

[54] INHALATION DEVICE

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[51] Int. Cl. **A61m 15/00, A61m 15/06**

[58] Field of Search **128/208, 266, 206, 209**

[56] **References Cited**

UNITED STATES PATENTS

3,507,277	4/1970	Altounyan et al.	128/208
3,518,992	7/1970	Altounyan et al.	128/208
3,635,219	1/1972	Altounyan et al.	128/266
3,669,113	6/1972	Altounyan et al.	128/266
2,517,482	8/1950	Hall	128/206

Primary Examiner—Aldrich F. Medbery

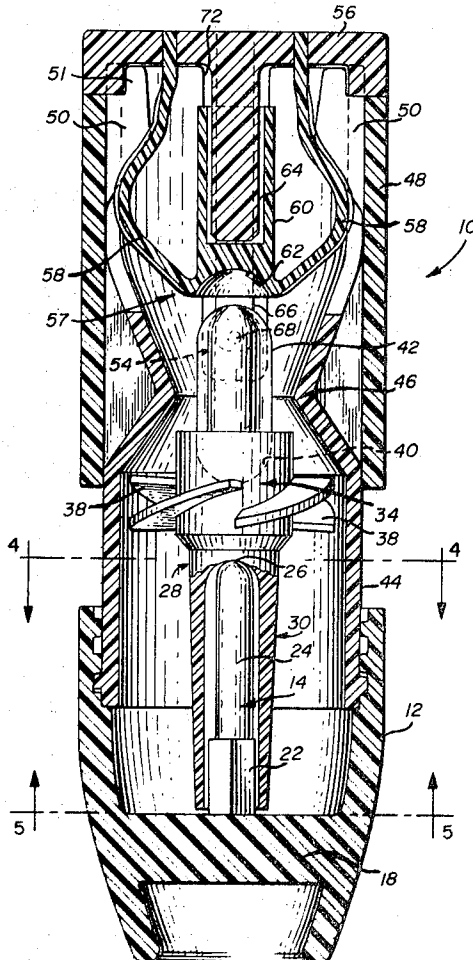
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[57]

ABSTRACT

An inhalation device having means to engage the free end of a powdered medicament-holding capsule as the capsule is pierced to provide outlet ports for the powdered medicament held therein. Such engagement ensures that the capsule is completely seated in the rotary member on which it is supported and thus ensures that the outlet ports are positioned at the desired locations adjacent the shoulder of the capsule. Additionally, such engagement enables the piercing operation to be conducted in any orientation of the inhalation device. The rotary member, which supports the capsule during inhalation, is itself supported by a shaft having a polygon shaped base having n sides. The rotary member has a hollow sleeve which fits over the shaft, the sleeve having a polygon shaped inner surface having at least $n + 1$ sides. During inhalation which causes the rotary member to spin about the supporting shaft, contact of the adjacent polygon shaped surfaces with each other positively causes the walls of the capsule to undergo repeated changes or radial acceleration whereby the powdered medicament is dispersed from the capsule.

21 Claims, 5 Drawing Figures



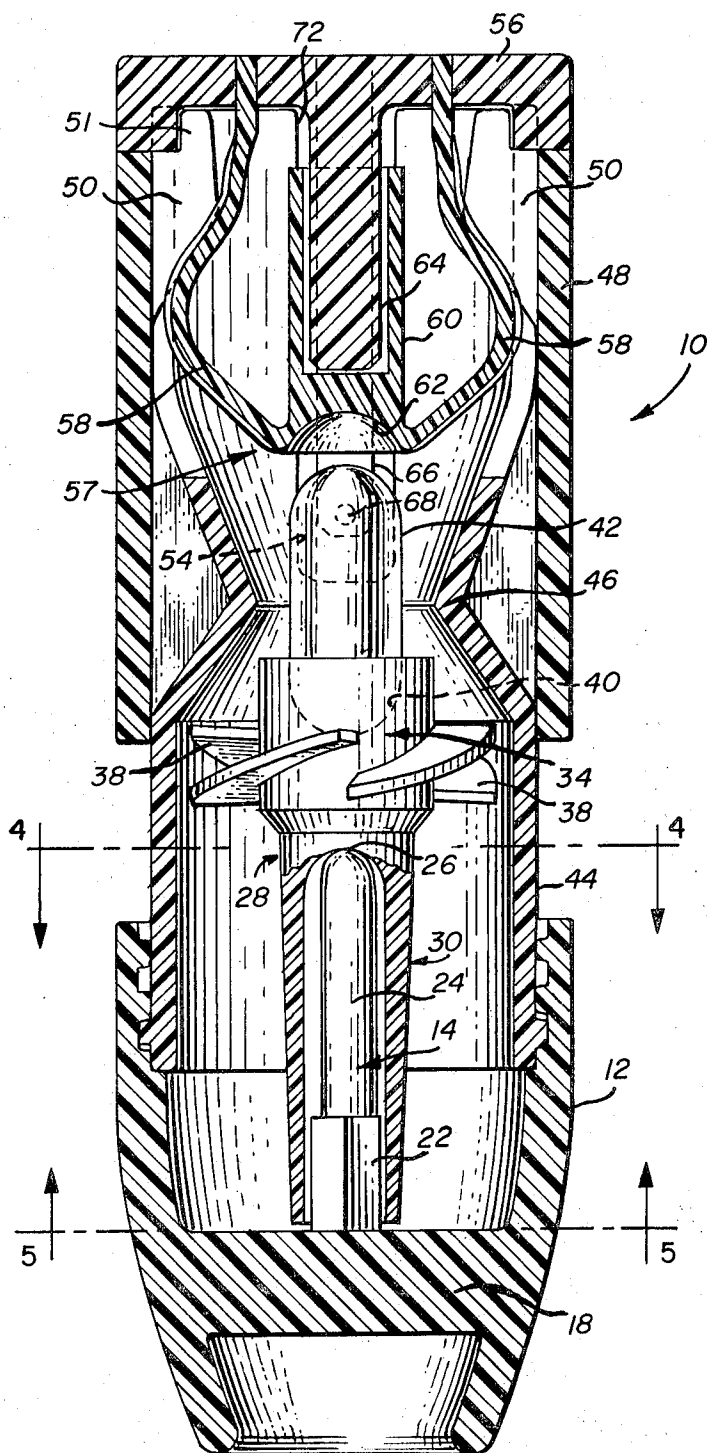


Fig. 1

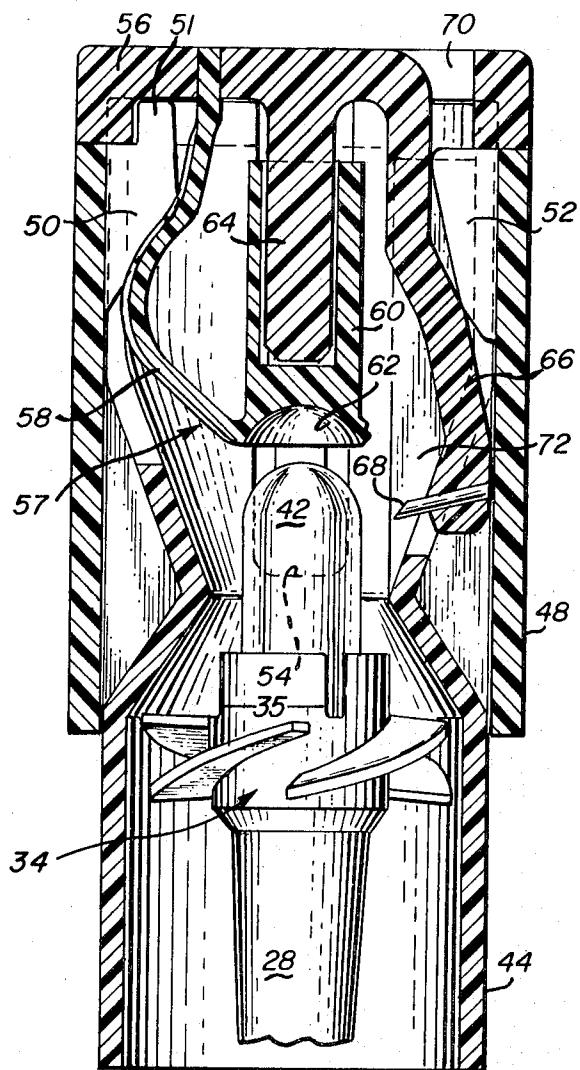


Fig. 2

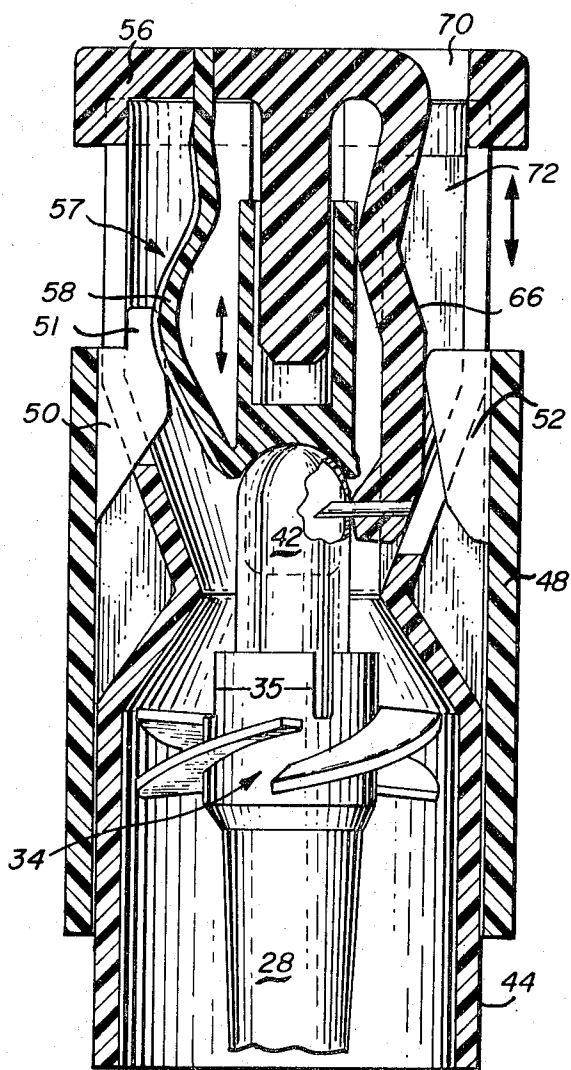


Fig. 3

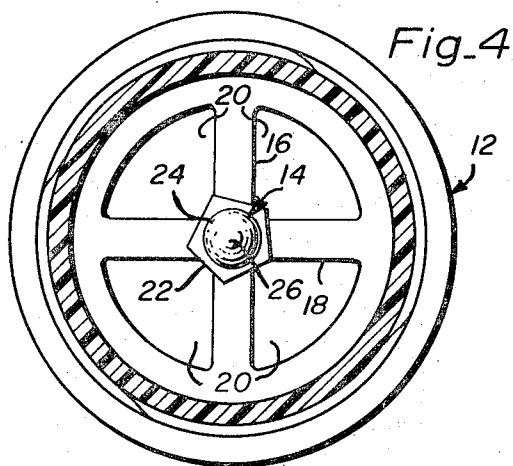


Fig. 4

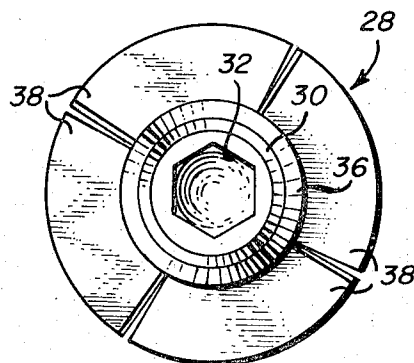


Fig. 5

INHALATION DEVICE

FIELD OF THE INVENTION

This invention is related to devices for the administration of powdered medicaments by oral inhalation. More particularly, this invention relates to an oral inhalation device having means to engage the free end of a powdered medicament-holding capsule as the capsule is pierced to provide outlet ports through which the powdered medicament is dispensed during inhalation. During inhalation, novel means associated with the support for the rotary member positively induces the desired eccentric motion which serves to dispense the powdered medicament through the outlet ports.

BACKGROUND OF THE INVENTION

Related inhalation devices as shown in U.S. Pat. Nos. 3,507,277; 3,518,922; 3,635,219; and, 3,669,113. Other inhalation devices include those shown in U.S. Pat. Nos. 2,517,482 and 2,573,918; and Belgium Patent 781,102.

SUMMARY OF THE INVENTION

The oral inhalation device of the present invention includes means to engage the free end of a powdered medicament-holding capsule as the capsule is pierced to provide outlet ports for the powdered medicament held therein. As used in this application, the "free end" of the capsule refers to that end of the capsule remote from the end of the device which is inserted into the mouth of the user. In the embodiment disclosed herein, the engagement means is actuated by the camming means which causes the capsule to be pierced at the desired locations adjacent the shoulder of the free end of the capsule. During the first portion of movement of the camming means, as it is manually moved to cause the capsule to be pierced, the engagement means seats against the free end of the capsule and gently forces it, to the extent possible, into the recess in the rotary member in which the capsule has been placed. This action ensures that the capsule will be completely seated in the recess in the rotary member. During the latter portion of the movement of the camming means, the engagement means rigidly holds the capsule in the desired position and thereby assists the piercing means in piercing the capsule at the desired locations on the shoulder of the free end of the capsule. Upon manual movement of the camming means back to its original position, the piercing means and the capsule engaging means are returned to their initial position, thus freeing the capsule for rotation upon inhalation.

The rotary member, which holds the powdered medicament-holding capsule during inhalation, is supported by a shaft which has a polygon shaped base having n sides, preferably four to six sides. The rotary member has a hollow sleeve which fits over the shaft in such a manner that the polygon shaped inner surface of the hollow sleeve lies adjacent the polygon shaped surface of the shaft. The polygon shaped inner surface has at least $n + 1$ sides up to a maximum of about 12 sides, but preferably has $n + 1$ sides. During inhalation, which causes rotation of the rotary member due to the flow of air over the vanes thereon, contact of the polygon shaped surfaces with each other positively causes the rotary member to rotate in the desired orbital or eccentric manner such that the powdered medicament is dis-

persed from the capsule through the outlet ports made therein during the piercing operation. The powdered medicament is entrained in the air stream being inhaled, and carried through the mouth and into the bronchial tract and/or lungs of the user where the beneficial or therapeutic action of the medicament takes place.

BRIEF DESCRIPTION OF THE DRAWINGS

The foregoing and still further features and advantages of the present invention will become more apparent from the following detailed description, taken together with the accompanying drawings wherein:

FIG. 1 is a vertical cross-sectional view of an oral inhalation device incorporating the features of the present invention, the rotary member being shown only in partial cross-section;

FIG. 2 is a cross-sectional view of the upper portion of the inhalation device of FIG. 1 showing certain elements thereof in the "relaxed" position, the cross-sectional portion to the left of the center line of the device being taken through the center line of the nesting spring arm of the engagement means while the cross-sectional portion to the right of the center line of the device is taken through the center line of the piercing arms;

FIG. 3 is a cross-sectional view of the upper portion of the inhalation device of FIG. 1 showing the elements thereof in the piercing position, the cross-sectional portion to the left of the center line of the device being taken through the center line of the nesting spring arm of engagement means while the cross-sectional portion to the right of the center arm line of the device is taken through the center line of the piercing arms;

FIG. 4 is a cross-sectional view taken along line 4-4 of FIG. 1 showing the mouthpiece and the shaft thereon, but omitting the rotary member; and

FIG. 5 is a bottom view of the rotary member taken along line 5-5 of FIG. 1.

Referring to FIG. 1, there is shown an inhalation device 10 having a mouthpiece 12 supporting a shaft 14. As can best be seen in FIG. 4, shaft 14 is supported at the intersection of cross-arms 16 and 18. Openings or passageways 20 are provided to permit air to be drawn through the device and from the interior of the device into the mouth of the user. As shown, shaft 14 has a pentagon-shaped base 22 and an essentially cylindrical upper portion 24 terminating in a rounded end portion 26.

Supported on shaft 14 is rotary member 28 having, at the lower portion thereof, a hollow sleeve 30 which fits over and surrounds shaft 14, including pentagon-shaped base 22. As can best be seen in FIG. 5, the lower, internal portion 32 of sleeve 30 is hexagonally shaped about the inner periphery thereof adjacent pentagon-shaped base 22. The sleeve, and the polygon shaped inner portion thereof, are of such dimension that, during rotation, the rotary member rotates in a "wobbling" orbital or eccentric manner. Fins 38 are positioned about the outer periphery of upper portion 34 of rotary member 28 and cause the rotary member to rotate when air is drawn through device 10, as by inhalation. Upper portion 34 has a recess 40 therein in which a powdered medicament-holding capsule 42 is positioned prior to use. Upper portion 34 can have one or more (preferably two) slots 35 (as shown in FIGS.

2 and 3) to make the walls thereof sufficiently flexible to accept capsules of different diameters.

Connected to the interior end of mouthpiece 12 is a hollow elongate housing 44 having a necked-down portion 46 adjacent capsule 42. Slidably mounted on the outer surface of housing 44 is a tubular sleeve member 48 having two pair of opposed cams 50 and 52 spaced on the inner periphery thereof. Each cam is spaced 90° apart from the cam on each side thereof, and passes through an adjacent slot 54 in the upper portion of housing 44. Cams 52 are held in position and guided in movements by guide walls 72.

Supported at the end of housing 44 remote from mouthpiece 12 is end cap 56 which has attached thereto, on the inside thereof toward the interior of housing 44, engagement means 57 including nesting spring arms 58 and sleeve 60. At the end of spring arms 58 remote from end cap 56, the spring arm terminates in a recess 62 of the same shape as the near-by end portion of capsule 42. Extending from recess 62 away from capsule 42 and toward end cap 56 is a hollow cylindrical sleeve 60 adapted to slide over the outer surface of guide 64.

Before proceeding to a discussion of FIGS. 2 and 3, it should be noted that the cross-section of each of these two Figures to the left of the center line of the device is taken through the center line of one of the nesting spring arms 58 and that the cross-section of each of these two Figures to the right of the center line of the device is taken through the center line of one of the piercing arms 66 (ie, the cross-section in these views has been rotated clockwise 90° at the center point of each Figure). Thus, in FIG. 2, the position of one-half of the engagement means 57 and one of the opposed piercing arms 66 is shown in the relaxed position, while in FIG. 3 one-half of the engagement means and one of the opposed piercing arms is shown in the piercing position. The portions of the engagement means and the piercing arm not illustrated in these Figures will be the mirror images of the respective sides as illustrated in FIGS. 2 and 3.

Referring now to FIG. 2 where the engagement means 57 and piercing arm 66 are shown in the relaxed position, it will be seen that cam 52 contacts the outer surface of adjacent piercing arm 66 having needle 68 on the lower portion thereof adjacent capsule 42. In a similar manner, cam 50 contacts the adjacent surface of nesting spring arm 58. Such cam contact is repeated for the opposed nesting spring arm and piercing arm not illustrated.

Referring now to FIG. 3, it will be seen that sleeve 48 has been manually moved downwardly (ie, toward mouthpiece 12), whereby cams 52 cause opposed piercing arms 66 to move inwardly and, eventually, perforate capsule 42, to thereby provide outlet ports in the capsule for the dispensing of the powdered medicament held therein. Cams 50 contact the adjacent surface of opposed nesting spring arms 58 causing, by the resilient nature of the spring arms, the entire engagement means to extend toward capsule 42 which has been placed in recess 40. Prior to the time when needles 68 on opposed piercing arms 66 enter and, thus, perforate capsule 42, recess 60 is seated against the adjacent end of capsule 42 and, in so doing, causes the capsule to be gently forced completely into recess 40. Additionally, the engagement means serves to rigidly hold the capsule as piercing needles 68 perforate the

capsule on the opposed sides of the free end thereof. This can best be seen in FIG. 3.

Upon manual movement of tubular sleeve 48 back to its original position as shown in FIG. 2, opposed piercing arms 66 and nesting spring arms 58 are returned to their original position, whereby rotary member 28, now holding perforated capsule 42, is free to rotate as air passes over and through fins 38 during inhalation.

When sleeve 48 has been manually moved to the position shown in FIG. 3 (ie, to the full piercing position), extension 51 on cam 50, as shown in FIG. 3, contacts the bowed nesting spring arm 58 at its point of maximum width. The same is true for the opposed cam and nesting spring arm not shown. This configuration prevents the engagement means from relaxing slightly and thus relieving the pressure on capsule 42. In this manner, compression is maintained on capsule 42 during piercing.

In use, the patient unscrews mouthpiece 12 to expose rotary member 28. If a spent capsule remains in recess 40 it is removed and replaced with a new powdered medicament-holding capsule. The mouthpiece is then screwed back onto housing 44. Tubular sleeve 48, which is in position as shown in FIG. 2, is manually moved to the position shown in FIG. 3 to cause piercing arms 66 to perforate opposite sides of the capsule, and then is moved back to the position as shown in FIG. 2. The mouthpiece is inserted into the mouth of the user.

Upon inhalation, rotary member 28 rotates as air, drawn through passageways 70 (and others not shown) in end cap 56 and slots 54 in housing 44, passes through housing 44 over fins 38. As the rotary member rotates, the hexagon-shaped inner surface of hollow shaft 30 contacts pentagon-shaped base 22 of shaft 14 and positively causes an orbital or eccentric motion which, in turn, causes the powdered medicament held in capsule 42 to be dispensed through the outlet ports or perforations created by the piercing operation (ie, movement of sleeve 48 from the position shown in FIG. 2 to the position shown in FIG. 3, and back to the position shown in FIG. 2). The powdered medicament is entrained in the inhaled air, and is carried thereby into the bronchial tract and/or lungs of the user where the beneficial or therapeutic action takes place.

The orbital or eccentric motion referred to above is of a type generally described in U.S. Pat. No. 3,669,113. The polygon shaped surfaces of this invention positively ensure, however, that the desired rotational motion will be achieved, and thusly that the powdered medicament will be quickly dispersed during inhalation.

The entire device is preferably made of suitable plastic materials, such as nylon, acetal or polypropylene. A further advantage of the present invention is that the end cap, with the appropriate passageways therein, and the piercing arms, in bent U-shaped form, can be fabricated as an unitary member as opposed to the separate members as shown in U.S. Pat. No. 3,518,992. When fabricated according to specification, the normally resilient nature of the plastic material causes the return of the piercing arms from the piercing position to the non-piercing position as the tubular sleeve is manually moved from the position shown in FIG. 3 to the position shown in FIG. 2. Additionally, such a unitary design enables this part to be manufactured more easily, and to be assembled into the inhalation device of this

invention more rapidly, thereby effecting substantial cost reduction in the manufacturing process.

While the present invention has been described with reference to a specific embodiment thereof, it will be understood by those skilled in this art that various changes may be made and equivalents may be substituted without departing from the true spirit and scope of the invention. For example, if it is desired to utilize preperforated capsules, the piercing means and the engagement means can be omitted; or the piercing means and the engagement means can be retained and the polygon shaped surfaces of this invention replaced with other means affording the same function. Additionally, modifications may be made to adapt a particular situation, material or composition of matter, structural desirability or then-present objective to the spirit of this invention without departing from its essential teachings.

What is claimed is:

1. An oral inhalation device comprising a hollow elongate housing having one or more passageways at each end thereof to permit the passage of air there-through, one end thereof being adapted for insertion into the mouth of the user; a shaft supported by said housing in the hollow portion thereof, said shaft having a polygon-shaped base of n sides; and a rotary member supported by said shaft, said rotary member having, on the end thereof furthest from the end of said housing adapted for insertion into the mouth of the user, means to receive a medicament-holding capsule, said rotary member having a sleeve adapted to surround said shaft, said sleeve having on the hollow internal portion thereof a polygon-shaped surface having at least $n + 1$ sides; said polygon-shaped surfaces being positioned whereby contact thereof will occur during inhalation-induced rotation of said rotary member, such contact of said polygon-shaped surfaces serving to positively induce said rotary member and the capsule held thereby to move in an eccentric manner such that the medicament is dispensed from the capsule through outlet ports therein.

2. The inhalation device of claim 1 wherein said polygon-shaped base of said shaft has four to six sides.

3. The inhalation device of claim 1 wherein said polygon-shaped inner surface of said sleeve has five to 12 sides.

4. The inhalation device of claim 1 wherein said polygon-shaped base of said shaft has n sides and the polygon-shaped inner surface of said sleeve has $n + 1$ sides.

5. The inhalation device of claim 1 wherein said polygon-shaped base of said shaft has n sides and the polygon-shaped inner surface of said sleeve has $n + 1$ sides, where n is either 4, 5, or 6.

6. The inhalation device of claim 1 further including means to pierce the capsule adjacent the free end thereof, the free end of the capsule being the end thereof remote from the end of said housing adapted for insertion into the mouth of the user; and means to engage and rigidly support the free end of the capsule during piercing.

7. The inhalation device of claim 6 wherein said engagement means is actuated by the operation of said piercing means.

8. The inhalation device of claim 6 wherein said engagement means comprises resilient spring means terminating in a recess adapted to receive the free end of the capsule when said spring means is extended from its

original position to the position where said engagement means contacts the free end of the capsule, said recess receiving the free end of the capsule prior to the piercing of the capsule by said piercing means.

9. The inhalation device of claim 8 wherein said piercing means comprises a pair of opposed piercing members connected by a bent resilient bridging member and means for urging the piercing members together for perforating a capsule held by said rotary member to provide opposed outlet ports therein; said urging means also having cam means supported thereby for causing said engagement means to extend from its original position into contact with the free end of the capsule prior to the piercing of the capsule by said piercing means.

10. The inhalation device of claim 9 wherein said urging means comprises a tubular sleeve surrounding said hollow elongate housing and mounted for slideable movement thereon, said tubular housing having four cams on the inner periphery thereof spaced apart 90° apart, one pair of opposed cams serving to urge said piercing members together for perforating the capsule, and the other pair of opposed cams serving to urge said engagement means into contact with the free end of the capsule prior to the piercing of the capsule by said piercing means.

11. The inhalation device of claim 1 further including a medicament-holding capsule mounted on said rotary member.

12. An article intended for use with a rotary member to thereby define an oral inhalation device, the rotary member supporting a medicament-holding capsule; said article comprising a hollow elongate housing having one or more passageways at each end thereof to permit the passage of air therethrough, one end thereof being adapted for insertion into the mouth of a user of the inhalation device; a shaft supported by said housing in the hollow portion thereof, said shaft adapted to support the rotary member such that a capsule held thereby is adjacent the end of said housing remote from the end thereof adapted for insertion into the mouth of the user; means to pierce the capsule adjacent the free end thereof, the free end of the capsule being the end thereof remote from the end of said housing adapted for insertion into the mouth of the user; and means to engage and rigidly support the free end of the capsule during movement of said piercing means through the walls of the capsule during piercing and withdrawal of said piercing means from the inner portions of the capsule.

13. The article of claim 12 wherein said engagement means is actuated by the operation of said piercing means.

14. The article of claim 12 wherein said engagement means comprises resilient spring means terminating in a recess adapted to receive the free end of the capsule when said spring means is extended from its original position to the position where said engagement means contacts the free end of the capsule, said recess receiving the free end of the capsule prior to the piercing of the capsule by said piercing means.

15. The article of claim 14 wherein said piercing means comprises a pair of opposed piercing members connected by a bent resilient bridging member and means for urging the piercing members together for perforating a capsule held by the rotary member to provide opposed outlet ports therein; said urging means

also having cam means supported thereby for causing said engagement means to extend from its original position into contact with the free end of the capsule prior to the piercing of the capsule by said piercing means.

16. The article of claim 15 wherein said urging means comprises a tubular sleeve surrounding said hollow elongate housing and mounted for slideable movement thereon, said tubular housing having four cams on the inner periphery thereof spaced about 90° apart, one pair of opposed cams serving to urge said piercing members together for perforating the capsule, and the other pair of opposed cams serving to urge said engagement means into contact with the free end of the capsule prior to the piercing of the capsule by said piercing means.

17. The article of claim 12 further including a rotary member supported on said shaft, said rotary member having a medicament-holding capsule mounted thereon.

18. A rotary member for use with a hollow elongate housing to thereby define an oral inhalation device, the housing having means for rotatably supporting the rotary member in the hollow internal portion thereof; said rotary member comprising a body portion having a recess therein for receiving a medicament-holding

capsule; said body portion having, on the external portion thereof, a plurality of fins for causing the rotation of said rotary member as air is drawn over and around said fins when said rotary member is positioned on the rotary member supporting means during inhalation; said body portion having, on the end thereof opposite said recess, a downwardly depending, elongated, hollow sleeve, said sleeve having on the hollow internal portion thereof a polygon-shaped surface; said polygon-shaped surface cooperating with the surface of the rotary member supporting means when said rotary member is positioned thereon to positively induce said rotary member and a capsule held thereby to move in an eccentric manner during inhalation.

19. The rotary member of claim 18 wherein said body member has, adjacent said recess, a plurality of slots for causing the walls of said body member to be sufficiently flexible to receive capsules of different diameters.

20. The rotary member of claim 18 wherein said polygon-shaped surface has five to 12 sides.

21. The rotary member of claim 18 wherein said polygon-shaped surface has five to seven sides.

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