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 minimally dimensioned component comprising an ingestible

event marker and a pharmaceutically acceptable solid carrier; and a shelf-life stability component entirely enclosing ~~a~~ the minimally dimensioned component to provide a protective barrier for the minimally dimensioned component, wherein at least a portion of the shelf-life stability component is configured to disrupt when the shelf-life stability component is in contact with a liquid; wherein the ~~an~~ ingestible ~~device comprising~~ event marker comprises: a control device; and a partial power source comprising first and second consumable electrodes formed of dissimilar electromechanical materials configured to contact an electrically conductive fluid and generate a voltage to energize the ingestible event marker ~~device when the first and second electrodes are in contact with an electrically conductive fluid~~ ; and ~~to supply power to the ingestible device,~~ wherein the energized ingestible ~~device~~ event marker is configured to produce a conductive current flow through the electrically conductive fluid ~~when energized~~; wherein the control device is configured to control the conductive current flow; and wherein the shelf-life stability component comprises a water-vapor desensitizer comprising a desiccant.

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

WHAT IS CLAIMED IS:

1. A composition comprising:

a minimally dimensioned component comprising an ingestible event marker and a pharmaceutically acceptable solid carrier; and

a shelf-life stability component entirely enclosing thea minimally dimensioned component to provide a protective barrier for the minimally dimensioned component, wherein at least a portion of the shelf-life stability component is configured to disrupt when the shelf-life stability component is in contact with a liquid;

an wherein the ingestible event marker comprisesdevice comprising:

a control device; and

a partial power source comprising first and second consumable electrodes formed of dissimilar electrochemical materials configured to contact an electrically conductive fluid and generate a voltage to energize the ingestible event marker device when the first and second electrodes are in contact with an electrically conductive fluid ; and to supply power to the ingestible device,

wherein the energized ingestible event marker device is configured to produce a conductive current flow through the electrically conductive fluid when energized;

wherein the control device is configured to control the conductive current flow; and

wherein the shelf-life stability component comprises a water-vapor desensitizer comprising a desiccant.

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.

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

34. 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%.

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

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

47. The composition according to Claim 16, wherein the shelf-life stability component ~~protective barrier~~ comprises a homogeneous layer of a single material.

58. The composition according to Claim 16, wherein the shelf-life stability component ~~protective barrier~~ comprises two or more distinct materials.

69. The composition according to Claim 58, wherein the two or more distinct materials are present as a single homogeneous or heterogeneous layer.

710. The composition according to Claim 58, wherein the two or more distinct materials are present as a multilayer structure.

811. The composition according to Claim 58, wherein the two or more distinct materials exhibit different aqueous medium solubility.

912. The composition according to Claim 58, wherein the two or more distinct materials exhibit different aqueous medium physical properties.

10~~13~~.The composition according to Claim 5~~8~~, wherein the two or more distinct materials comprise a first material and a second material that solubilizes the first material.

11~~14~~.The composition according to Claim 1~~6~~, wherein the shelf-life stability component ~~protective barrier~~ comprises a lipid.

12~~15~~. The composition according to Claim 1~~6~~, wherein the shelf-life stability component ~~protective barrier~~ comprises a low-melting point material.

13~~16~~. The composition according to Claim 1~~6~~, wherein the shelf-life stability component ~~protective barrier~~ is a galvanic protective barrier.

14~~17~~. The composition according to Claim 1~~6~~, wherein the shelf-life stability component ~~protective barrier~~ is configured to be disruptable by ~~a~~ the ingestible event marker~~device present in the composition~~.

15~~18~~. The composition according to Claim 1~~6~~, wherein the shelf-life stability component ~~protective barrier~~ is configured to provide aqueous liquid passage through the shelf-life stability component ~~protective barrier~~ upon contact of ingestible composition with an aqueous liquid.

16~~19~~. The composition according to Claim 1~~6~~, wherein the shelf-life stability component ~~protective barrier~~ comprises a liquid passageway.

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

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

17. The composition according to claim 1, wherein the shelf-life stability component further comprises at least one of the following:

an electrochemical material variant;

an antioxidant; and

a stabilizer.

18. The composition according to claim 1, further comprising at least one additional shelf-life stability component.

19. The composition according to claim 1, wherein the desiccant comprises an indicator compound that provides an indication of whether or not the desiccant has reached capacity with respect to an amount of water the desiccant is able to sequester.