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Novitch

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[45] **July 30, 1974**

[54] **METHOD OF PACKAGING RADIOACTIVE MATERIALS**

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[73] Assignee: **New England Nuclear Corporation,** Boston, Mass.

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[21] Appl. No.: **297,791**

Related U.S. Application Data

[62] Division of Ser. No. 190,490, Oct. 19, 1971.

[52] **U.S. Cl.**..... **53/27,** 53/30, 53/37

[51] **Int. Cl.**..... **B65b 29/00,** B65b 3/04, B65b 53/00

[58] **Field of Search**..... 53/3, 15, 27, 30, 37, 42; 215/37 R

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Primary Examiner—Robert L. Spruill

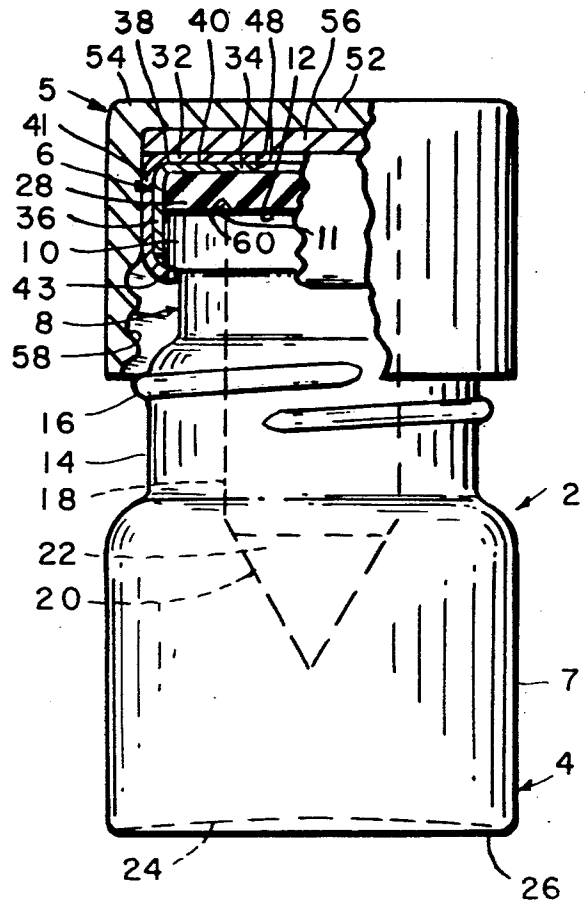
Attorney, Agent, or Firm—Dike, Bronstein, Roberts & Cushman

[57] **ABSTRACT**

A dually sealable, non-leaking vial for shipping liquid radioactive materials, particularly sterile radioactive materials, and other sterile liquid materials in which the mouth of the vial, as shipped, is sealed by a needle pierceable septum seal and in which a threaded cap is located and held over the septum seal and mouth with the threads thereby held out of engagement with mating threads on the vial by the septum seal. However, upon removal of the sepum seal after shipment, the threads of the cap mate with the threads of the vial whereby the cap can be removably threaded tightly over the mouth to seal it.

The capped and septum-sealed loaded vial is placed in a heat shrinkable plastic envelope having a bottom end wall and an upstanding cylindrical wall of greater height than the capped, septum-sealed vial and of lesser thickness than the bottom end wall and the envelope is heat shrunk circumferentially, tightly and sealably around the capped septum-sealed vial with the upper part of the envelope being shrunk circumferentially and downwardly tightly over the margin of the upper surface of the cap to securely seal the capped septum-sealed vial.

3 Claims, 10 Drawing Figures



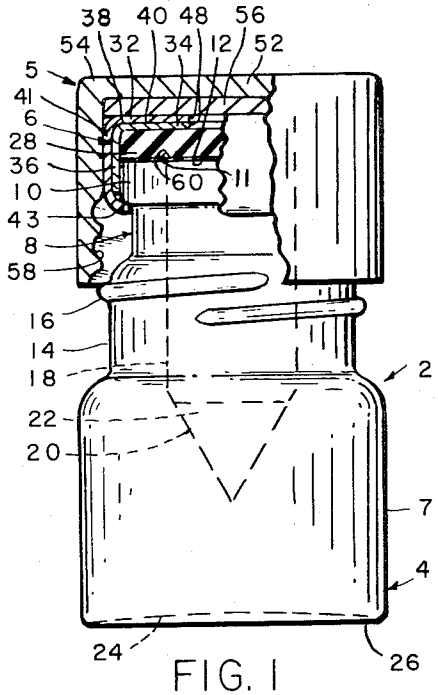


FIG. 1

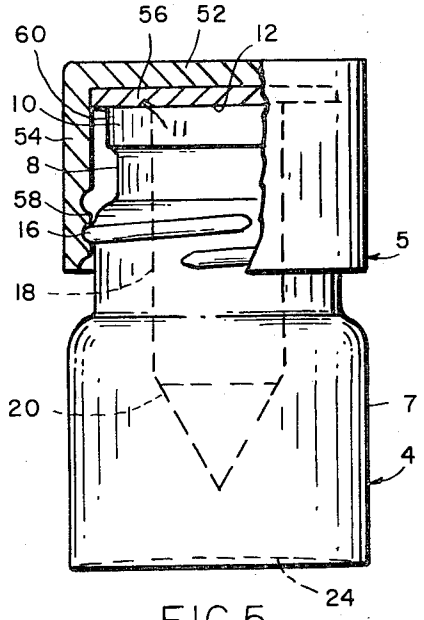


FIG.5

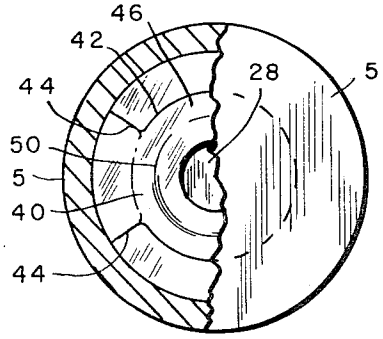


FIG.2

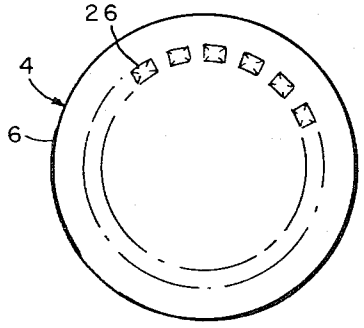


FIG.3

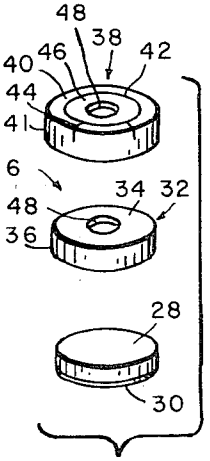


FIG.4A

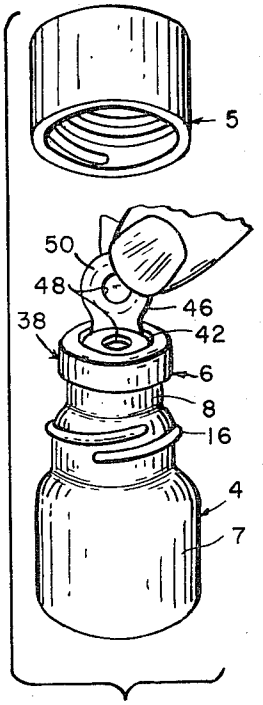


FIG.4

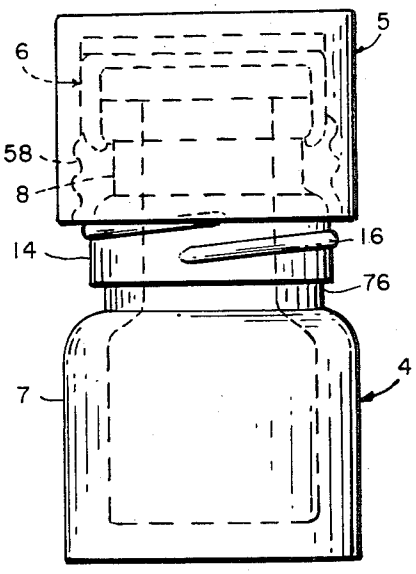


FIG.6

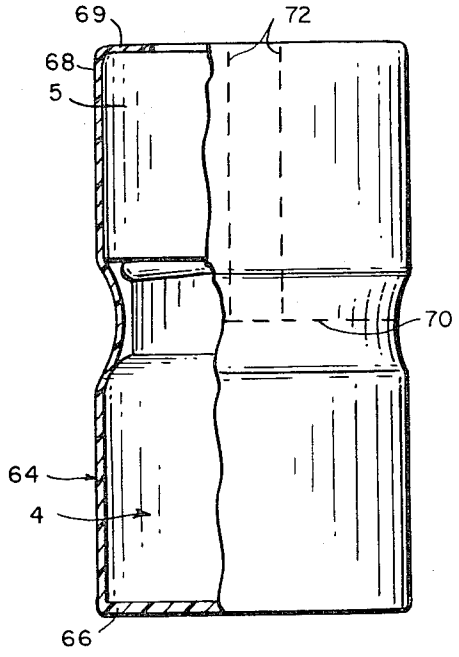


FIG.8

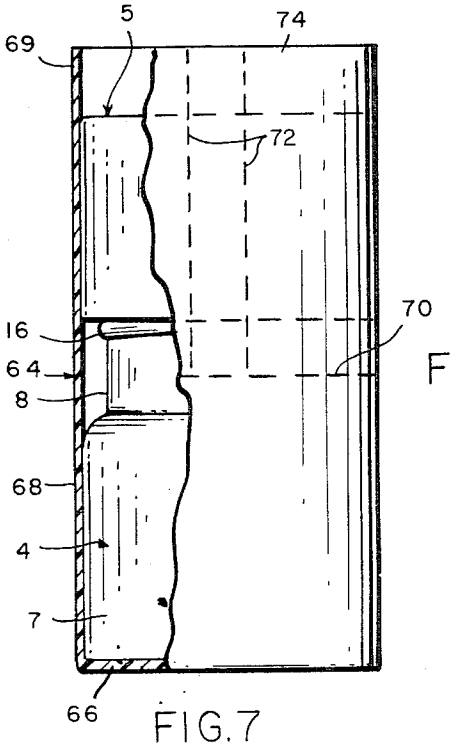


FIG.7

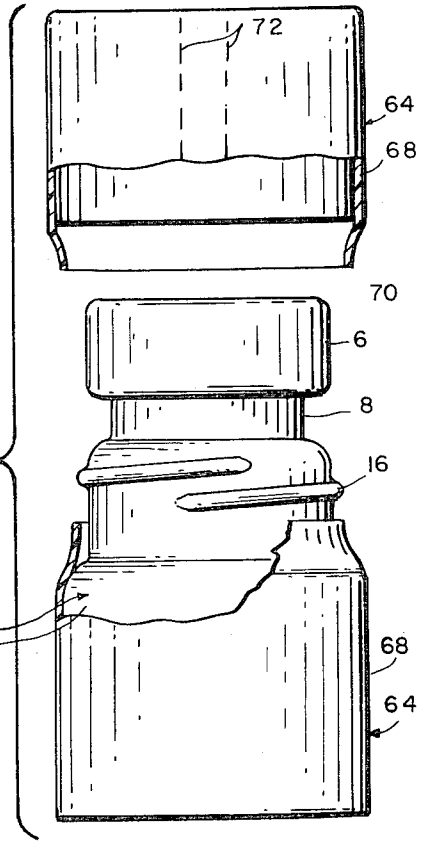


FIG.9

METHOD OF PACKAGING RADIOACTIVE MATERIALS

This is a division, of application Ser. No. 190,490, filed on Oct. 19, 1971.

STATEMENT OF THE INVENTION

The invention relates to a shipping vial for liquid radio-active materials, particularly sterile radioactive materials, e.g., solutions or dispersions of radioactive compounds, and other sterile liquid materials and more particularly to such a vial which is dually sealable and non-leaking.

For many years a recurring problem in shipping radioactive liquids has been the leakage that can occur if a package is so roughly handled that the cap works loose or if a cap was improperly sealed in the plant. This problem is especially serious because the leakage of radioactive materials can be hazardous and also because in many cases the radioactive material is sterile for medical purposes (the vial is also sterile) and the leaking liquid becomes a source of contamination of the sterile liquid while in the vial or when removed from the vial. Consequently, this problem receives greater attention by shippers and customers of radioactive liquids.

The present invention solves this problem by providing a shipping vial, the mouth of which is sealed during shipment by a needle-pierceable septum seal closure removably secured over the mouth and over which a threaded cap is located for sealing the vial by the customer upon removal of the septum seal. In most cases, the vial contains a multidose, i.e., more than one dose, so that the customer uses only part of the radioactive contents of the vial at a time. The first part or dose can be removed from the vial by a syringe (forcing the hypodermic needle of the syringe through the needle-pierceable septum seal). However, after the septum seal has been pierced once by a hypodermic needle for partial removal of the radioactive liquid contents, the integrity of the septum seal may be broken and it may be safer with respect to possible contamination of the remaining sterile radioactive materials in the vial and with respect to subsequent leakage thereof, particularly when an organic solvent, such as benzene or alcohol, is present, to remove the septum seal. Thereafter the vial and remaining radioactive liquid in the vial can be sealed by threading the screw cap tightly over the mouth of the vial and can be removed in parts by pipette as desired by removing the screw cap.

The present invention also permits convenient sterilization of the solutions by autoclaving with the screw cap removed. Conventional screw caps usually can't be used because the seal thereof will not stand autoclaving temperatures.

In accordance with the invention, the septum seal, when removably secured over the mouth, holds internal threads of the cap upwardly, out of mating relationship with cooperating external threads on the vial. The screw cap is held over the septum seal and mouth by a slight friction fit.

The vial has an enlarged diameter body portion and a reduced diameter neck portion which extends upwardly at one end into an enlarged diameter lip forming the mouth of the vial and downwardly at the other end into an enlarged diameter externally threaded portion having the aforesaid external threads.

The height of the reduced neck portion and thickness of the septum seal above the lip cooperate with the distance of the internal threads of the cap from the end wall of the cap to hold such internal threads out of mating or threading engagement with the external threads of the vial. In this respect the internal threads of the cap are located on the inner surface of the cylindrical wall depending from the end wall of the cap around the mouth, septum seal and reduced neck portion.

However, when the septum seal is removed the internal threads of the cap, when placed over the mouth, are located in mating or threading position with respect to the external threads of the vial, whereby the cap can be removably threaded tightly over the mouth to seal the mouth.

In a preferred embodiment, the floor of the interior of the vial is conical-shaped with the apex of the cone located at the bottom of the interior to thereby concentrate a small volume of highly concentrated radioactive liquids to facilitate removal.

Another aspect of the invention employes a cylindrical-shaped envelope of heat shrinkable material, e.g., a resin such as polyvinyl chloride or polyethylene, which has a bottom end wall of greater thickness than the cylindrical wall, which is open at its upper end, which is of greater height than the capped, septum-sealed vial and which snugly receives the periphery of the enlarged body portion of the vial and the periphery of the cap with the bottom of the vial resting on the bottom end wall of the envelope and with the cylindrical wall of the envelope extending upwardly beyond the top of the cap. The capped septum-sealed vial loaded with radioactive liquid is placed in the envelope whereafter the envelope is heat shrunk circumferentially, tightly and sealably around the capped, septum-sealed vial with the open upper end portion of the envelope extending above the cap being heat shrunk circumferentially, downwardly, tightly and sealable over the marginal portions of the top of the cap. In this way, the capped septum-sealed vial is further sealed and the cap is firmly secured in place over the septum seal, mouth and neck of the bottle.

In a preferred embodiment, the envelope is provided with a circumferential line of weakness between the cap-enclosing portion and the enlarged vial body-enclosing portion so that by twisting the cap relative to the vial the sealing envelope breaks along the circumferential line of weakness to permit removal of the cap from the vial.

BRIEF DESCRIPTION OF DRAWINGS

Further advantages of the invention will be apparent from the following description for illustrative purposes of preferred embodiments of the invention and from the accompanying drawings in which:

FIG. 1 is a front view in elevation with sections broken away of a vial embodying the present invention, as shipped, with the envelope removed, with the septum seal in place over the mouth and with the screw cap located over the septum seal;

FIG. 2 is a top view in plan with section broken away of the vial of FIG. 2;

FIG. 3 is a bottom plan view of the vial of FIG. 1;

FIG. 4 is an exploded view in perspective of the vial of FIG. 1 with the screw cap removed and the septum seal being removed;

FIG. 4A is an exploded view in perspective of the three parts of the septum seal of FIG. 1;

FIG. 5 is a view like FIG. 1 of the vial of FIG. 1 with the septum seal removed and the screw cap screwed over the vial mouth to seal the vial;

FIG. 6 is a view like FIG. 1 disclosing another embodiment of the invention in which the interior of the vial is not conical shaped at its bottom as in FIG. 1;

FIG. 7 is a view like FIG. 1 of the vial of FIG. 1 placed in the heat shrinkable envelope but before heat shrinkage;

FIG. 8 is a view like FIG. 7, with the heat shrinkable envelope shrunk around the capped septum-sealed vial;

FIG. 9 is a view like FIG. 8 but in which the cap has been removed from the septum-sealed vial by breaking the heat shrunk envelope along a circumferential line of weakness by twisting the cap relative to the vial.

With reference to the figures, **2** represents the capped, septum-sealed vial made up of a glass or plastic vial **4**, a plastic cap **5** and a septum seal **6**.

The glass vial **4** consists of an enlarged diameter body portion **7**, a reduced neck portion **8** extending upwardly into an enlarged diameter lip **10**, which has a slight upstanding circular ridge **11** at its inner margin and which forms the mouth **12** of the vial, and downwardly into an enlarged diameter externally threaded portion **14** having external threads **16**. Threaded portion **14** is of smaller diameter than body portion **7**.

The hollow interior **18** of the vial has a conical shaped floor **20** containing a sterile radioactive liquid **22**.

The outer bottom surface of the vial is dished centrally inwardly at **24** to form a marginal rim **26** which rests against the supporting surface for the vial and which is stippled or corrugated to reduce risk of toppling or sliding.

The septum seal **6** is conventional and is made up of (a) a needle pierceable circular rubber disc **28** having secured to its lower surface a thin layer **30** of teflon, (b) a cylindrical-shaped malleable aluminum holder **32** for the disc **28** and having an apertured end wall **34** located over the top of the disc **28** and a depending cylindrical wall **36** which snugly receives the periphery of disc **28**, and (c) a cylindrical shaped aluminum securing member **38** having an apertured end wall **40** located over the top of disc **28** and over the end wall **34** of holding member **32** and a depending cylindrical wall **41**, which snugly receives the periphery of holder **32** and which extends downwardly beyond the lower edge of holder **32** and is crimped at **43** under the lip **10**, as shown, to urge the teflon coated layer **30** of resilient disc **28** snugly and sealably against the upper surface **60** and upstanding ridge **11** of the lip **10**, the ridge **11** becoming embedded in the resilient teflon coated layer **30**, as shown, to provide an excellent seal.

The upper end wall **40** has a semi-circular cut line **42** the ends of which extend into score lines **44** which extend radially to the outer edge of end wall **40** and downwardly in parallel relation a substantial distance along the depending wall **41**. The semi-circular cut line **42** forms a tab **46** which, when cap **5** is removed, can be lifted as shown in FIG. **4** and pulled or peeled back to break the securing member **38** by tearing the end wall **40** and cylindrical wall **41** along one or both of the score lines **44**. Upon breaking the securing member, the whole septum seal is removed.

The axially aligned apertures **48** in the end walls of holding member **32** and securing member **38** expose the rubber disc **28** for piercing by the hypodermic needle of a syringe.

The end wall **40** of the securing member has a circular upstanding rib **50** stamped into it between the aperture **48** and semi-circular cut line **42**.

The rigid plastic cap **5** has an end wall **52** and a cylindrical wall **54** depending downwardly therefrom around the septum seal **6**, the mouth **30**, the neck **8** and the upper part of threaded portion **14**, as shown.

The inner surface of end wall **52** is provided with a sealing disc **56** of flexible material, such as mylar lined pulp (cardboard) or teflon or cork or rubber, and the inner surface of depending wall **54** has internal threads **58** for cooperating with the external threads **16** of the vial to thread the cap **5** tightly over the mouth **12** and neck **8** of the bottle and thereby urge the sealing disc **56** tightly and sealably against the upper annular surface **60** and upstanding ridge **11** of lip **10** to seal the vial after the septum seal **6** has been removed, as aforesaid, the ridge **11** becoming embedded in the flexible disc **56** to increase the sealing effect.

However, when the septum seal is secured to the mouth of the vial, the thickness of such seal above the lip **10** together with the height of neck **8** and the distance of the internal threads **58** from the lower inner surface of sealing disc **56** of the cap holds such internal threads **58** upwardly out of threading or mating engagement with external threads **16**, thereby preventing threading of the cap on the vial. In this respect, when the cap **5** is placed on the septum-sealed mouth of the vial it is pushed downwardly over the septum seal and mouth until the inner surface of sealing disc **56** of cap **5** rests against the top of the septum seal, as shown in FIG. **1**. In this position the cap is held on the septum-sealed vial by light friction but cannot be threaded on the vial, as aforesaid. It can be threaded to the vial to form a seal only after removal of the septum seal.

The capped septum-sealed vial of FIG. **1** is preferably shipped in a cylindrical envelope **64** (FIGS. **7–9**) made of a thin film of flexible heat-shrinkable resin, such as heat shrinkable polyvinyl chloride or polyethylene, which is closed at its bottom by an end wall **66** substantially thicker by **4** or **5** times and more rigid than the cylindrical wall **68** of the envelope, which is greater in height than the height of the capped, septum-sealed vial so that the open end portion **69** thereof extends above the top of cap **5**, and which snugly but slidably receives the enlarged diameter body portion **7** of the vial and the outer periphery of cap **5**, which in the drawings is the same in diameter as the enlarged body portion **7** of the vial, all as shown in FIG. **7**. The cylindrical wall **68** of the envelope has a circumferential line of weakness **70**, in this case a perforated line **70**, extending around the circumference thereof between the portion thereof enclosing cap **5** and the portion thereof enclosing body portion **7**, and a pair of closely spaced parallel lines of weakness **72**, i.e., perforated or score lines, extending longitudinally between circumferential score line **70** and the upper open end **74** of the envelope **64**.

The capped, septum-sealed vial of FIG. **1**, loaded with sterile radioactive liquid, is placed in the envelope **64**, as shown in FIG. **7**, with the bottom of the vial resting on the lower end wall **66** of the envelope, after which the envelope is heat shrunk circumferentially,

tightly and sealably around the periphery of the capped septum-sealed vial with the portion **69** of the envelope being heat shrunk circumferentially and downwardly tightly and sealably against the outer margin of the top surface of cap **5**, as shown in FIG. **8**, to seal the capped septum-sealed vial and to secure and seal the cap **5** to the vial.

In this way, a plural seal is provided, the cap is firmly secured to the vial and the envelope protects the label applied to the outside of the vial and also seals within it any radioactive contamination on the outside of the vial and/or cap caused by handling.

By twisting the cap **5** relative to vial **4**, the adhesion of the envelope to the cap **5** and body portion **7** of the vial causes the upper part of the envelope above score line **70** to twist relative to the lower part thereof below such score line to thereby cause the envelope to break at **70**, whereupon the cap with the envelope still adhered thereto can be lifted off the septum-sealed vial with the envelope still adhered thereto, as shown in FIG. **9**, whereafter the envelope can be aspectically removed from the cap by pulling off the strip of envelope formed by the score lines **72**. This can be done by grasping the strip at its lower end and pulling it up to break the envelope at the score lines.

The thicker end wall **66** of the envelope prevents it from buckling and wrinkling because of heat shrinkage during heat shrinking of the envelope about the vial. Buckling and wrinkling of this end wall which supports the vial would reduce the stability of the vial on supporting surfaces.

The embodiment shown in FIG. **6** is the same as that shown in FIGS. **1–5** except for the conical-shaped interior floor and except that there is a second neck **76** of reduced diameter between the externally threaded portion **14** and the body portion **7** of the vial.

When the internally sterile vial package is received by the customer, the cap is aseptically removed from the sterile septum-sealed vial, as aforesaid. The first dose of the sterile radioactive liquid in the internally sterile vial can be removed aseptically by a sterile syringe by piercing the sterile septum-seal with the needle of the syringe or the septum-seal can be aseptically removed, as aforesaid, and the first dose removed aseptically by a sterilized pipette. If the first dose is taken by syringe, the septum-seal is then removed aseptically and the cap, after removal of the envelope **64** therefrom, is threaded tightly over the mouth of the vial to seal the vial, whereafter further doses can be aseptically removed as desired by pipette after first aseptically unscrewing the cap.

The vial may be sterilized before being aseptically loaded with the sterile liquid radioactive material and aseptically sealed by the aseptic septum seal or may be sterilized after loading and either before or after sealing by the septum seal but before the screw cap is applied, followed by placing the sterile screw cap over the sterile septum seal and aseptically sealing with the sterile envelope. A preferred manner of sterilizing is by autoclaving.

The aforesaid description and accompanying drawings are for purposes of illustration only, and it is not intended that the invention be limited thereby or thereto, the invention being limited only to the products and methods claimed in the aforesaid claims and their equivalents.

What I claim is:

1. A method of packaging a sterile liquid material comprising placing a predetermined amount of said liquid material in the body portion of a vial also having a neck portion forming a mouth for receiving the liquid material, said mouth being formed by an enlarged diameter lip at one end of said neck portion, the other end of which extends into an externally threaded portion, securing to said mouth a septum seal having a needle pierceable disc and means for sealably securing said disc to said mouth, placing a threaded cap over said septum seal said cap having a wall depending around said septum seal, placing the capped septum-sealed vial in a cylindrical heat shrinkable envelope, which is of greater height than said capped vial and which is open at its top and closed at its bottom by a bottom wall, with the bottom of the vial resting on said bottom wall of said envelope and the cylindrical wall of said envelope extending upwardly beyond the top of said cap and with the enlarged body portion of said vial snugly received by said envelope, heat shrinking said envelope circumferentially, sealably and tightly around said capped septum-sealed vial with the portion of said envelope above said cap being heat shrunk inwardly, downwardly, tightly and sealably over the outer margin of the top surface of said cap to thereby seal the capped septum-sealed vial and secure the cap to the vial.

2. A method according to claim **1**, said liquid material being a radioactive material and said vial being sterilized either before or after loading with said liquid material.

3. A method according to claim **2**, also including aseptically removing said cap from said septum-sealed vial by twisting it relative to the vial to break a circumferential line of weakness in said envelope between the cap-enclosing portion thereof and the enlarged vial body-enclosing portion thereof, removing said septum seal from said mouth and threading said cap on said vial to seal said mouth.

* * * * *