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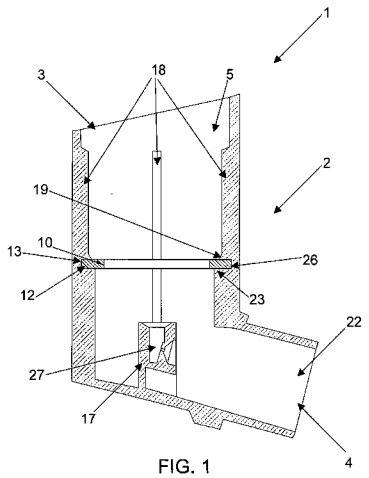

FIG. 1

(57) **Abstract:** An inhalation apparatus for dispensing substances for inhalation. The inhalation apparatus comprises a housing, the housing comprising an air inlet and an outlet, the housing defining a socket for receiving therein a dispensing container, the dispensing container having a portion of reduced cross sectional area. The inhalation apparatus further comprises a section of reduced diameter intermediate the air inlet and the outlet. In use, the dispensing container is movable within the socket between positions one, two and three. In the first position (the rest position) the section of reduced diameter interfaces with the dispensing container to prevent or substantially prevent flow of air between the air inlet and the outlet. In the second position (the flow position) the section of reduced diameter is at least partially aligned with the portion of reduced cross sectional area of the dispensing container to thereby form a gap sufficient to enable a flow of air between the air inlet and the outlet. The third position is associated with dispensation of a product from the dispensing container into the flow of air.

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Dispensing apparatus

This invention relates to an inhalation apparatus for dispensing substances for inhalation and, in particular, but not exclusively, an apparatus for dispensing medicinal products in aerosol form from a pressurised dispensing container.

Apparatus for dispensing a metered dose of a medicinal product for inhalation by a user are well known. Examples of medicinal products dispensed in this manner include those used in the treatment of asthma. In order to maximise the effective inhalation of the medicinal product it is desirable for the dispensation of the medicinal product to occur part way through a user's inhalation cycle. It is known to provide an inhalation apparatus which enables the user to begin inhaling air before the product is dispensed into the air stream. This has previously been achieved using a dispensing apparatus with airflow valves comprising moving parts, such as the apparatus disclosed in GB2323041. A disadvantage of using airflow valves is that such apparatus requires a number of component parts which must be assembled during manufacture. In addition, the necessity for a moving stemblock can be problematic because an orifice in the stemblock needs to line up with the centre of the mouthpiece prior to actuation of the valve.

The present invention provides an inhalation apparatus comprising a housing, the housing comprising an air inlet and an outlet, the housing defining a socket for receiving therein a dispensing container, the dispensing container having a portion of reduced cross sectional area,

the inhalation apparatus comprising a section of reduced diameter intermediate the air inlet and the outlet;

wherein, in use, the dispensing container is movable within the socket from a first, rest, position in which the section of reduced diameter interfaces with the dispensing container to prevent or substantially prevent flow of air between the air inlet and the outlet to a second, flow, position in which the section of reduced diameter is at least partially aligned with the portion of reduced cross sectional area of the dispensing container to thereby form a gap sufficient to enable a flow of air between the air inlet and the air outlet; the dispensing container being further movable in use into a third position associated with dispensation of a product from the dispensing container into the flow of air.

An advantage of the present invention is that an inexpensive apparatus is provided that allows the dispensation of the medicament to occur part way through the user's inhalation cycle. The apparatus can be formed from two components, fixed with respect to each other. The apparatus is therefore less complicated to manufacture than those described in the prior art.

Preferably, the section of reduced diameter is integral to the housing.

Preferably, the section of reduced diameter is an inward projection substantially perpendicular to the axis in which, in use, the dispensing container is movable.

In a first embodiment, the section of reduced diameter is formed by a component coupled to the housing.

Preferably, the component is an insert receivable in the socket of the housing. The insert may be annular and the insert may be coupled to the housing by means of an interference fit.

Preferably, the housing further comprises a non-return feature which allows insertion of the insert but prevents or impedes removal of the insert.

Preferably, the non-return feature is an angled projection presenting a sloped face on an air inlet side of the angled projection for allowing the insert to ride over the angled projection on insertion of the insert and presenting an abutment surface on an outlet side of the angled projection for preventing or impeding removal of the insert.

Alternatively, the non-return feature is a flexible barb projecting beyond the external diameter of the insert.

The inserted component may be formed from, for example, plastic or metal.

The component may be coupled to the housing by means of bonding.

Preferably, the housing further comprises supports which support the section of reduced diameter.

Preferably the housing further comprises aligning ribs which ensure that the component is correctly aligned.

The air inlet may be provided by an open end of the housing and the outlet may be a mouthpiece.

In a second embodiment, the housing may comprise an upper housing part and a lower housing part which are connectable together.

The section of reduced diameter is located at the distal end of the upper housing part.

Preferably the upper housing part and the lower housing part are connectable together by a snap fit mechanism.

The inhalation apparatus may be used with a dispensing container to form an inhalation apparatus assembly, wherein

the dispensing container has a portion of reduced cross sectional area.

Preferably, a cross section of the dispensing container at the portion of reduced cross sectional area of the dispensing container is substantially circular shaped.

Alternatively, the cross section of the dispensing container at the portion of reduced cross sectional area of the dispensing container is substantially non-circular in shape.

The dispenser body may comprise a container body, a valve and a ferrule.

The portion of reduced cross sectional area may be formed by shaping the container body or by shaping the ferrule or a combination of shaping the container body and the ferrule.

Additionally or alternatively, the dispensing container may comprise an external casing in which a container body and or valve and or ferrule of the dispensing container is at least partially received. For example, the casing may be a sleeve or cap received over, or attached to, the container body.

The portion of reduced cross sectional area may be formed by shaping the external casing.

The portion of reduced cross sectional area may be formed by shaping any one of or any combination of the container body, the ferrule and the external casing.

The portion of reduced cross sectional area may be formed by shaping the container body or by shaping the ferrule or a combination of shaping the container body and the ferrule.

Alternatively, the dispensing container may comprises an external casing in which a container body and or valve

and or ferrule of the dispensing container is at least partially received.

The portion of reduced cross sectional area may be formed by shaping the external casing.

The portion of reduced cross sectional area may be formed by shaping any one of or any combination of the container body, the ferrule and the external casing.

Alternatively or additionally, the inhalation apparatus assembly further comprises an ancillary unit which is coupled to the dispensing container.

The ancillary unit may be a dose counter unit.

The portion of reduced cross sectional area may be formed by shaping any one of or a combination of the dispensing container and the ancillary unit.

Preferably, the ancillary unit is coupled to the dispensing container by one or more of a snapfit arrangement, weld or adhesive.

The inhalation apparatus may further comprises a dose counter mechanism to increment the number of doses taken or decrement the number of doses remaining on actuation of the apparatus.

It will be appreciated that the portion of reduced cross-sectional area must be formed by a feature of the dispensing container so that the portion of reduced cross-sectional area moves axially with the dispensing container. However, the portion of reduced cross-sectional area may be formed by any part of the dispensing container or any part of any component coupled to the dispensing container.

The dispensing apparatus may further comprise a dose counter mechanism to increment the number of doses taken or decrement the number of doses remaining on actuation of the apparatus.

The dispensing apparatus may be a pharmaceutical dispensing device, such as, for example, a pulmonary, nasal, or sub-lingual delivery device. A preferred use of the dispensing apparatus is as a pharmaceutical metered dose aerosol inhaler device. The term pharmaceutical, as used herein, is intended to encompass any pharmaceutical, compound, composition, medicament, agent or product which can be delivered or administered to a human being or animal, for example pharmaceuticals, drugs, biological and medicinal products. Examples include antiallergics, analgesics, bronchodilators, antihistamines, therapeutic proteins and peptides, antitussives, anginal preparations, antibiotics, anti-inflammatory preparations, hormones, or sulfonamides, such as, for example, a vasoconstrictive amine, an enzyme, an alkaloid, or a steroid, including combinations of two or more thereof. In particular, examples include isoproterenol [alpha-(isopropylaminomethyl) protocatechuyl alcohol], phenylephrine, phenylpropanolamine, glucagon, adrenochrome, trypsin, epinephrine, ephedrine, narcotine, codeine, atropine, heparin, morphine, dihydromorphinone, ergotamine, scopolamine, methapyrilene, cyanocobalamin, terbutaline, rimiterol, salbutamol, flunisolide, colchicine, pirbuterol, beclomethasone, orciprenaline, fentanyl, and diamorphine, streptomycin, penicillin, procaine penicillin, tetracycline, chlorotetracycline and hydroxytetracycline, adrenocorticotropic hormone and adrenocortical hormones, such as cortisone, hydrocortisone, hydrocortisone acetate and prednisolone, insulin, cromolyn sodium, and mometasone, including combinations of two or more thereof.

The pharmaceutical may be used as either the free base or as one or more salts conventional in the art, such as, for example, acetate, benzenesulphonate, benzoate,

bicarbonate, bitartrate, bromide, calcium edetate, camsylate, carbonate, chloride, citrate, dihydrochloride, edetate, edisylate, estolate, esylate, fumarate, fluceptate, gluconate, glutamate, glycollylarsanilate, hexylresorcinate, hydrobromide, hydrochloride, hydroxynaphthoate, iodide, isethionate, lactate, lactobionate, malate, maleate, mandelate, mesylate, methylbromide, methylnitrate, methylsulphate, mucate, napsylate, nitrate, pamoate, (embonate), pantothenate, phosphate, diphosphate, polygalacturonate, salicylate, stearate, subacetate, succinate, sulphate, tannate, tartrate, and triethiodide, including combinations of two or more thereof. Cationic salts may also be used, for example the alkali metals, e.g. Na and K, and ammonium salts and salts of amines known in the art to be pharmaceutically acceptable, for example glycine, ethylene diamine, choline, diethanolamine, triethanolamine, octadecylamine, diethylamine, triethylamine, 1-amino-2-propanol-amino-2-(hydroxymethyl)propane-1,3-diol, and 1-(3,4-dihydroxyphenyl)-2 isopropylaminoethanol.

The pharmaceutical will typically be one which is suitable for inhalation and may be provided in any suitable form for this purpose, for example as a solution or powder suspension in a solvent or carrier liquid, for example ethanol, or isopropyl alcohol. Typical propellants are HFA134a, HFA227 and di-methyl ether.

The pharmaceutical may, for example, be one which is suitable for the treatment of asthma. Examples include salbutamol, beclomethasone, salmeterol, fluticasone, formoterol, terbutaline, sodium chromoglycate, budesonide and flunisolide, and physiologically acceptable salts (for example salbutamol sulphate, salmeterol xinafoate,

fluticasone propionate, beclomethasone dipropionate, and terbutaline sulphate), solvates and esters, including combinations of two or more thereof. Individual isomers such as, for example, R-salbutamol, may also be used. As will be appreciated, the pharmaceutical may comprise of one or more active ingredients, an example of which is flutiform, and may optionally be provided together with a suitable carrier, for example a liquid carrier. One or more surfactants may be included if desired.

Rigid components of the dispensing apparatus may be formed from, for example, polyester, nylon, acetal or similar.

Embodiments of the present invention will now be described, by way of example only, with reference to the accompanying drawings, in which:

Figure 1 is a schematic cross sectional view of a first embodiment of dispensing apparatus according to the present invention;

Figure 2 is a schematic cross sectional view of a dispensing apparatus assembly comprising the dispensing apparatus of Figure 1 and a dispensing container received into a socket of the dispensing apparatus and with the dispensing container shown in a first, rest, position;

Figure 3 is a schematic cross sectional view of the dispensing apparatus assembly of Figure 2 with the dispensing container shown in a second, flow, position;

Figure 4 is a schematic cross sectional view of the dispensing apparatus assembly of Figure 2 with the dispensing container shown in a third position associated with dispensation of a product from the dispensing container;

Figure 5A is a perspective view of an insert of the first embodiment of the present invention;

Figure 5B is a schematic cross sectional view of part of the housing of the dispensing apparatus of the first embodiment and includes the non return feature;

Figure 6 is a schematic cross sectional view of a second embodiment of dispensing apparatus according to the present invention;

Figure 7 is a schematic cross sectional view of a dispensing apparatus comprising the dispensing apparatus of Figure 6 and a dispensing container received into a socket of the dispensing apparatus and with the dispensing container shown in a first, rest, position;

Figure 8 is a schematic cross sectional view of the dispensing apparatus assembly of Figure 7 with the dispensing container shown in a second, flow, position; and

Figure 9 is a schematic cross sectional view of the dispensing apparatus assembly of Figure 7 with the dispensing container shown in a third position associated with dispensation of a product from the dispensing container.

A first embodiment of an inhalation apparatus assembly 50 is shown in Figures 2, 3 and 4. The inhalation apparatus assembly comprises an inhalation apparatus 1 and a dispensing container 6. Figure 1 shows the inhalation apparatus 1 without the dispensing container 6 inserted.

The dispensing container 6 consists of a body 7 and a metering valve 25 which itself is provided with a valve stem 8. The body 7 is formed as an open-topped cylindrical container which defines a storage volume for a product. A portion of reduced cross sectional area 9 is located towards

the open top of the body 7. The body 7 is closed by means of the metering valve 25 which is tightly connected to the body 7 by a ferrule 24 which is crimped to the upper end of the body 7 such that the portion of reduced cross sectional area 9 is located adjacent to the ferrule 24. The ferrule 24 comprises an aperture through which the valve stem 8 protrudes.

The inhalation apparatus 1 comprises a housing 2 and an annular insert 12. The housing 2 defines a socket 5 which is shaped to receive the dispensing container 6. The housing 2 includes an air inlet 3 at an upper end of the socket 5 and an outlet 4 off of a lower end of the socket. A valve stem receiving block 17 is located at the end of the socket 5 closest to the outlet 4. The valve stem receiving block comprises a conduit 27 shaped to receive the valve stem 8 and direct outflow from the valve stem 8 through an orifice towards the mouthpiece 22. Aligning ribs 18 are located within the socket 5 to ensure the correct alignment of the insert 12 within the housing 2 and the container of the inhalation apparatus assembly. An angled projection 19 is present within the socket 5 adjacent to the location 26 where, on assembly, the insert is located. The angled projection 19 is shown in Figure 5B and is located on the air inlet 3 side of the location 26. Supports 23 are present within the socket 5 adjacent to the location 26 where, on assembly, the insert is located. The supports 23 are located on the outlet 4 side of the location 26. The outlet 4 is a mouthpiece 22. The angled projection 19 consists of a sloped face 20 and an abutment surface 21. The purpose of the angled projection 19 is to ensure that the insert 12 can be inserted on assembly but, once inserted, cannot easily be moved or removed.

The insert 12 is an annular member wherein the external diameter is shaped to fit into a location 26 with a correspondingly shaped internal diameter on the inside of the housing 2 within the socket 5. The correspondence between the location 26 and the insert 12 ensures that the insert 12 remains positioned in the location 26 by means of an interference fit 13. On assembly, the internal diameter of the insert 12 provides a section of reduced diameter 10 when compared with a remainder of the socket 5.

During assembly of the inhalation apparatus 1 the annular insert 12 is inserted into the location 26 with a correspondingly shaped internal diameter within the housing 2 via the air inlet end of the housing 2. The sloped face 20 of the angled projection 19 allows the insert 12 to ride over the angled projection 19 and the abutment surface 21 prevents or impedes the subsequent removal of the insert 12. The supports 23 act to further prevent or impede the movement of the insert 12 in the direction of the outlet 4. In addition, the supports 23 ensure the insert 12 is correctly aligned with respect to the housing 2.

In use, the dispensing container 6 is received in the socket 5 of the housing 2 with the valve stem 8 located as a push-fit in the conduit 27 of the valve stem receiving block 17 as shown in Figure 2. The process of operation requires the user to inhale on the mouthpiece 22 and then to depress the dispensing container 6 with respect to the inhalation apparatus 1 in one continuous movement. When depressed the dispensing container 6 moves from a first, rest, position through a second, flow, position to a third position associated with dispensation.

In the first, rest, position, as shown in Figure 2, the section of reduced diameter 10 of the inhalation apparatus 1

interfaces with the dispensing container 6 such that there is no gap or only a small gap between the insert 12 and the dispensing container 6. Consequently this first, rest, position acts to prevent or substantially prevent the flow of air between the air inlet 3 and the outlet 4. In use, a user will inhale on the mouthpiece 22. In this position, since a flow of air between the air inlet 3 and the outlet 4 is prevented or substantially prevented, the resistance to inhalation is large. As a result the user will inhale slowly.

Next, the user depresses the dispensing container 6 at the opposite end to the metering valve 25 to move the dispensing container 6 with respect to the apparatus 1 into the second, flow, position which is illustrated in Figure 3. In this position the portion of reduced cross sectional area 9 of the dispensing container 6 is at least partially aligned with the section of reduced diameter 10 of the apparatus 1 thereby forming a gap 11 between the housing 2 and the dispensing container 6 sufficient to enable a substantial flow of air between the air inlet 3 and the outlet 4. Consequently, the user will inhale more rapidly than when the apparatus was in the first, rest, position.

The user continues to move the dispensing container 6 with respect to the apparatus 1 into a third position shown in Figure 4. In this position the gap 11 is maintained between the housing 2 and the dispensing container 6. Also, the dispensing the valve stem 8 has moved relative to the remainder of the metering valve sufficient to actuate the valve 25 resulting in dispensation of the product into the already established air flow via the valve stem 8 and the conduit 27 of the valve stem receiving block 17. The user

continues to inhale the air flow which now contains the dispensed product.

Rigid components of the apparatus may be made using one or more of the following materials: polypropylene (PP), Acetal (POM), Polyester (PBT), Acrylonitrile Butadiene Styrene (ABS), Co-polyester, Stainless steel, and aluminium.

In one example tested, when in the first, rest, position and tested at a flow rate of 28.3 litres per minute, the pressure drop between the air inlet and the outlet is likely to be in excess of 2500 Pascals. When in the third position and tested at a flow rate of 28.3 litres per minute, the pressure drop between the air inlet and the outlet is likely to be less than 120 Pascals.

The embodiment described above may be varied by using an insert which is not annular. The essential requirement is that in the first, rest, position the size and shape of the opening in the insert 12 closely matches the external size and shape of the part of the container 6 against which it interfaces so that no or a minimal airflow is produced on inhalation. For example, the container 6 could be square shaped in which case the opening in the insert would also be square shaped. It should be further noted that in the second, flow, position it is not necessary for a gap to be formed all the way round the container 6. For example the container may simply comprise an indentation at one or more points around its circumference which constitute one or more discontinuities in the cross-section of the container body. In this way alignment of an indentation with an insert produces the required gap to allow an airflow to be established.

A second embodiment of the present invention is illustrated in Figure 6 to Figure 9. The same reference

numbers have been used to identify parts which correspond to those of the first embodiment.

In this second embodiment the housing 2 includes an upper housing part 14 and a lower housing part 15. The section of reduced diameter 10 of the apparatus 1 is integral to the upper housing part and is formed by an inwardly directed flange formed at a lower end of the upper housing part 14. The upper housing part 14 is coupled to the lower housing part 15 using a snap fit mechanism 16. Figure 6 shows the inhalation apparatus 1 of the second preferred embodiment.

Figure 7 shows the inhalation apparatus assembly 50 including the inhalation apparatus 1 and a dispensing container 6 in the first, rest, position. The dispensing container 6 is of the same type as described above in relation to the first embodiment. Figure 8 shows the apparatus 1 and a dispensing container 6 with a portion of reduced cross sectional area 9 in the second, flow, position. Figure 9 shows the apparatus 1 and dispensing container 6 with a portion of reduced cross sectional area 9 in the third position associated with dispensation of the product.

Assembly of the second embodiment of the invention requires the upper housing 14 and the lower housing 15 to be connected together. The second embodiment of the present invention is operated in the same way as the first embodiment of the present invention.

Claims:

1. An inhalation apparatus comprising a housing, the housing comprising an air inlet and an outlet, the housing defining a socket for receiving therein a dispensing container, the dispensing container having a portion of reduced cross sectional area,

the inhalation apparatus comprising a section of reduced diameter intermediate the air inlet and the outlet;

wherein, in use, the dispensing container is movable within the socket from a first, rest, position in which the section of reduced diameter interfaces with the dispensing container to prevent or substantially prevent flow of air between the air inlet and the outlet to a second, flow, position in which the section of reduced diameter is at least partially aligned with the portion of reduced cross sectional area of the dispensing container to thereby form a gap sufficient to enable a flow of air between the air inlet and the outlet; the dispensing container being further movable in use into a third position associated with dispensation of a product from the dispensing container into the flow of air.

2. The inhalation apparatus as claimed in claim 1 wherein the section of reduced diameter is integral to the housing.

3. The inhalation apparatus as claimed in claim 2 wherein the section of reduced diameter is an inward projection substantially perpendicular to an axis in which, in use, the dispensing container is movable.

4. The inhalation apparatus as claimed in claim 2 or claim 3 wherein the housing and the section of reduced diameter are moulded as an integral component.

5. The inhalation apparatus as claimed in claim 2 or claim 3 wherein the housing comprises an upper housing part and a lower housing part which are connectable together.

6. The inhalation apparatus as claimed in claim 5 wherein the section of reduced diameter is located at the distal end of the upper housing part.

7. The inhalation apparatus as claimed in claim 5 or claim 6 wherein the upper housing part and the lower housing part are connectable together by a snap fit mechanism.

8. The inhalation apparatus as claimed in claim 1 wherein the section of reduced diameter is formed by a component coupled to the housing.

9. The inhalation apparatus as claimed in claim 8 wherein the component is an insert receivable in the socket of the housing.

10. The inhalation apparatus as claimed in claim 9 wherein the insert is annular.

11. The inhalation apparatus as claimed in claim 9 or claim 10 wherein the insert is coupled to the housing by means of an interference fit.

12. The inhalation apparatus of any of claims 9 to 11 wherein the housing further comprises a non-return feature which allows insertion of the insert but prevents or impedes removal of the insert.

13. The inhalation apparatus as claimed in claim 12 wherein the non-return feature is an angled projection presenting a sloped face on an air inlet side of the angled projection for allowing the insert to ride over the angled projection on insertion of the insert and presenting an abutment surface on an outlet side of the angled projection for preventing or impeding removal of the insert.

14. The inhalation apparatus as claimed in any of claims 8 to 13 wherein the component is coupled to the housing by means of bonding.

15. The inhalation apparatus as claimed in any of claims 8 to 14 wherein the housing further comprises supports which support the section of reduced diameter.

16. The inhalation apparatus as claimed in any of claims 8 to 15 wherein the housing further comprises aligning ribs which ensure that the component is correctly aligned.

17. The inhalation apparatus as claimed in any preceding claim wherein the air inlet is provided by an open end of the housing.

18. The inhalation apparatus as claimed in any preceding claim wherein the outlet is a mouthpiece.

19. An inhalation apparatus assembly comprising the inhalation apparatus of any preceding claim and a dispensing container wherein the dispensing container has a portion of reduced cross sectional area.

20. The inhalation apparatus assembly as claimed in claim 19 wherein a cross section of the dispensing container at the portion of reduced cross sectional area of the dispensing container is substantially circular shaped.

21. The inhalation apparatus assembly as claimed in claim 19 wherein a cross section of the dispensing container at the portion of reduced cross sectional area of the dispensing container is substantially non-circular in shape.

22. The inhalation apparatus assembly as claimed in any of claims 19 to 21 wherein the dispensing container comprises a container body, a valve and a ferrule.

23. The inhalation apparatus assembly as claimed in claim 22 wherein the portion of reduced cross sectional area is formed by shaping the container body or by shaping the ferrule or a combination of shaping the container body and the ferrule.

24. The inhalation apparatus assembly as claimed in any one of claims 19 to 21 wherein the dispensing container comprises an external casing in which a container body and or valve and or ferrule of the dispensing container is at least partially received.

25. The inhalation apparatus assembly as claimed in claim 24 wherein the portion of reduced cross sectional area is formed by shaping the external casing.

26. The inhalation apparatus assembly as claimed in claim 24 wherein the portion of reduced cross sectional area is formed by shaping any one of or any combination of the container body, the ferrule and the external casing.

27. The inhalation apparatus assembly as claimed in any one of claims 19 to 22 wherein the inhalation apparatus assembly further comprises an ancillary unit which is coupled to the dispensing container.

28. The inhalation apparatus assembly as claimed in claim 27 wherein the ancillary unit is a dose counter unit.

29. The inhalation apparatus assembly as claimed in claim 27 or 28 wherein the portion of reduced cross sectional area is formed by shaping any one of or a combination of the dispensing container and the ancillary unit.

30. The inhalation apparatus as claimed in any one of claims 27 to 29 wherein the ancillary unit is coupled to the dispensing container by one or more of a snapfit arrangement, weld or adhesive.

31. The inhalation apparatus of any preceding claim wherein the inhalation apparatus further comprises a dose counter mechanism to increment the number of doses taken or decrement the number of doses remaining on actuation of the apparatus.

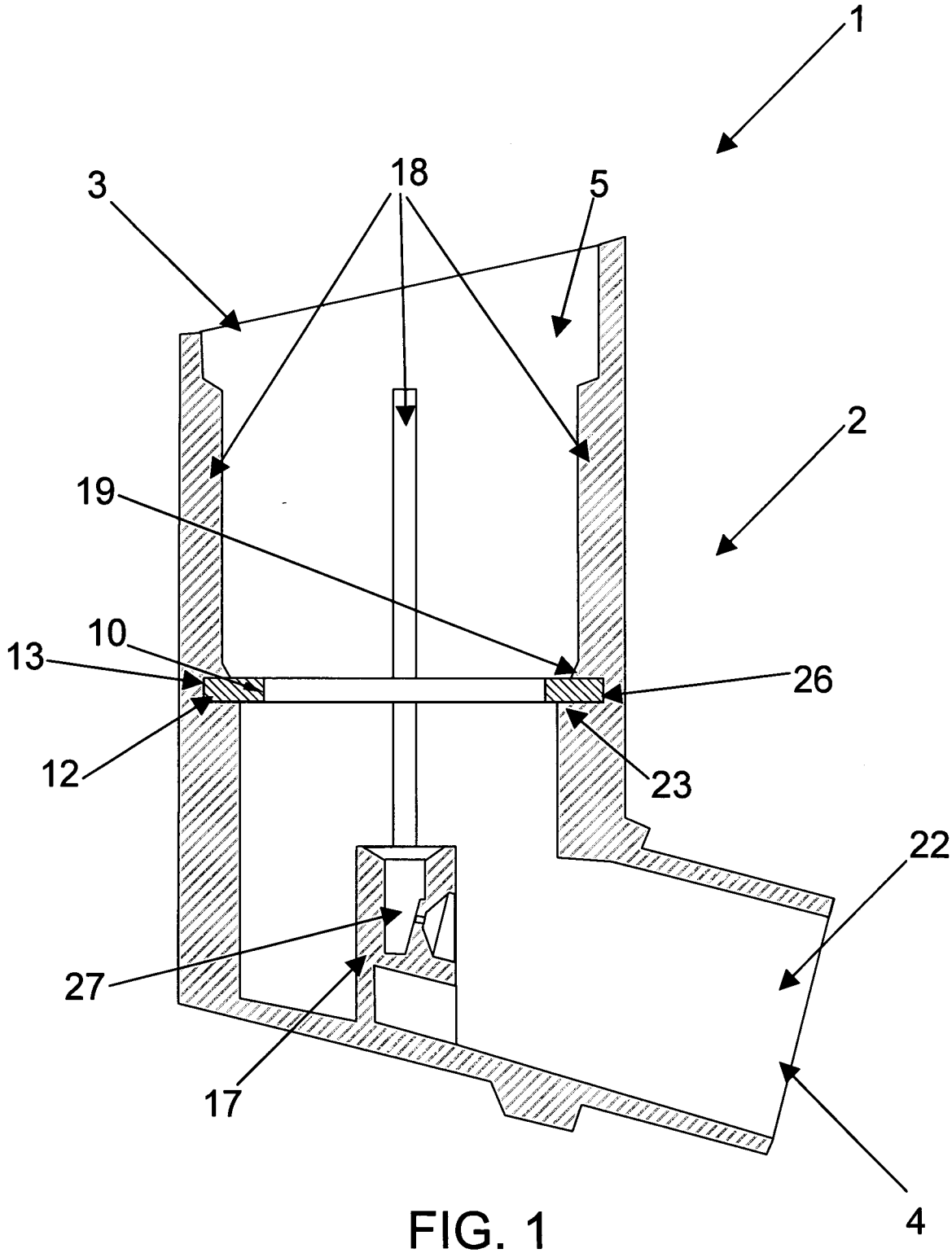

FIG. 1

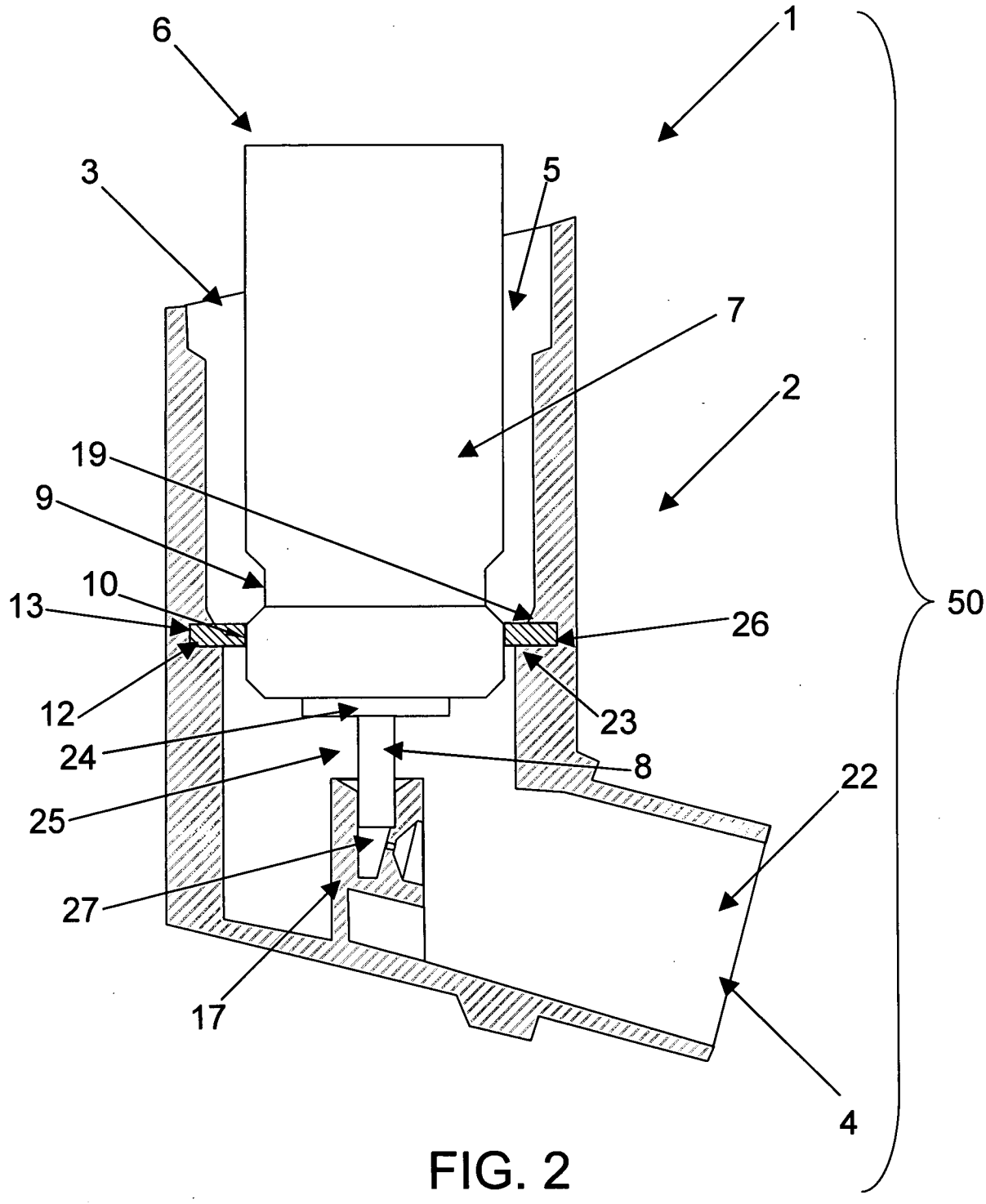

FIG. 2

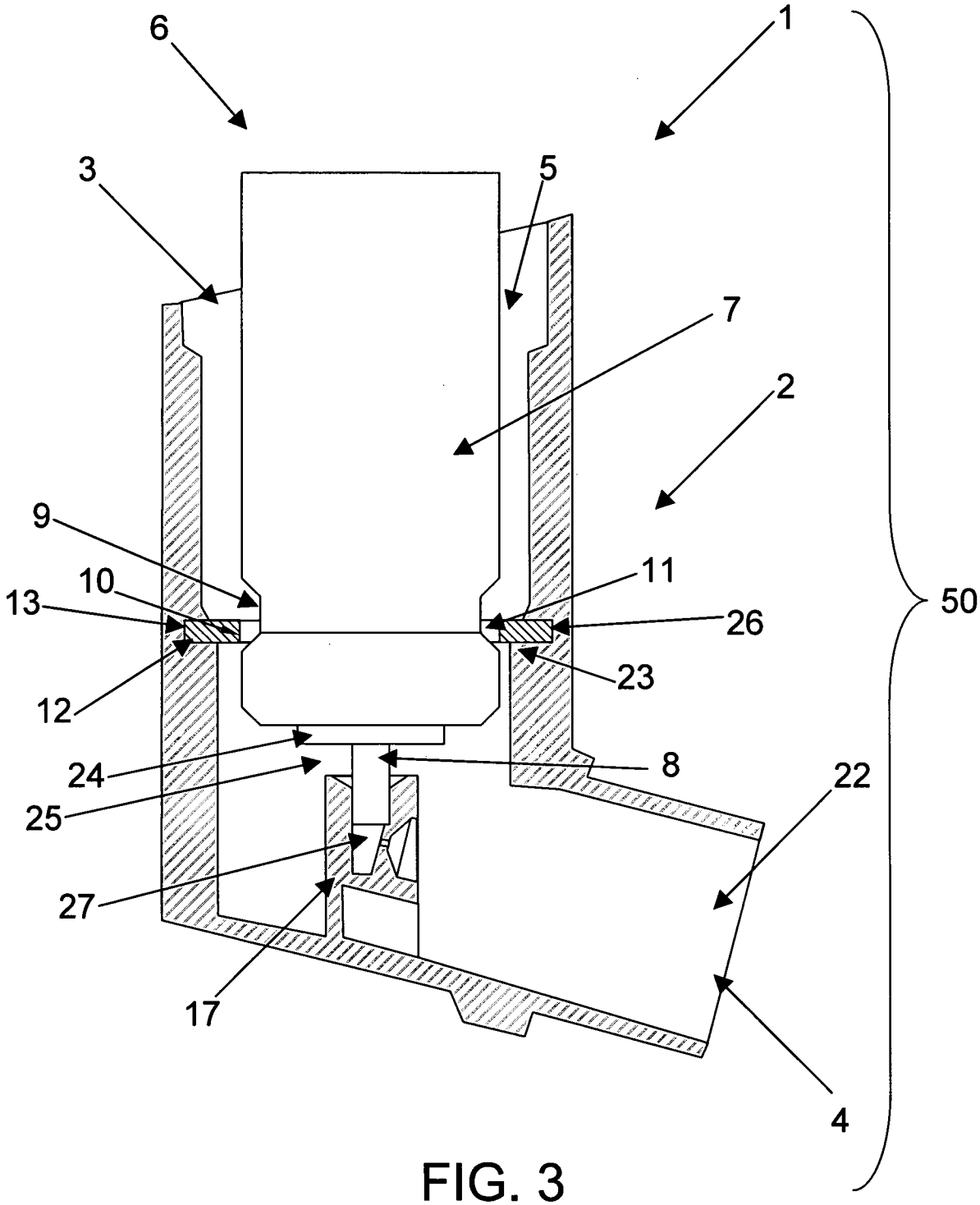

FIG. 3

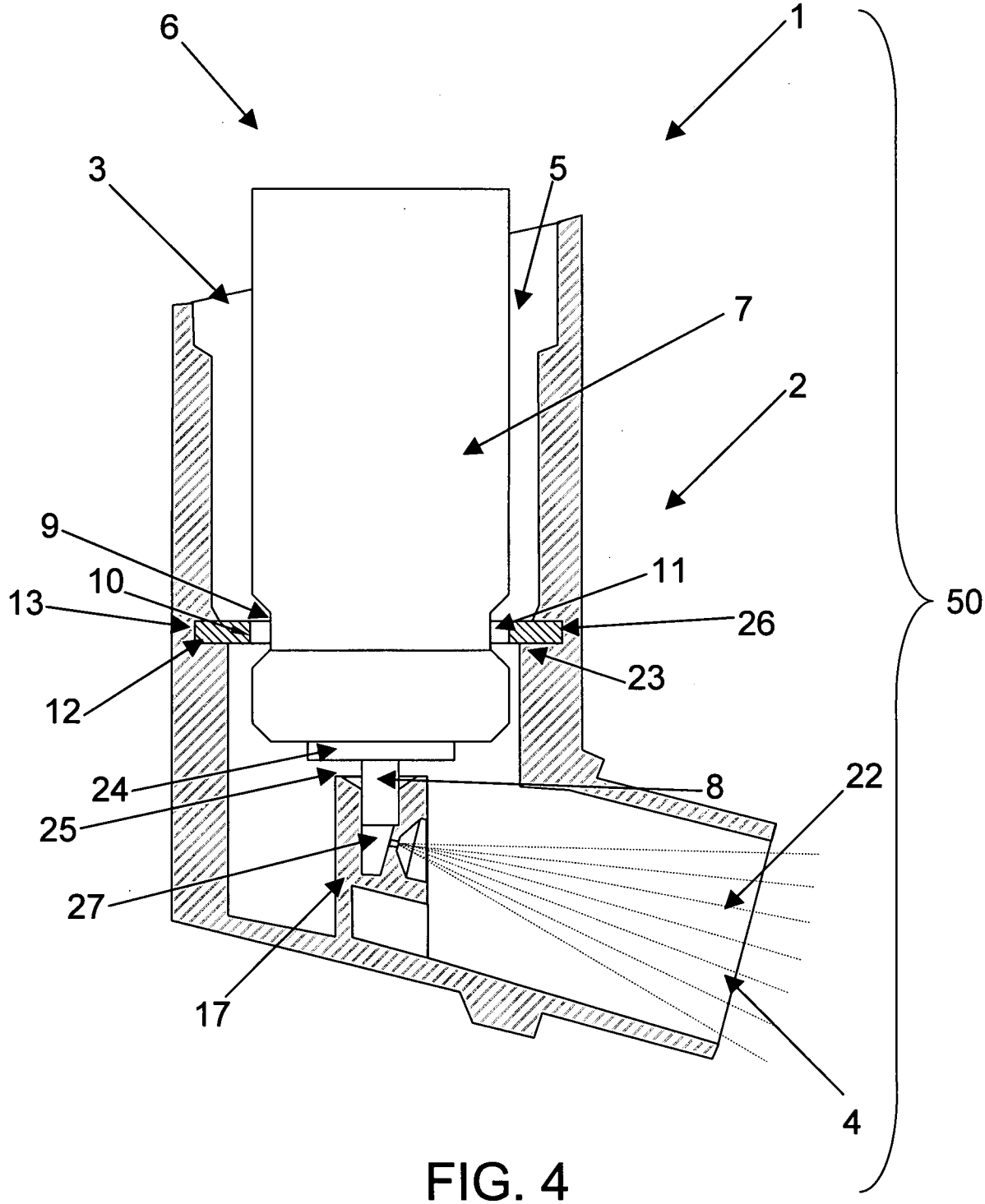

FIG. 4

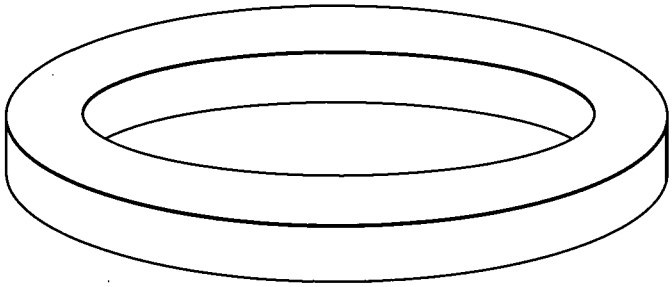

FIG. 5A

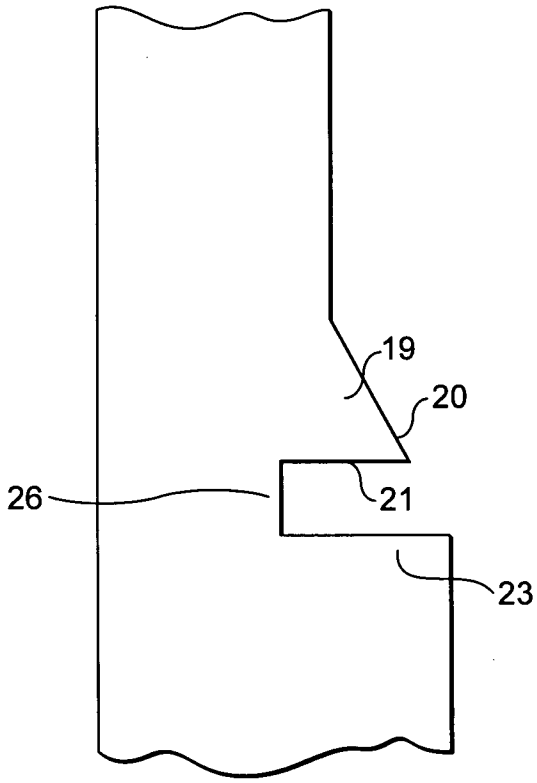

FIG. 5B

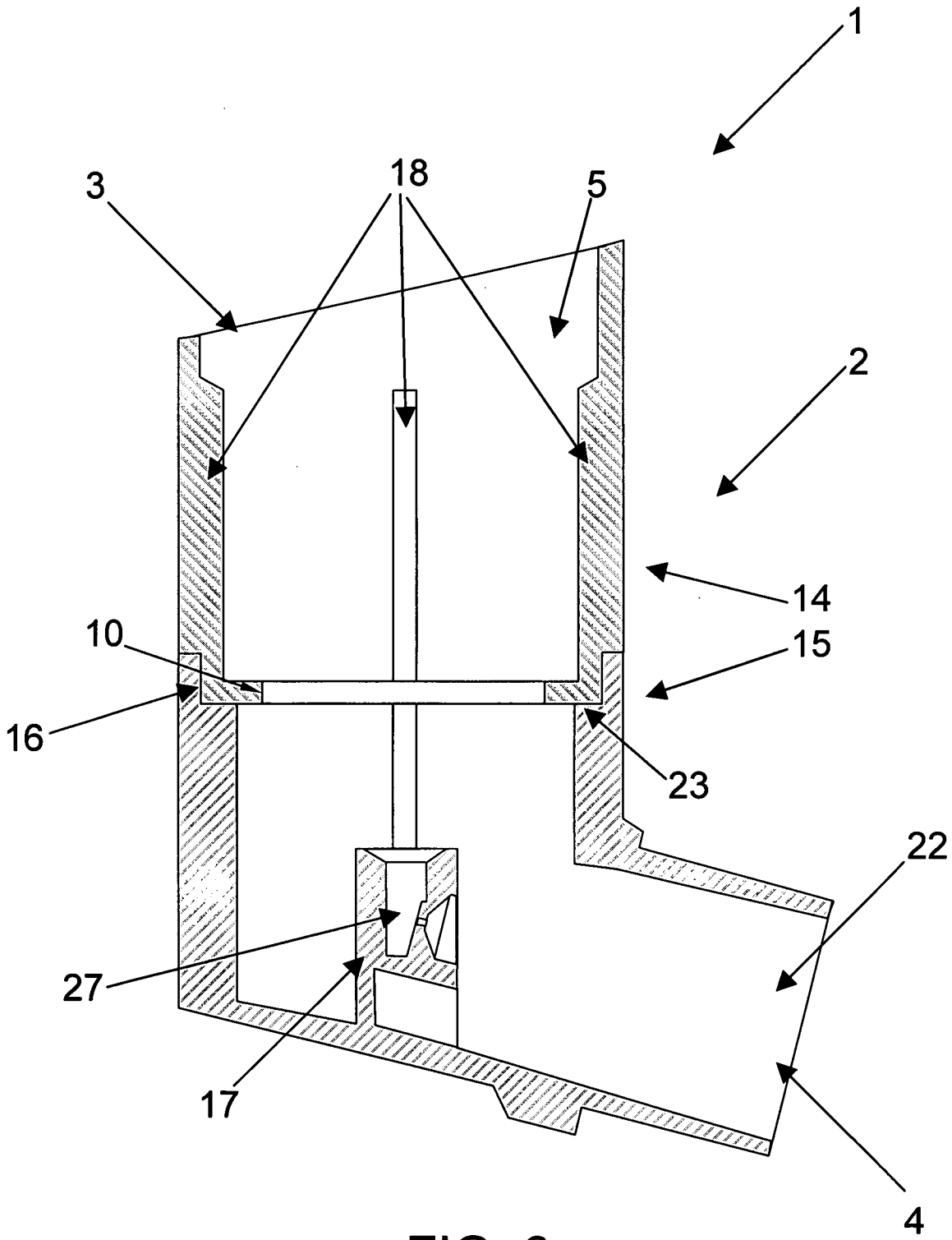

FIG. 6

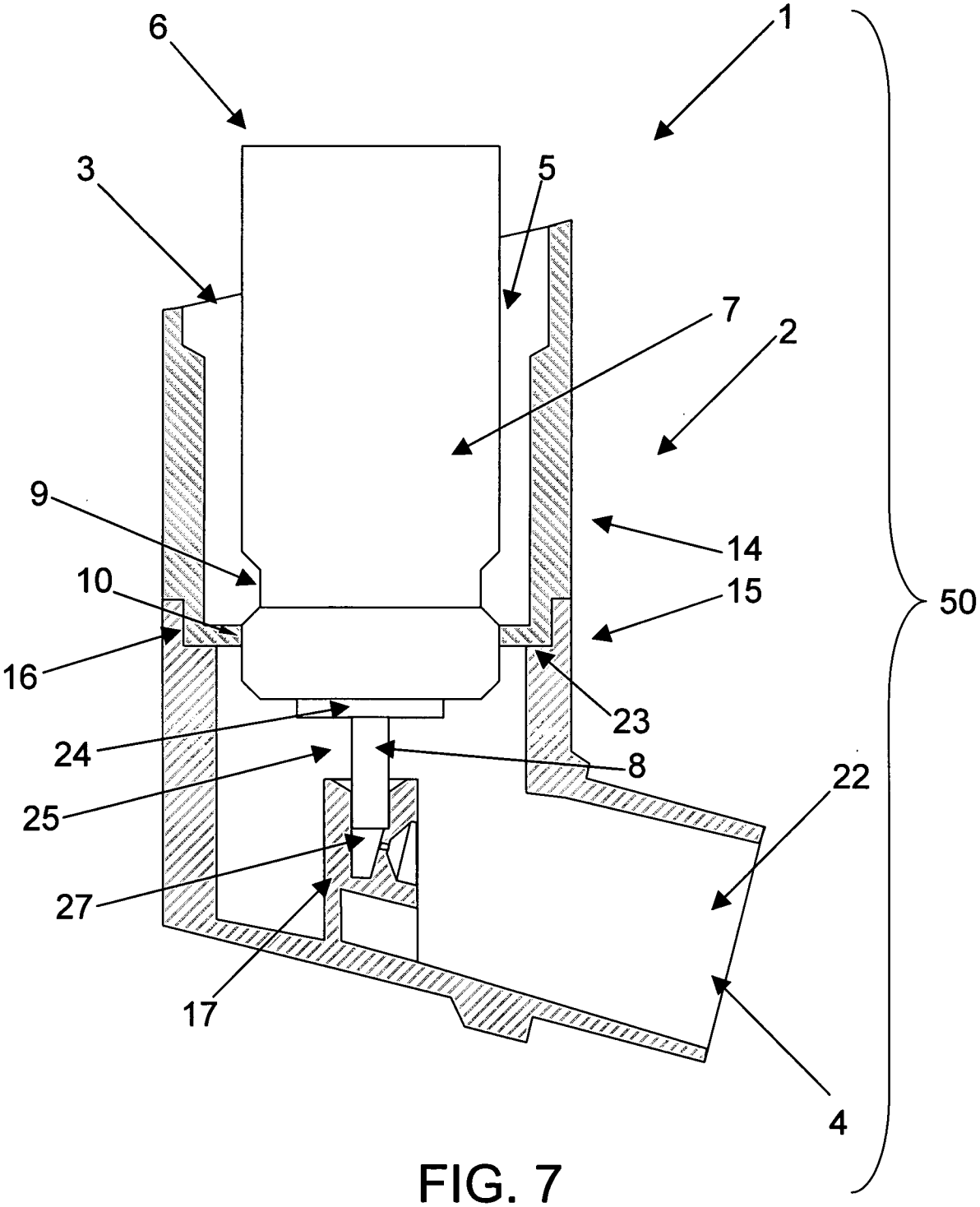

FIG. 7

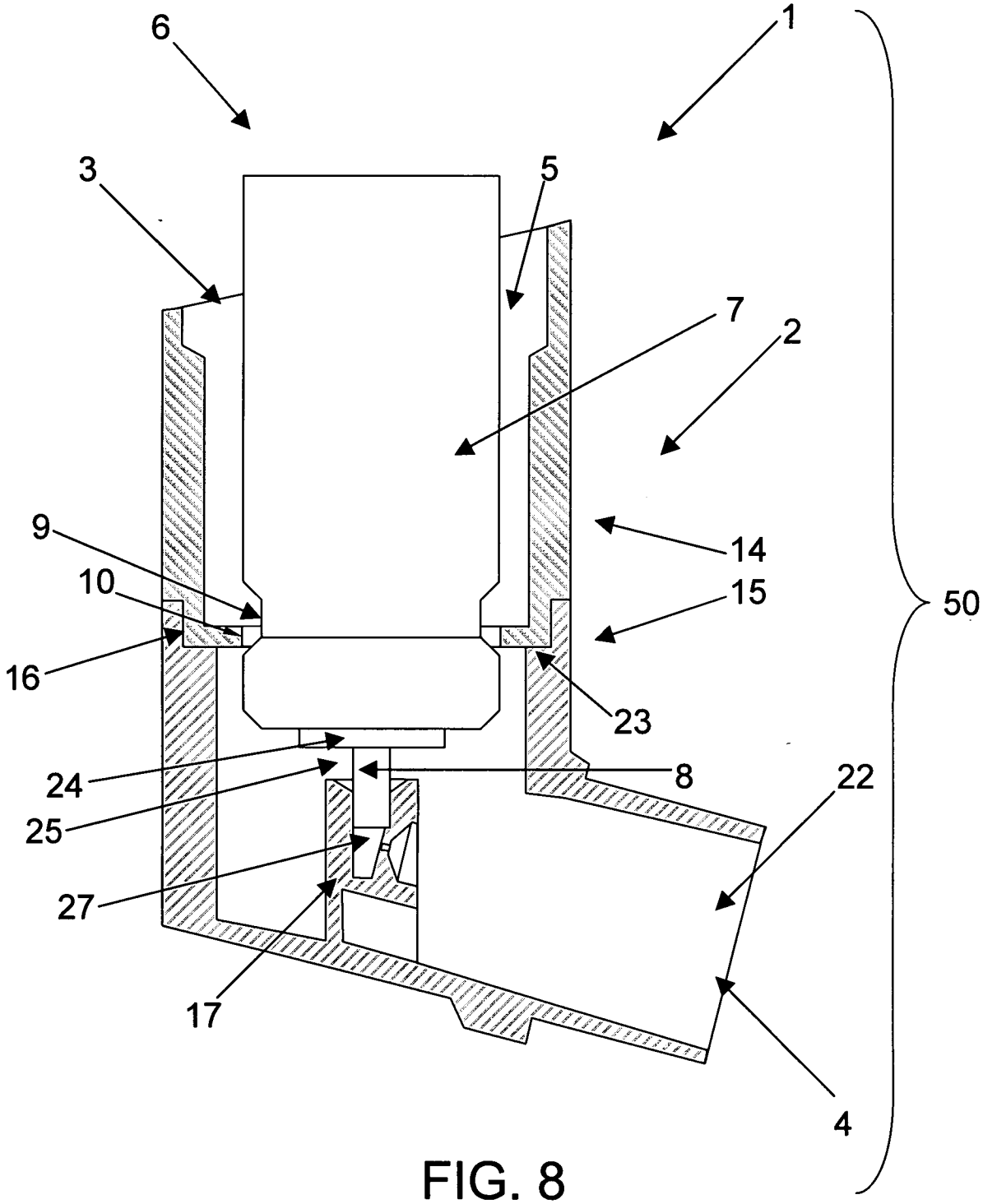

FIG. 8

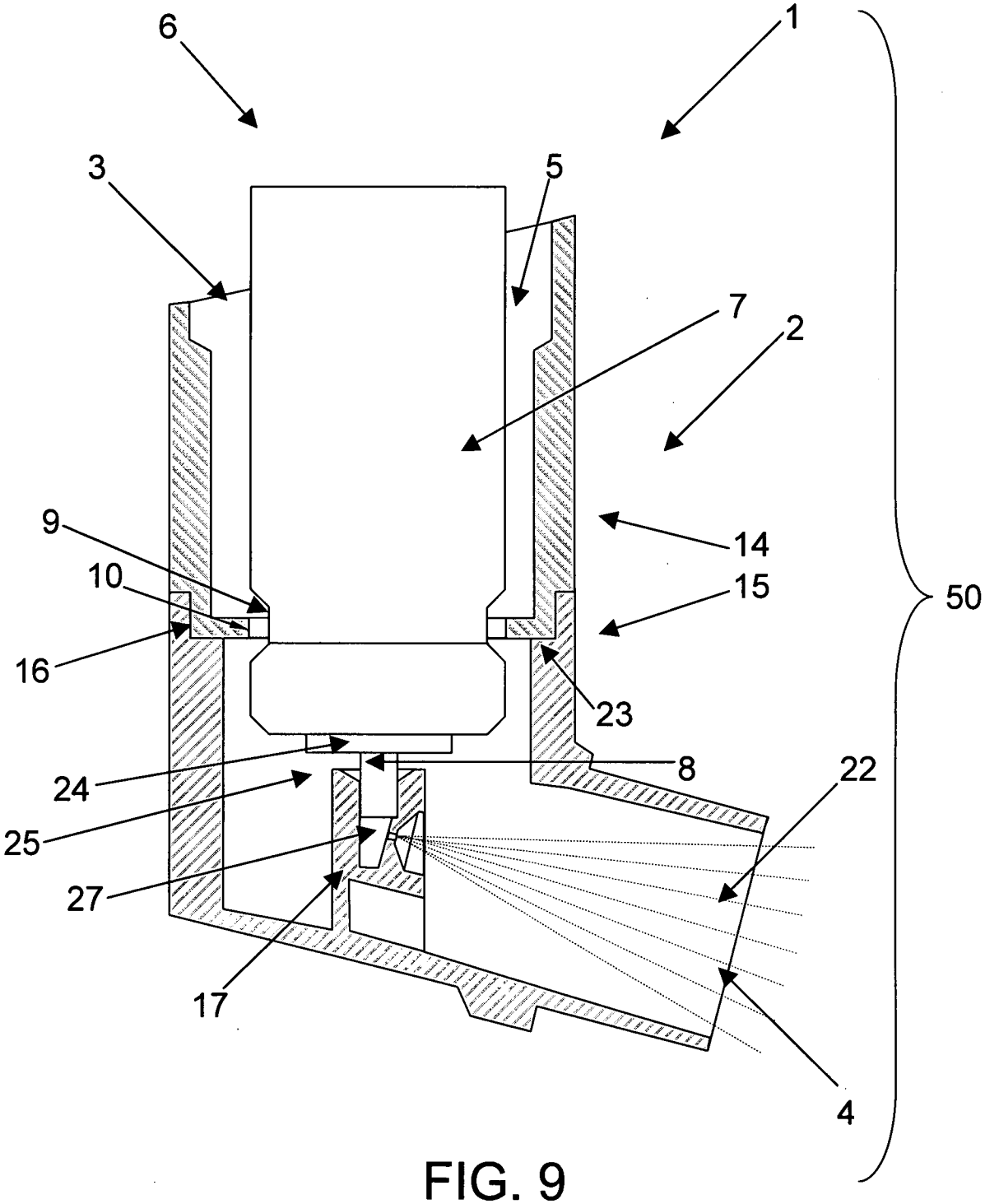

FIG. 9