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SUPERINTENDENCIA DE INDUSTRIA Y COMERCIO DIVISIÓN DE NUEVAS CREACIONES

E. S. D.

Re: Expediente No. 01.000.526
Solicitud de Patente en nombre de
THE PROCTER & GAMBLE COMPANY

SUPERINTENDENCIA Y COMERCIO
Indicación : 01000526 00000001 Folios: 20
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Trámite : ONE PATENTES D I REGISTRO/ 229 COMPLEMEN
Dependencia: 2020 DIVISION DE NUEVAS CREACIONES

Yo, JIMENA ESCOBAR URIBE, identificada como aparece al pie de mi firma, domiciliada en Bogotá, en la Carrera 11 A No. 94-76 Of. 305, obrando como apoderada de la sociedad THE PROCTER & GAMBLE COMPANY., solicitante de la patente de la referencia, anexo al presente memorial los siguientes documentos:

Copia certificada de la solicitud de Patente Número 09/479968 presentada en los Estados Unidos de América el día 10 de enero del 2000, respectivamente, con la debida traducción de lo pertinente, incluyendo el capítulo reivindicatorio.

A este mismo respecto, debe tenerse en cuenta que en la primera página de la copia en mención la Oficina de Patentes correspondiente certificó la fecha de presentación de esa solicitud, cumpliéndose de esta forma todos y cada uno de los requisitos establecidos en el inciso segundo del artículo 10 de la Decisión 486 de la Comisión de la Comunidad Andina.

Señor Superintendente,


JIMENA ESCOBAR URIBE
C.C.39.779.452 de usaquén
T.P. 68.228
Cod. 5376

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**ESTADOS UNIDOS DE AMERICA
A TODOS AQUELLOS A QUIENES EL PRESENTE
LLEGUE:**

**DEPARTAMENTO DE COMERCIO DE LOS ESTADOS
UNIDOS
Oficina de Patentes y Marcas de los Estados Unidos**

diciembre 5, 2000

La presente es para certificar que el anexo es una copia fiel de los registros de la Oficina de Patentes y Marcas de los Estados Unidos, de los documentos de la solicitud de patente identificada más adelante, que cumplieron con los requerimientos para concederse una fecha de presentación de acuerdo con 35 USC 111.

Número de Solicitud: 09/479,968

Fecha de Presentación: enero 10, 2000

Por la autoridad del
Comisionado de Patentes y Marca

(fdo) L. EDELEN
Oficial Certificador
Sello oficial de la Oficina de Patentes y Marcas de los
Estados Unidos de América

REIVINDICACIONES

1. Un dispositivo de inhalación de polvo seco, que comprende:
 - (a) una caja que tiene una entrada para un gas, una salida, y una cámara adecuada para contener un material en partículas;
 - (b) un fluidizador de partículas para proveer una circulación fluidizada del material en partículas antes mencionado con el gas antes mencionado en la cámara antes mencionada al poner en funcionamiento el dispositivo; y
 - (c) un clasificador de partículas en comunicación por fluido con la circulación fluidizada antes mencionada entre la cámara antes mencionada y la salida antes mencionada.
2. El dispositivo de la Reivindicación 1, en donde el fluidizador de partículas causa una circulación de torbellino del material en partículas fluidizado antes mencionado, y el clasificador de partículas antes mencionado permite que partículas dentro del material en partículas fluidizado antes mencionado con un tamaño inferior e incluyendo el tamaño e inercia predeterminados se desvíen de la circulación de torbellino antes mencionada y salgan de la cámara antes mencionada, y excluye partículas dentro del material en partículas fluidizado antes mencionado con tamaño superior al tamaño e inercia predeterminados antes mencionado de salir de la cámara antes mencionada.
3. El dispositivo de la Reivindicación 2, en donde la circulación de torbellino antes mencionada genera

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- (a) una región central de baja presión dentro de la cámara antes mencionada, en donde la región central de baja presión antes mencionada está en comunicación por fluido con la entrada antes mencionada, según el cual el gas antes mencionado circula a dentro de la cámara antes mencionada; y
 - (b) una región exterior de alta presión dentro de la cámara antes mencionada, en donde la región exterior de alta presión antes mencionada está en comunicación por fluido con la salida antes mencionada, según el cual el gas antes mencionado circula desde la región exterior de alta presión antes mencionada y sale a través de la salida antes mencionada.
 - 4. El dispositivo de la Reivindicación 3, en donde las partículas antes mencionadas dentro del material en partículas fluidizado antes mencionado con menos del e incluyendo un tamaño e inercia predeterminados que se desvían de la circulación de torbellino antes mencionado y salen de la cámara antes mencionada, salen del dispositivo antes mencionado con el gas antes mencionado que circula desde la región exterior de alta presión antes mencionada y salen a través de la salida antes mencionada.
 - 5. El dispositivo de la Reivindicación 1, en donde el dispositivo antes mencionado es uno de los siguientes: dosis unitaria, polvo a granel, o dosis múltiple.
 - 6. El dispositivo de la Reivindicación 1, en donde el fluidizador de partículas antes mencionado comprende un impulsor.

7. El dispositivo de la Reivindicación 6, en donde el impulsor antes mencionado tiene un eje de rotación substancialmente concéntrico alrededor del eje longitudinal de la cámara.
8. El dispositivo de la Reivindicación 3, en donde la entrada antes mencionada comprende un orificio de entrada exterior, un conducto de entrada, y un orificio de entrada interior, y el orificio de entrada interior antes mencionado está localizado cerca de la región central de baja presión antes mencionada.
9. El dispositivo de la Reivindicación 3, en donde el clasificador de partículas antes mencionado comprende un orificio de entrada y un orificio de salida, y las partículas antes mencionadas dentro del material en partículas fluidizado antes mencionado con menos de e incluyendo un tamaño e inercia predeterminado que se desvía desde la circulación de torbellino antes mencionado y sale de la cámara antes mencionada y entra en el clasificador de partículas antes mencionado a través del orificio de entrada antes mencionado.
10. El dispositivo de la Reivindicación 9, en donde el orificio de entrada antes mencionado del clasificador de partículas antes mencionado hace frente en una dirección similar a la circulación de torbellino antes mencionado.
11. El dispositivo de la Reivindicación 10, en donde las partículas antes mencionadas dentro del material en partículas fluidizado antes mencionado con menos de un tamaño e inercia predeterminados que se desvían de la circulación de torbellino antes mencionada en una dirección opuesta a la circulación de

torbellino antes mencionada.

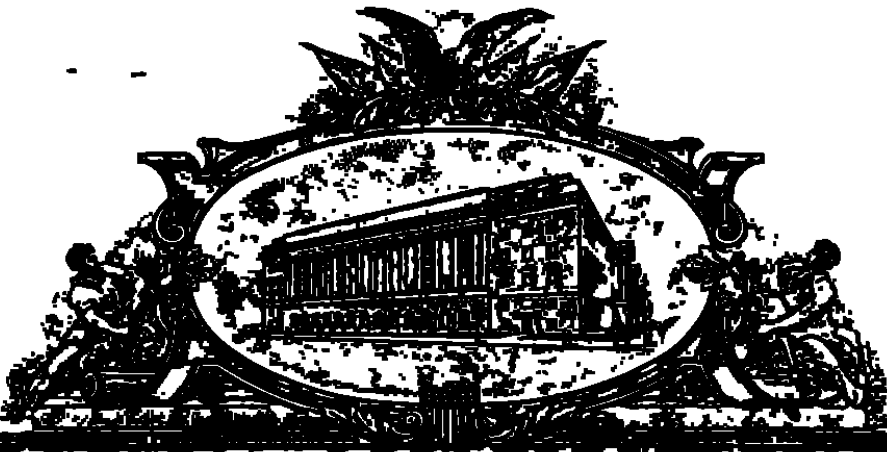
12. El dispositivo de la Reivindicación 1, en donde el clasificador de partículas antes mencionada es un conducto.
13. El dispositivo de la Reivindicación 1, en donde el clasificador de partículas antes mencionado es un clasificador de partículas cónico.
14. El dispositivo de la Reivindicación 1, el fluidizador de partículas fluidiza el material en partículas antes mencionado mediante uno de los siguientes: abrasión, fractura, choque con el fluidizador de partículas, que causa que el material en partículas choque con la cámara antes mencionada, o que cause choque entre el material en partículas.
15. El dispositivo de la Reivindicación 2, en donde el clasificador en partículas antes mencionado se dimensiona de modo que por lo menos 90% del material en partículas fluidizado antes mencionado que pasa a través de la salida antes mencionada tiene un tamaño promedio de partícula de 0,5 a 10 micrones, aproximadamente, de diámetro.
16. El dispositivo de la Reivindicación 15, en donde el clasificador de partículas antes mencionado se dimensiona de modo que por lo menos 99% del material en partículas fluidizado antes mencionado que pasa a través de la salida antes mencionada tiene un tamaño promedio de partícula de 2 a 6 micrones, aproximadamente, de diámetro.
17. El dispositivo de la Reivindicación 1, en donde se dispensa aproximadamente 1 miligramo por minuto de material en

partículas fluidizado.

18. El dispositivo de la Reivindicación 1, en donde el dispositivo antes mencionado comprende adicionalmente una boquilla según la cual la porción antes mencionada del material en partículas fluidizado que sale de la salida antes mencionada se puede inhalar a través de la misma.
19. El dispositivo de la Reivindicación 1, en donde el fluidizador en partículas antes mencionado está accionado eléctricamente.
20. El dispositivo de la Reivindicación 1, en donde el dispositivo antes mencionado comprende una fuente de energía autónoma.
21. El dispositivo de la Reivindicación 20, en donde la fuente de energía antes mencionada es una batería.
22. El dispositivo de la Reivindicación 1, en donde el material en partículas es cloruro de sodio.
23. Un método de dispensar un material en partículas aerosolizado para inhalación, que comprende:
 - proveer una caja que tiene una entrada para un gas, una salida, y una cámara adecuada para contener un material en partículas;
 - fluidizar una circulación de material en partículas antes mencionado con el gas antes mencionado en la cámara antes mencionada;
 - clasificar la circulación fluidizada antes mencionada; y
 - dispensar la circulación fluidizada clasificada antes mencionada.

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**THE UNITED STATES OF AMERICA****TO ALL TO WHOM THESE PRESENTS SHALL COME:****UNITED STATES DEPARTMENT OF COMMERCE****United States Patent and Trademark Office****December 05, 2000**

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OFFICE OF THOSE PAPERS OF THE BELOW IDENTIFIED PATENT
APPLICATION THAT MET THE REQUIREMENTS TO BE GRANTED A
FILING DATE UNDER 35 USC 111.**

APPLICATION NUMBER: 09/479,968

FILING DATE: January 10, 2000



**By Authority of the
COMMISSIONER OF PATENTS AND TRADEMARKS**

**L. EDELEN
Certifying Officer**

Please type a plus sign (+) inside this box → [+]

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PTO/SB/05 (12/97)

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**UTILITY
PATENT APPLICATION
TRANSMITTAL**

Attorney Docket No.

7902

Total Pages

16

First name inventor or Application Identifier

ROBERT S. DIRKSING

Express Mail Label No.

EL431551010US

APPLICATION ELEMENTS

See MPEP Chapter 600 concerning utility patent application contents.

ADDRESS TO:

Assistant Commissioner for Patents
Box Patent Application
Washington, D.C. 20231

1. ☒ Fee Transmittal Form
(Submit an original, and a duplicate for fee processing)

2. ☒ Specification Total Pages [16]
(preferred arrangement set forth below)

- Descriptive Title of the Invention
- Cross References to Related Applications
- Statement Regarding Fed sponsored R&D
- Reference to Microfiche Appendix
- Background of the Invention
- Brief summary of the invention
- Brief Description of the Drawings (if filed)
- Detailed Description
- Claim(s)
- Abstract of the Disclosure

3. ☒ Drawing(s) (35 USC 113) Total Sheets [2]

4. Oath or Declaration

- a. ☐ Newly executed (original or copy)
- b. ☐ Copy from a prior application (37 CFR 1.63(d))
(for continuation/divisional with Box 17 completed)
[Note Box 5 below]

L ☐ DELETION OF INVENTORS

Signed statement attached deleting inventor(s) named in the prior application, see 37 CFR 1.63(d)(2) and 1.33(b).

5. ☐ Incorporation By Reference (useable if Box 4b is checked)

The entire disclosure of the prior application, from which a copy of the oath or declaration is supplied under Box 4b, is considered as being part of the disclosure of the accompanying application and is hereby incorporated by reference therein.

17. If a CONTINUING APPLICATION, check appropriate box and supply the requisite information:

☐ Continuation ☐ Divisional ☐ Continuation-in-part (CIP) of prior application No. /

18. CORRESPONDENCE ADDRESS

[] Customer Number or Bar Code Label

(Insert Customer No. or Attach bar code label here)

or [] New correspondence address below

NAME	Vanessa M. Nichols				
ADDRESS	The Procter & Gamble Company				
CITY	West Chester	STATE	Ohio	ZIP CODE	46089
COUNTRY	U.S.	TELEPHONE	(513) 634-5171	FAX	(513) 634-8108

Burden Hour Statement: This form is estimated to take 0.2 hours to complete. Time will vary depending upon the needs of the individual case. Any comments on the amount of time you are required to complete this form should be sent to the Chief Information Officer, Patent and Trademark Office, Washington, D.C. 20231. DO NOT SEND FEES OR COMPLETED FORMS TO THIS ADDRESS. SEND TO: Assistant Commissioner for Patents, Box Patent Application, Washington, D.C. 20231.

FEE TRANSMITTAL FORM

CLAIMS	(1) FOR	(2) NUMBER FILED	(3) NUMBER EXTRA	(4) RATE	(5) CALCULATIONS
	TOTAL CLAIMS (37 CFR 1.16 (a))	- 23	3	x \$22.00 =	\$506
	INDEPENDENT CLAIMS (37 CFR 1.16 (a))	- 2		x \$82.00 =	\$0
	MULTIPLE DEPENDENT CLAIMS (if applicable) (37 CFR 1.16(d))			+ \$280.00 =	\$0
				BASIC FEE (37 CFR 1.16(a))	\$680.00
	Total of above Calculations =				\$758.00
	Reduction by 50% for filing by email entity (Note 37 CFR 1.9, 1.27, 1.28).				
	TOTAL =				\$758.00

19. The Commissioner is hereby authorized to charge payment of the following fees associated with this communication or credit any overpayment to Deposit Account No. 16-2480. A duplicate copy of this sheet is enclosed.

- a. ☒ Any patent application filing fees required under 37 CFR 1.16.
b. ☒ Any patent application processing fees under 37 CFR 1.17.

20. The Commissioner is hereby authorized to charge payment of the following fees during the pendency of this application or credit any overpayment to Deposit Account No. 16-2480. A duplicate copy of this sheet is enclosed.

- a. ☒ Any patent application processing fees under 37 CFR 1.17.
b. ☐ The issue fee set in 37 CFR 1.18 at or before mailing of the Notice of Allowance, pursuant to 37 CFR 1.311(b).
c. ☒ Any filing fees under 37 CFR 1.16 for presentation of extra claims.

21. The total number of duplicate copies enclosed is 5. The Commissioner is hereby authorized to make any additional copies of this sheet needed to accomplish the purposes provided for herein and to charge any fee for such copies to Deposit Account No. 16-2480.

Richard E. Hildebrand IV

22. SIGNATURE OF APPLICANT, ATTORNEY, OR AGENT REQUIRED

NAME	Vanesa M. Nichols (REG. NO. 44,872)
SIGNATURE	<i>Vanesa M. Nichols</i>
DATE	January 10, 2000

"Express Mail" mailing label number 9542391234567890

Date of Mailing: January 10, 2000

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Vanesa M. Nichols
Name

Vanesa M. Nichols

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Vanessa M. Nichols

Vanessa M. Nichols
Signature

CASE 7902

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Device for Dry Powder Inhalation

Robert Stanley Dirksing

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Field of the Invention

The present invention relates to a device suitable for producing an aerosol of a dry powdered material. More particularly, the present invention relates to a device that can produce and deliver an aerosol of dry powdered medicament into the respiratory system of a user.

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Background of the Invention

Respiratory diseases have long been treated by the inhalation of aerosolized medicament. "Aerosolized" refers to a colloidal dispersion of a liquid or a solid in a gas. The medicament is aerosolized so that it may be transported by the inhaled air stream into the respiratory system. There are many advantages to delivering medicament via inhalation, including a rapid onset of action, avoiding drug degradation in the gastrointestinal tract, and low dosages to minimize adverse reactions.

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Two predominant types of systems for aerosolizing medicament are available in the market: propellant-based inhalers and dry powder inhalers (DPIs), which do not use propellants. Propellants are undesirable as many are believed to adversely affect the ozone layer of the atmosphere, and even those propellants believed to be safe for the environment are nevertheless often associated with environmental issues, regardless. It is also desirable to minimize the introduction of any unnecessary materials in inhalation devices used for delivering active ingredients to

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the respiratory system to minimize the occurrence of irritation, allergic reaction, or other undesirable side effect.

DPIs are often designed such that air stream generated by the inhaled breath of a user aerosolizes the dry powder. The user takes slow deep breaths to accomplish delivery of the aerosolized powder into the lower portions of the respiratory system. Aerosolizing the dry powder with slow deep breaths can be a challenge, especially if the very ailment for which the DPI is being employed prevents the user from generating sufficient airflow to aerosolize the dry powder. Thus, it is desirable to provide an inhaler that does not solely rely on inhalation by the user to accomplish aerosolization of the dry powder.

Most inhalation devices for delivery of aerosolized dry powder medicament are intended to deliver medicament to the lower respiratory tract, primarily to the large surface and thin membranes of the lungs. The efficacy of inhalation devices is governed by quantity of medicament reaching the lower portion of the lower respiratory tract. Medicament with particle sizes that are less than 0.5 microns in diameter tend to be exhaled, whereas particle sizes larger than 10.0 microns in diameter generally deposit in the upper respiratory tract. Accordingly, inhalation devices generally are designed to deliver particles in the preferred size range from about .5 microns to about 10 microns in diameter, more preferably from about 1 to 6 microns in diameter.

Manufacturers conventionally process the dry powder medicament to the desired particle size distribution prior to market distribution. Unfortunately, many types of dry powder medicaments in the preferred particle size range tend to agglomerate during handling and storage. This tendency is aggravated if moisture is present.

Numerous approaches have been proposed to solve the problems attributable to powder agglomeration. Some devices include features that deagglomerate the dry powder at the point of use, for example, jets of gas or mechanic vibration. Other devices have one or more channels with bends through which the aerosolized medicament must pass whereby the shear and wall friction forces promote deagglomeration of the particles. In short, these devices promote particle size distribution of inhaled powder, but do not ensure that only particles of the desired particle size range are dispensed. Therefore, it is desirable to provide an inhalation device that provides both deagglomeration at the point of use and improved control of particle size distribution to within a predetermined range.

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Summary of the Invention

The present invention provides a device suitable for dry powder inhalation. The particles of dry powder are fluidized with air and cause a vortex flow of the fluidized particulate material. A particle classifier permits fluidized particulate material of a predetermined size and inertia to flow from the chamber to the outlet and excludes fluidized particulate material with greater than the predetermined size and inertia from flowing from the chamber to the outlet.

More particularly, the device of the present invention can comprise a housing having an inlet, an outlet, and a chamber suitable for containing a particulate material, a particle fluidizer for providing a fluidized flow of the particulate material with a gas in the chamber upon operation of the device, wherein the flow in the chamber is a vortex flow, and a particle classifier in fluid communication with the fluidized flow of the chamber between the chamber and the outlet.

Brief Description of the Drawings

While the specification concludes with claims which particularly point out and distinctly claim the present invention, it is believed that the present invention will be better understood from the following description of preferred embodiments, taken in conjunction with the accompanying drawings, in which like reference numerals identify like elements and wherein:

FIG. 1 is a partially sectioned side elevational view of an embodiment of an inhalation device of the present invention having a conduit particle classifier;

FIG. 2 is an enlarged cross-sectional view thereof, taken along section line 2-2 of FIG. 1 showing an upward view into the interior of the chamber according to the embodiment of Figure 1;

FIG. 3 is a cross-sectional side elevational view of an alternate embodiment of an inhalation device of the present invention having a conical particle classifier;

FIG. 4 is a partially sectioned front view of the embodiment of FIG. 3; and

FIG. 5 is an enlarged sectioned top plan view of the conical particle classifier of FIG. 3.

Detailed Description of the Invention and Preferred Embodiments

Typically, inhalation devices are conveniently divided into category types of unit dose, bulk powder multi-dose and pre-metered multi-dose. Unit dose generally refers to a device that usually the user inserts a single dose of the medicament into the device before operation. Bulk powder multi-dose generally refers to a device that contains a bulk quantity of medicament for many doses. Pre-metered multi-

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dose generally refers to a device that is designed to deliver a metered dose of the drug multiple times. Examples of pre-metered multi-dose devices include, but are not limited to, capsule and blister package types. The inhalation device of the present invention can comprise any one of the above types of inhalation devices or others known in the art.

Referring now to the drawings, Figures 1-2 depict an embodiment of the present invention having a bulk powder, which provides an inhalation device 10 that produces and dispenses an aerosol of a fine powdered particulate material. Device 10 generally comprises a housing 20, a particle fluidizer, and a particle classifier. In the configuration shown in Figures 1-2, the particle fluidizer is an impeller 50 and the particle classifier is an egress conduit 37, as will be discussed hereafter.

Housing 20 generally comprises a chamber 60, a support frame 30, an inlet and an outlet. Housing 20 is arranged to provide air passage from the inlet, through the chamber, and then through the outlet. Chamber 60 comprises peripheral wall 21, base wall 22, and upper chamber wall 31. Chamber 60 is suitable for containing dry powder or other particulate material. Preferably, the chamber 60 may also be used to store unfluidized particles. Alternatively, a separate storage container for particulate material may be provided.

Tube 32 extends from upper chamber wall 31. In the configuration shown in Figures 1-2, the inlet comprises ingress conduit 33, having external ingress port 34 and internal ingress port 36. Ingress conduit 33 permits ambient air external to device 10 to enter chamber 60. Tube 32 contains at least a portion of the ingress conduit 33. The ingress conduit 33 is arranged such that internal ingress port 34 is located in proximity to the axis of rotation of impeller 55.

The particle classifier is in fluid communication with chamber 60. The particle classifier can be any means for separating particles, including, but not limited to, preventing particles above the desired size from entering the classifier or ~~preventing~~ ^{permitting} only particles less than ^{and including} the predetermined size and inertia to exit the device and others being redirected back into the flow for further de-agglomeration or particle size reduction.

The particle classifier in the embodiment shown in Figures 1-2 comprises egress conduit 37, having internal egress port 38 and external egress port 39. The egress conduit particle classifier 37 is arranged so that air flows from the chamber 60, through internal egress port 38, through egress conduit 37, and then exits the housing 20 through the egress port 39. Internal egress port 38 and external egress port 39 can be sized as desired to control the rate of flow of the air through chamber 60, wherein reducing the restriction through the ports, e.g. increasing the size of the ports, increases the rate of

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flow. The internal dimension of the internal egress port 38 can be substantially larger than the predetermined particle size. In the configuration shown in figures 1-2, the outlet further comprises external egress port 39. Additionally, the egress conduit 37 is placed such that the internal egress port 38 is axially located within the upper portion 61 of the chamber 60 between ingress port 36 and peripheral wall 21, as will be described in further detail below.

As stated above, in Figures 1-2 the particle fluidizer is an impeller drive 50. Preferably, the fluidizer is a device that mechanically intermixes gas and the particles to create a flow of the mixture, referred to herein as fluidized particles or fluidized particulate material. However, the particle fluidizer may be any type of device capable of fluidizing dry powder known in the art. For example, without limitation, the particle fluidizer may be an irregular disk or a blade. The impeller drive 50 can be powered by an electrical source comprising motor 51, battery 52, button 53, drive shaft 54, and impeller 55. In assembly, impeller drive 50 is affixed to housing 20. Drive shaft 54 is inserted through tube 32. An end of drive shaft 54 extends beyond the lower end of tube 32 so that impeller 55 may be press fit or otherwise fastened to the lower end of drive shaft 54. The axis of rotation of impeller 55 is substantially concentric about the longitudinal axis of the chamber. Motor 51 is snap fit or otherwise fastened to a mating recess in support frame 30. Further, motor 51 is electrically connected to battery 52, button 53, and drive shaft 54 (which is connected to impeller 55), such that when button 53 is depressed, electrical current passes through motor 51. Thus, drive shaft 54, and thereby impeller 55, is caused to rotate rapidly in a direction indicated by arrow 71 in Figure 2.

If a specific life span of the dispensing device 110 is desired, a zinc air battery that is activated upon first use may be employed. Also, means other than button 153 may be employed to activate the device 110, such as a pressure switch in the inhalation tube 143 that activates upon inhalation by the user.

Base wall 22 is affixed to peripheral wall 21. The upper edge of peripheral wall 21 of housing 20 is press fit or otherwise fastened to a mating ring about upper chamber wall 31, thereby forming enclosed chamber 60. A charge of particulate material 15 is introduced into chamber 60 before enclosing said chamber. Base wall 22 is conical in shape, such that particulate material 15 tends to settle near the axis of rotation of impeller 55. Consequently, the starting moment is reduced as impeller 55 begins to rotate within particulate material 15, relative to a flat bottom configuration of base wall 22.

As impeller 55 rotates rapidly, particulate material 15 is fluidized with the air in the chamber to form a vortex flow of fluidized particulate material. The vortex flow

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hereof can be characterized as a flow in a circular path or otherwise having an angular velocity. The vortex flow of the device as shown in Figure 1 generates a cyclonic or centrifugal condition within the chamber such that a relative low pressure region forms near the center, i.e. near the axis of impeller 55, with regions having progressively
5 higher pressure radially outward toward peripheral wall 21. The low pressure region has a pressure lower than the ambient air at atmospheric pressure in preferred embodiments. The high pressure region has a pressure higher than the ambient air at atmospheric pressure in preferred embodiments. The pressure differential is generally a function of the rate of rotation, diameter and frontal area of the impeller 55, amount of
10 particulate material 15, and the diameter of chamber 60.

Alternatively, gases other than the ambient air may be introduced to fluidize the particulate material, including, but not limited to other gases, such as oxygen and nitrogen, or a propellant, such as halogenated hydrocarbons like dichlorodifluoromethane. Most preferably, ambient air is used.

15 The low pressure region near the axis of impeller 55 is in fluid communication with the ingress conduit 33 via internal ingress port 36, which is located in proximity to the axis of rotation of impeller 55, such that upon rotation of the impeller 55, ambient air from outside device 10 is drawn through said ingress conduit 33. The high pressure region near peripheral wall 21 is in fluid communication with the egress conduit 37 via
20 internal egress port 38, which is located in an upper portion of chamber 60 between the axial location of ingress port 36 and peripheral wall 21, such that upon rotation of the impeller 55, air inside the chamber 60 is expelled through said egress conduit 37. These pressure differentials cause airflow through the ingress conduit 33, through chamber 60, and out through egress conduit 37.

25 Further, interior egress port 38 is oriented such that it faces a direction similar to the direction of the vortex flow formed within chamber 60, as indicated by arrow 71 in Figure 2. Thus, the air stream that exits through egress conduit 37 must deviate from the direction of the vortex flow prior to entering into the interior egress port 38, as indicated by arrow 73. Generally, the size and inertia of the rapidly rotating fluidized
30 particulate material prohibits the particulate material particles from deviating direction and entering interior egress port 38. Abrasion, fracturing, or the like of particulate material 15, either from impact with impeller 55, rubbing against peripheral wall 21 of the chamber, or between the particles of particulate material 15 themselves, produces finer particles of the particulate material 15. Consequently, a broad distribution of
35 particle sizes of particulate material 15 will be produced within the chamber. As finer and finer particles of particulate material are produced, the finer particles have sufficiently low size and inertia to permit deviation from the vortex flow into the air

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stream caused by the pressure differential and exit the housing through the egress conduit 37 via interior egress port 38, as indicated by arrow 73. In this way, egress conduit serves as a classifier of particle size to insure that only particles of a predetermined size ^{or less} are permitted to flow from the chamber to the outlet and particles with greater than the predetermined size are excluded from flowing from the chamber to the outlet. As this is an ongoing process, a stream of aerosolized particles will be dispensed.

Figures 3-5 depict an alternate embodiment of the present invention having a bulk powder, which provides an inhalation device 110 that produces and dispenses an aerosol of a fine powdered particulate material. Device 110 generally comprises housing 120, a particle fluidizer, and a particle classifier. In the configuration shown in Figures 3-5, the particle fluidizer is an impeller drive 150 and the particle classifier is a conical particle classifier 140, as will be discussed hereafter.

Housing 120 generally comprises a chamber 160, a motor housing 123, a battery housing 124, an inlet and an outlet. Housing 120 is arranged to provide air passage from the inlet, through the chamber 160, through the particle classifier 140, and then through the outlet.

Chamber 160 comprises a peripheral wall 121, a base wall 122, and upper chamber wall 131. Chamber 160 is suitable for containing dry powder or other particulate material. Preferably, the chamber 160 may also be used to store unfluidized particles. Alternatively, a separate storage container for particulate material may be provided.

Tube 170 extends from upper chamber wall 131. In the configuration shown in Figures 3-5, the inlet comprises ingress conduit 172 having external ingress port 174 and internal ingress port 176. Ingress conduit 172 permits ambient air external to device 110 to enter chamber 160. Tube 170 contains at least a portion of the ingress conduit 172. The ingress conduit is arranged such that internal ingress port 176 is located in proximity to the axis of rotation of impeller 155.

Housing 120 further includes fins 146 located adjacent the external ingress port 174. Fins 146 improve the grasp of the user's fingers in holding device 110 and prevent blockage of external ingress port 174 by the user's fingers.

The particle classifier is in fluid communication with chamber 160. The particle classifier can be any means for separating particles, including, but not limited to, preventing particles above the desired size from entering the classifier or ^{permitting} ~~preventing~~ only particles less than ^{and including} the predetermined size and inertia to exit the device and others being redirected back into the flow for further de-agglomeration or particle size reduction.

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The particle classifier of the alternate embodiment is a conical particle classifier 140. The conical classifier 140 comprises conical fitment 148, cone 181, and egress conduits 177. In assembly, the conical particle classifier 140 is arranged such that the cone 181 is inserted into the conical fitment 148, whereby egress conduits 177 are
5 formed. Preferably, egress conduits 177 are helical. Subsequent to assembly, egress conduits 177 further comprise internal egress ports 178 and intermediate egress ports 179. The interior egress ports 178 are located in an upper portion of chamber 160 between the axial location of ingress port 176 and peripheral wall 121. The conical particle classifier 140 is arranged so that air flows from the chamber 160, through
10 internal egress ports 178, through egress conduit 177, through intermediate egress ports 179, and then exits the housing 120 through the outlet. Internal egress ports 178 and intermediate egress ports 179 can be sized as desired to control the rate of flow of the air through chamber 160, wherein reducing the restriction through the ports, e.g. increasing the size of the ports, increases the rate of flow. The internal dimension of the internal egress port 38 can be substantially larger than the predetermined particle size. In this
15 configuration, the outlet comprises inhalation tube 144 having mouthpiece 143. Alternatively, the present invention may be designed for use for inhalation through a nose.

Tube 172 is inserted into and fastened to upper chamber wall 131. The cone
20 181 is integrally molded about tube 172 and conical fitment 148 is integrally molded to upper chamber wall 131.

As discussed above, in Figures 3-5 the particle fluidizer is an impeller drive 150. However, the particle fluidizer may be any type of device capable of fluidizing dry powder. For example, without limitation, the particle fluidizer may be an irregular disk
25 or a blade. The impeller drive 150 is powered by an electrical source and comprises motor 151, battery 152, button 153, drive shaft 154, impeller 155, and conductors 156 and 157. In assembly, impeller drive 150 is affixed to housing 120. Drive shaft 154 is inserted through an opening in base wall 122 so that an end of drive shaft 154 extends beyond the lower surface of base wall 122. Impeller 155 is press fit or otherwise
30 fastened to the upper end of drive shaft 154. The axis of rotation of the impeller 155 is substantially concentric about the longitudinal axis of the chamber. Motor 151 is snap fit or otherwise fastened within supports 125 of motor housing 123. Battery 152 is located within the battery housing 124. The components of the impeller drive 150 are electrically connected, such that when button 153 is depressed, electrical current passes
35 through battery 124 and conductors 156 and 157 to motor 151. Thus, drive shaft 154, and thereby impeller 155, is cause to rotate rapidly in a direction indicated by an arrow 190 in Figure 5.

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Base wall 122 is affixed to peripheral wall 121. The upper edge of peripheral wall 121 of housing 120 is press fit or otherwise fasted to a mating ring about upper chamber wall 131, thereby forming enclosed chamber 160. Prior to assembly of housing 120, a charge of friable particulate material 115 is introduced into chamber 160 before enclosing said chamber. Base wall 122 is conical in shape, such that the particulate material 115 tends to settle near the axis of rotation of impeller 155. Consequently, the starting moment is reduced as impeller 155 begins to rotate within particulate material 15, relative to a flat bottom configuration of base wall 122.

As impeller 155 rotates rapidly, particulate material 115 is fluidized with the air in the chamber to form a vortex flow of fluidized particulate material. The vortex flow generates a cyclonic or centrifugal condition within the chamber such that a relative low pressure region forms near the center, i.e. near the axis of impeller 155, with regions having progressively higher pressure radially outward toward peripheral wall 121. The low pressure region has a pressure lower than the ambient air at atmospheric pressure in preferred embodiments. The high pressure region has a pressure higher than the ambient air at atmospheric pressure in preferred embodiments. The pressure differential is generally a function of the rate of rotation, diameter and frontal area of the impeller 155, amount of particulate material 115, and the diameter of chamber 160.

Alternatively, gases other than the ambient air may be introduced to fluidize the particulate material, including, but not limited to other gases, such as oxygen and nitrogen, or a propellant, such as halogenated hydrocarbons like dichlorodifluoromethane. Most preferably, ambient air is used.

The low pressure region near the axis of impeller 155 is in fluid communication with the ingress conduit 172 via internal ingress port 176, which is located near the axis of rotation of impeller 155, such that upon rotation of the impeller 155, ambient air from outside device 110 is drawn through said ingress conduit 172. The high pressure region near peripheral wall 121 is in fluid communication with the interior egress ports 178, which are located in an upper portion of chamber 160 between the axial location of ingress port 176 and peripheral wall 121, such that upon rotation of the impeller 155, air inside the chamber 160 is expelled through the egress conduits 177. These pressure differentials cause airflow through ingress conduit 172 through the chamber 160, through the conical particle classifier 140, and exit through the outlet.

Further, interior egress ports 178 of particle classifier 140 face a direction similar to the direction of the vortex flow within chamber 160, as shown by arrow 190 in Figure 5. Thus, the air stream that exits through egress conduit 177 must deviate from its general direction prior to entering into the interior egress ports 178, as indicated by arrow 191. Generally, the size and inertia of the rapidly rotating fluidized particulate

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material prohibits the particulate material particles from deviating from the direction of the vortex flow and entering interior egress ports 178. Abrasion, fracturing, or the like of granular particulate material 115, either from impact with impeller 155, rubbing against peripheral wall 21 of the chamber, or between the granules of particulate material 115 themselves, generates finer particles of the granular particulate material 115. Consequently, a broad distribution of particle sizes of particulate material 115 will be produced within the chamber. As finer and finer particles of particulate material 115 are formed within the chamber, the finer particles have sufficiently low size and inertia to permit deviation from the general cyclonic airflow into to the exiting air stream through particle classifier 140 into inhalation tube 144 of mouthpiece 143 via intermediate egress port 179. In this way, the conical particle classifier serves to insure that only particles of a predetermined size ^{and less} are permitted to flow from the chamber to the outlet and particles with greater than the predetermined size are excluded from flowing from the chamber to the outlet. As this is an ongoing process, a stream of aerosolized particles will be dispensed.

The user of the present device for dispensing an aerosol of a fine powdered particulate material 110 places his or her lips about mouthpiece 143 and while depressing button 153, inhales the fluidized particulate material through inhalation tube 144.

The present invention is suitable for a wide range of particulate materials, including, but not limited to medicaments, drugs, biologically active substances and the like. Additionally, the particulate material may be comprised of more than one active, excipients, enhancers, or the like. Alternatively, the granules or beads of a different composition than the desired dispensed particulate material maybe added to the particulate material to facilitate agitation of the particulate material in operation or prior to operation, as by shaking. The initial particle size of the particulate material can also range widely, particularly in view of the benefits provided by the invention of excluding particles that are too large and de-agglomerating or otherwise reducing particle sizes as described above.

The present invention is presently of interest for dispensing sodium chloride. In general, without limitation, it is contemplated that particle sizes ranging from as low as 0.5 (or other lower limit as may be desired) to 500 microns may be used. Preferably, a quantity of larger particles is used for two reasons. First, smaller particles tend to adhere to the walls of the chamber and are not affected by gravity. The larger particles impact the small particles that are adhered to the walls and free them of adhesion, thereby allowing the smaller particles to exit the chamber. Second, the larger particles maintain the vortex flow within the chamber. When large particles are used, preferably

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they will be in the form of agglomerations of smaller particles or be a frangible material that is capable of being reduced in size upon operation of the device.

If immediate output of an aerosol is desired, an initial small quantity of fine particulate material may be mixed with a granular particulate material, preferably 5 to 20% by weight of the particles are 10 microns or less in diameter and about 80-95% by weight of the particles are between 300 to 400 microns in diameter. Generally, the impeller may rotate from about 1000 to 5000 rpm, depending upon desired flow rate, which depends on particle size and density. Also, if desired, a separate particle size reducer, such as an impeller, blender, grinder, mixer, etc. may be included.

High degrees of dispensing particulate material within the desired size can be obtained, including levels as high as 99% by weight. In general, particle sizes delivered will preferably be between about .5 and about 10 microns in diameter, more preferably between about 2 and 6 microns in diameter, though it is not intended to limit the present invention to exclude particle sizes outside of this range if such larger or smaller sizes are determined to be desirable.

Examples

Example 1

An example of a highly preferred embodiment generally corresponding to the type of design shown in Figures 1-2, the particulate material is granular sodium chloride having a typical cubic dimension of about 300 to 400 microns. The chamber has a diameter of about 25 mm and depth from upper wall to the bottom of base wall of about 40 mm. The included angle of the conical form of base wall is about 90°. The impeller is about 22 mm across and the clearance between impeller and base wall is about 1.5 mm. The impeller rotates at about 3000 rpm. The interior egress port 38 and exterior egress port 39 of egress conduit 37 both have an internal diameter of about 2.5 mm.

In this exemplary embodiment, sodium chloride particles between 2 to 6 microns generally have sufficiently low size and inertia as to be classified and carried by the exiting fluidized stream through the conduit. With a chamber initially containing 1 gram of sodium chloride, approximately 1 milligram per minute of fine particles are dispensed, and of the particles dispensed as an aerosol of a fine powder, over 99 % of the particles dispensed are between 2 to 6 microns.

Example 2

An example of a highly preferred embodiment generally corresponding to the type of design shown in Figures 3-5, the particulate material is granular sodium chloride having a typical cubic dimension of about 300 to 400 microns. The chamber has a

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diameter of about 27 mm and depth from upper wall to the bottom of base wall of about 36 mm. The included angle of the conical form of base wall is about 110°. The housing, upper support frame, and tube insert are injection molded of LUSTRAN 348 @ acrylonitrile butadiene styrene produced by the BAYER CORPORATION POLYMERS DIVISION, 100 Bayer Road, Pittsburgh, PA, 15205. The impeller is about 22 mm across and the clearance between the impeller and base wall is about 1.5 mm. The impeller is molded of Vectra @ liquid crystal polymer produced by HOECHST TECHNICAL POLYMERS, 90 Morris Ave., Summit, NJ, 07901. The impeller rotates at about 3000 rpm. The impeller is driven by an electric motor. A suitable permanent magnet electric motor is model SU-020RA-1665 supplied by MABUCHI MOTOR AMERICA CORP. of 3001 West Big Beaver Road, Troy, MI. The battery is a standard AAA such as a DURACELL Alkaline Battery produced by Duracell, Inc., Bethel, CT, 06801. The ingress conduit has an internal diameter of about 2.5 mm. The egress conduits are about 1.3 mm by 1.3 mm.

15 In this exemplary embodiment, sodium chloride particles between 2 to 6 microns generally have sufficiently low mass and sufficiently large aerodynamic surface as to be carried by the exiting air stream through the classifier. With a chamber initially containing 1 gram of sodium chloride, approximately 1 milligram per minute of fine particles are dispensed, and of the particles dispensed as an aerosol of a fine powder, 20 over 99 % of the particles dispensed are between 2 to 6 microns.

While particular embodiments of the present invention have been illustrated and described, it will be obvious to those skilled in the art that various changes and modifications may be made without departing from the spirit and scope of the invention, and it is intended to cover in the appended claims all such modification 25 that are within the scope of the invention.

What is claimed is:

1. A dry powder inhalation device, comprising:
 - (a) a housing having an inlet for a gas, an outlet, and a chamber suitable for containing a particulate material;
 - (b) a particle fluidizer for providing a fluidized flow of said particulate material with said gas in said chamber upon operation of the device; and
 - (c) a particle classifier in fluid communication with said fluidized flow between said chamber and said outlet.

2. The device of claim 1, wherein said particle fluidizer causes a vortex flow of said fluidized particulate material, and said particle classifier permits particles within said fluidized particulate material with less than ^{and including} a predetermined size and inertia to deviate from said vortex flow and exit said chamber, and excludes particles within said fluidized particulate material with greater than said predetermined size and inertia from exiting said chamber.

3. The device of claim 2, wherein said vortex flow generates
 - (a) a low pressure center region within said chamber, wherein said low pressure center region is in fluid communication with said inlet, whereby said gas flows into said chamber; and
 - (b) a high pressure outer region within said chamber, wherein said high pressure outer region is in fluid communication with said outlet, whereby said gas flows from said high pressure outer region and exits through said outlet.

4. The device of claim 3, wherein said particles within said fluidized particulate material with less than ^{and including} a predetermined size and inertia that deviate from said vortex flow and exit said chamber, exit said device with said gas that flows from said high pressure outer region and exits through said outlet.

5. The device of claim 1, wherein said device is one of the following: unit dose, bulk powder, or multi-dose.

6. The device of claim 1, wherein said particle fluidizer comprises an impeller.

7. The device of claim 6, wherein said impeller has an axis of rotation substantially concentric about the longitudinal axis of the chamber.

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8. The device of claim 3, wherein said inlet comprises an external ingress port, an ingress conduit, and an internal ingress port, and said internal ingress port is located near said low pressure center region.
9. The device of claim 3, wherein said particle classifier comprises a ingress port and an egress port, and said particles within said fluidized particulate material with less than ^{and including} a predetermined size and inertia that deviate from said vortex flow and exit said chamber enter said particle classifier through said ingress port.
10. The device of claim 9, wherein said ingress port of said particle classifier faces in a direction similar to said vortex flow.
11. The device of claim 10, wherein said said particles within said fluidized particulate material with less than ^{and including} a predetermined size and inertia that deviate from said vortex flow flow in a direction opposite said vortex flow.
12. The device of claim 1, wherein said particle classifier is a conduit.
13. The device of claim 1, wherein said particle classifier is a conical particle classifier.
14. The device of claim 1, said particle fluidizer fluidizes said particulate material by one of the following: abrasion, fracturing, impact with said particle fluidizer, causing particulate material to impact with said chamber, or causing impact between said particulate material.
15. The device of claim 2, wherein said particle classifier is sized such that at least 90% of said fluidized particulate material that passes though said outlet has an average particle size of about .5 to about 10 microns in diameter.
16. The device of claim 15, wherein said particle classifier is sized such that at least 99% of said fluidized particulate material that passes though said outlet has an average particle size of about 2 to about 6 microns in diameter.
17. The device of claim 1, wherein approximately 1 milligram per minute of fluidized particulate material is dispensed.

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18. The device of claim 1, wherein said device further comprises a mouthpiece whereby said portion of fluidized particulate material that exits said outlet can be inhaled through.

19. The device of claim 1, wherein said particle fluidizer is electrically powered.

20. The device of claim 1, wherein said device comprises a self-contained power source.

21. The device of claim 20, wherein said power source is a battery.

22. The device of claim 1, wherein said particulate material is sodium chloride.

23. A method of dispensing an aerosolized particulate material for inhalation, comprising:

providing a housing having an inlet for a gas, an outlet, and a chamber suitable for containing a particulate material;

5 fluidizing a flow of said particulate material with said gas in said chamber; classifying said fluidized flow; and dispensing said classified fluidized flow.

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Abstract of the Disclosure

The present invention provides a device suitable for dry powder inhalation. The particles of dry powder are fluidized with air and cause a vortex flow of the fluidized particulate material. A particle classifier permits fluidized particulate material of a predetermined size and inertia to flow from the chamber to the outlet and excludes fluidized particulate material with greater than the predetermined size and inertia from flowing from the chamber to the outlet.

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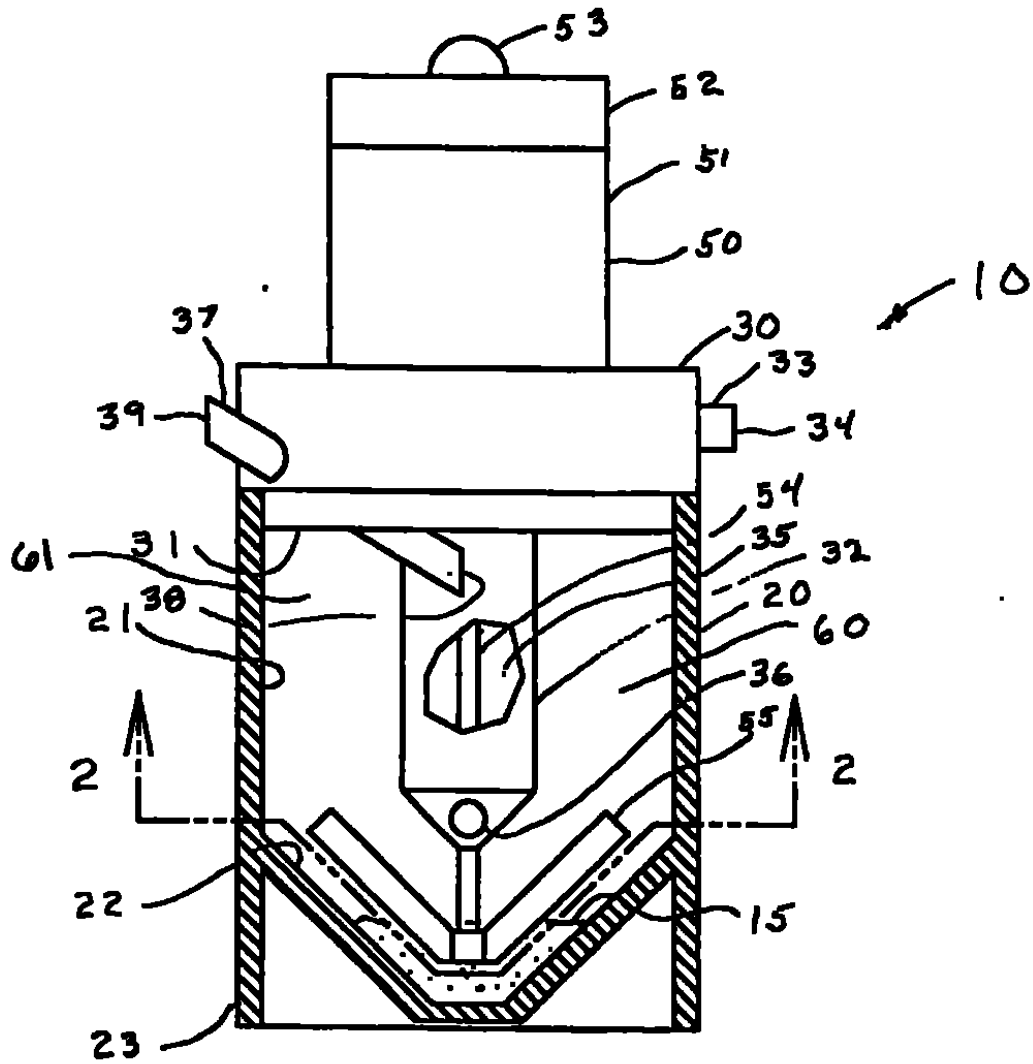


FIG. 1

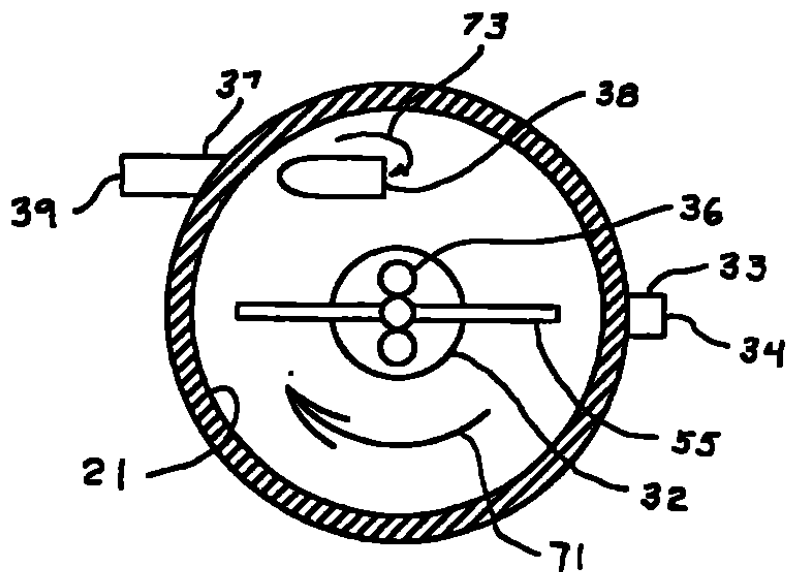


FIG. 2

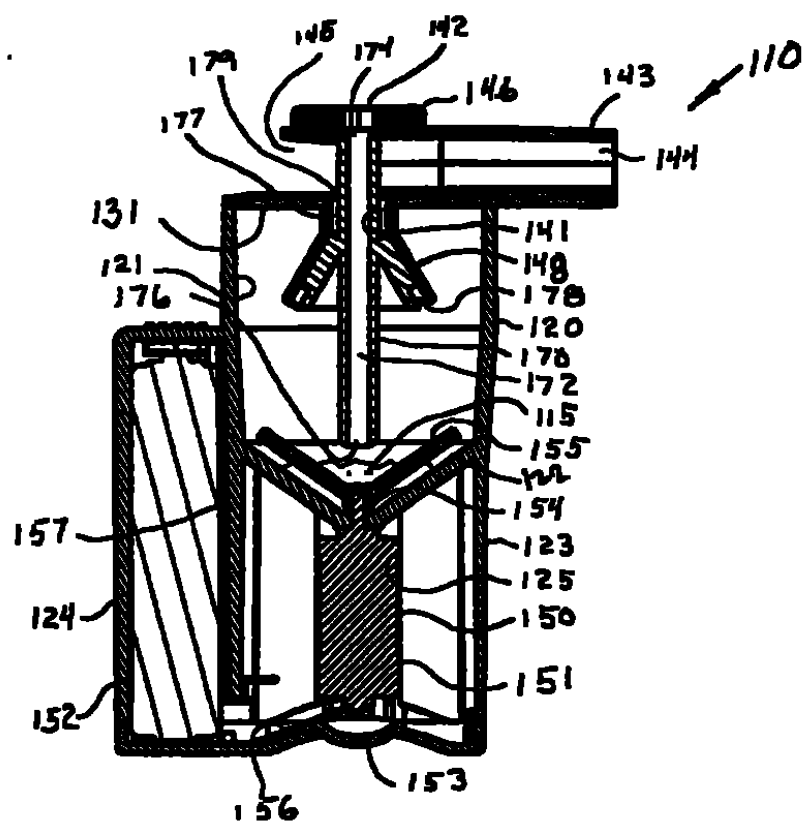


FIG 3

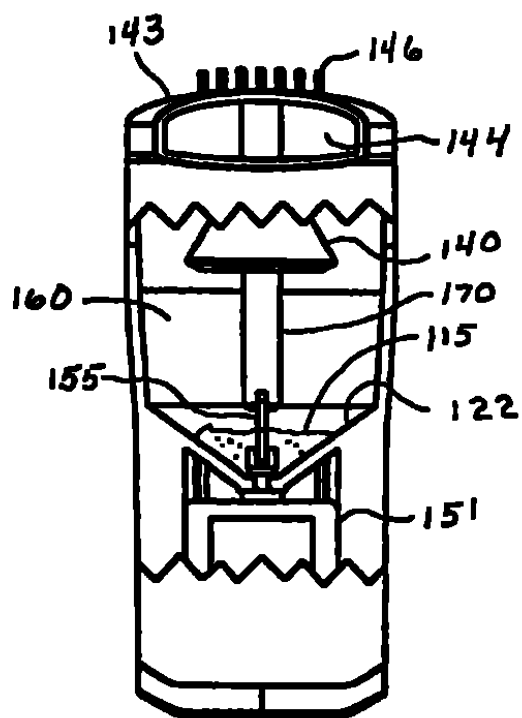


FIG 4

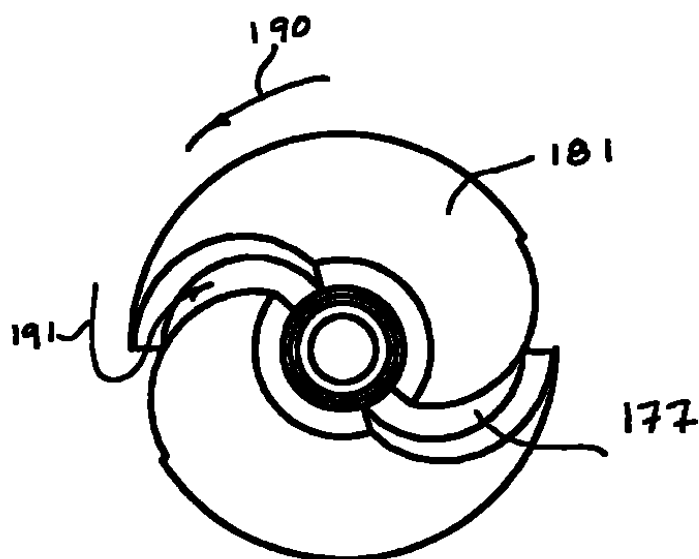


FIG 5