

[54] **DUALLY SEALABLE, NON-LEAKING VIAL FOR SHIPPING RADIOACTIVE MATERIALS**

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[51] Int. Cl. **B65d 51/22**
[58] Field of Search **215/37 R, 38 R, DIG. 3, 215/40**

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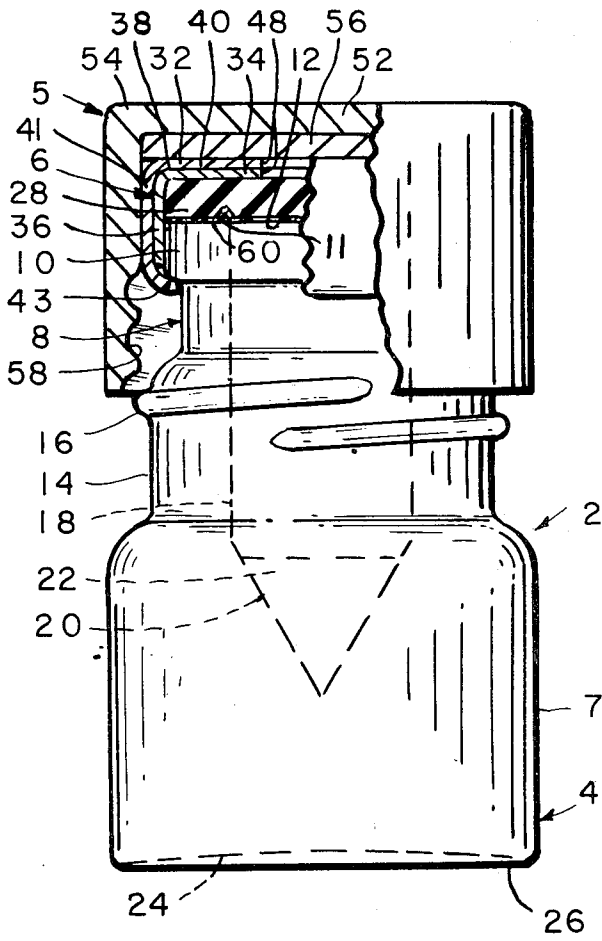
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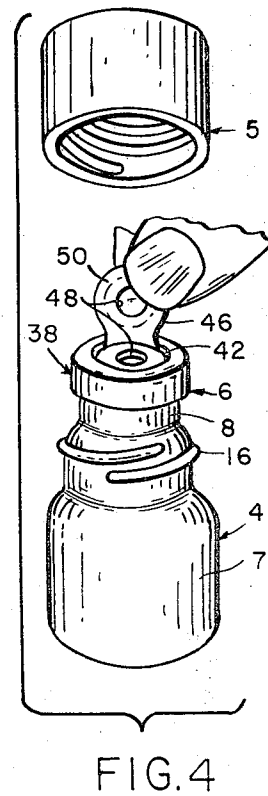
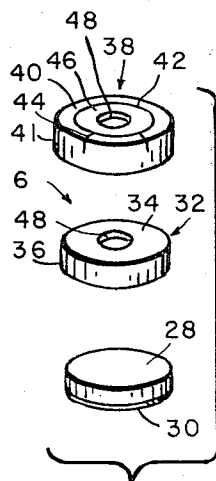
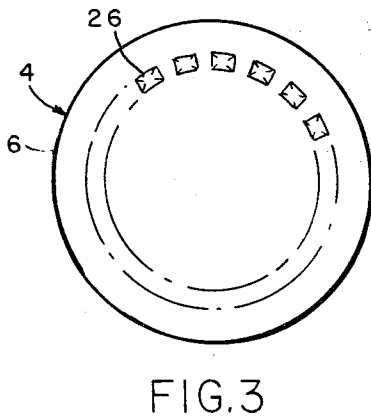
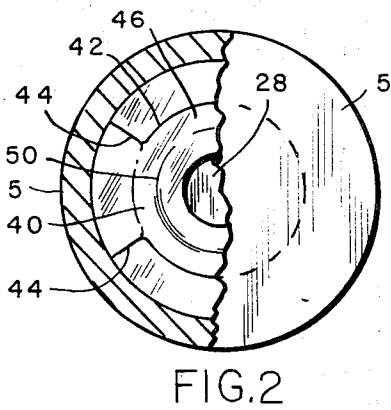
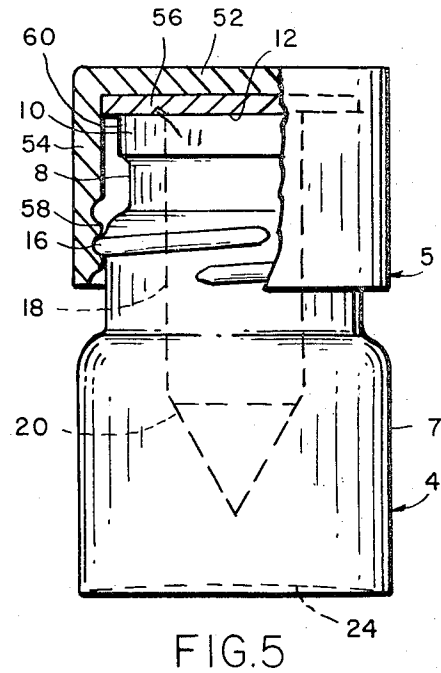
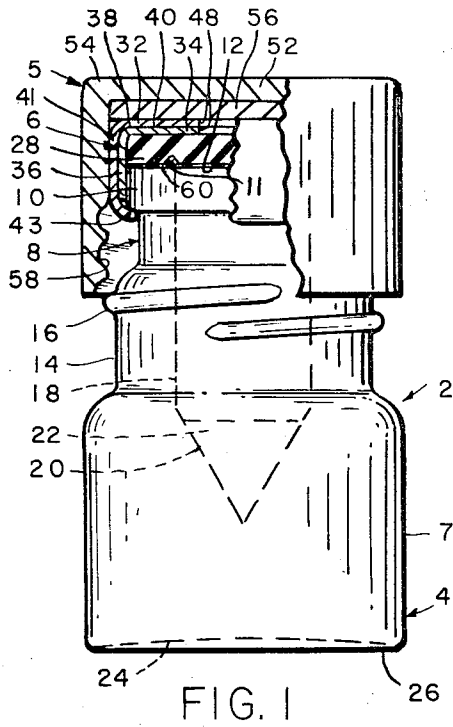
[57] **ABSTRACT**

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 septum 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.

6 Claims, 10 Drawing Figures





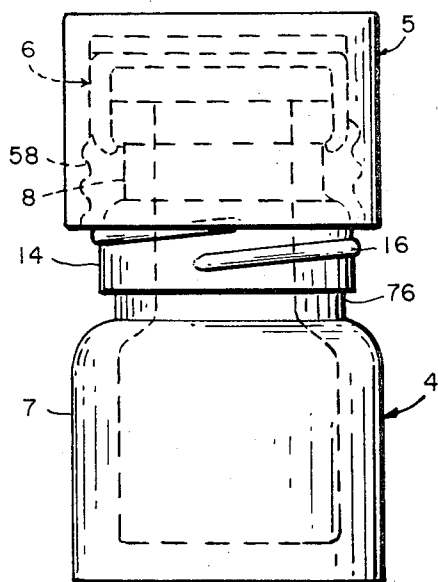


FIG. 6

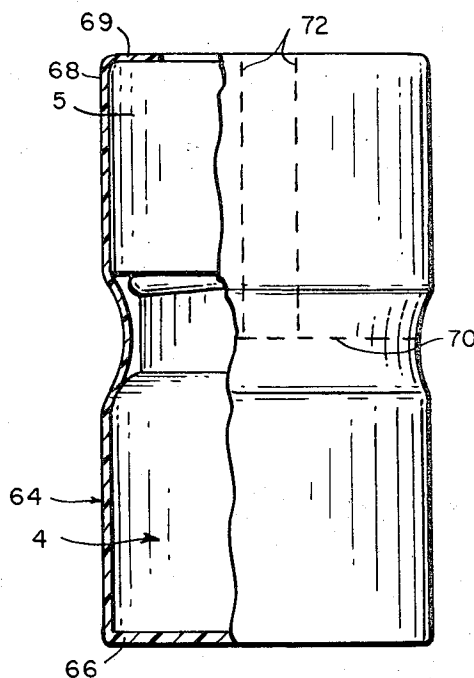


FIG. 8

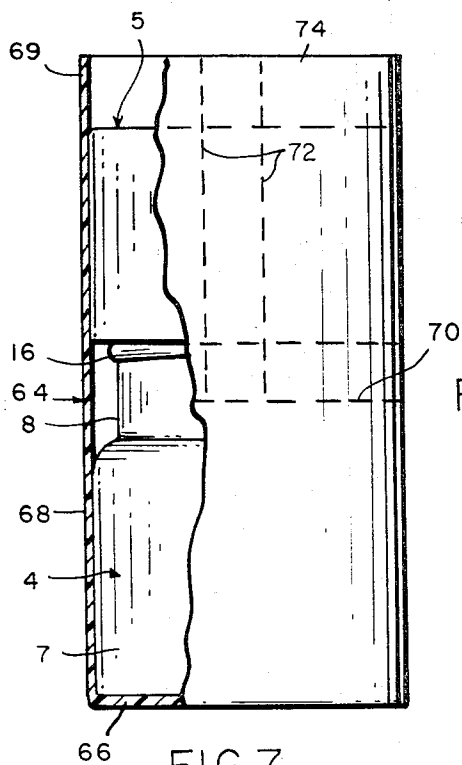
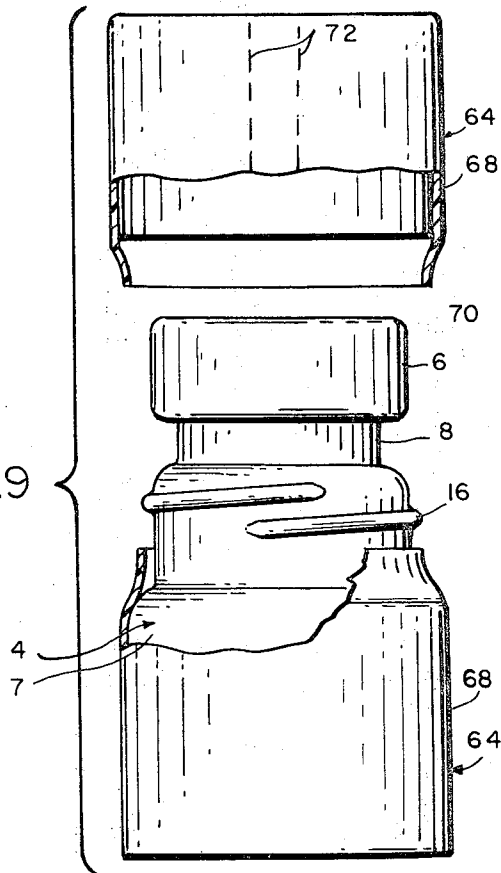


FIG. 7

FIG. 9



DUALLY SEALABLE, NON-LEAKING VIAL FOR SHIPPING RADIOACTIVE MATERIALS

STATEMENT OF THE INVENTION

The invention relates to a shipping vial for liquid radioactive 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 employs 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 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 as 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 aseptically 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 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.

I claim:

1. A sealed vial for shipping liquid radioactive materials comprising in combination a vial having a mouth and threaded portion below said mouth, a needle-pierceable septum seal removably and sealably secured over said mouth, a sealing cap located over said septum seal and mouth and having threads held out of mating engagement with said threads of said vial by the thickness of said septum seal when said septum seal is located over said mouth, said cap threads being located in mating engagement with said threads of said vial when said septum seal is removed from said mouth whereby said sealing cap may be removably threaded over said mouth to seal the mouth when said septum seal is removed.

2. A vial according to claim 1, said vial comprising an enlarged body portion and a reduced neck portion extending upwardly into a enlarged lip forming said mouth and downwardly into said threaded portion, the threads of which are external, said cap comprising an end wall and a cylindrical wall depending therefrom around said septum seal, mouth and reduced neck, said cap threads being located on the internal surface of said depending wall and being held above said external threads of said vial by said neck and septum seal to hold said internal threads out of mating engagement with said external threads.

3. A vial according to claim 2, the inner surface of said end wall of said cap having a sealing disc secured thereto which is urged into sealing engagement with said lip when said cap is threaded over said mouth to seal the mouth when the septum seal is removed from said mouth.

4. A vial according to claim 2, the outer surface of the bottom wall of said vial being dished in at its center with the outer margin thereof being corrugated.

5. A vial according to claim 1, the interior of said vial being conical shaped at its bottom to concentrate the radioactive material in the vial, said mouth being formed by an enlarged lip having an upstanding ridge for cooperating with the septum seal to increase sealing effect.

6. A vial according to claim 1, said septum seal comprising a pierceable rubbery disc secured to said lip by a securing member having an apertured upper end wall located over the top of said disc and a cylindrical end wall depending downwardly around the peripheries of said disc and lip and thence under said lip to urge said disc sealably against said lip, said end wall of said securing member over said disc being cut to form a tab for pulling said securing member and disc off said mouth of said vial to thereby remove the septum seal from said mouth whereby said cap can be sealably threaded thereon.

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