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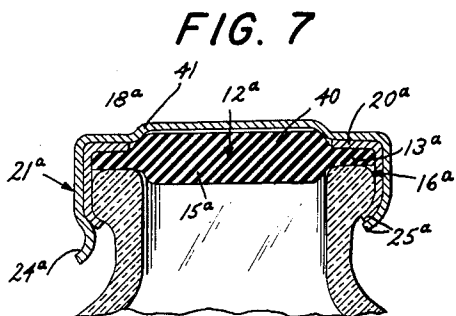
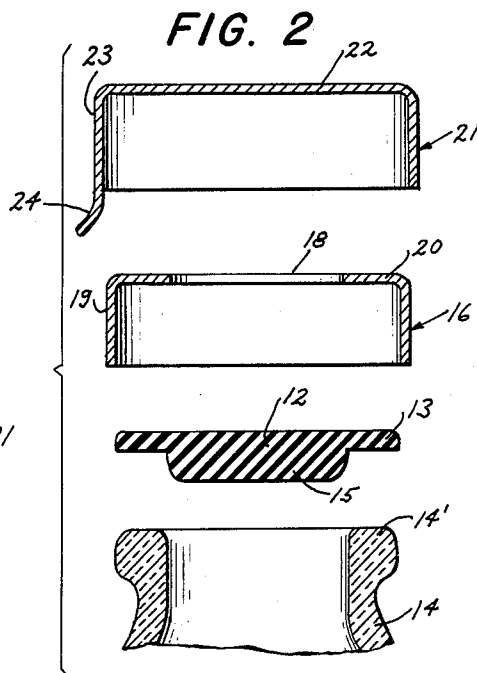
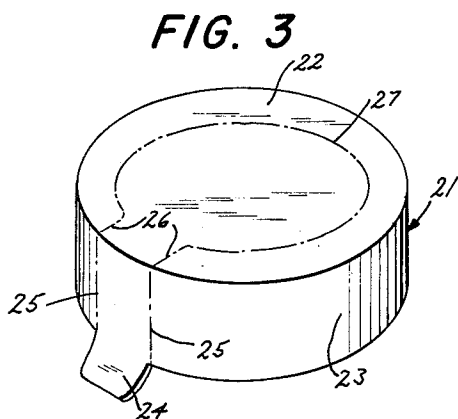
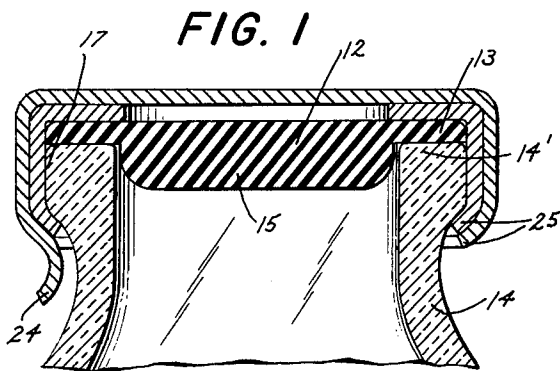
J. U. GOULD

3,013,687

CLOSURE FOR PACKAGES OF BIOLOGICAL PRODUCTS

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2 Sheets-Sheet 1



INVENTOR.
JACK U. GOULD

BY
Dean, Fairbank & Kirsch
ATTORNEYS

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CLOSURE FOR PACKAGES OF BIOLOGICAL PRODUCTS

Jack U. Gould, Brooklyn, N.Y., assignor to Ferdinand Gutmann & Co., a corporation of New York
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The present invention relates to bottle closures that have specialized utility in assuring maintenance of sterility after withdrawal of successive doses from the bottle by means of a hypodermic syringe.

The present invention is a continuation in part of my earlier application, Serial No. 520,227 filed July 6, 1955, which issued as Patent No. 2,891,689 on June 23, 1959.

It is among the objects of the invention to attain the advantages set forth in the earlier application above identified, with the use of the special form of gasket which the present application has in common with said earlier application and, in addition, to protect the entire area of the gasket face from access of dust or contamination until the outer or tear cap has been removed and access is first to be had to the biologic preparation, yet to assure secure and permanent retention of the gasket in place and in one embodiment to protect the entire area of the gasket face from access of dust or dirt thereto after the outer tear cap has been removed and the hypodermic syringe needle repeatedly inserted and withdrawn for removing each of successive doses from the bottle.

In the accompanying drawings in which are shown one or more of various possible embodiments of the several features of the invention,

FIG. 1 is a transverse sectional view of one embodiment of the invention showing the closure installed on a bottle;

FIG. 2 is a dropped side elevation of the component elements of the closure in their correlation to the bottle neck to which the same is to be applied;

FIG. 3 is a perspective view of the outer or tear cap of the closure;

FIG. 4 is a view similar to FIG. 1 of another embodiment of the invention;

FIG. 5 is a view similar to FIG. 2 of the embodiment of FIG. 4;

FIG. 6 is a view similar to FIG. 3 of the embodiment shown in FIG. 4;

FIG. 7 is a view similar to FIG. 1 showing a modification of the embodiment of FIGS. 1, 2 and 3; and

FIG. 8 is a view similar to FIG. 4 of a modification of the embodiment of FIGS. 4, 5 and 6.

Referring now to FIGS. 1 to 3 of the drawings, the closure cap embodies a gasket 12, preferably of a suitable formulation of natural rubber, though suitable synthetic elastomer or blends thereof, including or excluding natural rubber, may serve for some uses. All such materials are embraced within the term "elastomer" as used in certain of the claims. The gasket has an outer rim or annular portion 13 of relatively small thickness, which ordinarily may be in the order of .050". That thickness is adequate for effecting a complete seal against the rim 14' of the bottle neck 14 when the flange or skirt of a sheet metal cap of aluminum or other suitable material is crimped in place as more fully to be described below, under the bead 17 around the rim of the bottle 14.

The central portion of the gasket 12 is of much greater thickness, which serves as a pilot 15 for proper positioning of the gasket, said pilot portion being preferably in the order of .130" in thickness, which is ordinarily required to assure adequate automatic reseat of the puncture in the gasket made by the needle of a hypodermic syringe (not shown), inserted for effecting removal of a dose of the biologic material from the bottle.

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In a preferred application, the thickened or pilot portion 15 of the gasket extends wholly below or from the underface of the annular rim portion 13 which is to rest upon the bottle rim 14', to which the closure is to be applied. Thus in a preferred embodiment the rim would be of thickness of about .050", as above indicated, while the center or pilot portion 15 would be of thickness in the order of .080" protruding from the underface of the rim thickness.

The thicker pilot portion 15 of the gasket is to be accommodated concentrically in the neck of the bottle and has a maximum diameter somewhat less than the bore diameter of the bottle neck 14, thereby to extend loosely into said neck.

The closure in this embodiment includes two metal cap members, viz. an inner cap member 16, the cap disc of which has a large central aperture 18 of diameter substantially equal to that of the pilot 15 of the gasket and a skirt or flange 19 and an annular rim 20. The closure also has an outer cap 21 which completely encompasses the inner cap and comprises a flange or skirt 23 and a cap disc 22 that covers the aperture 18 of said inner cap 16, as well as its annular portion 20 that is in engagement with the annular rim portion 13 of the gasket 12.

The skirts 19 and 23 respectively of the inner cap 16 and the outer cap 21 are of widths such as to afford facilities for crimping the same at 25^a under the bead 17 near the rim of the bottle neck 14 and thereby to exert and maintain pressure of annular rim 20 against the annular rim portion 13 of the gasket 12.

The outer cap 21 is preferably provided with a pull tab 24 protruding downwardly from the lower rim of skirt 23. Extending from the sides of said pull tab 24 is a tear line extending at 25 the height of the side wall of the cap and radially inward therefrom at 26, these radially inward portions 26 being connected by a circular tear line 27 which may be concentric with the cap disc 22.

Thus when access is to be had to withdraw biologic substance from the bottle as it comes from the manufacturer, the physician will grasp the pull tab 24 and sever the tear area by a sharp pull thereon, whereupon the mutilated outer cap 21 may readily be removed from the bottle. Thus, the central aperture 18 of the inner cap 16 exposes substantially the entire central area of the gasket 12. The physician may now pierce the gasket with the needle of a usual hypodermic syringe and after withdrawal of said syringe with its contained dose of biologic material, the gasket of elastomer will reseat to close the little aperture that had been made by the needle. The inner cap 16 crimped on as at 25^a maintains the gasket 12 securely pressed at its rim 13 against the rim 14' of the bottle neck, so that the gasket may again be pierced as required until the contents have been spent, by the needle of the hypodermic syringe for withdrawing further doses, it being understood that the physician will swab the exposed face of the gasket with alcohol to sterilize it prior to introducing the needle each time.

In the embodiment of FIGS. 4, 5 and 6, there is utilized in addition to the inner cap 16' and the outer cap 21' an intervening dust cap 30. The inner cap in the embodiment of FIGS. 4, 5 and 6 is identical with the inner cap 16 in the embodiment of FIGS. 1, 2 and 3. The outer cap 21 may also be identical with the outer cap 21 of FIGS. 1, 2 and 3, except that illustratively, the tear cap has its pull tab 31 severed at 31' concentrically with the cap disc 22' about almost its entire periphery. Pull tab 31 may be of diameter approximately that of the central aperture 18' in the inner cap, leaving the annular rim 20' in the disc of cap 16'. Weakened lines 33 extend outwardly from the root 32 of the pull tab 31 to the rim of the cap and thence downwardly at 34 along the flange or skirt 23' of the same.

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The dust cap 30 has an imperforate end wall 36 and a flange or skirt 37 of length or height less than those of the inner cap 16' and the outer cap 21'. Thus, in the closure as assembled to the bottle, the lower rim of the dust cap 30 is located above the lower edge of the maximum diameter portion of the bottle bead 17', while the skirt 23' of the outer cap 21' is of length sufficient to be crimped under the bottle neck, together with the edge of the inner cap 16' whose skirt is also of sufficient length to permit such crimping as best shown at 25' in FIG. 4.

To gain access to the biologic substance in the embodiment of FIGS. 4 to 6, the physician will grasp the pull tab 31 and pull outward and downward thereon to remove the same, since the cap will tear along the tear lines 33 and along the tear lines 34 on the flange or skirt 23'. Thus the cap 23' becomes split and may then readily be removed from the bottle. The physician will then remove the dust cap 30 thereby exposing the aperture 18' of the inner cap 16'. After penetration of the gasket with a hypodermic needle and withdrawing a dose of biologic substance therewith, immediate resealing of the little aperture formed in the gasket 12' by the needle will occur by virtue of the inherent resiliency of the gasket 12'. The physician will then slip the dust cap 30 on, thus protecting the otherwise exposed central area of the gasket 12' from access of dust or dirt. Access may be had again and again to the contents of the bottle to remove successive doses in the manner previously set forth.

Referring now to the embodiment of FIG. 7, which is a variant of FIGS. 1, 2 and 3, the gasket is there shown with a pilot portion 15^a and a corresponding upwardly extending portion 40. In other words, the pilot may be of about one-half the thickness of that shown in FIG. 1, the other half of that thickness being taken up by the portion 40 extending above the rim portion 13^a of the gasket 12^a. Thus, the rim portion of the gasket may be of thickness of .050" as in the embodiment of FIGS. 1 to 3, the pilot 15^a of thickness of about .040", and the upwardly extending central thickened portion 40 also of thickness of about .040".

In this embodiment the central aperture 18^a in the inner cap 16^a is of such diameter that the rim 20^a will encompass with little clearance the upwardly extending gasket portion 40. The outer cap 21^a is preferably dished slightly as at 41 to accommodate the protruding central thickened portion 40 of the gasket.

The embodiment of FIG. 8 shows a variant of that of FIGS. 4 to 6, utilizing the same symmetrical gasket construction shown in the embodiment of FIG. 7, parts corresponding to those of FIGS. 4, 5, 6 and 7 being designated by the same reference numbers with exponent b.

The invention in all of the embodiments described has the advantage that unlike the elastic plug commonly used in the prior art, the gasket permits venting or escape of compressed air by reason of its loose fit between the thicker pilot portion of the gasket and the bore of the bottle neck, which is not permitted by the conventional plug which among other drawbacks will when forced to position trap and greatly compress the air above the biologic product, so that there is a tendency for the stopper to be propelled partly out of the bottle in subsequent expansion of such compressed air.

By reason of the pilot on the gasket, that gasket when laid upon the bottle after it has been charged with biologic material, will not become displaced or slid off the bottle in the subsequent handling prior to capping, nor will the gasket become displaced in the capping operation.

While the embodiments of FIGS. 1 to 6 are ordinarily preferred, the embodiments of FIGS. 7 and 8 have the advantage that the symmetrical construction of gasket dispenses with the need for guarding against mechanically laying the gasket upon the bottle neck in reverse position.

Thus, by the present invention, all of the advantages of the specialized gasket shown in the drawings are attained,

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while assurance is had that the loose-fitting gasket is yet maintained securely in place upon the bottle by a cap for the purpose, which cap affords free access to the gasket by the hypodermic syringe, and this despite the complete removal of the outer tear cap present on the unopened bottle.

In the embodiments of FIGS. 4, 5, 6 and 8, the use of the dust cap which is removable and replaceable after the outer or tear cap has been discarded, serves to protect the gasket from access of dust or dirt by covering the large central aperture 18' or 18^b in the inner cap 16' or 16^b respectively.

After removal of the outer cap, a relatively large central area of gasket becomes exposed, that area being substantially equal to that of the bore area of the bottle neck. Thus, the physician can puncture the gasket with a hypodermic needle repeatedly for withdrawing successive doses of biologic substance until the bottle is empty, and this without likelihood of two or more needle pricks through the gasket coming so close together as to coalesce. This is to be contrasted with the difficulty arising where the well known flanged rubber stopper is used for the purpose, for here the shank of the stopper is too thick for convenient piercing by the hypodermic needle, so that there is available but a small portion near the very center of the stopper through which alone the needle can penetrate. Thus, the danger of ineffective sealing by the elasticity of the rubber closure due to the coalescence of two or more neighboring needle pricks is avoided by the present invention.

As many changes could be made in the above construction, and many apparently widely different embodiments of this invention could be made without departing from the scope of the claims, it is intended that all matter contained in the above description or shown in the accompanying drawings shall be interpreted as illustrative and not in a limiting sense.

Having thus described my invention, what I claim as new and desire to secure by Letters Patent of the United States is:

1. A bottle closure of the character described, comprising an imperforate gasket of elastomer with a thinner annular rim area for engaging the rim of a bottle and a thicker pilot portion substantially concentric with and protruding below the bottom face of said rim area and into the neck of the bottle, the maximum diameter of said thicker portion of the gasket being less than the bore diameter of said bottle neck, thereby loosely extending into said neck, said closure comprising an inner cap of sheet metal having a central aperture of approximately the diameter of said pilot portion of the gasket, and an outer cap of sheet metal encompassing the inner cap, both the inner and the outer cap having skirt portions adapted to be secured to the mouth of said bottle, the outer cap portion having tear areas to facilitate its removal for access to the bottle contents by the needle of a hypodermic syringe to penetrate the gasket.

2. A bottle closure of the character described, comprising an imperforate gasket of elastomer with a thinner annular rim area for engaging the rim of a bottle and a thicker pilot portion substantially concentric with and protruding below the bottom face of said rim area and into the neck of the bottle, the maximum diameter of said thicker portion of the gasket being less than the bore diameter of said bottle neck, thereby loosely extending into said neck, said closure comprising an inner cap of sheet metal having a central aperture of approximately the diameter of said pilot portion of the gasket, a dust cap resting on top of the inner cap and encompassing a substantial portion of its side wall, an outer cap encompassing said dust cap, said inner cap and said outer cap both having skirt lengths adapted to be secured to the mouth of said bottle, the dust cap having a skirt of lesser length than the inner and the outer cap to extend no further when assembled on the bottle than the region of maximum diameter of the bottle bead, the outer cap having a tab portion to facilitate its removal from the bottle so that access may be had thereto

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by removal of the dust cap and replacing the dust cap after withdrawal of a dose by the needle of a hypodermic syringe passed through the gasket.

3. A bottle closure of the character described, comprising an imperforate gasket of elastomer with a thinner annular rim area for engaging the rim of a bottle and a thicker pilot portion substantially concentric with and protruding below the bottom face of said rim area and into the neck of the bottle, the maximum diameter of said thicker portion of the gasket being less than the bore diameter of said bottle neck, thereby loosely extending into said neck, said gasket having another concentric portion similar to the pilot portion extending outwardly from the rim area thereof, an inner cap having an annular portion over the rim portion of the gasket, encompassing the outwardly extending portion of the gasket and an outer cap encompassing the inner cap, and having a central domed portion to afford clearance for the outwardly extending portion of the gasket, said inner cap and said outer cap both having

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skirt lengths adapted to be secured to the mouth of said bottle, said outer cap having a tear portion to facilitate its removal from the bottle, the inner cap in the absence of said outer cap maintaining the gasket securely assembled to the bottle.

4. The combination recited in claim 3 in which a dust cap intervenes between the inner and the outer cap, said dust cap being bowed at its central portion to accommodate the outwardly extending portion of the gasket, said dust cap having a flange narrower than that of the other caps to facilitate its removal from the bottle after tearing away and discarding the outer cap.

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