COMPOSITIONS COMPRISING A SHELF-LIFE STABILITY COMPONENT

CROSS REFERENCE TO RELATED APPLICATIONS

[001] This application claims priority to U.S. Patent Application Serial No.13/304,260 filed on November 23, 2011; the disclosure of which is herein incorporated by reference.

INTRODUCTION

[002] A variety of different ingestible compositions have been developed for nutritional, therapeutic and non-therapeutic uses. Examples of different types of ingestible compositions include orally ingestible tablets, capsules and liquids. A given orally ingestible formulation may include a variety of different components, such as active agents, carrier materials (including binders, bulking agents and other excipients), flavoring agents, coloring agents, etc. More recently, ingestible compositions which include a device component, such as an RFID tag or an ingestible event marker, have been developed.

[003] As with many consumer products, ingestible compositions are not manufactured at the time of and location of use. Instead, they are generally manufactured at one or more fabrication facilities, stored for a period of time and then shipped to the end-user. Upon receipt, the end-user may further store them for a period of time before use.

[004] During the multiple storage periods, and even manufacturing periods, such as mentioned above, the quality of the ingestible composition, e.g., in terms of effectiveness, may be degraded in some way. For example, exposure to humidity, elevated temperatures, microorganisms and oxidizing agents, as well other environmental hazards, can negatively impact the quality of the ingestible composition. Shelf-life stability of ingestible compositions is therefore a significant consideration in their manufacture and use.

SUMMARY

[005] According to an aspect, there is provided a composition comprising: a shelf-life stability component entirely enclosing a minimally

dimensioned component to provide a protective barrier for the minimally dimensioned component, wherein the shelf-life stability component is configured to disrupt when the shelf-life stability component is in contact with a liquid; an ingestible device comprising: a partial power source comprising first and second consumable electrodes formed of dissimilar materials configured to generate a voltage to energize the ingestible device when the first and second electrodes are in contact with an electrically conductive fluid to supply power to the ingestible device, wherein the ingestible device is configured to produce a conductive current flow through the electrically conductive fluid when energized.

[005a] According to embodiments, ~~C~~compositions that include a shelf-life stability component are provided. In some instances, the compositions are ingestible

compositions which include the shelf-life stability component and an ingestible component. ~~Aspects~~ Embodiments of the disclosure further include methods of making and using the compositions.

BRIEF DESCRIPTION OF THE FIGURES

[006] FIGS. 1A and 1B provide side and top views, respectively, of one aspect of an ingestible event marker (IEM);

[007] FIG. 2 provides a side view of one aspect of an ingestible composition that includes a mono-layer protective barrier;

[008] FIG. 3 provides a side view of one aspect of an ingestible composition that includes a protective barrier made of a homogeneous blend of two different materials;

[009] FIG. 4 provides a side view of one aspect of an ingestible composition that includes a protective barrier made of a heterogeneous structure of two different materials;

[010] FIGS. 5A and 5B provide side views of one aspect of an ingestible composition that includes a multi-layer protective barrier;

[011] FIG. 6 provides a side view of one aspect of an ingestible composition that includes a protective barrier made of an inter-digitated structure of two different materials;

[012] FIG. 7 provides a side view of one aspect of an ingestible composition that includes a protective barrier made of an overlapping structure of two different materials;

[013] FIG. 8 provides a side view of one aspect of an ingestible composition that includes a multi-layer protective barrier;

[014] FIG. 9 provides a side view of one aspect of an ingestible composition that includes a multi-layer protective barrier;

[015] FIG. 10 provides a side view of one aspect of an ingestible composition that includes a galvanic protective barrier;

[016] FIG. 11 provides a side view of one aspect of an ingestible composition that includes a mono-layer protective barrier with one or more fluid passageways;

WHAT IS CLAIMED IS:

1. A composition comprising:

a shelf-life stability component entirely enclosing ~~physically associated with~~ a minimally dimensioned component to provide a protective barrier for the minimally dimensioned component, wherein the shelf-life stability component is configured to disrupt when the shelf-life stability component is in contact with a liquid;

an ingestible device comprising:

a partial power source comprising first and second consumable electrodes formed of dissimilar materials configured to generate a voltage to energize the ingestible device when the first and second electrodes are in contact with an electrically conductive fluid to supply power to the ingestible device, wherein the ingestible device is configured to produce a conductive current flow through the electrically conductive fluid when energized.

2. The composition according to Claim 1, wherein the composition is an ingestible composition comprising the shelf-life stability component and the minimally dimensioned component, wherein the minimally dimensioned component is an ingestible component ~~physically associated with the ingestible composition~~.

~~3. The ingestible composition according to Claim 2, wherein the composition further comprises an ingestible device.~~

43. The ingestible composition according to Claim ~~3~~1, wherein the ingestible device is an ingestible event marker.

~~5~~4. The composition according to Claim 1, wherein the ingestible composition is stable for 1 year or longer under conditions in which the temperature ranges from 10 to 40°C, the pressure ranges from 0.5 to 2.0 ATM and the relative humidity ranges from 10 to 100%.

~~6~~5. The composition according to Claim 1, wherein the shelf-life stability component comprises a water-vapor desensitizer.

~~7~~6. The composition according to Claim ~~6~~5, wherein the water-vapor desensitizer comprises a protective barrier that rapidly disrupts upon contact with a liquid.

~~8~~7. The composition according to Claim ~~7~~6, wherein the protective barrier comprises a homogeneous layer of a single material.

~~9~~8. The composition according to Claim ~~7~~6, wherein the protective barrier comprises two or more distinct materials.

~~109~~. The composition according to Claim ~~98~~, wherein the two or more distinct materials are present as a single homogeneous or heterogeneous layer.

~~1110~~. The composition according to Claim ~~98~~, wherein the two or more distinct materials are present as a multilayer structure.

~~1211~~. The composition according to Claim ~~98~~, wherein the two or more distinct materials exhibit different aqueous medium solubility.

~~1312~~. The composition according to Claim ~~98~~, wherein the two or more distinct materials exhibit different aqueous medium physical properties.

~~1413~~. The composition according to Claim ~~98~~, wherein the two or more distinct materials comprise a first material and a second material that solubilizes the first material.

~~1514~~. The composition according to Claim ~~76~~, wherein the protective barrier comprises a lipid.

~~1615~~. The composition according to Claim ~~76~~, wherein the protective barrier comprises a low-melting point material.

~~1716~~. The composition according to Claim ~~76~~, wherein the protective barrier is a galvanic protective barrier.

~~1817~~. The composition according to Claim ~~76~~, wherein the protective barrier is configured to be disruptable by a device present in the composition.

~~1918~~. The composition according to Claim ~~76~~, wherein the protective barrier is configured to provide aqueous liquid passage through the protective barrier upon contact of ingestible composition with an aqueous liquid.

~~20~~19. The composition according to Claim ~~7~~6, wherein the protective barrier comprises a liquid passageway.

~~21~~20. The composition according to Claim ~~6~~5, wherein the water-vapor desensitizer comprises a desiccant.

~~22~~21. The composition according to Claim 1, wherein minimally dimensioned component is a micro-battery.

~~23. A system comprising:~~
~~an ingestible composition comprising:~~
~~a shelf-life stability component; and~~
~~an ingestible component associated with the shelf-life stability component; and~~
~~a receiver configured to receive a communication associated with the ingestible composition.~~

~~24. A method comprising combining a minimally dimensioned component and a shelf-life stability component.~~

~~25. The method according to Claim 24, wherein the minimally dimensioned component is an ingestible component and the method produces an ingestible composition.~~

~~26. The method according to Claim 25, wherein the method comprises stably associating the ingestible component and the shelf-life stability component.~~

~~27. The method according to Claim 26, wherein the method comprises one or more protocols selected from the group consisting of laminating, pressing, stamping, extruding, molding and coating.~~

~~28. The method according to Claim 27, wherein at least a portion of the method is automated.~~