container **70** and the contents **18** of the dispensing package **10**. Where the medicament **18** is dry, the walls of the container **12** may be compressed and the tip or discharge end **36** submerged in the intravenous solution **76** by inverting the assembled system. The powder plug **100** prevents the discharge of the powder during this operation. A suitable portion of the intravenous solution **76** may be drawn into the container **12** in order to dissolve the dry medicament. The reconstituted medicament solution may be discharged from the package **10** by compressing the sides of the container **12**. The reconstituted medicament passes through the passages **106** and **108** into the parenteral solution container **70**. The steps may be repeated to flush the container, if desired.

Similarly, the package of FIG. **1** may be used with an open system parenteral solution container, not shown, by inserting the shank **22** of the container into the mouth of the parenteral solution container.

The terms and expressions which have been employed are used as terms of description and not of limitation, and there is no intention in the use of such terms and expressions of excluding any equivalents of the features shown and described or portions thereof, but it is recognized that various modifications are possible within the scope of the invention claimed.

I claim:

1. A dispensing package for powdered medicaments to be added to a parenteral solution prior to parenteral administration comprising:

A. A reservoir adapted to contain a medicament;

B. A conduit connected to said reservoir, and adapted to convey said medicament from said reservoir to a parenteral solution container;

C. A fluid guide structure disposed in said conduit, said fluid guide structure having

1. A conical surface with its apex directed toward said medicament, the slope of said conical surface being greater than the angle of repose of said medicament; and

2. First and second septa connected to said fluid guide structure and engaging interior surfaces of said conduit.

2. A dispensing package as defined in claim **1** wherein each of said first and second septa have a ridge defined on their outer surfaces and said conduit has a groove defined on its inner surfaces adapted to be engaged by said ridges on said first and second septa.

3. A dispensing package as defined in claim **1** wherein said fluid guide structure further comprises a plurality of septa and said conduit further comprises a substantially planar surface adapted to be sealably engaged by said plurality of septa and said planar surface together with said plurality of septa define an elongated passageway.

4. A dispensing package as defined in claim **3** wherein the length of said passageway is at least five times the height of said passageway.

5. A dispensing package as defined in claim **3** wherein said septa are of substantially semicircular configuration centered about a common axis.

6. A dispensing package as defined in claim **3** wherein the ratio of the height of said passageway to the length of said passageway is less than the tangent of the angle of repose of said powdered medicament.

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