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(54) **Medical Inhalation Devices**

(57) An inhalation device for administering medicaments in an aerosol container to a patient. The device has a housing (1) in which an aerosol container (2) can be located. The aerosol container (2) normally protrudes through an open end of the housing (1). An outlet mouthpiece (8) leads from the interior of the housing (1). A passage (9) is provided between the housing (1) and the outlet (8) through which air can flow when a patient inhales through the outlet (8). A valve (14) is located in the passage. The valve (14) is biassed so as normally to be in the open condition but will close automatically when the rate of flow of air inhaled by the patient exceeds a pre-determined amount. The valve (14) is conveniently a hinged flap which is spring-loaded towards the open position.

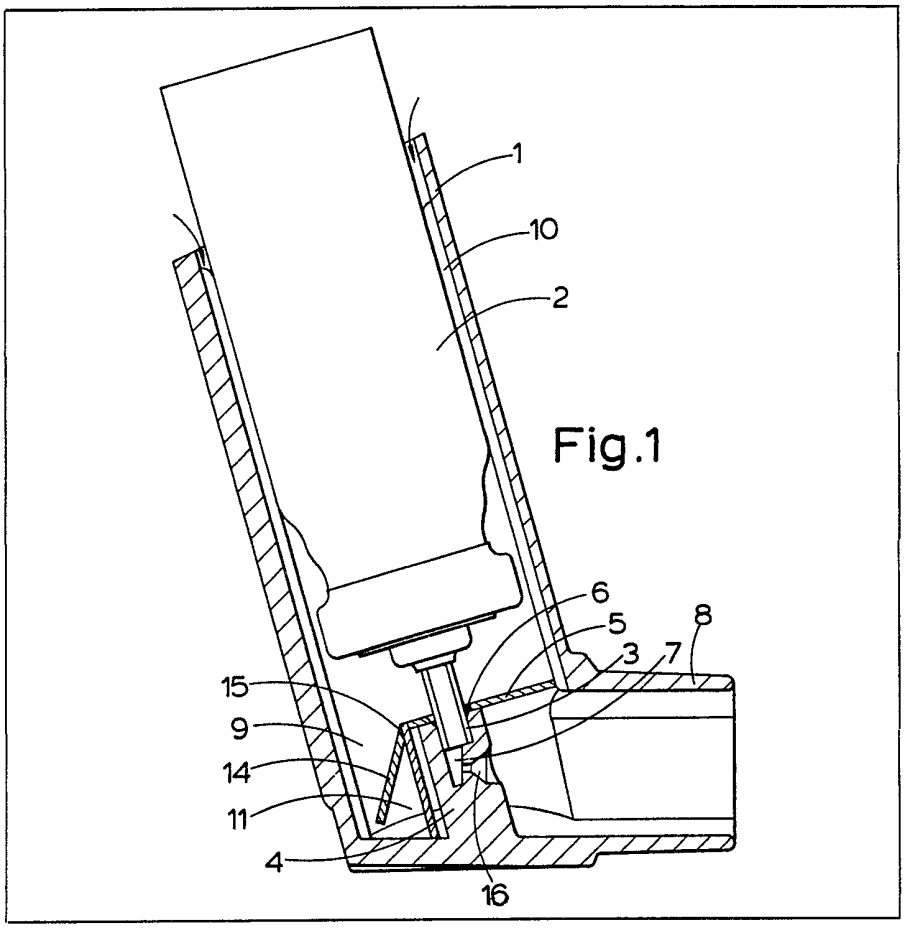

Fig.1

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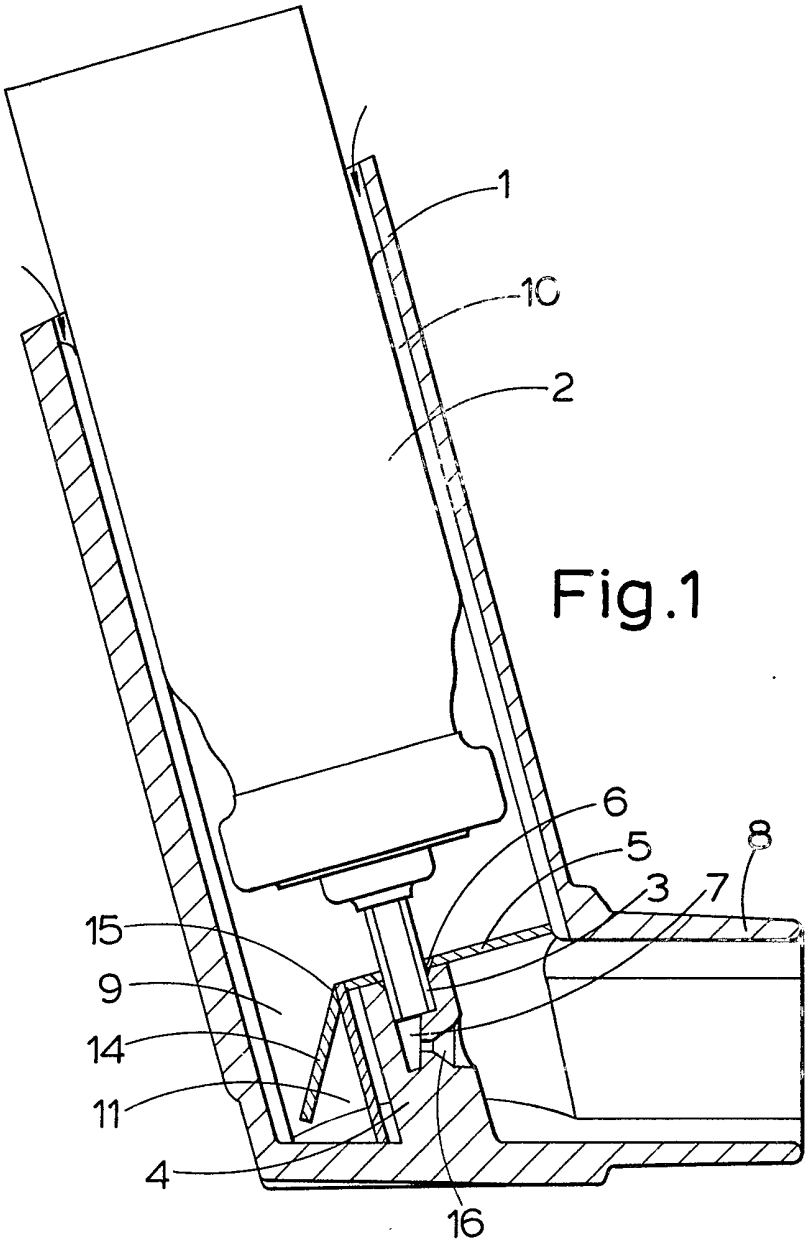

Fig.1

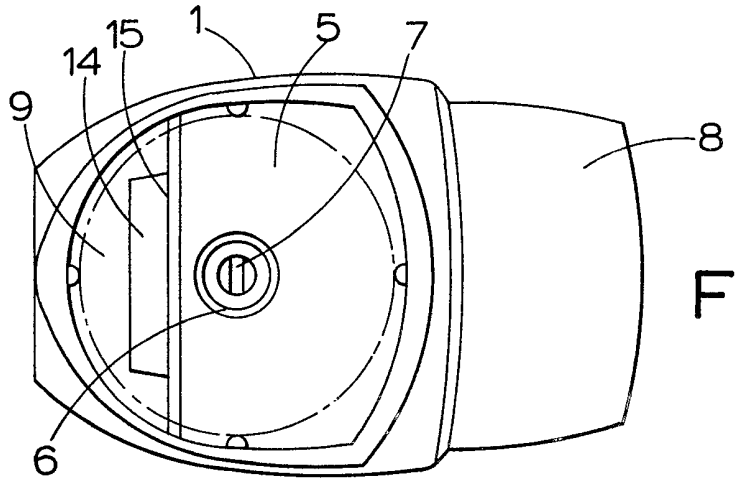

Fig.2

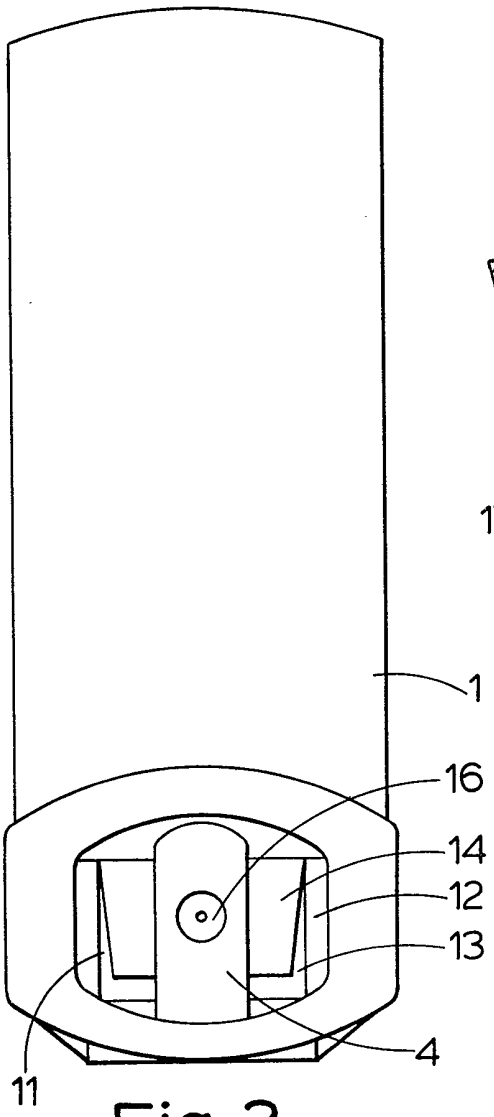

Fig.3

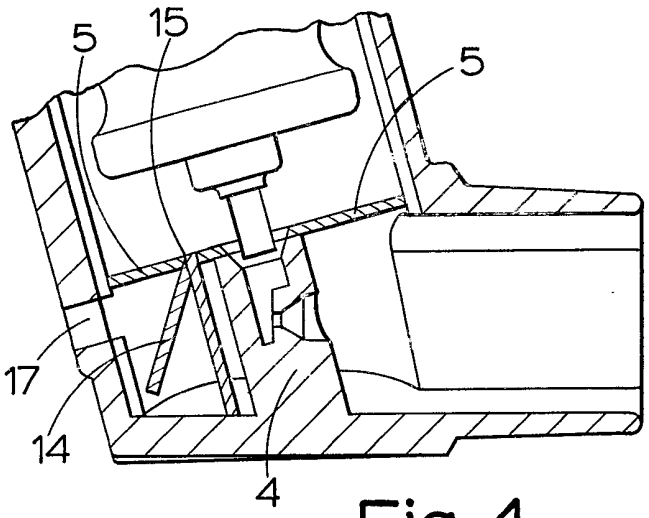

Fig.4

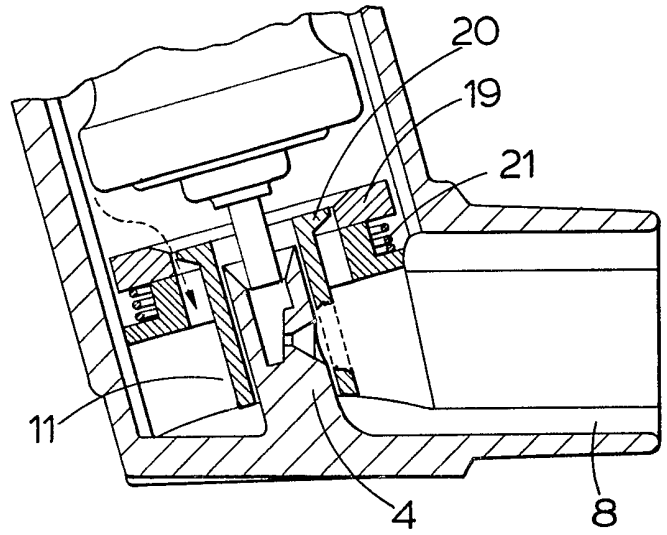

Fig.6

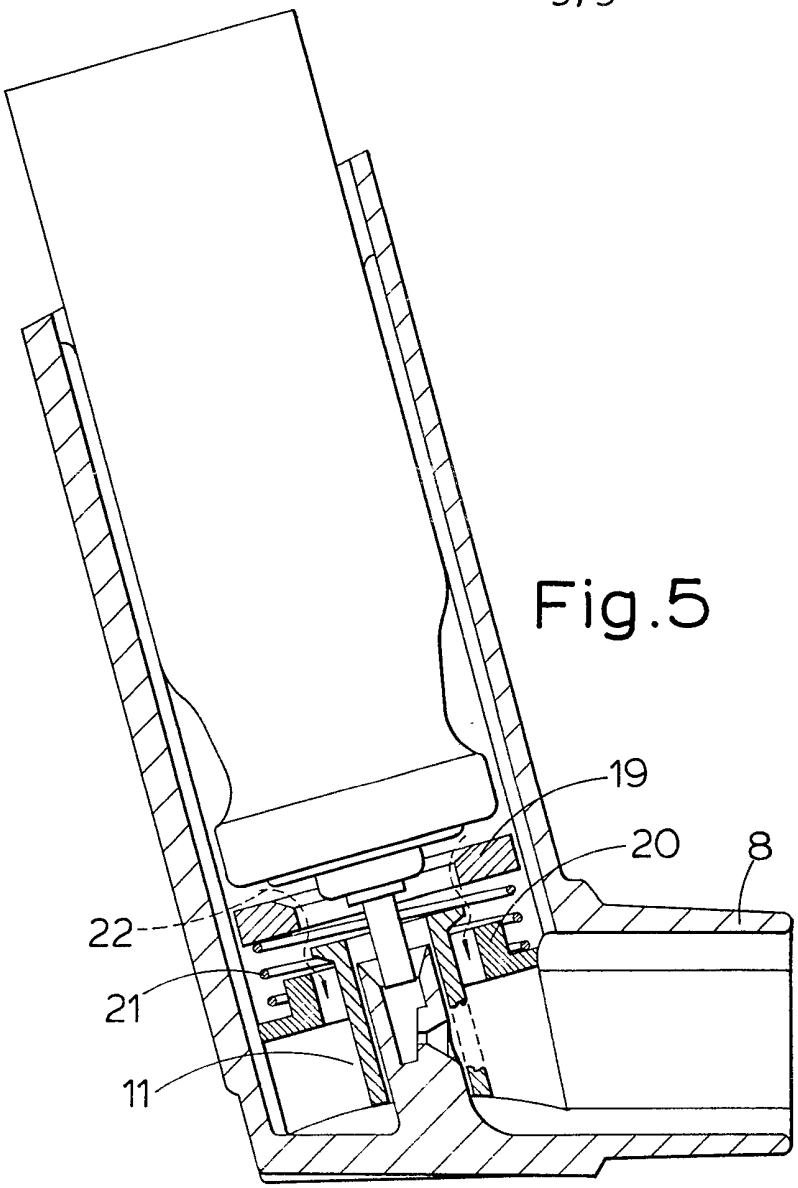

Fig.5

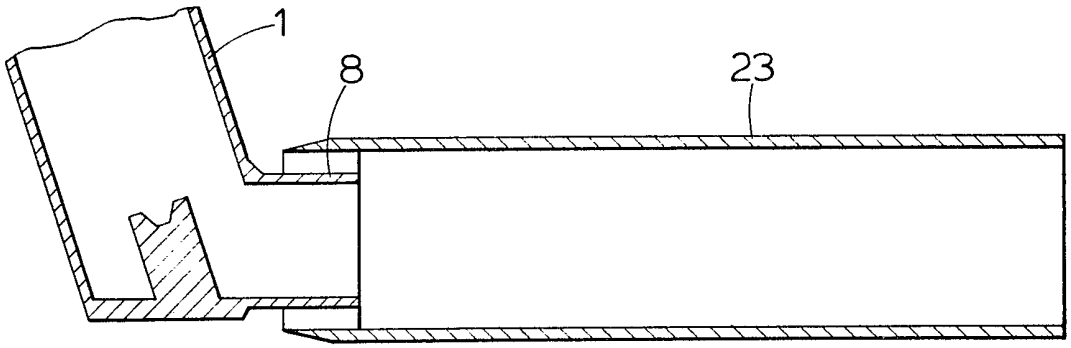

Fig.7

SPECIFICATION

Medical Inhalation Devices

This invention relates to an inhalation device by which a medicament contained in an aerosol can be administered to a patient.

It is well known to treat patients with medicament contained in an aerosol, for example, in bronchodilator therapy. It is known to use for such therapy medicaments which are contained in an aerosol and are administered to be patient by means of an inhalation device comprising a tubular housing or sleeve in which an aerosol container is located and a mouthpiece leading out of the tubular housing. In use, the aerosol container is placed in the tubular housing which is then held by the patient in a more or less upright condition and the mouthpiece of the inhalation device is placed in the mouth of the patient. The patient inhales while operating the aerosol container to dispense medicament from the container through the mouthpiece into the patient. It has been found in practice that proper co-ordination between the act of inhaling and the act of operating the aerosol container to dispense the medicament is very difficult for some patients. Attempts have been made to solve this problem by providing such a device with a means for producing an audible signal when the aerosol container should be operated to dispense the medicament, i.e. when there is a proper rate of inhaled air flow. These known devices do not provide a really satisfactory solution to this problem. They can, for example, be extremely noisy when used in public with consequent embarrassment to a patient already under some stress.

An object of the present invention is to overcome this disadvantage.

We have also discovered that it is often desirable to increase the resistance to inhaled air flow during the use of such a device by a patient. A further object of the present invention is therefore to provide such an inhalation device with which the resistance to inhaled air flow will automatically be increased while a patient inhales through the device.

With these objects in view, the present invention provides an inhalation device for medicament in an aerosol container which device comprises a housing in which an aerosol container can be located, and an outlet leading from the housing and communicating with the interior of the housing, wherein a passage is provided between the housing and the outlet through which air can flow when a patient inhales through the outlet, a valve being located in the passage and arranged so as normally to be in the open condition but being also arranged to close automatically when the rate of flow of air inhaled by the patient exceeds a pre-determined amount.

The valve is preferably a hinged flap which is movable from a normal or inoperative position when the valve is open to a closed position in which it partially closes an aperture through which air can flow from the housing to the mouthpiece. In another embodiment, the valve completely closes the aperture and an inlet for air is provided to permit air to enter the housing on the mouthpiece side of the closed valve. In yet another embodiment, a slidable spring-loaded collar is used in the valve instead of the flap member, the collar being biassed by the spring towards the inoperative position.

A preferred embodiment of the invention is illustrated in the accompanying schematic drawings in which:

Figure 1 is a sectional view of an inhalation device according to the invention.

Figure 2 is a top view,

Figure 3 is a front view,

Figure 4 is a scrap sectional view of a modification

Figures 5 and 6 are sectional views illustrating another modification, and

Figure 7 schematically illustrates a mouthpiece extension of the device.

In the embodiment of the invention illustrated in Figs. 1 to 3, an inhalation device primarily, but not exclusively, intended for use in pulmonary therapy with anti-inflammatory steroids and other agents is moulded from plastics material and comprises a tubular housing or sleeve 1 in which an aerosol container 2 (shown only in Fig. 1) is located. The drawings illustrate the inhalation device when it is in its normal position of use and the device will be described as in this position. The housing 1 has an open top through which the aerosol container 2 can protrude. The aerosol container 2 is placed in the housing 1 in the inverted condition, that is to say with its outlet 3 at the bottom. The outlet is supported by a support pillar 4 which passes through a partition 5 which partly closes the lower end of the tubular housing 1. An aperture 6 communicates with a passage 7 through which the contents of the aerosol container can pass to an atomising nozzle 16 and thus to a mouthpiece 8 projecting laterally outwards from the tubular housing.

It will be seen from the drawings that the partition 5 does not completely close the lower end of the tubular housing 1, a space 9 being provided through which air inhaled by the patient through the mouthpiece can pass. When a patient inhales, air enters the housing 1 in the directions indicated by the arrows. The aerosol container 2 is held spaced from the inner wall of the housing 1 by internal ribs 10 so that air can flow between the outside of the aerosol container and the inside of the housing through the space 9 and an opening 11 into the mouthpiece 8.

In the arrangement of the present invention, a flap valve is provided to control part of the

flow of inhaled air. For this purpose a valve surround or seat 12 (Fig. 3) extends downwards from the partition 5 and has an opening 13 which can be closed by a flap 14 hinged to the partition at 15. The flap valve and the surround are moulded from plastics material in such a way that the hinged connection between them has a spring action. The parts are moulded together to form a so-called "living hinge". The spring action of the hinge is arranged so that the valve is normally biassed to an open position as clearly indicated particularly in Fig. 1. When there is a pre-determined rate of air flow through the housing 1, determined by the loading of the spring action at the hinge 15 and the size, shape and opened position of the flap and the profile of the housing around the flap, the valve will close automatically. When the flap valve 14 closes, the patient can sense the action of the flap valve closing against the support pillar 4 which acts as a stop giving a distinct sound a feel through the lips. Simultaneously, the patient can also sense the sudden increase in air resistance. The sound is discreet and would not embarrass a patient using the device in public. The detection of the flap closing indicates to the patient that the aerosol container should be depressed immediately to eject aerosol from the container so that it can pass into the mouthpiece.

If desired, instead of constructing the flap valve and its partition as a moulding with a living hinge, a weak spring could be used to bias the flap to the open position. Such a spring could either be incorporated in the hinge itself, or could be separately mounted to bear on the flap.

When the flap valve 14 is closed a lesser quantity of air can still be inspired through a valve opening 11 in the surround 12 around the flap valve 14.

The air resistance of the device when the flap is open can be very low, for example about 1–2 cm water at 60 litres/min. The resistance when the flap is closed can, if desired, be pre-set to a considerably higher value as desired by suitably selecting the size, shape and opened position of the flap and the profile of the housing around the flap. It will be seen from Fig. 3 that the flap valve 14 in its closed position does not completely close the opening through the valve surround 12. It has been suggested that resistance to air flow when the valve is in its closed postion should be relatively high, for example 30–50 cm water at 60 litres/min to encourage the patient to take a long deep breath and thus to obtain greater deposition of the medicament in the aerosol into the lungs. Alternatively, if desired, the resistance can be kept low after the flap valve closes by use of an auxiliary air hole through the partition 5 of the flap valve, or by arranging a suitable air gap round the flap in the closed position.

An alternative air inlet 17 (Fig. 4) may be provided near the valve 14 to give a straight air pathway from the inlet past the atomising nozzle to the mouthpiece. In that event, the partition 5 occupies the whole area of the interior of the housing and completely closes the lower end of the housing 1 as shown in Fig. 4. If desired, a plurality of inlets 17 may be provided. The inlet or inlets is/are provided with a dust cover (not shown). The device can also be modified to provide a spring of adjustable strength to control the opening of the flap valve 14. An indicator of the loading of the spring could be provided so as to be visible outside the device. This could give an adjustable indication of the point at which the aerosol should be fired. Alternatively, it could be so calibrated to provide an inspirational flow gauge for monitoring the condition of a patient.

Figs. 5 and 6 illustrate a modification in which the flap valve 14 is replaced by a slidable collar 19 which is movable to and from a fixed valve seat 20 surrounding a tubular member 24 containing the opening 11. A coil spring 21 urges the collar 19 to the inoperative or open position shown in Fig. 5 and when a patient inhales, the collar is drawn against the biassing action of the spring 21 towards the closed position illustrated in Fig. 5 in which it partially closes the space between the valve seat 20 and the tubular member 24. The air flow is indicated by arrows 22.

If desired, the mouthpiece 8 may be longer relative to the size of the housing 1 than is indicated in the drawings Figs. 1 to 5 and of adequate length and diameter in order to promote increased drying and deceleration of the spray droplets from the aerosol without excessive impingement in the mouthpiece before these impinge on the oropharynx and deeper large airways. This would reduce deposition of medicament in the oropharynx and other large airways. Fig. 6 illustrates an extension member 23 which is removable from the mouthpiece 8.

CLAIMS

1. An inhalation device for medicament in an aerosol container, the said device comprising a housing in which an aerosol container can be located and an outlet leading from the housing and communicating with the interior of the housing, wherein a passage is provided between the housing and the outlet through which air can flow when a patient inhales through the outlet and a valve is located in the passage and is arranged so as normally to be in the open condition but being also arranged to close automatically when the rate of flow of air inhaled by the patient exceeds a pre-determined amount.

2. A device as claimed in claim 1, wherein the housing is a tubular housing in which an

aerosol container can be received, the said housing being open at one end; the outlet extends laterally from the tubular housing near the other end of the housing; a partition is provided in the housing and has an aperture through which the contents of the aerosol container can pass to the outlet; a valve surround extends from the partition on the outlet side thereof and has a valve opening therein; a hinged flap is movable between an open position in which the said valve opening is fully open and a closed position; and means for biassing the flap valve to its open position.

3. A device as claimed in claim 2, wherein the partition does not completely close the interior of the housing; and the valve flap is so arranged that when it is in the closed position, the valve opening is not completely closed whereby a lesser quantity of air can still be inspired through the outlet.

4. A device as claimed in claim 2, wherein the partition occupies the whole area of the interior of the tubular housing and at least one air inlet is provided through the housing on the outlet side of the partition, the flap valve being arranged completely to close the opening in the valve surround.

5. A device as claimed in claim 1, wherein the housing is a tubular housng in which an aerosol container can be received, the said housing being open at one end; the outlet extends laterally from the tubular housing near the other of the housing; a partition is provided inside the housing and has an aperture therein; a tubular member on the outlet side of the partition, the said member communicating with the outlet and being arranged so that the contents of the aerosol can enter therein before passing to the outlet; a valve seat surrounding and spaced from the tubular member so that air can flow between them; a valve collar movable between an open position in which it is spaced from the valve seat and a closed position in which it partly closes the space between the tubular member and the valve seat; and means for biassing the valve collar to its open position.

6. A device as claimed in any one of claims 2 to 5 wherein the tubular housing has internal ribs arranged to space the aerosol container from the interior of the housing.

7. A device as claimed in any one of the preceding claims wherein the outlet is a mouthpiece having an extension member removably fitted thereon.

8. An inhalation device substantially as described with reference to the accompanying drawings.

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