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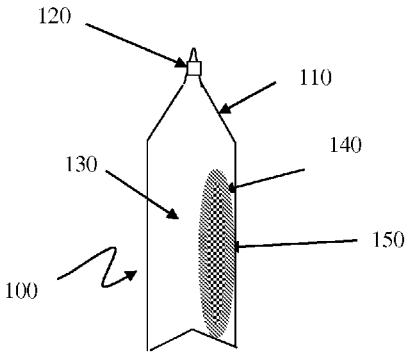


FIG. 1A

(57) Abstract: General medication disposal systems are provided. Aspects of the systems include devices having a sealable container dimensioned to accommodate a pharmaceutical composition; and an amount of an inactivating substance, e.g., granulated or pelletized activated carbon, present inside of the of sealable container. Aspects of the invention further include methods of making and using the systems, as well as kits comprises the devices of the system.

GENERAL MEDICATION DISPOSAL SYSTEM

CROSS-REFERENCE TO RELATED APPLICATIONS

Pursuant to 35 U.S.C. § 119 (e), this application claims priority to the filing date of United States Provisional Patent Application Serial No. 61/542,026 filed on September 30, 2011; the disclosure of which application is herein incorporated by reference.

INTRODUCTION

The temptation and potential for prescription drug abuse by ingestion, injection, etc., and particularly, of narcotics and other controlled substances is well known. This widespread abuse issue is exemplified by the current problems associated with morphine, oxycontin, fentanyl, and many others.

Unfortunately, problems associated with medications are not limited to abusable narcotics. According to a recent investigative report by the Associated Press, Americans flush 250 million pounds of pharmaceuticals down the drain every year (see e.g., Living on Earth.org online interview with the EPA, October 3, 2008). Furthermore, this practice of pharmaceutical composition disposal has resulted in contamination of the drinking water supply of numerous major cities throughout the U.S. (see e.g., Air Force Print News Today, March 24, 2008).

These contaminants pose risk to the environment; affecting people, fish and wildlife. Potential problems include abnormal physiological processes, reproductive impairment, increased evidence of cancer, and development of anti-microbial resistant organisms (reference: Kansas Dept of Health and Environment, March 22, 2007). A significant source of pharmaceutical environmental contamination lies with disposal of unused or expired medications (reference eMedicineHealth March 21, 2008). Historically, these medications are flushed down the toilet or thrown into the trash, with a likely outcome that they will eventually end up in groundwater supplies. The only medications that the FDA condones flushing down the toilet are controlled substances with abuse potential. Thus, many people are faced with a dilemma of how best to dispose of unused and expired medications.

Of particular interest is the potential for abuse or environmental release associated with medications contained in transdermal patch technology.

Unfortunately, with transdermal patches significant amounts of drug compound remain in the patches after patients have worn them for the prescribed period of time. The need for this excess amount of drug is well known; it is required to ensure an adequate driving force in the transdermal application for the full wear time period. For example, in a published test of Duragesic® (trademark of Johnson & Johnson) patches worn for the full 72-hour wear period, 28-84.4% of the original loading of fentanyl still remained in the patches. The authors of the study concluded that the residual dosage represented amounts sufficient for abuse and misuse and was even potentially lethal (Marquardt et al, Ann Pharmacother, 1995, 29:969-71).

Environmental and abuse problems are certainly not limited to medications in transdermal patch form. In fact, medications are most often in oral pill or liquid solution form. Once unused or expired oral medications are discarded, these medications may be recovered from the trash and abused by others. In addition, compounds from large amounts of discarded medications are inevitably released to the ground water supply over time.

SUMMARY

Medication disposal systems are provided. Aspects of the systems include devices having a sealable container dimensioned to accommodate a pharmaceutical composition; and an amount of an inactivating substance, e.g., granulated or pelletized activated carbon, present inside of the of sealable container. Aspects of the invention further include methods of making and using the systems, as well as kits comprises the devices of the system.

BRIEF DESCRIPTION OF THE FIGURES

Figure 1A provides a view of an embodiment pharmaceutical composition disposal device having an inner pouch that contains a water permeable/carbon impermeable separator barrier. Figure 1B shows a variation of the device shown in Figure 1A that includes a vent.

Figures 2A to 2G depict the sequence of how the device depicted in Figure1A may be used to dispose of a pharmaceutical composition.

Figure 3 provides experimental results with comparisons of deactivation between Untreated Control, Cat Litter, Coffee Grounds, Granular Activated Carbon

(Design A, Free Carbon), and Granular Activated Carbon contained in an Inner Pouch (Design B, Carbon in Pouch).

DETAILED DESCRIPTION

Medication disposal systems are provided. Aspects of the systems include devices having a sealable container dimensioned to accommodate a pharmaceutical composition; and an amount of an inactivating substance, e.g., granulated or pelletized activated carbon, present inside of the of sealable container. Aspects of the invention further include methods of making and using the systems, as well as kits comprises the devices of the system.

Before the present invention is described in greater detail, it is to be understood that this invention is not limited to particular embodiments described, as such may, of course, vary. It is also to be understood that the terminology used herein is for the purpose of describing particular embodiments only, and is not intended to be limiting, since the scope of the present invention will be limited only by the appended claims.

Where a range of values is provided, it is understood that each intervening value, to the tenth of the unit of the lower limit unless the context clearly dictates otherwise, between the upper and lower limit of that range and any other stated or intervening value in that stated range, is encompassed within the invention. The upper and lower limits of these smaller ranges may independently be included in the smaller ranges and are also encompassed within the invention, subject to any specifically excluded limit in the stated range. Where the stated range includes one or both of the limits, ranges excluding either or both of those included limits are also included in the invention.

Certain ranges are presented herein with numerical values being preceded by the term "about." The term "about" is used herein to provide literal support for the exact number that it precedes, as well as a number that is near to or approximately the number that the term precedes. In determining whether a number is near to or approximately a specifically recited number, the near or approximating unrecited number may be a number which, in the context in which it is presented, provides the substantial equivalent of the specifically recited number.

Unless defined otherwise, all technical and scientific terms used herein have the same meaning as commonly understood by one of ordinary skill in the art to which this invention belongs. Although any methods and materials similar or equivalent to those described herein can also be used in the practice or testing of the present invention, representative illustrative methods and materials are now described.

All publications and patents cited in this specification are herein incorporated by reference as if each individual publication or patent were specifically and individually indicated to be incorporated by reference and are incorporated herein by reference to disclose and describe the methods and/or materials in connection with which the publications are cited. The citation of any publication is for its disclosure prior to the filing date and should not be construed as an admission that the present invention is not entitled to antedate such publication by virtue of prior invention. Further, the dates of publication provided may be different from the actual publication dates which may need to be independently confirmed.

It is noted that, as used herein and in the appended claims, the singular forms “a”, “an”, and “the” include plural referents unless the context clearly dictates otherwise. It is further noted that the claims may be drafted to exclude any optional element. As such, this statement is intended to serve as antecedent basis for use of such exclusive terminology as “solely,” “only” and the like in connection with the recitation of claim elements, or use of a “negative” limitation.

As will be apparent to those of skill in the art upon reading this disclosure, each of the individual embodiments described and illustrated herein has discrete components and features which may be readily separated from or combined with the features of any of the other several embodiments without departing from the scope or spirit of the present invention. Any recited method can be carried out in the order of events recited or in any other order which is logically possible.

In further describing various embodiments of the invention, aspects of the devices are reviewed first in greater detail, followed by a detailed description of embodiments of using the devices and a review of kits that include the devices.

DEVICES

As summarized above, devices for use in disposal of pharmaceutical compositions are provided. Aspects of the devices include a sealable container and an amount of an inactivating agent present in the container. The sealable container may have any convenient configuration. In some instances, the sealable container is dimensioned to accommodate a pharmaceutical composition that is to be inactivated. Configurations of interest for the container include, but are not limited to, bottles, bags, pouches, etc., where the walls of the container may be rigid or flexible, as desired. In those embodiments where the containers are dimensioned to accommodate a pharmaceutical composition, the interior volume of the container will be such that the pharmaceutical composition can be positioned inside of the container, where in some instances when the pharmaceutical composition is placed inside of there is also additional space to accommodate a volume of liquid, e.g., from 1/4 cup to 2 cups of liquid or more. Accordingly, the volume of the container may range in some instances from 50 to 500 ml, such as 100 to 400 ml, including 200 to 375 ml. Where the container has a pouch or bag configuration, the dimensions of such may vary, ranging in some instances from 2×3 inches to 8×10 inches. While the thickness of the walls of the container may vary, in some instances the walls have a thickness ranging from 0.1 to 2.0 mm, such as 0.1 to 1.0 mm. The container may be fabricated from any convenient material that is impermeable to liquid, e.g., an aqueous liquid, where materials of interest include polymeric materials (e.g., polyvinylchloride, polyethylene, polyvinylacetate, etc.,) which materials may be transparent, translucent or opaque, as desired.

As summarized above, the container is sealable. Accordingly, the container includes a sealable closure device (e.g., a resealable closure device), which when opened provides access to deposit the pharmaceutical composition into the container. The sealable closure device for closing the container or pouch also provides a closed system for disposing of the used medication. The closure system may include an adhesive seal or plastic container reseal device such as those associated with the trademark ZIPLOC® to seal the pharmaceutical composition in the container.

Present inside of the container is an amount of an inactivating substance. Inactivating substances of interest are those substances which, upon contact with the active agent of the pharmaceutical composition, at least partially inactivate the

active agent, i.e., at least diminish if not destroy the activity of the active agent. Inactivating substances of interest include, but are not limited to binding agents, where the term "binding agent" means a substance or combination of substances that immobilize or otherwise deactivate an active agent on contact. Binding agents of interest include adsorption substances that adsorb the active agent or chemisorb substances that chemically bind the active agent. Substances of interest are ones which begin to perform the immobilization or other deactivation immediately on contact with the active agent of the pharmaceutical composition.

Binding agents of interest include agents that immobilize the medication and preclude future separation by normally available means. Specific examples of such agents include, without limitation, zeolites, clays, silica gel, aluminum oxide and activated carbon. Activated carbon is suitable for the adsorption or chemisorption of active agents, including synthetic opioids such as fentanyl. The term "activated carbon" is used in its conventional sense to refer to a form of carbon that has been processed to provide for a surface area in excess of 500 m^2. When present as the binding agent, the activated carbon may be in powder, granular or pelletized form. Powdered activated carbon is a particular carbon composition having an average particle size of 0.25 mm or less, e.g., from 0.15 to 0.25 mm, while granular or pelletized activated carbon is made up of particles or pellets having an average size of 0.25 mm or higher, such as from 0.25 to 5.0 mm. In some instances in which the activated carbon is present in powder form (as well as other forms), the activated carbon will not be free-flowing in the container, i.e., the activated carbon will be stably associated with another component of the container, e.g., a wall of the container, a solid support in the container, or a pouch inside of the container, such as described in greater detail below. In yet other instances where the activated carbon is present in granular or pelletized form, the granular or pelletized form of the activated carbon may be free-flowing in the container.

In addition or alternatively to binding agents, the inactivating substance may include other substances which in some way render the active agent of the pharmaceutical composition unusable. Accordingly, the inactivating substance may contain one or more of an antagonist, an oxidizing compound, an irritant compound or an anti-abuse distressing agent. Such compounds may be used singly or in combination and instead of the binding agent or in addition to the binding agent in the inactivating substance. When used in combination with the binding agent, such

compounds may be pre-adsorbed on a portion of the binding agent, as desired. Antagonists of interest are those which exhibit antagonist activity relative to the active agent of the pharmaceutical composition, e.g., naloxone or naltrexone for opioids. Examples of such oxidizing agents include perborates, percarbonates, peroxides, and hypochlorites. Examples of irritant compounds include capsaicin or ipecac. Examples of anti-abuse distressing agents include bitter taste agents, such as dehydrocholic acid.

The amount of the inactivating substance in the container may vary, and may be selected to be more than theoretically required to substantially inactivate the amount of active agent in the pharmaceutical composition for which the device has been configured. While the exact amount may vary, in some instances the weight ratio of inactivating substance (e.g., activated carbon) to active agent is 2 (i.e., 2/1) or higher, such as 3 or higher, including 4 or higher, such as 5 or higher.

As indicated above, in some instances the inactivating substance is not free-flowing inside of the container. In other words, the inactivating substance is stably associated with some other component of the container, e.g., an inside wall of the container, a support present in the container, a liquid permeable pouch inside of the container, etc. By "stably associated" is meant that the inactivating substance is immobilized relative to the other component at least prior to use of the container, e.g., prior to inclusion of liquid in the container. As such, in some instances the inactivating substance may be adhered to an inner surface of the container, e.g., as a layer on the inner surface of the container. Where desired, a liquid permeable cover (i.e., liner) may be positioned over the layer. In other embodiments, a support (e.g., a flexible or rigid, permeable or impermeable, solid structure) may be provided inside of the container and unattached to the container, where the inactivating substance is stably associated with one or more surfaces of the support.

In some instances, inactivating substance may be present in a liquid, e.g., water, permeable enclosure (such as a pouch), which enclosure allows for liquid to pass into the inside of the enclosure but holds the contents of the enclosure inside of the enclosure, at least prior to contact with liquid. In some instances, the enclosure is fabricated from a water permeable material which maintains the inactivating substance inside of the enclosure after the enclosure has been contacted with liquid. Any convenient material may be employed for the inner enclosure, including materials commonly employed for tea bags, e.g., cellulose materials, etc. In some

instances, the material is one that dissolves in liquid, e.g., water, i.e., the material is water-soluble. In such embodiments, pouch materials of interest include polymeric materials, e.g., which are formed into a film or sheet. The pouch material can, for example, be obtained by casting, blow-molding, extrusion or blown extrusion of the polymeric material, for example. Polymers, copolymers or derivatives thereof suitable for use as pouch material include, but are not limited to: polyvinyl alcohols, polyvinyl pyrrolidone, polyalkylene oxides, acrylamide, acrylic acid, cellulose, cellulose ethers, cellulose esters, cellulose amides, polyvinyl acetates, polycarboxylic acids and salts, polyaminoacids or peptides, polyamides, polyacrylamide, copolymers of maleic/acrylic acids, polysaccharides including starch and gelatine, natural gums such as xanthum and carragum; polyacrylates and water-soluble acrylate copolymers, methylcellulose, carboxymethylcellulose sodium, dextrin, ethylcellulose, hydroxyethyl cellulose, hydroxypropyl methylcellulose, maltodextrin, polymethacrylates, polyvinyl alcohols, polyvinyl alcohol copolymers and hydroxypropyl methyl cellulose (HPMC), and combinations thereof. The polymer can have any weight average molecular weight, such as from 1000 to 1,000,000, e.g., from 10,000 to 300,000 , including from 20,000 to 150,000. Mixtures of polymers can also be used as the pouch material. This can be beneficial to control the mechanical and/or dissolution properties of the compartments or pouch, depending on the application thereof and the required needs. Suitable mixtures include for example mixtures wherein one polymer has a higher water-solubility than another polymer, and/or one polymer has a higher mechanical strength than another polymer. Also suitable are mixtures of polymers having different weight average molecular weights, for example a mixture of PVA or a copolymer thereof of a weight average molecular weight of 10,000-40,000, such as around 20,000, and of PVA or copolymer thereof, with a weight average molecular weight of 100,000 to 300,000, such as 150,000. Also suitable herein are polymer blend compositions, for example comprising hydrolytically degradable and water-soluble polymer blends such as polylactide and polyvinyl alcohol, obtained by mixing polylactide and polyvinyl alcohol, e.g., comprising about 1-35% by weight polylactide and about 65% to 99% by weight polyvinyl alcohol. The inner enclosure may or may not be joined to the container.

In some instances, the container further includes one or more excipients which impart additional functionality to the container. For example, buffering agents may be included in the container to provide for pH adjustment to a pH which

provides for optimal inactivation, e.g., via adsorption, of the active agent. Any convenient buffering agent that provides for the desired pH during use may be employed. Another type of excipient of interest is salt, such as a divalent metal cation salt, e.g., where the divalent metal cation is selected from the group consisting of Ca^{2+} and Mg^{2+}. Such salts may be employed in amount sufficient to prevent the "swelling" (water absorption) of hydrogel patches when the patch is the pharmaceutical composition. An example ion is the use of calcium or magnesium salts that can be used to minimize the water absorption and expansion of Lidoderm hydrogel patches. Yet another excipient of interest is a suspending agent. For example, the container may include an amount of gelling agent which enables suspension of the activated carbon and medication together in a viscous slurry to achieve intimate contact between the activated carbon and dissolved medication throughout the slurry. One gelling agent that of interest is HPMC (Hydroxypropylmethylcellulose), at a concentration by weight of from 0.5 to 5.0% (w/w) when mixed with an amount of water. The process using a gelling agent has an additional advantage because the viscous gel helps retain the mixture, including medications in dissolved form, within the container, e.g., it will not leak out readily as would a non-viscous solution should there be a breach in the container. The above excipients may be used singly or in combination, and may be provided in the container separate from the inactivating substance or combined with the inactivating substance.

Where desired, the container may include a vent. The vent may have any configuration that allows for passage of gas generated during use of the device from the inside to the outside of the container. Vents of interest include one way gaseous vents which allow for passage of gas from inside the container to outside of the container but not vice versa, such as vents typically found in coffee bags, e.g., as described in U.S. Patent No. 4,000,846.

Turning now to the Figures, Figure 1A provides a view of a pharmaceutical composition disposal device 100 according to one embodiment of the invention. The device 100 includes a container in the form of a re-sealable pouch 110 having a ZIPLOC® type seal 120 at the top. Inside of the container 110 is an inner pouch 130 which contains a water permeable/granular activated carbon impermeable barrier 140 containing an amount of granular activated carbon 150. Shown in Figure 1B is

variation of the device shown in Figure 1A, which includes a one-way gas vent 160 located proximal to the seal 120.

The devices of the invention may be fabricated according to any convenient protocol. Such methods generally include placing an amount of inactivating substance, e.g., granulated or pelletized activated carbon, into a re-sealable container, e.g., as described above. Fabrication may further include placement of other components, e.g., excipients, into the container, e.g., as described above.

METHODS OF USE

Aspects of the invention further include methods of disposing a pharmaceutical composition by using devices such as described above. In practicing methods of the invention, the pharmaceutical composition to be disposed of is placed inside of the container. A variety of different types of pharmaceutical compositions may be disposed of via embodiments of the invention, where the pharmaceutical compositions may be liquids or solids, where solid pharmaceutical compositions may be pills (i.e., tablets), capsules, topical compositions, such as patches or tapes, among other forms.

Where the pharmaceutical composition is a liquid, the liquid pharmaceutical composition may simply be placed in the container and the container sealed, with no additional liquid introduced into the container. Where the pharmaceutical composition is a solid, a volume of liquid, e.g., an aqueous medium, such as pure water, may be employed, e.g., to enhance contact of the active agent from the pharmaceutical composition and the inactivating substance. In certain embodiments, the amount of liquid is less than the amount necessary to completely dissolve the pharmaceutical composition. For example, if a drug is soluble at 1 gram per liter, adding less than 1 liter will be ultimately more effective for adsorption of the 1 gram of drug. Thus, certain embodiments include addition of water less than the solubility volume for the medication to be deactivated. When employed, the volume of liquid may vary, ranging in some instances from 1/4 cup to 2 cups. The protocol in such instances may vary, with the liquid being introduced into the container prior to the pharmaceutical composition, or the pharmaceutical composition being introduced into the container prior to the liquid. After the pharmaceutical composition and liquid have been introduced into the container, the container is sealed.

Where desired, the contents of the sealed container may be mixed, e.g., by agitating the container, manipulating the container if the container is flexible, etc. However, in some instances, the method does not comprise any mixing of the contents of the container following sealing of the container. For example, where the pharmaceutical composition is a topical composition such as a patch or tape, methods may include simply introducing the composition into the container with an amount of liquid and sealing the container, without subsequent mixing. When the pharmaceutical composition is patch, the patch may be covered with a water permeable layer, e.g., tissue paper, prior to placement into the container, e.g., provide for ease of handling. Where desired, the patch may be folded, e.g., in half, prior to placement in the container.

After the pharmaceutical composition (and optionally liquid) is placed inside of the container and the container is resealed, the container may be maintained for a storage period prior to ultimate disposal of the container, e.g., in a municipal sanitation system. When employed, the container may be stored for a period ranging from 1 day to 2 weeks, e.g., 1 to 7 days. During storage, the container may be maintained at any convenient temperature, e.g., room temperature.

Figures 2A to 2G provide sequential images of a method of disposing a pharmaceutical composition using a device of the invention as depicted in Figure 1A. In Figure 2A, a sealed device containing an inner pouch which in turn includes an amount of granular carbon is shown. During use, the container is opened (see Figure 2B) and a number of pills are placed inside of the container (Figure 2C). Next, a volume of water sufficient to cover the pills and the pouch is placed inside of the container (Figure 2D) and the container is resealed (Figure 2E). Figure 2F illustrates dissolution of the pills and active agent contained therein in the water. Figure 2G illustrates adsorption of the active agent into the granular activated carbon present inside of the inner pouch.

UTILITY

The devices of the invention find use in disposal of a variety of different types of pharmaceutical compositions, e.g., where the pharmaceutical compositions may

be liquids or solids, where solid pharmaceutical compositions may be pills (i.e., tablets), capsules, topical compositions, such as patches or tapes, among other forms. Methods and devices of the invention find use is disposing any type of active agent, including those that may be subject to abuse, e.g., opioids and other painkillers, hormones, etc., in a manner that prevents abuse and is environmentally sound (e.g., in that it prevents the active agent from entering the ecosystem).

KITS

Kits for use in practicing certain methods described herein are also provided. In certain embodiments, the kits include one or more devices as described above. In certain embodiments, the kits include additional components that find use in the methods, e.g., an amount of liquid for introducing into the container, tissue paper, etc., as described above. In a given kit that includes two or more compositions, the compositions may be individually packaged or present within a common container.

In certain embodiments, the kits will further include instructions for practicing the subject methods or means for obtaining the same (e.g., a website URL directing the user to a webpage which provides the instructions), where these instructions may be printed on a substrate, where substrate may be one or more of: a package insert, the packaging, reagent containers and the like. In the subject kits, the one or more components are present in the same or different containers, as may be convenient or desirable.

ADDITIONAL EMBODIMENTS

1. A device for use in disposing an amount of a pharmaceutical composition, the device comprising:

a sealable container dimensioned to accommodate the pharmaceutical composition; and

an amount of granulated or pelletized activated carbon present inside of the of sealable container.

2. The device according to Clause 1, wherein the sealable container is a re-sealable container.

3. The device according to Clause 1 or 2, wherein the container is configured as a pouch.

4. The device according to Clause 1, 2 or 3, wherein the granulated or pelletized activated carbon comprises activated carbon particles ranging in size from .25 to 5.0 mm.

5. The device according to any of the preceding clauses, wherein the amount of granulated or pelletized activated carbon is contained in a liquid permeable enclosure inside of the sealable container.

6. The device according to Clause 5, wherein the liquid permeable enclosure is a water permeable enclosure.

7. The device according to Clause 5, wherein the device further comprises an anti-abuse distressing agent.

8. The device according to Clause 7, wherein the anti-abuse distressing agent is combined with the granular activated carbon.

9. The device according to Clause 7, wherein the anti-abuse distressing agent is a bitter- tasting agent.

10. The device according to any of the preceding clauses, wherein the amount of granulated activated carbon is selected to be more than theoretically required to substantially inactivate the amount of pharmaceutical composition for which the device has been configured.

11. The device according to any of the preceding clauses, wherein the container further comprises an excipient.

12. The device according to Clause 11, wherein the excipient is a buffering agent.

13. The device according to Clause 11, wherein the excipient comprises a salt.

14. The device according to Clause 13, wherein the salt is a salt of a divalent metal cation.

15. The device according to Clause 14, wherein the divalent metal cation is selected from the group consisting of Ca^{2+} and Mg^{2+}.

16. The device according to any of the preceding clauses, wherein the container comprises a vent.

17. The device according to any of the preceding clauses, wherein the container further comprises an amount of a liquid.

18. The device according to Clause 17, wherein the liquid is an aqueous liquid.

19. The device according to any of the preceding clauses, wherein the device comprises a suspending agent.

20. A method of disposing an amount of a pharmaceutical composition, the method comprising:

placing the amount of the pharmaceutical composition into a sealable container comprising an amount of granulated or pelletized activated carbon present inside of the of sealable container; and

sealing the sealable container.

21. The method according to Clause 20, wherein the sealable container comprises an amount of a liquid.

22. The method according to Clause 21, wherein the liquid is an aqueous liquid.

23. The method according to Clause 21, wherein the method comprises introducing the amount of liquid into the sealable container.

24. The method according to Clause 21, wherein the amount of liquid is less than the amount necessary to completely dissolve the pharmaceutical composition.

25. The method according to any of the preceding clauses, wherein the method does not comprise any mixing of the contents of the container following sealing of the container.

26. The method according to any of the preceding clauses, wherein the pharmaceutical composition is a liquid.

27. The method according to any of the preceding clauses, wherein the pharmaceutical composition is a solid.

28. The method according to Clause 27, wherein the pharmaceutical composition is a tablet.

29. The method according to Clause 27, wherein the pharmaceutical composition is a capsule.

30. The method according to Clause 27, wherein the pharmaceutical composition is a patch.

31. The method according to Clause 30, wherein the method comprises folding the patch prior to placement of the patch in the sealable container.

32. The method according to Clause 30, wherein the method comprises positioning tissue paper in contact with an adhesive layer of the patch prior to placement of the patch in the sealable container.

33. The method according to any of the preceding clauses, wherein the method comprises maintaining the sealed container for an incubation period prior to disposing the container.

34. The method according to Clause 33, wherein the incubation period ranges from 1 to 7 days.

35. The method according to Clause 33, wherein the method comprises disposing the container in a municipal sanitation system.

36. A kit comprising:
a sealable container; and
an amount of granulated or pelletized activated carbon.

37. The kit according to Clause 36, wherein the amount of granulated or pelletized activated carbon is present inside of the sealable container.

38. The kit according to Clause 36 or 37, wherein the amount or granulated pelletized activated carbon is contained in a liquid permeable enclosure inside of the sealable container.

39. The kit according to Clause 36, 37 or 38, wherein the kit further comprises an amount of liquid.

40. The kit according to any of the preceding clauses, wherein the kit further comprises tissue paper.

41. A method comprising placing an amount of granulated or pelletized activated carbon into a re-sealable container.

42. The method according to Clause 41, wherein the amount granulated or pelletized activated carbon is contained in a liquid permeable enclosure.

43. The method according to Clause 41 or 42, wherein the method further comprises placing an amount of an anti-abuse distressing agent into the re-sealable container.

44. The method according to Clause 41, 42 or 43, wherein the method further comprises placing an amount of an excipient into the re-sealable container.

45. The method according to Clause 44, wherein the excipient is selected from the group consisting of buffering agents, salts of divalent cations and combinations thereof.

46. A device for use in disposing an amount of a pharmaceutical composition, the device comprising:

a sealable container dimensioned to accommodate the pharmaceutical composition; and

an amount of an inactivating substance present inside of the sealable container, wherein the inactivating substance is not present in a free-flowing form.

47. The device according to Clause 46, wherein the inactivating substance is activated carbon.

48. The device according to Clause 47, wherein the activated carbon is present in powdered, granulated or pelletized form.

49. The device according to any of the preceding clauses, wherein the amount of inactivating substance is present in a liquid permeable pouch or the amount of inactivating substance is adhered to at least a portion of the inner surface of the container or the amount of inactivating substance is secured to a portion of the inner surface of the container by a liquid permeable liner or the amount of inactivating substance is adhered to a surface of a solid support.

50. The device according to any of the preceding clauses, wherein the device further comprises an anti-abuse distressing agent.

51. The device according to Clause 50, wherein the anti-abuse distressing agent is combined with the granular activated carbon.

52. The device according to Clause 50, wherein the anti-abuse distressing agent is a bitter- tasting agent.

The following examples are offered by way of illustration and not by way of limitation. Specifically, the following examples are of specific embodiments for carrying out the present invention. The examples are for illustrative purposes only, and are not intended to limit the scope of the present invention in any way.

EXAMPLES

I. Test of the General Medication Deactivation System, using A) Granular Activated Carbon in direct contact with the solution, and B) Granular Activated Carbon self contained in a water permeable inner pouch

A. Procedure:

Using 4 mg Dexamethasone pills as a model drug, 30 pills are placed into each of five pouches containing: 1) no absorbent (Control); 2) 45 grams of Generic Cat Litter; 3) 45 grams of Used Coffee Grounds; 4) MedsAway™ Design "A": 45 grams of freely accessible granular activated carbon (analogous to the device shown in FIG. 1A without the inner pouch but with free granular activated carbon); and 5) MedsAway™ Design "B": 45 Grams of Granular Activated Carbon contained in an inner water permeable/carbon impermeable pouch (analogous to FIG. 1A). 1 cup of tap water is added to each pouch followed by a 7–day incubation period. The drug contained in the water solution is analyzed. In a final wash-out test, the contents of each pouch is diluted in 1 gallon tap water, mixed periodically for 1 day, and the water-released dexamethasone is analyzed by HPLC.

B. Results:

The results of the experiment are presented graphically in Figure 3. No measureable dexamethasone was released into either MedsAway Design "A" or MedsAway Design "B". A significant amount of dexamethasone was released in all other conditions.

Although the foregoing invention has been described in some detail by way of illustration and example for purposes of clarity of understanding, it is readily apparent to those of ordinary skill in the art in light of the teachings of this invention that certain changes and modifications may be made thereto without departing from the spirit or scope of the appended claims.

Accordingly, the preceding merely illustrates the principles of the invention. It will be appreciated that those skilled in the art will be able to devise various arrangements which, although not explicitly described or shown herein, embody the principles of the invention and are included within its spirit and scope. Furthermore, all examples and conditional language recited herein are principally intended to aid the reader in understanding the principles of the invention and the concepts contributed by the inventors to furthering the art, and are to be construed as being without limitation to such specifically recited examples and conditions. Moreover, all statements herein reciting principles, aspects, and embodiments of the invention as well as specific examples thereof, are intended to encompass both structural and functional equivalents thereof. Additionally, it is intended that such equivalents include both currently known equivalents and equivalents developed in the future, i.e., any elements developed that perform the same function, regardless of structure. The scope of the present invention, therefore, is not intended to be limited to the exemplary embodiments shown and described herein. Rather, the scope and spirit of present invention is embodied by the appended claims.

WHAT IS CLAIMED IS:

1. A device for use in disposing an amount of a pharmaceutical composition, the device comprising:

a sealable container dimensioned to accommodate the pharmaceutical composition; and

an amount of granulated or pelletized activated carbon present inside of the of sealable container.

2. The device according to Claim 1, wherein the sealable container is a re-sealable container.

3. The device according to Claims 1 or 2, wherein the container is configured as a pouch.

4. The device according to any of the preceding claims, wherein the amount of granulated or pelletized activated carbon is contained in a liquid permeable enclosure inside of the sealable container.

5. The device according to Claim 4, wherein the liquid permeable enclosure is a water permeable enclosure.

6. The device according to any of the preceding claims, wherein the device further comprises an anti-abuse distressing agent.

7. The device according to any of the preceding claims, wherein the container comprises a vent.

8. The device according to any of the preceding claims, wherein the container further comprises an amount of a liquid.

9. The device according to any of the preceding claims, wherein the device comprises a suspending agent.

10. A method of disposing an amount of a pharmaceutical composition, the method comprising:

placing the amount of the pharmaceutical composition into a sealable container according to any of Claims 1 to 9; and

sealing the sealable container.

11. The method according to Claim 10, wherein the method does not comprise any mixing of the contents of the container following sealing of the container.

12. The method according to Claims 10 or 11, wherein the method comprises folding the patch prior to placement of the patch in the sealable container.

13. The method according to Claims 10, 11 or 12, wherein the method comprises disposing the container in a municipal sanitation system.

14. A kit comprising:

a sealable container according to any of Claims 1 to 9; and

tissue paper.

15. A method comprising placing an amount of granulated or pelletized activated carbon into a re-sealable container to produce a sealable container according to any of Claims 1 to 9.

16. A device for use in disposing an amount of a pharmaceutical composition, the device comprising:

a sealable container dimensioned to accommodate the pharmaceutical composition; and

an amount of an inactivating substance present inside of the sealable container, wherein the inactivating substance is not present in a free-flowing form.

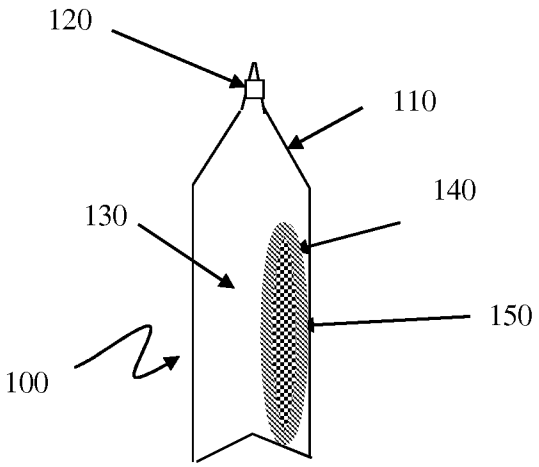


FIG. 1A

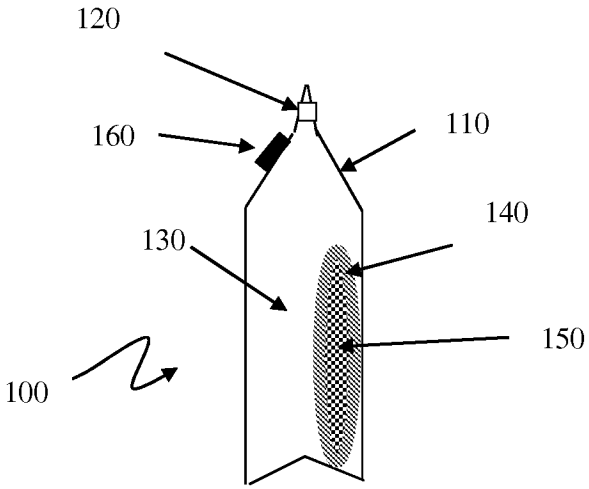
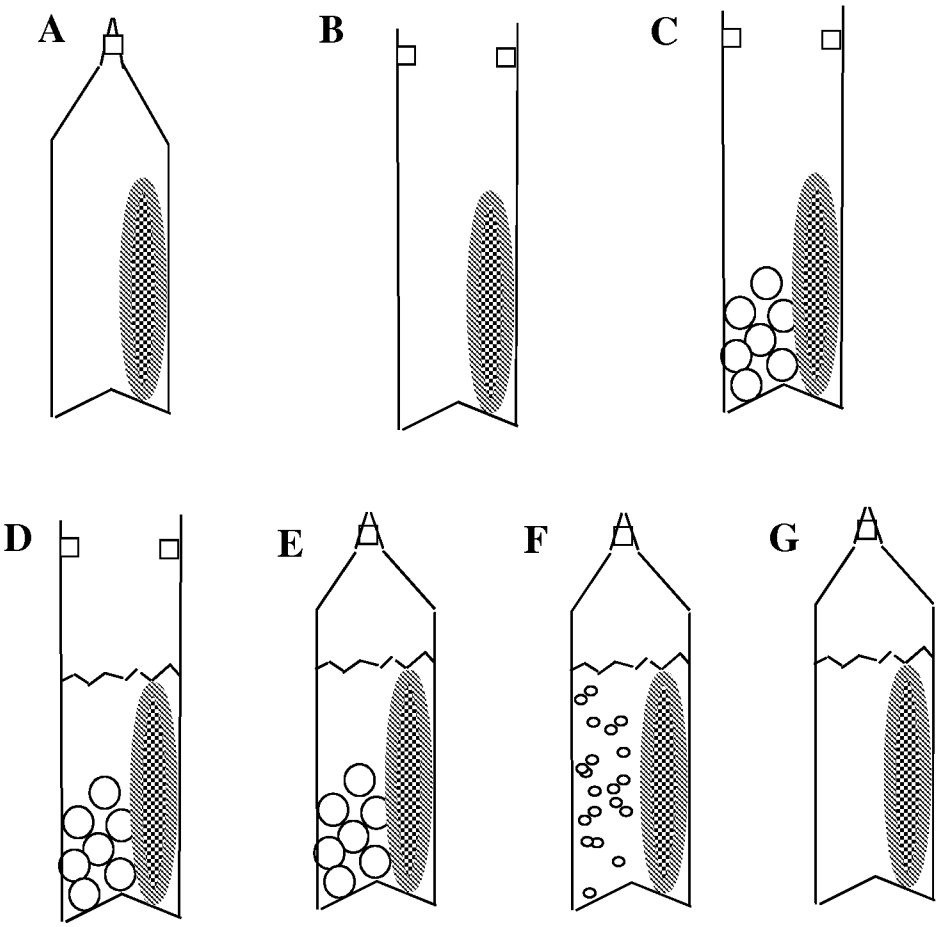


FIG. 1B

FIG. 2



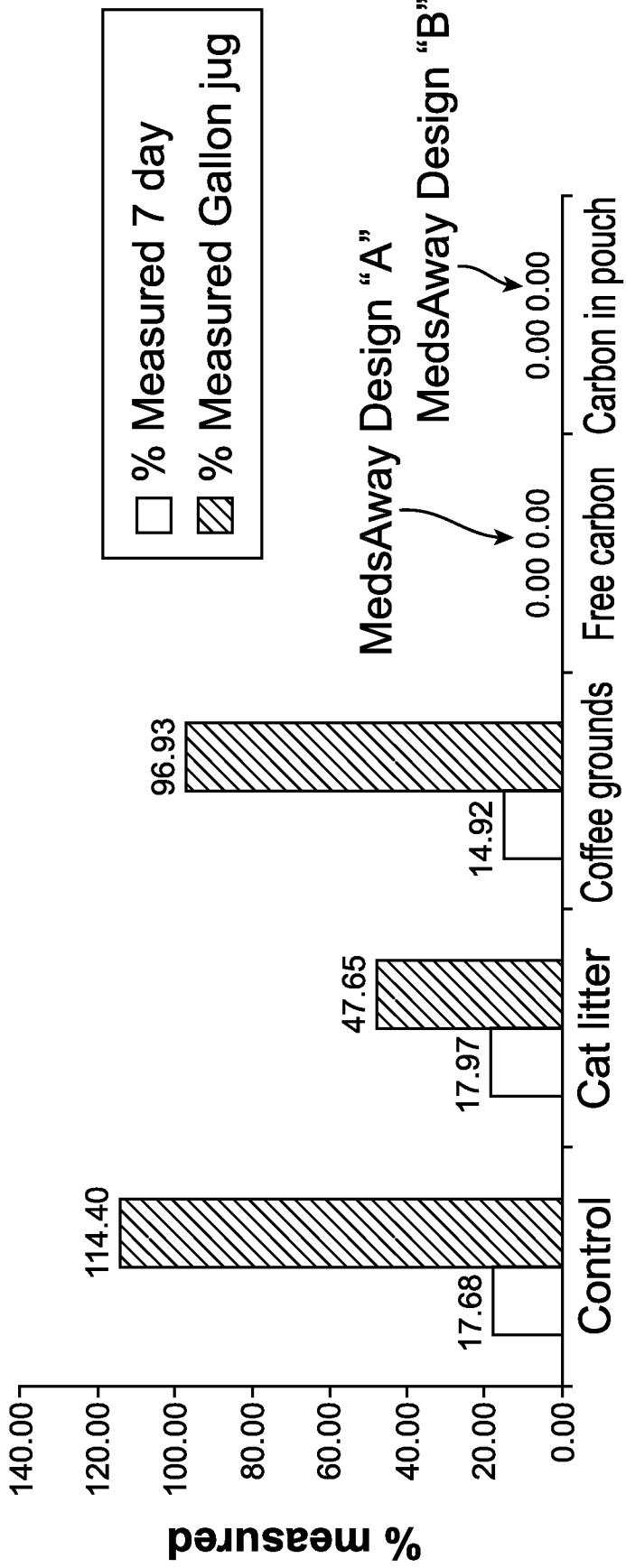

Percent Dexamethasone measured after 7 days and overnight stay in gallon jug
% Measured 7 day
% Measured Gallon jug
% measured
140.00
120.00
100.00
80.00
60.00
40.00
20.00
0.00
114.40
17.68
47.65
17.97
96.93
14.92
0.00 0.00
0.00 0.00
MedsAway Design "A"
MedsAway Design "B"
Control
Cat litter
Coffee grounds
Free carbon
Carbon in pouch

FIG. 3

INTERNATIONAL SEARCH REPORT

International application No.
PCT/US2012/057615

A. CLASSIFICATION OF SUBJECT MATTER

A61J 1/00(2006.01)i, B09B 3/00(2006.01)i, B01J 20/02(2006.01)i, B01J 19/00(2006.01)i

According to International Patent Classification (IPC) or to both national classification and IPC

B. FIELDS SEARCHED

Minimum documentation searched (classification system followed by classification symbols)

A61J 1/00; A47G 19/14; A61J 1/03; B01J 19/00; A61L 11/00; A61M 15/00

Documentation searched other than minimum documentation to the extent that such documents are included in the fields searched

Korean utility models and applications for utility models
Japanese utility models and applications for utility models

Electronic data base consulted during the international search (name of data base and, where practicable, search terms used)

eKOMPASS(KIPO internal) & Keywords: disposal, medication, sealable container, permeable

C. DOCUMENTS CONSIDERED TO BE RELEVANT

Category*	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.
X	US 2009-0180936 A1 (ANDERSON et al.) 16 July 2009. See paragraphs [0016],[0036]-[0038]; and figure 1.	1-3,16
A	US 6024012 A (ROBERT S. LUZENBERG, JR.) 15 February 2000. See column 6,line 25; column 9,lines 45-46; column 13,lines 13-27; and column 12,lines 27-30.	1-3,16
A	US 2009-0131732 A1 (SHERRY DAY) 21 May 2009. See paragraphs [0017],[0026]; and claims 1,10, 18.	1-3,16
A	WO 2009-019668 A2 (RANBAXY LAB. LTD. et al.) 12 February 2009. See page 3,lines 21-22; page 4,lines 14-15; page 5,line 19; and page 6,lines 10-13.	1-3,16
A	US 2010-0083963 A1 (WHARTON et al.) 08 April 2010. See paragraph [0248] and figure 56.	1-3,16

☐ Further documents are listed in the continuation of Box C.

☒ See patent family annex.

* Special categories of cited documents:

"A" document defining the general state of the art which is not considered to be of particular relevance

"E" earlier application or patent but published on or after the international filing date

"L" document which may throw doubts on priority claim(s) or which is cited to establish the publication date of citation or other special reason (as specified)

"O" document referring to an oral disclosure, use, exhibition or other means

"P" document published prior to the international filing date but later than the priority date claimed

"T" later document published after the international filing date or priority date and not in conflict with the application but cited to understand the principle or theory underlying the invention

"X" document of particular relevance; the claimed invention cannot be considered novel or cannot be considered to involve an inventive step when the document is taken alone

"Y" document of particular relevance; the claimed invention cannot be considered to involve an inventive step when the document is combined with one or more other such documents,such combination being obvious to a person skilled in the art

"&" document member of the same patent family

Date of the actual completion of the international search	Date of mailing of the international search report
26 FEBRUARY 2013 (26.02.2013)	**27 FEBRUARY 2013 (27.02.2013)**

Name and mailing address of the ISA/KR

Facsimile No. 82-42-472-7140

Authorized officer

CHANG, Bong Ho

Telephone No. 82-42-481-3353

INTERNATIONAL SEARCH REPORT

Information on patent family members

International application No.

PCT/US2012/057615

Patent document cited in search report	Publication date	Patent family member(s)	Publication date
US 2009-0180936 A1	16.07.2009	AU 2010-229336 A1	30.09.2010
		CA 2754215 A1	30.09.2010
		CN 102341164 A	01.02.2012
		EP 1720498 A2	15.11.2006
		EP 2421639 A1	29.02.2012
		IL 213942 D0	31.07.2011
		JP 04642784 B2	10.12.2010
		JP 2007-518819 A	12.07.2007
		JP 2010-248238 A	04.11.2010
		JP 2012-521263 A	13.09.2012
		KR 10-2011-0122105 A	09.11.2011
		MX 2011007888 A	04.11.2011
		SG 174894 A1	28.11.2011
		US 2005-0163717 A1	28.07.2005
		US 2010-0068250 A1	18.03.2010
		US 2011-0066130 A1	17.03.2011
		US 2011-0092926 A1	21.04.2011
		US 7867511 B2	11.01.2011
		US 8329212 B2	11.12.2012
		WO 2005-070003 A2	04.08.2005
		WO 2005-070003 A3	04.08.2005
		WO 2010-110837 A1	30.09.2010
US 6024012 A	15.02.2000	AU 1999-25756 A1	16.08.1999
		CN 1173657 C0	03.11.2004
		CN 1294496 A0	09.05.2001
		EP 1059852 A1	20.12.2000
		EP 1059852 B1	22.09.2004
		JP 2002-501735 A	22.01.2002
		KR 10-2001-0040553 A	15.05.2001
		US 6541055 B1	01.04.2003
		WO 99-38395 A1	05.08.1999
US 2009-0131732 A1	21.05.2009	US 7918776 B2	05.04.2011
WO 2009-019668 A2	12.02.2009	EP 2178486 A2	28.04.2010
		WO 2009-019668 A3	02.04.2009
US 2010-0083963 A1	08.04.2010	AU 2006-225241 A1	26.10.2006
		AU 2006-225241 B2	17.07.2008
		CN 101547717 A	30.09.2009
		EP 2076304 A1	08.07.2009
		WO 2008-040062 A1	10.04.2008

INTERNATIONAL SEARCH REPORT

International application No.
PCT/US2012/057615

Box No. II Observations where certain claims were found unsearchable (Continuation of item 2 of first sheet)

This international search report has not been established in respect of certain claims under Article 17(2)(a) for the following reasons:

1. ☐ Claims Nos.:
because they relate to subject matter not required to be searched by this Authority, namely:

2. ☒ Claims Nos.: 5, 11
because they relate to parts of the international application that do not comply with the prescribed requirements to such an extent that no meaningful international search can be carried out, specifically:

Claims 5 and 11 are unclear because they refer to multiple dependent claims 4 and 10 which do not comply with PCT Rule 6.4(a).

3. ☒ Claims Nos.: 4, 6-10, 12-15
because they are dependent claims and are not drafted in accordance with the second and third sentences of Rule 6.4(a).

Box No. III Observations where unity of invention is lacking (Continuation of item 3 of first sheet)

This International Searching Authority found multiple inventions in this international application, as follows:

1. ☐ As all required addtional search fees were timely paid by the applicant, this international search report covers all searchable claims.

2. ☐ As all searchable claims could be searched without effort justifying an additional fee, this Authority did not invite payment of any additional fee.

3. ☐ As only some of the required additional search fees were timely paid by the applicant, this international search report covers only those claims for which fees were paid, specifically claims Nos.:

4. ☐ No required additional search fees were timely paid by the applicant. Consequently, this international search report is restricted to the invention first mentioned in the claims; it is covered by claims Nos.:

Remark on Protest

☐ The additional search fees were accompanied by the applicant's protest and, where applicable, the payment of a protest fee.

☐ The additional search fees were accompanied by the applicant's protest but the applicable protest fee was not paid within the time limit specified in the invitation.

☐ No protest accompanied the payment of additional search fees.