June 8, 1965 R. I. MITCHELL ETAL 3,187,748

INHALATION-ACTUATED AEROSOL DEVICE

Filed April 29, 1963 2 Sheets-Sheet 1

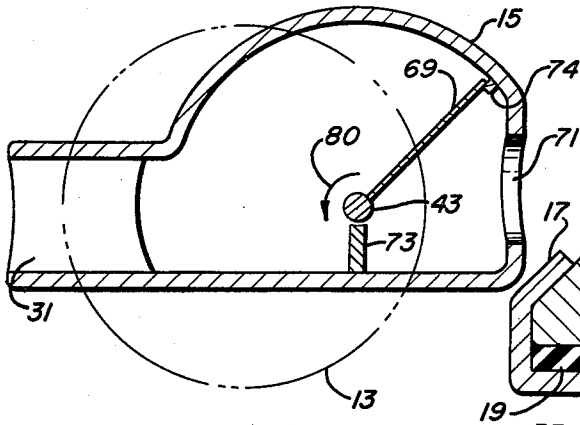

FIG. 2

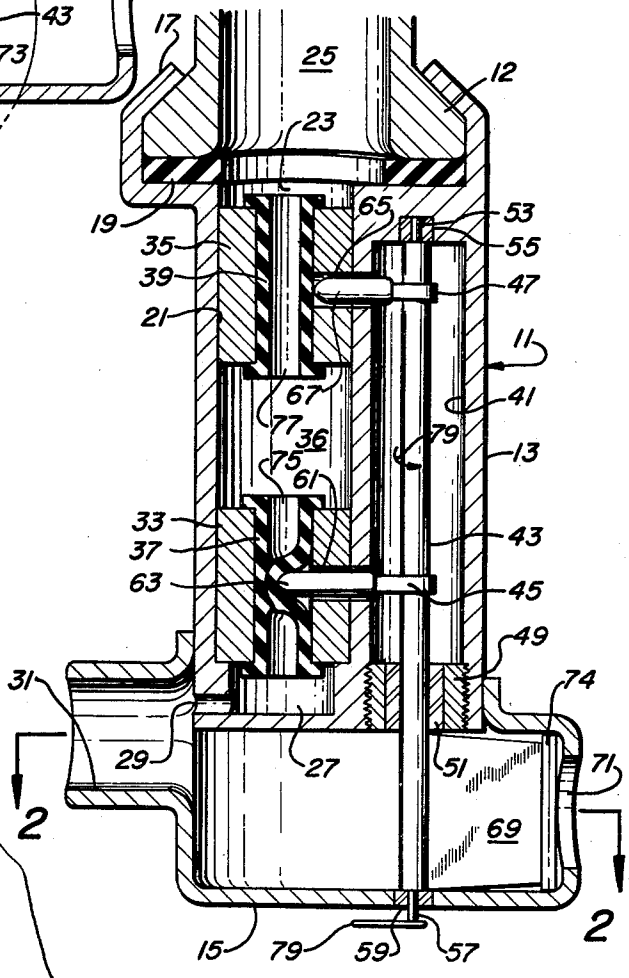

FIG. 1

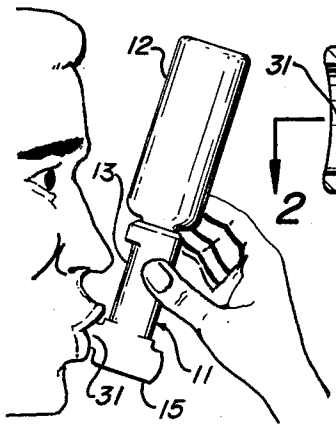

FIG. 3

INVENTOR.
RALPH I. MITCHELL
CLARENCE L. PAULLUS
BY
Rowley Johnson
ATTORNEY

June 8, 1965 R. I. MITCHELL ETAL 3,187,748

INHALATION-ACTUATED AEROSOL DEVICE

Filed April 29, 1963 2 Sheets-Sheet 2

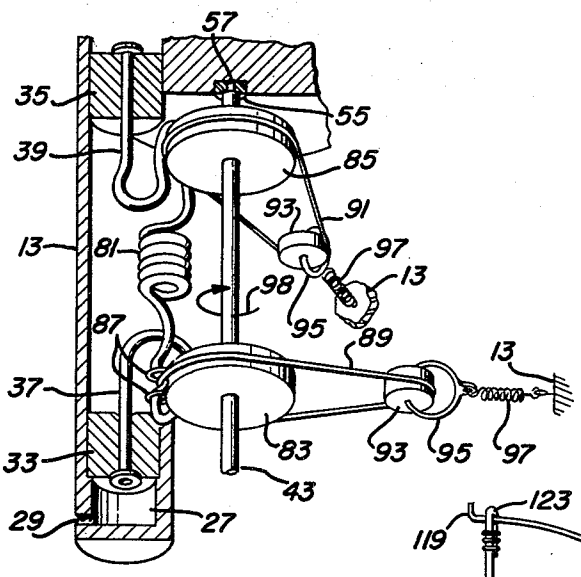

FIG. 4

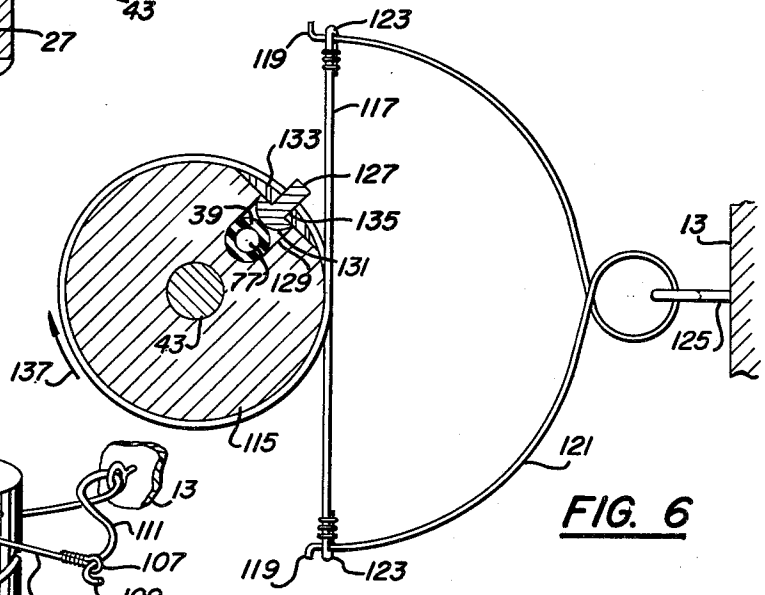

FIG. 6

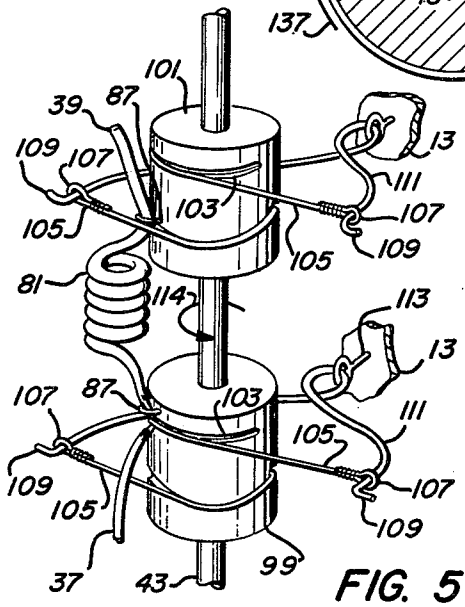

FIG. 5

INVENTOR.
RALPH I. MITCHELL
CLARENCE L. PAULLUS
BY Rewick Johnson
ATTORNEY

United States Patent Office 3,187,748 Patented June 8, 1965

3,187,748

INHALATION-ACTUATED AEROSOL DEVICE

Ralph I. Mitchell, Galena, and Clarence L. Paullus, Columbus, Ohio, assignors, by mesne assignments, to Merck and Company, Inc., Rahway, N.J., a corporation of New Jersey

Filed Apr. 29, 1963, Ser. No. 276,267
4 Claims. (Cl. 128—173)

This invention relates to dispensing devices for pressurized vessels of the aerosol type, and, more particularly, to pneumatically actuated vessels containing atomizable or volatilizable materials.

Vessels that have a material under pressure for dispensation by push button or other means are now used for a wide variety of products. Many of such products are released in the form of a mist or spray. The liquid, which may possibly contain a suspended, finely divided solid, is usually atomized by a nozzle as it is finally released from the dispensing valve or apparatus. Other materials, which may be a liquid within the pressurized vessel, become gaseous when they are released to the reduced pressure of the atmosphere. There are numerous types of containers and valves in the art for storing and releasing such products. Of these, there have been some constructed for releasing a measured or predetermined amount of the stored material.

The construction of devices for releasing predetermined amounts of material from pressurized containers was undertaken primarily for administering dosages of aerosol-type medicaments. Conventionally, most of such devices have springs and other mechanisms in their metering chambers that provide surfaces for the measured medicament to collect upon. The ideal apparatus has a dosage chamber that is a space with relatively uniform walls.

Another problem associated with many medicaments is their tendency to settle out when small portions of the medicament are isolated from the main body of the medicament in the container. This invention provides a metering space that communicates with the main body of medicament between periods of active use.

According to this invention, a construction for a metering valve is provided that includes means for pneumatic cocking and triggering of the valve by the patient's inhalation and means for measuring a predetermined amount of medicament for release to the patient upon triggering.

The important advantage of the metering valve is that an individual requiring the medicament stored in the pressurized vessel merely places his mouth over the mouthpiece of the apparatus and inhales. A predetermined or standardized amount of the medicament is isolated from the main body of the medicament stored in the vessel and released to the patient. The invention thus provides a construction that ensures that medicaments intended for treatment of respiratory ailments reach the portion of the human anatomy where they are needed and most beneficial. Since the individual must be inhaling to operate the valve, there can be no misapplication. Merely spraying a medicament into the throat is not considered sufficient. In many instances, the dosage of medicament will be small and it will be released rapidly. Therefore, the patient should be inhaling both before and after the medicament is released in order to ensure first of all that the medicament enters the respiratory system and secondly that the penetration is deep to reach all the afflicted areas. An effective treatment is not assured where the patient must coordinate push-button release with inhalation especially since patients having respiratory ailments will also have irregular breathing. Where breathing and release must be coordinated by the patient, there is always some question as to the quality of the treatment; where breathing and release are coordinated by the apparatus, quality of the treatment is assured.

One advantage of this invention is the fully pneumatic feature of the metering valve. The patient is not required to make any adjustments or settings. Another advantage is that the container and pneumatic metering valve can be stored, full of medicament, between treatments to the patient without qualitative or quantitative changes in successive dosages. Still other advantages will be apparent from the accompanying drawings, the description that follows, and the claims herein set forth.

In the drawings:

FIG. 1 is an elevational section of a dispensing device according to the invention;

FIG. 2 is a section taken along the line 2—2 of FIG. 1.

FIG. 3 illustrates the use of the pneumatically actuated aerosol device by a patient;

FIG. 4 is a perspective view of a construction useful for opening and closing the passage from the aerosol container to the spray nozzle according to the construction shown in FIG. 1.

FIG. 5 is a perspective view of another construction for opening and closing the passage from the aerosol container to the spray nozzle; and

FIG. 6 is a section of still another construction for opening and closing the aerosol passage of the device shown in FIG. 1.

In the drawings, the same reference numerals are applied to identical parts and to parts substantially identical in structure, function, and operation. Therefore, to eliminate confusing duplication, these parts, their interrelationship and their function will be described only in conjunction with a single embodiment, such description applying to all embodiments where these parts appear.

Referring to FIGS. 1 and 2, the pneumatic valve 11 is shown mounted on a flanged container 12. The valve 11 includes, in general, a main body 13 and a respirator cap 15 attached thereto. The valve 11 is fastened to the container 12 by having its end area 17 crimped around the top of the container 12 and sealed by suitable means such as a rubber gasket 19. The pneumatic valve 11 and the container 12 can be constructed as a single unit, and this is often desirable to eliminate fabrication steps, extra parts and extra seals. A unitary construction of valve 11 and container 12 is quite convenient when many of the parts of the apparatus are molded from a plastic material.

The main body 13 is provided with a bore 21 which communicates at one end 23 with the opening 25 of the container 12. The opposite end 27 of bore 21 is provided with a small opening 29 for releasing the medicament to a mouthpiece or respirator tube 31. Two sleeves 33 and 35 are positioned in bore 21 and may be fixed in place by any suitable means, as for example threads (not shown). A chamber 36 remains between the sleeves 33 and 35, with the chamber 36 being defined by the wall of the bore 21 and the ends of the sleeves 33 and 35. The central opening of each of the sleeves 33 and 35 is provided with a section of rubber tubing 37 and 39, respectively.

A second bore 41 is included in the main body 13 to provide free movement for a shaft 43 having two cams 45 and 47. The open end of bore 41 is closed with a threaded plug 49 having a bearing 51 centrally located and surrounding the shaft 43. The shaft 43 has a small diameter end 53 which is seated in a bearing 55, at the closed end of bore 41. The opposite end 57 of shaft 43 is also reduced in diameter and is fitted into a bearing 59 in the cap 15. The construction for mounting the shaft 43, just described, is not considered important because of the particular construction illustrated, rather the important aspect is that any construction for mounting the shaft 43 is ac-

ceptable so long as the shaft is free to rotate with very little force applied to it.

Sleeve 33 and the main body 13 between bores 21 and 41 are provided with a channel 61 into which is inserted a pin 63 having one end touching the rubber tubing 37 and the opposite end bearing against the cam 45. Similarly, sleeve 35 and the main body 13 are provided with a channel 65 containing a pin 67. One end of pin 67 touches the rubber tubing 39 and the opposite end bears against cam 47.

A movable vane 69 is disposed within the cap 15 and is attached to the shaft 43. The cap 15 is provided with an opening 71 and a fixed vane 73 so that an air passage exists between respirator tube 31 and opening 71 that is blocked by the movable vane 69.

In FIG. 2, the pneumatic vane 69 is shown in rest position with the vane 69 positioned against a stop 74. In FIG. 1, the apparatus is in the same position with pin 63 forced against the rubber tubing 37 closing off the central passage 75 and thus preventing the aerosol stored in the container 12 from being released. A corresponding central passage 77 in the rubber tubing 39 is, however, opened so that chamber 36 is filled with material from, and in communication with, container 12.

FIG. 3 shows the pneumatically actuated valve 11 in the normal operating position. The patient places the respirator tube 31 in his mouth and inhales. The air pressure differential in the cap 15, caused by the patient's inhalation, moves vane 69 so that the shaft 43 is rotated in the direction of the arrow 80 (shown in FIG. 2).

Rotation of shaft 43 in the direction of arrow 80, also rotates cams 45 and 47 (see FIG. 1) so that the pin 67 is forced against tube 39 closing passage 77, and pin 63 is allowed to move back so that passage 75 is opened. Thus, a quantity of medicament is released to the patient as he inhales. The amount of medicament is determined by the volume included in the passages 75 and 77 between pins 63 and 67, and primarily by the size of the chamber 36. The surfaces of cams 45 and 47 are shaped so that there is a momentary "dwell" period when pins 63 and 67 have closed both of the passages 75 and 77. This ensures that there is never any completely open passage between the opening 29 and the container 12, that is, the pins 63 and 67 are controlled so that either one or both of passages 75 and 77 are closed at all times.

When the vane 69 and shaft 43 are returned to the original rest position, the pin 63 again squeezes the tubing 37 closing passage 75, and pin 65 is released opening passage 77. The medicament can then refill metering chamber 36. Although the vane 69 and shaft 43 could be returned to rest position by a light spring, satisfactory results are obtained by providing a handle 79 at the end of shaft 43 so that the valve 11 may be reset to provide a second dose.

Referring to FIG. 4, an alternative construction for pinching off the sections of rubber tubing 37 and 39 is shown. In this construction, the sections of rubber tubing 37 and 39 are connected with a coil 81 of rubber tubing between them. The coil 81 serves as a metering chamber. A bulbous portion of rubber tubing of a size selected to isolate a predetermined amount of the medicament is also acceptable in place of the coil 81 to serve as a metering chamber. Shaft 43 is provided with two pulleys, 83 and 85, instead of cams 45 and 46. The tubing sections 37 and 39 are attached to the pulleys 83 and 85 by suitable means such as staples 87. Belts 89 and 91 pass partially around pulleys 83 and 85, respectively. For each of the belt 89 and 91, a second pulley 93 is provided. The pulleys 93—93 keep the belts 89 and 91 stretched tight around pulleys 83 and 85 by means of a holder 95 and a spring 97.

The spring 97 and holder 95 are fixedly attached to a point on the valve body 13 (not shown). The points of attachment are selected to position the belts 89 and 91 so that one section (section 37 in FIG. 4) of the rubber tubing will be pinched and the other section (section 39 in FIG. 4) will remain open by being positioned at a point on the periphery of the pulley where the belt does not touch the pulley. (Such a relationship is shown with pulley 85 and belt 91 in FIG. 4.) When the patient inhales, vane 69 rotates shaft 43 in the direction of the arrow 98 and consequently pulleys 83 and 85. Rotation of pulleys 83 and 85 (from the position shown in FIG. 4) moves tubing section 37 to a point where it is no longer pinched between belt 89 and pulley 83 while tubing section 39 moves to a point where it becomes pinched between belt 91 and pulley 85. An adequate amount of tubing is provided so that tubing sections 37 and 39 are free to move with the pulleys 83 and 85.

Releasing the pressure of belt 89 on tubing section 37 allows the medicament in coil 81 to be released through the aperture 29 to the patient. The volume of the tubing between the pinched points on pulleys 83 and 85 determines the amount of medicament or dosage received by the patient.

FIG. 5 shows a second pulley arrangement for pinching tubing and thus controlling the dosage and release of medicament to the aperture 29. In the construction shown, two pulleys 99 and 101 are attached to and rotate with the shaft 43. Each of the pulleys 99 and 101 has a guide groove 103 cut into its surface in the form of a spiral. A belt 105 is disposed around each pulley 99 and 101 and is fitted into the spiral guide groove 103. Tubing sections 37 and 39 are attached by suitable means such as staples 87—87 to pulleys 99 and 101, respectively. Each end of the belt 105 is provided with a loop 107—107 that is fitted over the ends 109—109 of a spring 111. Each spring 111 is fixedly mounted to the valve body 13 by suitable means such as an eyelet 113.

As shown in FIG. 5, the two pinching mechanisms are in "rest" position. Tubing section 37 is squeezed between belt 105 and pulley 99. Inhalation by the patient rotates shaft 43 in the direction of the arrow 114 so that tubing section 37 is released as tubing section 39 becomes pinched between belt 105 and pulley 101. As in the other examples shown, the volume of the length of tubing between the pinched points on tubing sections 37 and 39 determines the amount of medicament that the patient will receive. Also, coil 81 could be replaced by a bulbous section of tubing.

FIG. 6 is a section of still another construction for pinching the tube sections 37 and 39. In this embodiment, a pulley 115 is mounted on the shaft 43 and the tube section 39 is passed through the interior of pulley 115. A belt 117 is passed spirally around the pulley 115 and is held taut by the ends 119—119 of a spring 121 being attached to the end loops 123—123 of belt 117. Spring 121 is mounted on an eyelet 125 that is affixed to valve body 13. A pin 127 is inserted into a passage 129 in the pulley 115. The passage 129 communicates from the outside surface of the pulley 115 to the tubing section 39. The pin 127, which has a rounded head 131 for compressing tubing section 39, is free to move in passage 129. A plate 133 is placed over the passage 129. Plate 133 has an opening 135 that is smaller than the head 131 of pin 127. The plate 133 engages the pin head 131 and prevents the pin 127 from falling out of passage 129 when the pin 127 is forced outward by the resiliency of rubber tubing 39. When shaft 43 is rotated and rotates pulley 115 in the direction of the arrow 137, the end of pin 127 moves into engagement with belt 117, forcing the pin 127 inwardly against tubing section 39 collapsing tubing section 39 and closing off passage 77. In this embodiment, a second pulley identical in construction to pulley 115 is mounted on shaft 43 for constricting tubing section 37. The only difference is that the second pulley would be positionally rotated about 10 or 15 degrees opposite the direction of arrow 137 and the pin would already be held inward by the belt 117 constricting tubing section 37 and closing passage 75. Then, on rotation

of the second pulley in the direction of arrow 137 the pin 127 would be released to move outwardly and open passage 75.

While the invention is particularly useful with finely divided solid medicaments that are substantially insoluble in the "Freon" types of propellants that are commonly used at the present time in aerosol devices, and particularly where it is desired to have such a medicament delivered deep into the respiratory system of a person, various aspects of the invention are also useful where the medicaments (whether solid or liquid) are soluble in the propellants, and where the material propelled by the propellants is not a medicament. The amount of metered material discharged by such a device, as shown and described herein, is unusually small—about 35 milligrams by weight (or about 25 microliters by volume as measured in the containers). The amount of metered material can be adjusted to suit the intended use of the valve.

It will be understood, of course, that, while the forms of the invention herein shown and described constitute the preferred embodiments of the invention, it is not intended to illustrate all of the possible equivalent forms or ramifications of the invention. It will also be understood that the words used are words of description rather than of limitation, and that various changes, such as changes in shape, relative size, and arrangement of parts may be substituted without departing from the spirit or scope of the invention herein disclosed.

What is claimed is:

1. In an aerosol container and spray device, a pneumatic metering valve for dispensing small measured amounts of the contents of the aerosol container comprising:

(a) a container including a propellant in the contents of said container;

(b) a valve body attached over an opening in said container;

(c) a cap attached to said valve body, said cap having a mouthpiece and an opening opposite said mouthpiece;

(d) a vane, and its supporting shaft, disposed in said cap, said vane being positioned to block the passage between said opening and said mouthpiece, and said shaft being rotatably mounted on said valve body;

(e) a metering chamber in said valve body;

(f) a first passage communicating between said metering chamber and said container, said first passage being normally open;

(g) a second passage communicating between said mouthpiece and said metering chamber, said second passage being normally closed;

(h) closure means activated by movement of said vane and shaft to alternately close said first and second passages whereby human inhalation at said mouthpiece causes said vane to move in one direction closing said first passage and thereafter opening said second passage and whereby on movement of said vane in the opposite direction said second passage is closed and thereafter said first passage is opened.

2. A pneumatic metering valve as described in claim 1 in which the first and second passages are sections of resilient tubing and the closure means are blunt pins urged against said resilient tubing by cams disposed on the rotatable shaft thereby constricting said tubing.

3. A pneumatic metering valve as described in claim 1 in which the first and second passages are sections of resilient tubing and the closure means include, for each passage, a pulley mounted on the rotatable shaft and a belt surrounding at least a portion of the pulley, with each passage being attached to a pulley whereby closure occurs by rotation of said pulley to a point where said resilient tubing is constricted between said pulley and said belt.

4. A pneumatic metering valve as described in claim 2 in which the first and second passages are sections of resilient tubing and the closure means, for each passage, including:

(i) a pulley mounted on said shaft;

(ii) a first passage in said pulley substantially parallel to the axis of said pulley for containing said resilient tubing;

(iii) a second passage from the exterior surface of said pulley to said first passage;

(iv) a pin disposed in said second passage with the end of said pin extending beyond the surface of said pulley, said pin being moveable in said second passage to a position for constricting said resilient tubing; and

(v) a belt around at least a portion of said pulley whereby upon rotation of said pulley said belt contacts the extended portion of said pin moving said pin to said position for constricting said resilient tubing.

References Cited by the Examiner

UNITED STATES PATENTS

2,872,923	2/59	Birch et al.	128—184
2,992,645	7/61	Fowler	128—266
3,001,524	9/61	Maison et al.	128—208

RICHARD A. GAUDET, *Primary Examiner.*