

**IN THE UNITED STATES PATENT AND TRADEMARK OFFICE**

In re Application of: CYBIN IRL LIMITED Confirmation No.: 7679  
Serial No.: 18/561,152 Group No.:  
Filing or 371(c) Date: May 17, 2022 Examiner:  
Entitled: FORMULATIONS OF PSILOCYBIN

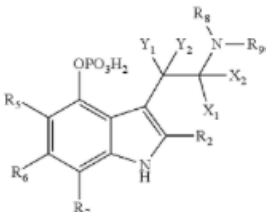
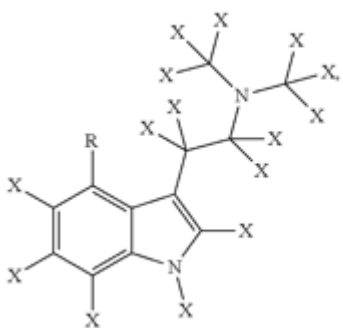
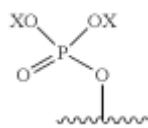
**THIRD-PARTY PRE-ISSUANCE SUBMISSION**

Examiner:

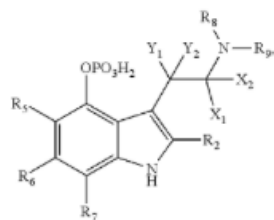
The following documents, which are also identified in the Form PTO/SB/429 filed herewith, are submitted for your consideration as being of potential relevance to the examination of the present application.

1. U.S. Pat. App. Pub. No. US/11000534B1 "Deuterated derivatives of psilocybin and uses thereof" (Published 11 May 2021)
2. ISHIER RAOTE (2007) "Serotonin Receptors in Neuobiology - Serotonin 2A (5-HT2A) Receptor Function: Ligand-Dependent Mechanisms and Pathways" *CRC Press/Taylor & Francis*. ISBN 0849339774. Pages 104-132.

Attached hereto is a claim chart providing a concise description of the relevance of each reference in the document list to the elements of the presently pending claims.

U.S.S.N. 18/561,152 Pending Claims	References
<p>1. A pharmaceutical composition, comprising: a solid dispersion comprising a therapeutically effective amount of a compound of Formula (I) in amorphous form dispersed in a polymer, or a pharmaceutically acceptable salt, stereoisomer, a tautomer, or solvate thereof, wherein:</p>  <p>R2, R5, R6, and R7 are independently selected from the group consisting of hydrogen and deuterium, R8 and R9 are independently selected from the group consisting of —CH3 and —CD3, and X1, X2, Y1, and Y2 are independently selected from the group consisting of hydrogen and deuterium.</p>	<p>1. U.S. Pat. App. Pub. No. US/11000534B1 “Deuterated derivatives of psilocybin and uses thereof” (Published 11 May 2021)</p> <p><b>From Summary of the Invention: The compositions described herein comprise deuterated psilocybin and deuterated psilocin. In certain embodiments, the composition comprises a compound of Formula (I):</b></p>  <p><b>or a pharmaceutically acceptable salt, prodrug, hydrate, or solvate thereof;</b> <b>wherein R is selected from —OX or</b></p>  <p><b>each X is independently protium or deuterium; and at least one X is enriched for deuterium.</b></p> <p><b>From Definitions: Reference to deuterated psilocybin or deuterated psilocin herein (i.e., a compound of Formula (I)) or a pharmaceutically acceptable salt, prodrug, hydrate, or solvate thereof, includes all amorphous and polymorph forms.</b></p> <p><b>From Detailed Description of Certain Embodiments of the Invention: In certain embodiments, a provided composition comprises one or more disintegrants or solubilizing agents, such as a cyclodextrin, or a carboxymethyl cellulose, calcium carboxymethyl cellulose, low-substituted hydroxypropyl cellulose, sodium croscarmellose, sodium carboxy starch, calcium carbonate, sodium carbonate and the like.</b></p> <p><i>From the patent of interest 18/561,152</i></p>

a compound of Formula (I) in amorphous form dispersed in a polymer, or a pharmaceutically acceptable salt, stereoisomer, a tautomer, or solvate thereof,



wherein:

**R2, R5, R6, and R7 are independently selected from the group consisting of hydrogen and deuterium,**

**R8 and R9 are independently selected from the group consisting of —CH3 and —CD3, and**

**X1, X2, Y1, and Y2 are independently selected from the group consisting of hydrogen and deuterium.**

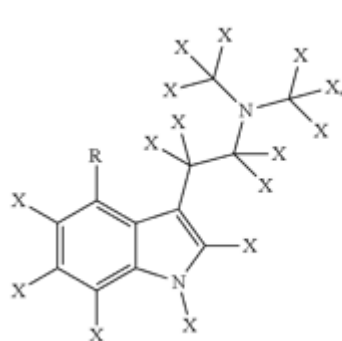
1. U.S. Pat. App. Pub. No. US/11000534B1 “Deuterated derivatives of psilocybin and uses thereof” (Published 11 May 2021)

**From Summary of the Invention: In certain embodiments, the percentage of the amount of the compound of Formula (I), or a pharmaceutically acceptable salt, prodrug, hydrate, or solvate thereof, relative to the total amount of psilocybin present in the composition ranges from about 1% to about 100%.**

2. The pharmaceutical composition of claim 1, wherein R2, R5, R6, and R7 are hydrogen.

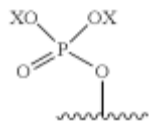
1. U.S. Pat. App. Pub. No. US/11000534B1 “Deuterated derivatives of psilocybin and uses thereof” (Published 11 May 2021)

**From Summary of the Invention: The compositions described herein comprise deuterated psilocybin and deuterated psilocin. In certain embodiments, the composition comprises a compound of Formula (I):**



**or a pharmaceutically acceptable salt, prodrug, hydrate, or solvate thereof;**

**wherein R is selected from —OX or**

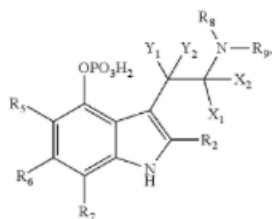


**each X is independently protium or deuterium; and at least one X is enriched for deuterium.**

**From Definitions: Reference to deuterated psilocybin or deuterated psilocin herein (i.e., a compound of Formula (I)) or a pharmaceutically acceptable salt, prodrug, hydrate, or solvate thereof, includes all amorphous and polymorph forms.**

**From Detailed Description of Certain Embodiments of the Invention: In certain embodiments, a provided composition comprises one or more disintegrants or solubilizing agents, such as a cyclodextrin, or a carboxymethyl cellulose, calcium carboxymethyl cellulose, low-substituted hydroxypropyl cellulose, sodium croscarmellose, sodium carboxy starch, calcium carbonate, sodium carbonate and the like.**

*From the patent of interest 18/561,152 a compound of Formula (I) in amorphous form dispersed in a polymer, or a pharmaceutically acceptable salt, stereoisomer, a tautomer, or solvate thereof,*



*wherein:*

**R<sub>2</sub>, R<sub>5</sub>, R<sub>6</sub>, and R<sub>7</sub> are independently selected from the group consisting of hydrogen and deuterium,**

**R<sub>8</sub> and R<sub>9</sub> are independently selected from the group consisting of —CH<sub>3</sub> and —CD<sub>3</sub>, and**

**X<sub>1</sub>, X<sub>2</sub>, Y<sub>1</sub>, and Y<sub>2</sub> are independently selected from the group consisting of hydrogen and deuterium.**

1. U.S. Pat. App. Pub. No. US/11000534B1 “Deuterated derivatives of psilocybin and uses thereof” (Published 11 May 2021)

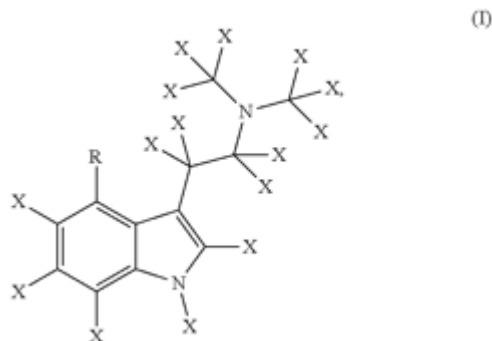
**From Summary of the Invention: In certain embodiments, the percentage of the amount of the compound of Formula (I), or a pharmaceutically acceptable salt, prodrug, hydrate, or solvate thereof, relative to the total amount of psilocybin present in the composition ranges from about 1% to about 100%.**

3. The pharmaceutical composition of claim 1,

1. U.S. Pat. App. Pub. No. US/11000534B1 “Deuterated derivatives of psilocybin and uses thereof” (Published 11 May 2021)

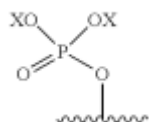
wherein R2, R5, R6, and R7 are deuterium.

From **Summary of the Invention: The compositions described herein comprise deuterated psilocybin and deuterated psilocin. In certain embodiments, the composition comprises a compound of Formula (I):**



**or a pharmaceutically acceptable salt, prodrug, hydrate, or solvate thereof;**

**wherein R is selected from —OX or**



**each X is independently protium or deuterium; and at least one X is enriched for deuterium.**

**From Definitions: Reference to deuterated psilocybin or deuterated psilocin herein (i.e., a compound of Formula (I)) or a pharmaceutically acceptable salt, prodrug, hydrate, or solvate thereof, includes all amorphous and polymorph forms.**

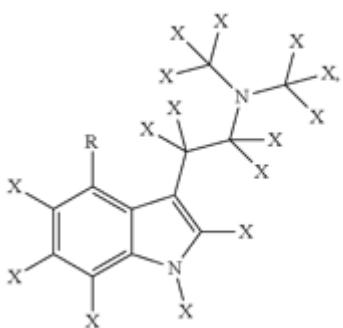
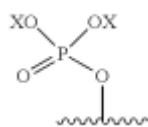
**From Detailed Description of Certain Embodiments of the Invention: In certain embodiments, a provided composition comprises one or more disintegrants or solubilizing agents, such as a cyclodextrin, or a carboxymethyl cellulose, calcium carboxymethyl cellulose, low-substituted hydroxypropyl cellulose, sodium croscarmellose, sodium carboxy starch, calcium carbonate, sodium carbonate and the like.**

1. U.S. Pat. App. Pub. No. US/11000534B1 “Deuterated derivatives of psilocybin and uses thereof” (Published 11 May 2021)

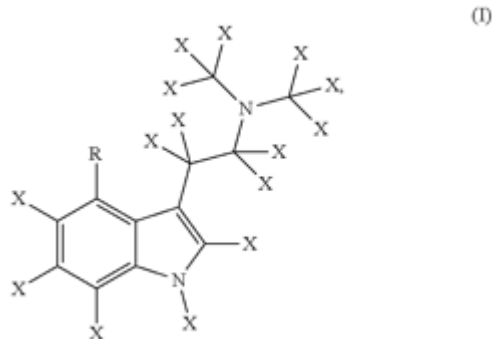
**From Summary of the Invention: In certain embodiments, the percentage of the amount of the compound of Formula (I), or a pharmaceutically acceptable salt, prodrug, hydrate, or solvate thereof, relative to the total amount of psilocybin present in the composition ranges from about 1% to about 100%.**

4. The pharmaceutical composition of claim 1,

1. U.S. Pat. App. Pub. No. US/11000534B1 “Deuterated derivatives of psilocybin and uses thereof” (Published 11 May 2021)

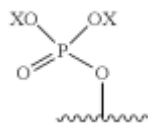
<p>wherein R8 and R9 are —CH3.</p>	<p>From <b>Summary of the Invention: The compositions described herein comprise deuterated psilocybin and deuterated psilocin. In certain embodiments, the composition comprises a compound of Formula (I):</b></p> <p style="text-align: center;">(I)</p>  <p>or a pharmaceutically acceptable salt, prodrug, hydrate, or solvate thereof; wherein R is selected from —OX or</p>  <p>each X is independently protium or deuterium; and at least one X is enriched for deuterium.</p> <p>From <b>Definitions: Reference to deuterated psilocybin or deuterated psilocin herein (i.e., a compound of Formula (I)) or a pharmaceutically acceptable salt, prodrug, hydrate, or solvate thereof, includes all amorphous and polymorph forms.</b></p> <p>From <b>Detailed Description of Certain Embodiments of the Invention: In certain embodiments, a provided composition comprises one or more disintegrants or solubilizing agents, such as a cyclodextrin, or a carboxymethyl cellulose, calcium carboxymethyl cellulose, low-substituted hydroxypropyl cellulose, sodium croscarmellose, sodium carboxy starch, calcium carbonate, sodium carbonate and the like.</b></p> <p>1. U.S. Pat. App. Pub. No. US/11000534B1 “Deuterated derivatives of psilocybin and uses thereof” (Published 11 May 2021)</p> <p>From <b>Summary of the Invention: In certain embodiments, the percentage of the amount of the compound of Formula (I), or a pharmaceutically acceptable salt, prodrug, hydrate, or solvate thereof, relative to the total amount of psilocybin present in the composition ranges from about 1% to about 100%.</b></p>
<p>5. The pharmaceutical composition of claim 1, wherein R8 and R9 are —CD3.</p>	<p>1. U.S. Pat. App. Pub. No. US/11000534B1 “Deuterated derivatives of psilocybin and uses thereof” (Published 11 May 2021)</p>

From **Summary of the Invention: The compositions described herein comprise deuterated psilocybin and deuterated psilocin. In certain embodiments, the composition comprises a compound of Formula (I):**



**or a pharmaceutically acceptable salt, prodrug, hydrate, or solvate thereof;**

**wherein R is selected from —OX or**



**each X is independently protium or deuterium; and at least one X is enriched for deuterium.**

From **Definitions: Reference to deuterated psilocybin or deuterated psilocin herein (i.e., a compound of Formula (I)) or a pharmaceutically acceptable salt, prodrug, hydrate, or solvate thereof, includes all amorphous and polymorph forms.**

From **Detailed Description of Certain Embodiments of the Invention: In certain embodiments, a provided composition comprises one or more disintegrants or solubilizing agents, such as a cyclodextrin, or a carboxymethyl cellulose, calcium carboxymethyl cellulose, low-substituted hydroxypropyl cellulose, sodium croscarmellose, sodium carboxy starch, calcium carbonate, sodium carbonate and the like.**

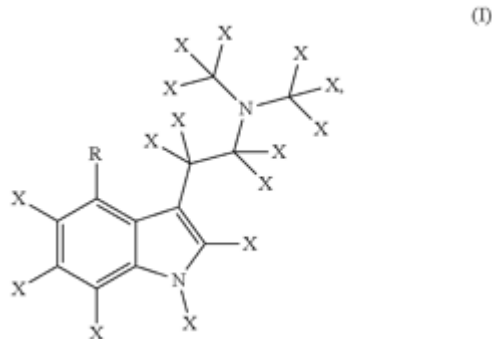
1. U.S. Pat. App. Pub. No. US/11000534B1 “Deuterated derivatives of psilocybin and uses thereof” (Published 11 May 2021)

From **Summary of the Invention: In certain embodiments, the percentage of the amount of the compound of Formula (I), or a pharmaceutically acceptable salt, prodrug, hydrate, or solvate thereof, relative to the total amount of psilocybin present in the composition ranges from about 1% to about 100%.**

6. The pharmaceutical composition of claim 1, wherein X1, X2, Y1, and Y2 are deuterium.

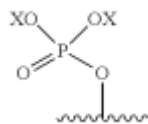
1. U.S. Pat. App. Pub. No. US/11000534B1 “Deuterated derivatives of psilocybin and uses thereof” (Published 11 May 2021)

From **Summary of the Invention: The compositions described herein comprise deuterated psilocybin and deuterated psilocin. In certain embodiments, the composition comprises a compound of Formula (I):**



**or a pharmaceutically acceptable salt, prodrug, hydrate, or solvate thereof;**

**wherein R is selected from —OX or**



**each X is independently protium or deuterium; and at least one X is enriched for deuterium.**

From **Definitions: Reference to deuterated psilocybin or deuterated psilocin herein (i.e., a compound of Formula (I)) or a pharmaceutically acceptable salt, prodrug, hydrate, or solvate thereof, includes all amorphous and polymorph forms.**

From **Detailed Description of Certain Embodiments of the Invention: In certain embodiments, a provided composition comprises one or more disintegrants or solubilizing agents, such as a cyclodextrin, or a carboxymethyl cellulose, calcium carboxymethyl cellulose, low-substituted hydroxypropyl cellulose, sodium croscarmellose, sodium carboxy starch, calcium carbonate, sodium carbonate and the like.**

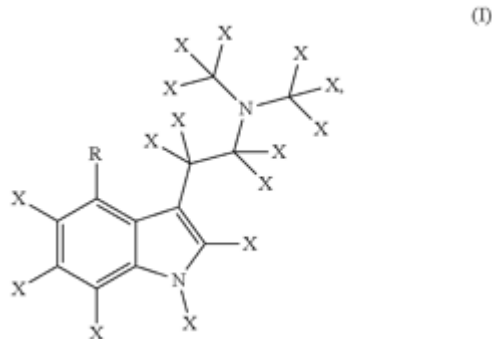
1. U.S. Pat. App. Pub. No. US/11000534B1 “Deuterated derivatives of psilocybin and uses thereof” (Published 11 May 2021)

From **Summary of the Invention: In certain embodiments, the percentage of the amount of the compound of Formula (I), or a pharmaceutically acceptable salt, prodrug, hydrate, or solvate thereof, relative to the total amount of psilocybin present in the composition ranges from about 1% to about 100%.**

9. The pharmaceutical composition of claim 1, wherein Y1 and Y2 are hydrogen.

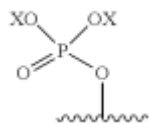
1. U.S. Pat. App. Pub. No. US/11000534B1 “Deuterated derivatives of psilocybin and uses thereof” (Published 11 May 2021)

From **Summary of the Invention: The compositions described herein comprise deuterated psilocybin and deuterated psilocin. In certain embodiments, the composition comprises a compound of Formula (I):**



**or a pharmaceutically acceptable salt, prodrug, hydrate, or solvate thereof;**

**wherein R is selected from —OX or**



**each X is independently protium or deuterium; and at least one X is enriched for deuterium.**

From **Definitions: Reference to deuterated psilocybin or deuterated psilocin herein (i.e., a compound of Formula (I)) or a pharmaceutically acceptable salt, prodrug, hydrate, or solvate thereof, includes all amorphous and polymorph forms.**

From **Detailed Description of Certain Embodiments of the Invention: In certain embodiments, a provided composition comprises one or more disintegrants or solubilizing agents, such as a cyclodextrin, or a carboxymethyl cellulose, calcium carboxymethyl cellulose, low-substituted hydroxypropyl cellulose, sodium croscarmellose, sodium carboxy starch, calcium carbonate, sodium carbonate and the like.**

1. U.S. Pat. App. Pub. No. US/11000534B1 “Deuterated derivatives of psilocybin and uses thereof” (Published 11 May 2021)

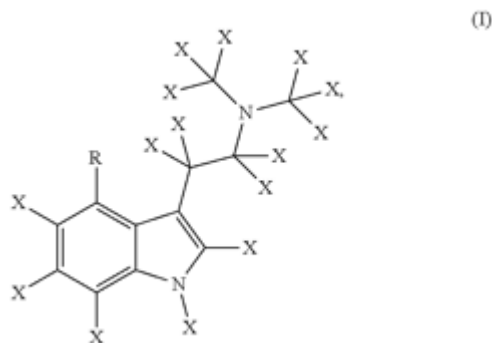
From **Summary of the Invention: In certain embodiments, the percentage of the amount of the compound of Formula (I), or a pharmaceutically acceptable salt, prodrug, hydrate, or solvate thereof, relative to the total amount of psilocybin present in the composition ranges from about 1% to about 100%.**

10. The pharmaceutical composition of claim 1, wherein the compound of Formula (I) is at

1. U.S. Pat. App. Pub. No. US/11000534B1 “Deuterated derivatives of psilocybin and uses thereof” (Published 11 May 2021)

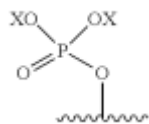
least one selected from the group consisting of: Figure US20240261306A1-20240808-C00011 Figure US20240261306A1-20240808-C00012 or a pharmaceutically acceptable salt, stereoisomer, a tautomer, or solvate thereof.

From **Summary of the Invention: The compositions described herein comprise deuterated psilocybin and deuterated psilocin. In certain embodiments, the composition comprises a compound of Formula (I):**



**or a pharmaceutically acceptable salt, prodrug, hydrate, or solvate thereof;**

**wherein R is selected from —OX or**



**each X is independently protium or deuterium; and at least one X is enriched for deuterium.**

From **Definitions: Reference to deuterated psilocybin or deuterated psilocin herein (i.e., a compound of Formula (I)) or a pharmaceutically acceptable salt, prodrug, hydrate, or solvate thereof, includes all amorphous and polymorph forms.**

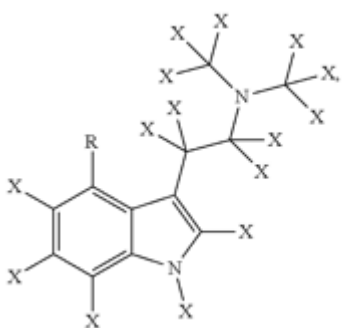
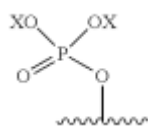
From **Detailed Description of Certain Embodiments of the Invention: In certain embodiments, a provided composition comprises one or more disintegrants or solubilizing agents, such as a cyclodextrin, or a carboxymethyl cellulose, calcium carboxymethyl cellulose, low-substituted hydroxypropyl cellulose, sodium croscarmellose, sodium carboxy starch, calcium carbonate, sodium carbonate and the like.**

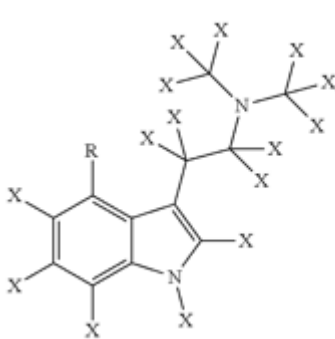
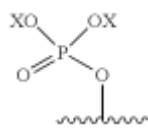
1. U.S. Pat. App. Pub. No. US/11000534B1 “Deuterated derivatives of psilocybin and uses thereof” (Published 11 May 2021)

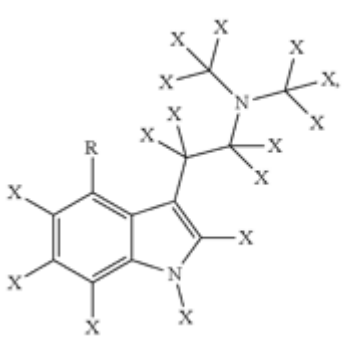
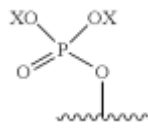
From **Summary of the Invention: In certain embodiments, the percentage of the amount of the compound of Formula (I), or a pharmaceutically acceptable salt, prodrug, hydrate, or solvate thereof, relative to the total amount of psilocybin present in the composition ranges from about 1% to about 100%.**

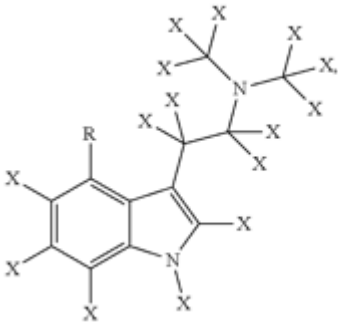
11. The pharmaceutical composition of claim 1, wherein the compound of Formula (I) is

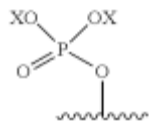


	<p><b>amount from about 0.001% to 50% based on the weight of all the components of the composition.</b></p> <p>1. U.S. Pat. App. Pub. No. US/11000534B1 “Deuterated derivatives of psilocybin and uses thereof” (Published 11 May 2021)</p> <p><b>From Summary of the Invention: In certain embodiments, the percentage of the amount of the compound of Formula (I), or a pharmaceutically acceptable salt, prodrug, hydrate, or solvate thereof, relative to the total amount of psilocybin present in the composition ranges from about 1% to about 100%.</b></p>
<p>16. The pharmaceutical composition of claim 1, wherein a weight ratio of the compound of Formula (I) to the polymer in the solid dispersion is from 1:9 to 9:1.</p>	<p>1. U.S. Pat. App. Pub. No. US/11000534B1 “Deuterated derivatives of psilocybin and uses thereof” (Published 11 May 2021)</p> <p><b>From Summary of the Invention: The compositions described herein comprise deuterated psilocybin and deuterated psilocin. In certain embodiments, the composition comprises a compound of Formula (I):</b></p> <div style="text-align: center;">  <p>(I)</p> </div> <p><b>or a pharmaceutically acceptable salt, prodrug, hydrate, or solvate thereof;</b>  <b>wherein R is selected from —OX or</b></p> <div style="text-align: center;">  </div> <p><b>each X is independently protium or deuterium; and at least one X is enriched for deuterium.</b></p> <p><b>From Definitions: Reference to deuterated psilocybin or deuterated psilocin herein (i.e., a compound of Formula (I)) or a pharmaceutically acceptable salt, prodrug, hydrate, or solvate thereof, includes all amorphous and polymorph forms.</b></p> <p><b>From Detailed Description of Certain Embodiments of the Invention: In certain embodiments, a provided composition comprises one or more disintegrants or solubilizing agents, such as a cyclodextrin, or a carboxymethyl cellulose, calcium carboxymethyl cellulose, low-</b></p>

	<p><b>substituted hydroxypropyl cellulose, sodium croscarmellose, sodium carboxy starch, calcium carbonate, sodium carbonate and the like.</b></p> <p><b>From Detailed Description of Certain Embodiments of the Invention: In another aspect, the compound of Formula (I), or a pharmaceutically acceptable salt, prodrug, hydrate, or solvate thereof, is included in an amount from about 0.001% to 50% based on the weight of all the components of the composition.</b></p> <p>1. U.S. Pat. App. Pub. No. US/11000534B1 “Deuterated derivatives of psilocybin and uses thereof” (Published 11 May 2021)</p> <p><b>From Summary of the Invention: In certain embodiments, the percentage of the amount of the compound of Formula (I), or a pharmaceutically acceptable salt, prodrug, hydrate, or solvate thereof, relative to the total amount of psilocybin present in the composition ranges from about 1% to about 100%.</b></p>
<p>17. The pharmaceutical composition of claim 1, wherein the polymer is at least one selected from the group consisting of a vinyl polymer, a methacrylate, a polysaccharide, gelatin, and a cellulose polymer, or a blend or a copolymer thereof.</p>	<p>1. U.S. Pat. App. Pub. No. US/11000534B1 “Deuterated derivatives of psilocybin and uses thereof” (Published 11 May 2021)</p> <p><b>From Summary of the Invention: The compositions described herein comprise deuterated psilocybin and deuterated psilocin. In certain embodiments, the composition comprises a compound of Formula (I):</b></p> <div style="text-align: center;">  <p>(I)</p> </div> <p><b>or a pharmaceutically acceptable salt, prodrug, hydrate, or solvate thereof;</b>  <b>wherein R is selected from —OX or</b></p> <div style="text-align: center;">  </div> <p><b>each X is independently protium or deuterium; and at least one X is enriched for deuterium.</b></p> <p><b>From Definitions: Reference to deuterated psilocybin or deuterated psilocin herein (i.e., a compound of Formula (I)) or a pharmaceutically acceptable salt, prodrug, hydrate, or solvate thereof, includes all amorphous and polymorph forms.</b></p>

	<p>From <b>Detailed Description of Certain Embodiments of the Invention:</b> <b>In certain embodiments, a provided composition comprises one or more disintegrants or solubilizing agents, such as a cyclodextrin, or a carboxymethyl cellulose, calcium carboxymethyl cellulose, low-substituted hydroxypropyl cellulose, sodium croscarmellose, sodium carboxy starch, calcium carbonate, sodium carbonate and the like.</b></p> <p>1. U.S. Pat. App. Pub. No. US/11000534B1 “Deuterated derivatives of psilocybin and uses thereof” (Published 11 May 2021)</p> <p>From <b>Summary of the Invention:</b> <b>In certain embodiments, the percentage of the amount of the compound of Formula (I), or a pharmaceutically acceptable salt, prodrug, hydrate, or solvate thereof, relative to the total amount of psilocybin present in the composition ranges from about 1% to about 100%.</b></p>
<p>18. The pharmaceutical composition of claim 1, wherein the polymer is at least one selected from the group consisting of gelatin, polyvinyl acetate, polyvinyl alcohol, polyvinylpyrrolidone, pullulan, hydroxypropyl methyl cellulose, hydroxypropyl methyl cellulose acetate succinate, and a methacrylate copolymer, or a blend or a copolymer thereof.</p>	<p>1. U.S. Pat. App. Pub. No. US/11000534B1 “Deuterated derivatives of psilocybin and uses thereof” (Published 11 May 2021)</p> <p>From <b>Summary of the Invention:</b> <b>The compositions described herein comprise deuterated psilocybin and deuterated psilocin. In certain embodiments, the composition comprises a compound of Formula (I):</b></p> <div style="text-align: center;">  <p>(I)</p> </div> <p><b>or a pharmaceutically acceptable salt, prodrug, hydrate, or solvate thereof;</b>  <b>wherein R is selected from —OX or</b></p> <div style="text-align: center;">  </div> <p><b>each X is independently protium or deuterium; and at least one X is enriched for deuterium.</b></p> <p>From <b>Definitions:</b> <b>Reference to deuterated psilocybin or deuterated psilocin herein (i.e., a compound of Formula (I)) or a pharmaceutically acceptable salt, prodrug, hydrate, or solvate thereof, includes all amorphous and polymorph forms.</b></p>

	<p>From <b>Detailed Description of Certain Embodiments of the Invention:</b> <b>In certain embodiments, a provided composition comprises one or more disintegrants or solubilizing agents, such as a cyclodextrin, or a carboxymethyl cellulose, calcium carboxymethyl cellulose, <b>low-substituted hydroxypropyl cellulose</b>, sodium croscarmellose, sodium carboxy starch, calcium carbonate, sodium carbonate <b>and the like.</b></b></p> <p>1. U.S. Pat. App. Pub. No. US/11000534B1 “Deuterated derivatives of psilocybin and uses thereof” (Published 11 May 2021)</p> <p>From <b>Summary of the Invention:</b> <b>In certain embodiments, the percentage of the amount of the compound of Formula (I), or a pharmaceutically acceptable salt, prodrug, hydrate, or solvate thereof, relative to the total amount of psilocybin present in the composition ranges from about 1% to about 100%.</b></p>
<p>19. The pharmaceutical composition of claim 1, wherein the polymer comprises gelatin.</p>	
<p>20. The pharmaceutical composition of claim 19, wherein the solid dispersion further comprises a pharmaceutically acceptable excipient.</p>	
<p>21. The pharmaceutical composition of claim 20, wherein the pharmaceutically acceptable excipient comprises mannitol.</p>	<p>1. U.S. Pat. App. Pub. No. US/11000534B1 “Deuterated derivatives of psilocybin and uses thereof” (Published 11 May 2021)</p> <p>From <b>Summary of the Invention:</b> <b>The compositions described herein comprise deuterated psilocybin and deuterated psilocin. In certain embodiments, the composition comprises a compound of Formula (I):</b></p> <p style="text-align: center;">(I)</p>  <p><b>or a pharmaceutically acceptable salt, prodrug, hydrate, or solvate thereof;</b>  <b>wherein R is selected from —OX or</b></p>



**each X is independently protium or deuterium; and at least one X is enriched for deuterium.**

**From Definitions: Reference to deuterated psilocybin or deuterated psilocin herein (i.e., a compound of Formula (I)) or a pharmaceutically acceptable salt, prodrug, hydrate, or solvate thereof, includes all amorphous and polymorph forms.**

**From Detailed Description of Certain Embodiments of the Invention: In certain embodiments, a provided composition comprises one or more disintegrants or solubilizing agents, such as a cyclodextrin, or a carboxymethyl cellulose, calcium carboxymethyl cellulose, low-substituted hydroxypropyl cellulose, sodium croscarmellose, sodium carboxy starch, calcium carbonate, sodium carbonate and the like.**

**From Detailed Description of Certain Embodiments of the Invention: In certain embodiments, pharmaceutical excipients for an oral formulation include:** diluents, such as, microcrystalline cellulose, starch, mannitol, calcium hydrogen phosphate anhydrous or co-mixtures of silicon dioxide, calcium carbonate, microcrystalline cellulose and talc

1. U.S. Pat. App. Pub. No. US/11000534B1 “Deuterated derivatives of psilocybin and uses thereof” (Published 11 May 2021)

**From Summary of the Invention: In certain embodiments, the percentage of the amount of the compound of Formula (I), or a pharmaceutically acceptable salt, prodrug, hydrate, or solvate thereof, relative to the total amount of psilocybin present in the composition ranges from about 1% to about 100%.**

22. The pharmaceutical composition of claim 1, wherein the polymer comprises a copolymer of vinyl pyrrolidone and vinyl acetate (PVP-VAc).

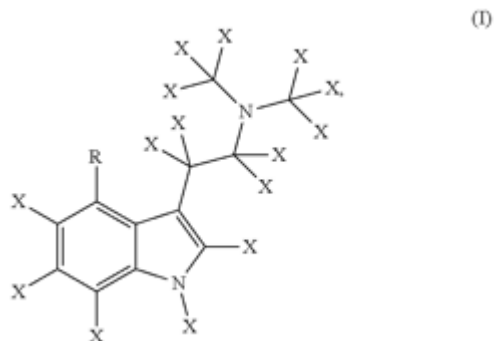
23. The pharmaceutical composition of claim 1, wherein the polymer comprises a methacrylate copolymer.

24. The pharmaceutical composition of claim 1,

1. U.S. Pat. App. Pub. No. US/11000534B1 “Deuterated derivatives of psilocybin and uses thereof” (Published 11 May 2021)

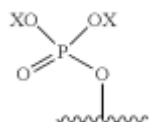
wherein the polymer comprises a cellulose polymer.

From **Summary of the Invention: The compositions described herein comprise deuterated psilocybin and deuterated psilocin. In certain embodiments, the composition comprises a compound of Formula (I):**



**or a pharmaceutically acceptable salt, prodrug, hydrate, or solvate thereof;**

**wherein R is selected from —OX or**



**each X is independently protium or deuterium; and at least one X is enriched for deuterium.**

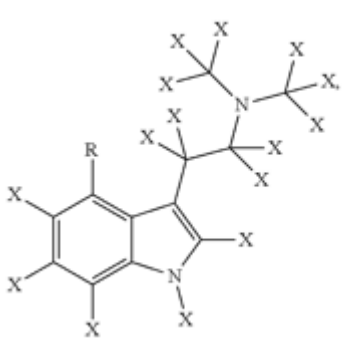
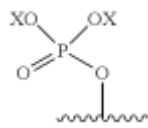
From **Definitions: Reference to deuterated psilocybin or deuterated psilocin herein (i.e., a compound of Formula (I)) or a pharmaceutically acceptable salt, prodrug, hydrate, or solvate thereof, includes all amorphous and polymorph forms.**

From **Detailed Description of Certain Embodiments of the Invention: In certain embodiments, a provided composition comprises one or more disintegrants or solubilizing agents, such as a cyclodextrin, or a carboxymethyl cellulose, calcium carboxymethyl cellulose, low-substituted hydroxypropyl cellulose, sodium croscarmellose, sodium carboxy starch, calcium carbonate, sodium carbonate and the like.**

1. U.S. Pat. App. Pub. No. US/11000534B1 “Deuterated derivatives of psilocybin and uses thereof” (Published 11 May 2021)

From **Summary of the Invention: In certain embodiments, the percentage of the amount of the compound of Formula (I), or a pharmaceutically acceptable salt, prodrug, hydrate, or solvate thereof, relative to the total amount of psilocybin present in the composition ranges from about 1% to about 100%.**

25. The pharmaceutical composition of claim 24, wherein the

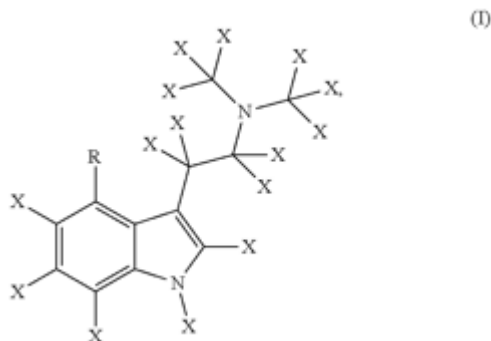
<p>cellulose polymer has a weight average molecular weight of from 150,000 g/mol to 5,000,000 g/mol.</p>	
<p>26. The pharmaceutical composition of claim 24, wherein the cellulose polymer has a weight average molecular weight of from 1,000 g/mol to 100,000 g/mol.</p>	
<p>27. The pharmaceutical composition of claim 24, wherein the cellulose polymer is hydroxypropyl methyl cellulose acetate succinate.</p>	
<p>28. The pharmaceutical composition of claim 24, wherein the cellulose polymer is hydroxypropyl methyl cellulose.</p>	<p>1. U.S. Pat. App. Pub. No. US/11000534B1 “Deuterated derivatives of psilocybin and uses thereof” (Published 11 May 2021)</p> <p>From <b>Summary of the Invention: The compositions described herein comprise deuterated psilocybin and deuterated psilocin. In certain embodiments, the composition comprises a compound of Formula (I):</b></p> <p style="text-align: center;">(I)</p>  <p><b>or a pharmaceutically acceptable salt, prodrug, hydrate, or solvate thereof;</b>  <b>wherein R is selected from —OX or</b></p>  <p><b>each X is independently protium or deuterium; and</b>  <b>at least one X is enriched for deuterium.</b></p> <p>From <b>Definitions: Reference to deuterated psilocybin or deuterated psilocin herein (i.e., a compound of Formula (I)) or a pharmaceutically</b></p>

	<p>acceptable salt, prodrug, hydrate, or solvate thereof, <b>includes all amorphous</b> and polymorph forms.</p> <p>From <b>Detailed Description of Certain Embodiments of the Invention:</b>  <b>In certain embodiments, a provided composition comprises one or more disintegrants or solubilizing agents, such as a cyclodextrin, or a carboxymethyl cellulose, calcium carboxymethyl cellulose, low-substituted hydroxypropyl cellulose, sodium croscarmellose, sodium carboxy starch, calcium carbonate, sodium carbonate and the like.</b></p> <p>1. U.S. Pat. App. Pub. No. US/11000534B1 “Deuterated derivatives of psilocybin and uses thereof” (Published 11 May 2021)</p> <p>From <b>Summary of the Invention:</b> <b>In certain embodiments, the percentage of the amount of the compound of Formula (I), or a pharmaceutically acceptable salt, prodrug, hydrate, or solvate thereof, relative to the total amount of psilocybin present in the composition ranges from about 1% to about 100%.</b></p>
<p>29. The pharmaceutical composition of claim 1, wherein the polymer is a blend of hydroxypropyl methyl cellulose and polyvinylpyrrolidone.</p>	
<p>32. The pharmaceutical composition of claim 1, wherein the solid dispersion has a glass transition (T<sub>g</sub>) onset of from 110° C. to 200° C., as determined by modulated differential scanning calorimetry (mDSC).</p>	
<p>33. The pharmaceutical composition of claim 1, wherein the solid dispersion has a heat capacity change (<math>\Delta C_p</math>), in J/(g·° C.), of from 0.1 to 0.75, as determined by modulated differential scanning calorimetry (mDSC).</p>	

34. The pharmaceutical composition of claim 1, wherein the compound of Formula (I) is present in an amount of 0.1 to 1000 mg.

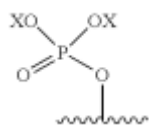
1. U.S. Pat. App. Pub. No. US/11000534B1 “Deuterated derivatives of psilocybin and uses thereof” (Published 11 May 2021)

**From Summary of the Invention: The compositions described herein comprise deuterated psilocybin and deuterated psilocin. In certain embodiments, the composition comprises a compound of Formula (I):**



**or a pharmaceutically acceptable salt, prodrug, hydrate, or solvate thereof;**

**wherein R is selected from —OX or**



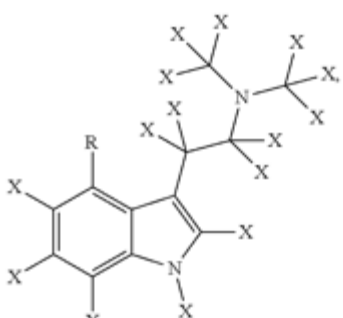
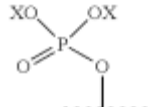
**each X is independently protium or deuterium; and at least one X is enriched for deuterium.**

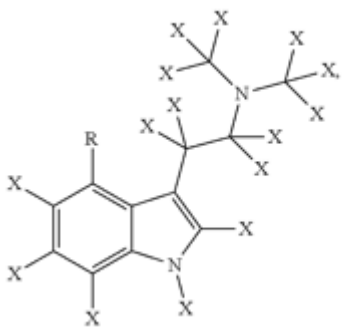
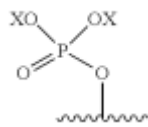
**From Definitions: Reference to deuterated psilocybin or deuterated psilocin herein (i.e., a compound of Formula (I)) or a pharmaceutically acceptable salt, prodrug, hydrate, or solvate thereof, includes all amorphous and polymorph forms.**

**From Detailed Description of Certain Embodiments of the Invention: In certain embodiments, a provided composition comprises one or more disintegrants or solubilizing agents, such as a cyclodextrin, or a carboxymethyl cellulose, calcium carboxymethyl cellulose, low-substituted hydroxypropyl cellulose, sodium croscarmellose, sodium carboxy starch, calcium carbonate, sodium carbonate and the like.**

**From Claim 1: A pharmaceutical composition comprising a deuterated compound of Formula (IA-2) or (IA-3): or a pharmaceutically acceptable salt, prodrug, hydrate, or solvate thereof; wherein the pharmaceutical composition comprises about 0.5 mg to 500 mg of the compound of Formula (IA-2) or (IA-3).**

1. U.S. Pat. App. Pub. No. US/11000534B1 “Deuterated derivatives of psilocybin and uses thereof” (Published 11 May 2021)

	<p>From <b>Summary of the Invention: In certain embodiments, the percentage of the amount of the compound of Formula (I), or a pharmaceutically acceptable salt, prodrug, hydrate, or solvate thereof, relative to the total amount of psilocybin present in the composition ranges from about 1% to about 100%.</b></p>
<p>39. The pharmaceutical composition of claim 1, which is adapted for oral administration.</p>	<p>1. U.S. Pat. App. Pub. No. US/11000534B1 “Deuterated derivatives of psilocybin and uses thereof” (Published 11 May 2021)</p> <p>From <b>Summary of the Invention: The compositions described herein comprise deuterated psilocybin and deuterated psilocin. In certain embodiments, the composition comprises a compound of Formula (I):</b></p> <div style="text-align: center;">  <p>(I)</p> </div> <p><b>or a pharmaceutically acceptable salt, prodrug, hydrate, or solvate thereof;</b>  <b>wherein R is selected from —OX or</b></p> <div style="text-align: center;">  </div> <p><b>each X is independently protium or deuterium; and at least one X is enriched for deuterium.</b></p> <p>From <b>Definitions: Reference to deuterated psilocybin or deuterated psilocin herein (i.e., a compound of Formula (I)) or a pharmaceutically acceptable salt, prodrug, hydrate, or solvate thereof, includes all amorphous and polymorph forms.</b></p> <p>From <b>Detailed Description of Certain Embodiments of the Invention: In certain embodiments, a provided composition comprises one or more disintegrants or solubilizing agents, such as a cyclodextrin, or a carboxymethyl cellulose, calcium carboxymethyl cellulose, low-substituted hydroxypropyl cellulose, sodium croscarmellose, sodium carboxy starch, calcium carbonate, sodium carbonate and the like.</b></p> <p>From <b>Summary of the Invention: In certain embodiments, the composition is suitable for oral administration or consumption.</b></p>

	<p>1. U.S. Pat. App. Pub. No. US/11000534B1 “Deuterated derivatives of psilocybin and uses thereof” (Published 11 May 2021)</p> <p>From <b>Summary of the Invention</b>: In certain embodiments, the <b>percentage of the amount of the compound of Formula (I)</b>, or a pharmaceutically acceptable salt, prodrug, hydrate, or solvate thereof, <b>relative to the total amount of psilocybin present in the composition ranges from about 1% to about 100%.</b></p>
<p>40. The pharmaceutical composition of claim 1, which is adapted for extended-release.</p>	
<p>42. A method of treating a subject with a disease or disorder associated with a serotonin 5-HT<sub>2</sub> receptor, comprising: administering to the subject the pharmaceutical composition of claim 1.</p>	<p>1. U.S. Pat. App. Pub. No. US/11000534B1 “Deuterated derivatives of psilocybin and uses thereof” (Published 11 May 2021)</p> <p>From <b>Summary of the Invention</b>: The compositions described herein <b>comprise deuterated psilocybin and deuterated psilocin. In certain embodiments, the composition comprises a compound of Formula (I):</b></p> <div style="text-align: center;">  <p>(I)</p> </div> <p><b>or a pharmaceutically acceptable salt, prodrug, hydrate, or solvate thereof;</b>  <b>wherein R is selected from —OX or</b></p> <div style="text-align: center;">  </div> <p><b>each X is independently protium or deuterium; and at least one X is enriched for deuterium.</b></p> <p>From <b>Definitions</b>: Reference to deuterated psilocybin or deuterated psilocin herein (i.e., a compound of Formula (I)) or a pharmaceutically acceptable salt, prodrug, hydrate, or solvate thereof, <b>includes all amorphous and polymorph forms.</b></p> <p>From <b>Detailed Description of Certain Embodiments of the Invention</b>: <b>In certain embodiments, a provided composition comprises one or more disintegrants or solubilizing agents, such as a cyclodextrin, or a carboxymethyl cellulose, calcium carboxymethyl cellulose, low-</b></p>

**substituted hydroxypropyl cellulose, sodium croscarmellose, sodium carboxy starch, calcium carbonate, sodium carbonate and the like.**

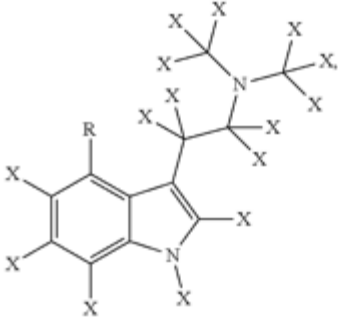
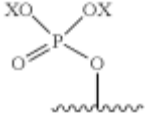
1. U.S. Pat. App. Pub. No. US/11000534B1 “Deuterated derivatives of psilocybin and uses thereof” (Published 11 May 2021)

**From Summary of the Invention: In certain embodiments, the percentage of the amount of the compound of Formula (I), or a pharmaceutically acceptable salt, prodrug, hydrate, or solvate thereof, relative to the total amount of psilocybin present in the composition ranges from about 1% to about 100%.**

**From Methods of Use and Uses: In certain embodiments, the disease is a psychiatric disorder. The term “psychiatric disorder” refers to a disease of the mind and includes diseases and disorders listed in the Diagnostic and Statistical Manual of Mental Disorders—Fourth Edition (DSM-IV), published by the American Psychiatric Association, Washington D. C. (1994). Psychiatric disorders include anxiety disorders (e.g., acute stress disorder agoraphobia, generalized anxiety disorder, obsessive-compulsive disorder, panic disorder, posttraumatic stress disorder, separation anxiety disorder, social phobia, and specific phobia), childhood disorders, (e.g., attention-deficit/hyperactivity disorder, conduct disorder, and oppositional defiant disorder), eating disorders (e.g., anorexia nervosa and bulimia nervosa), mood disorders (e.g., depression, bipolar disorder, cyclothymic disorder, dysthymic disorder, and major depressive disorder), personality disorders (e.g., antisocial personality disorder, avoidant personality disorder, borderline personality disorder, dependent personality disorder, histrionic personality disorder, narcissistic personality disorder, obsessive-compulsive personality disorder, paranoid personality disorder, schizoid personality disorder, and schizotypal personality disorder), psychotic disorders (e.g., brief psychotic disorder, delusional disorder, schizoaffective disorder, schizophreniform disorder, schizophrenia, and shared psychotic disorder), substance-related disorders (e.g., alcohol dependence, amphetamine dependence, cannabis dependence, cocaine dependence, hallucinogen dependence, inhalant dependence, nicotine dependence, opioid dependence, phencyclidine dependence, and sedative dependence), adjustment disorder, autism, delirium, dementia, multi-infarct dementia, learning and memory disorders (e.g., amnesia and age-related memory loss), and Tourette's disorder.**

2. ISHIER RAOTE (2007) “Serotonin Receptors in Neuobiology - Serotonin 2A (5-HT<sub>2A</sub>) Receptor Function: Ligand-Dependent Mechanisms and Pathways” *CRC Press/Taylor & Francis*. ISBN 0849339774. Pages 104-132.

**From Implications in Diseases: Given the extensive localization of this receptor to brain areas that mediate cognitive functions and social interaction, it suggests that the 5-HT<sub>2A</sub> receptor might be involved in**

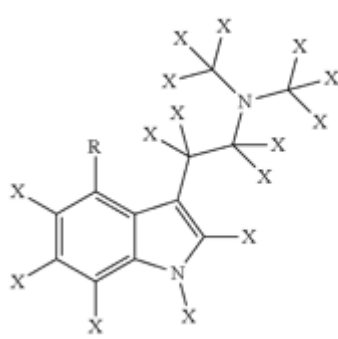
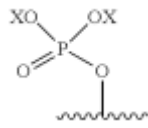
	<p>diseases in which these functions are impaired. Disorders in which the 5-HT<sub>2A</sub> receptor seems to be involved range from schizophrenia, depression, obsessive compulsive disorder (OCD), and attention deficit-hyperactivity disorder (ADHD), to eating disorders such as anorexia nervosa, to autism spectrum disorders.</p>
<p>43. The method of claim 42, wherein the disease or disorder is a neuropsychiatric disease or disorder or an inflammatory disease or disorder.</p>	<p>1. U.S. Pat. App. Pub. No. US/11000534B1 “Deuterated derivatives of psilocybin and uses thereof” (Published 11 May 2021)</p> <p>From <b>Summary of the Invention: The compositions described herein comprise deuterated psilocybin and deuterated psilocin. In certain embodiments, the composition comprises a compound of Formula (I):</b></p> <p style="text-align: center;">(I)</p>  <p>or a pharmaceutically acceptable salt, prodrug, hydrate, or solvate thereof; wherein R is selected from —OX or</p>  <p>each X is independently protium or deuterium; and at least one X is enriched for deuterium.</p> <p>From <b>Definitions: Reference to deuterated psilocybin or deuterated psilocin herein (i.e., a compound of Formula (I)) or a pharmaceutically acceptable salt, prodrug, hydrate, or solvate thereof, includes all amorphous and polymorph forms.</b></p> <p>From <b>Detailed Description of Certain Embodiments of the Invention: In certain embodiments, a provided composition comprises one or more disintegrants or solubilizing agents, such as a cyclodextrin, or a carboxymethyl cellulose, calcium carboxymethyl cellulose, low-substituted hydroxypropyl cellulose, sodium croscarmellose, sodium carboxy starch, calcium carbonate, sodium carbonate and the like.</b></p> <p>1. U.S. Pat. App. Pub. No. US/11000534B1 “Deuterated derivatives of psilocybin and uses thereof” (Published 11 May 2021)</p>

From **Summary of the Invention**: In certain embodiments, the percentage of the amount of the compound of Formula (I), or a pharmaceutically acceptable salt, prodrug, hydrate, or solvate thereof, relative to the total amount of psilocybin present in the composition ranges from about 1% to about 100%.

From **Methods of Use and Uses**: In certain embodiments, the disease is a psychiatric disorder. The term “psychiatric disorder” refers to a disease of the mind and includes diseases and disorders listed in the **Diagnostic and Statistical Manual of Mental Disorders—Fourth Edition (DSM-IV)**, published by the American Psychiatric Association, Washington D. C. (1994). Psychiatric disorders include anxiety disorders (e.g., acute stress disorder agoraphobia, generalized anxiety disorder, obsessive-compulsive disorder, panic disorder, posttraumatic stress disorder, separation anxiety disorder, social phobia, and specific phobia), childhood disorders, (e.g., attention-deficit/hyperactivity disorder, conduct disorder, and oppositional defiant disorder), eating disorders (e.g., anorexia nervosa and bulimia nervosa), mood disorders (e.g., depression, bipolar disorder, cyclothymic disorder, dysthymic disorder, and major depressive disorder), personality disorders (e.g., antisocial personality disorder, avoidant personality disorder, borderline personality disorder, dependent personality disorder, histrionic personality disorder, narcissistic personality disorder, obsessive-compulsive personality disorder, paranoid personality disorder, schizoid personality disorder, and schizotypal personality disorder), psychotic disorders (e.g., brief psychotic disorder, delusional disorder, schizoaffective disorder, schizophreniform disorder, schizophrenia, and shared psychotic disorder), substance-related disorders (e.g., alcohol dependence, amphetamine dependence, cannabis dependence, cocaine dependence, hallucinogen dependence, inhalant dependence, nicotine dependence, opioid dependence, phencyclidine dependence, and sedative dependence), adjustment disorder, **autism, delirium, dementia, multi-infarct dementia, learning and memory disorders (e.g., amnesia and age-related memory loss), and Tourette's disorder.**

2. ISHIER RAOTE (2007) “Serotonin Receptors in Neuobiology - Serotonin 2A (5-HT<sub>2A</sub>) Receptor Function: Ligand-Dependent Mechanisms and Pathways” *CRC Press/Taylor & Francis*. ISBN 0849339774. Pages 104-132.

From **Implications in Diseases**: Given the extensive localization of this receptor to brain areas that mediate cognitive functions and social interaction, it suggests that the 5-HT<sub>2A</sub> receptor might be involved in diseases in which these functions are impaired. Disorders in which the 5-HT<sub>2A</sub> receptor seems to be involved range from schizophrenia, depression, obsessive compulsive disorder (OCD), and attention deficit–hyperactivity disorder (ADHD), to eating disorders such as anorexia nervosa, to autism spectrum disorders.

	<p>From <b>Implications in Diseases:</b> In addition, the 5-HT<sub>2A</sub> receptor has also been implicated in other diseases with less established etiologies... The receptor has also been implicated in the pathophysiology of diseases like bipolar disorders, Alzheimer’s disease, progressive multifocal leukoencephalopathy, obstructive sleep apnea syndrome, and thermal or inflammatory pain</p>
<p>44. The method of claim 42, wherein the disease or disorder is a central nervous system (CNS) disorder.</p>	<p>1. U.S. Pat. App. Pub. No. US/11000534B1 “Deuterated derivatives of psilocybin and uses thereof” (Published 11 May 2021)</p> <p>From <b>Summary of the Invention:</b> The compositions described herein comprise deuterated psilocybin and deuterated psilocin. In certain embodiments, the composition comprises a compound of Formula (I):</p> <div style="text-align: center;">  <p>(I)</p> </div> <p>or a pharmaceutically acceptable salt, prodrug, hydrate, or solvate thereof;  wherein R is selected from —OX or</p> <div style="text-align: center;">  </div> <p>each X is independently protium or deuterium; and  at least one X is enriched for deuterium.</p> <p>From <b>Definitions:</b> Reference to deuterated psilocybin or deuterated psilocin herein (i.e., a compound of Formula (I)) or a pharmaceutically acceptable salt, prodrug, hydrate, or solvate thereof, <b>includes all amorphous and polymorph forms.</b></p> <p>From <b>Detailed Description of Certain Embodiments of the Invention:</b> In certain embodiments, a provided composition comprises one or more disintegrants or solubilizing agents, such as a cyclodextrin, or a carboxymethyl cellulose, calcium carboxymethyl cellulose, low-substituted hydroxypropyl cellulose, sodium croscarmellose, sodium carboxy starch, calcium carbonate, sodium carbonate <b>and the like.</b></p> <p>1. U.S. Pat. App. Pub. No. US/11000534B1 “Deuterated derivatives of psilocybin and uses thereof” (Published 11 May 2021)</p>

**From Summary of the Invention:** In certain embodiments, the percentage of the amount of the compound of Formula (I), or a pharmaceutically acceptable salt, prodrug, hydrate, or solvate thereof, relative to the total amount of psilocybin present in the composition ranges from about 1% to about 100%.

**From Methods of Use and Uses:** In certain embodiments, the disease is a psychiatric disorder. The term “psychiatric disorder” refers to a disease of the mind and includes diseases and disorders listed in the *Diagnostic and Statistical Manual of Mental Disorders—Fourth Edition (DSM-IV)*, published by the American Psychiatric Association, Washington D. C. (1994). Psychiatric disorders include anxiety disorders (e.g., acute stress disorder agoraphobia, generalized anxiety disorder, obsessive-compulsive disorder, panic disorder, posttraumatic stress disorder, separation anxiety disorder, social phobia, and specific phobia), childhood disorders, (e.g., attention-deficit/hyperactivity disorder, conduct disorder, and oppositional defiant disorder), eating disorders (e.g., anorexia nervosa and bulimia nervosa), mood disorders (e.g., depression, bipolar disorder, cyclothymic disorder, dysthymic disorder, and major depressive disorder), personality disorders (e.g., antisocial personality disorder, avoidant personality disorder, borderline personality disorder, dependent personality disorder, histrionic personality disorder, narcissistic personality disorder, obsessive-compulsive personality disorder, paranoid personality disorder, schizoid personality disorder, and schizotypal personality disorder), psychotic disorders (e.g., brief psychotic disorder, delusional disorder, schizoaffective disorder, schizophreniform disorder, schizophrenia, and shared psychotic disorder), substance-related disorders (e.g., alcohol dependence, amphetamine dependence, cannabis dependence, cocaine dependence, hallucinogen dependence, inhalant dependence, nicotine dependence, opioid dependence, phencyclidine dependence, and sedative dependence), adjustment disorder, autism, delirium, dementia, multi-infarct dementia, learning and memory disorders (e.g., amnesia and age-related memory loss), and Tourette's disorder.

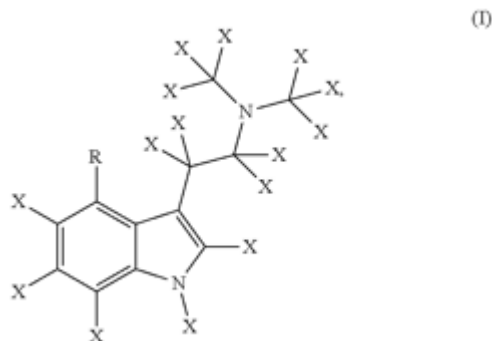
2. ISHIER RAOTE (2007) “Serotonin Receptors in Neuobiology - Serotonin 2A (5-HT<sub>2A</sub>) Receptor Function: Ligand-Dependent Mechanisms and Pathways” *CRC Press/Taylor & Francis*. ISBN 0849339774. Pages 104-132.

**From Implications in Diseases:** Given the extensive localization of this receptor to brain areas that mediate cognitive functions and social interaction, it suggests that the 5-HT<sub>2A</sub> receptor might be involved in diseases in which these functions are impaired. Disorders in which the 5-HT<sub>2A</sub> receptor seems to be involved range from schizophrenia, depression, obsessive compulsive disorder (OCD), and attention deficit–hyperactivity disorder (ADHD), to eating disorders such as anorexia nervosa, to autism spectrum disorders.

45. The method of claim 44, wherein the central nervous system (CNS) disorder is at least one selected from the group consisting of major depressive disorder (MDD), treatment-resistant depression (TRD), post-traumatic stress disorder (PTSD), bipolar and related disorders, obsessive-compulsive disorder (OCD), generalized anxiety disorder (GAD), social anxiety disorder, a substance use disorder, an eating disorder, Alzheimer's disease, cluster headache and migraine, attention deficit hyperactivity disorder (ADHD), pain and neuropathic pain, aphantasia, childhood-onset fluency disorder, major neurocognitive disorder, mild neurocognitive disorder, suicidal ideation, suicidal behavior, major depressive disorder with suicidal ideation or suicidal behavior, melancholic depression, atypical depression, dysthymia, non-suicidal self-injury disorder (NSSID), chronic fatigue syndrome, Lyme's disease, gambling disorder, a paraphilic disorder, sexual dysfunction,

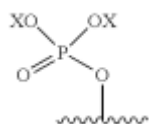
1. U.S. Pat. App. Pub. No. US/11000534B1 "Deuterated derivatives of psilocybin and uses thereof" (Published 11 May 2021)

From **Summary of the Invention: The compositions described herein comprise deuterated psilocybin and deuterated psilocin. In certain embodiments, the composition comprises a compound of Formula (I):**



**or a pharmaceutically acceptable salt, prodrug, hydrate, or solvate thereof;**

**wherein R is selected from —OX or**



**each X is independently protium or deuterium; and at least one X is enriched for deuterium.**

From **Definitions: Reference to deuterated psilocybin or deuterated psilocin herein (i.e., a compound of Formula (I)) or a pharmaceutically acceptable salt, prodrug, hydrate, or solvate thereof, includes all amorphous and polymorph forms.**

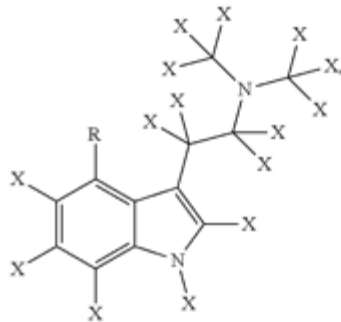
From **Detailed Description of Certain Embodiments of the Invention: In certain embodiments, a provided composition comprises one or more disintegrants or solubilizing agents, such as a cyclodextrin, or a carboxymethyl cellulose, calcium carboxymethyl cellulose, low-substituted hydroxypropyl cellulose, sodium croscarmellose, sodium carboxy starch, calcium carbonate, sodium carbonate and the like.**

1. U.S. Pat. App. Pub. No. US/11000534B1 "Deuterated derivatives of psilocybin and uses thereof" (Published 11 May 2021)

From **Summary of the Invention: In certain embodiments, the percentage of the amount of the compound of Formula (I), or a pharmaceutically acceptable salt, prodrug, hydrate, or solvate thereof, relative to the total amount of psilocybin present in the composition ranges from about 1% to about 100%.**

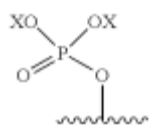
<p>peripheral neuropathy, and obesity.</p>	<p>From <b>Methods of Use and Uses</b>: In certain embodiments, the disease is a psychiatric disorder. The term “psychiatric disorder” refers to a disease of the mind and includes diseases and disorders listed in the <b>Diagnostic and Statistical Manual of Mental Disorders—Fourth Edition (DSM-IV)</b>, published by the American Psychiatric Association, Washington D. C. (1994). Psychiatric disorders include anxiety disorders (e.g., acute stress disorder agoraphobia, generalized anxiety disorder, obsessive-compulsive disorder, panic disorder, posttraumatic stress disorder, separation anxiety disorder, social phobia, and specific phobia), childhood disorders, (e.g., attention-deficit/hyperactivity disorder, conduct disorder, and oppositional defiant disorder), eating disorders (e.g., anorexia nervosa and bulimia nervosa), mood disorders (e.g., depression, bipolar disorder, cyclothymic disorder, dysthymic disorder, and major depressive disorder), personality disorders (e.g., antisocial personality disorder, avoidant personality disorder, borderline personality disorder, dependent personality disorder, histrionic personality disorder, narcissistic personality disorder, obsessive-compulsive personality disorder, paranoid personality disorder, schizoid personality disorder, and schizotypal personality disorder), <b>psychotic disorders (e.g., brief psychotic disorder, delusional disorder, schizoaffective disorder, schizophreniform disorder, schizophrenia, and shared psychotic disorder)</b>, substance-related disorders (e.g., alcohol dependence, amphetamine dependence, cannabis dependence, cocaine dependence, hallucinogen dependence, inhalant dependence, nicotine dependence, opioid dependence, phencyclidine dependence, and sedative dependence), <b>adjustment disorder, autism, delirium, dementia, multi-infarct dementia, learning and memory disorders (e.g., amnesia and age-related memory loss), and Tourette's disorder.</b></p> <p>2. ISHIER RAOTE (2007) “Serotonin Receptors in Neuobiology - Serotonin 2A (5-HT<sub>2A</sub>) Receptor Function: Ligand-Dependent Mechanisms and Pathways” <i>CRC Press/Taylor &amp; Francis</i>. ISBN 0849339774. Pages 104-132.</p> <p>From <b>Implications in Diseases</b>: Given the extensive localization of this receptor to brain areas that mediate cognitive functions and social interaction, it suggests that the 5-HT<sub>2A</sub> receptor might be involved in diseases in which these functions are impaired. Disorders in which the 5-HT<sub>2A</sub> receptor seems to be involved range from schizophrenia, depression, obsessive compulsive disorder (OCD), and attention deficit-hyperactivity disorder (ADHD), to eating disorders such as anorexia nervosa, to autism spectrum disorders.</p>
<p>46. The method of claim 44, wherein the central nervous system (CNS) disorder is major depressive disorder (MDD).</p>	<p>1. U.S. Pat. App. Pub. No. US/11000534B1 “Deuterated derivatives of psilocybin and uses thereof” (Published 11 May 2021)</p> <p>From <b>Summary of the Invention</b>: The compositions described herein comprise deuterated psilocybin and deuterated psilocin. In certain embodiments, the composition comprises a compound of <b>Formula (I)</b>:</p>

(I)



or a pharmaceutically acceptable salt, prodrug, hydrate, or solvate thereof;

wherein R is selected from —OX or



each X is independently protium or deuterium; and at least one X is enriched for deuterium.

From **Definitions: Reference to deuterated psilocybin or deuterated psilocin herein (i.e., a compound of Formula (I))** or a pharmaceutically acceptable salt, prodrug, hydrate, or solvate thereof, **includes all amorphous and polymorph forms.**

From **Detailed Description of Certain Embodiments of the Invention: In certain embodiments, a provided composition comprises one or more disintegrants or solubilizing agents, such as a cyclodextrin, or a carboxymethyl cellulose, calcium carboxymethyl cellulose, low-substituted hydroxypropyl cellulose, sodium croscarmellose, sodium carboxy starch, calcium carbonate, sodium carbonate and the like.**

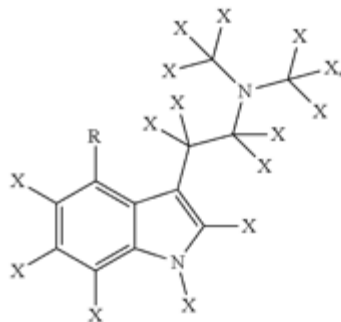
1. U.S. Pat. App. Pub. No. US/11000534B1 “Deuterated derivatives of psilocybin and uses thereof” (Published 11 May 2021)

From **Summary of the Invention: In certain embodiments, the percentage of the amount of the compound of Formula (I), or a pharmaceutically acceptable salt, prodrug, hydrate, or solvate thereof, relative to the total amount of psilocybin present in the composition ranges from about 1% to about 100%.**

From **Methods of Use and Uses: In certain embodiments, the disease is a psychiatric disorder. The term “psychiatric disorder” refers to a disease of the mind and includes diseases and disorders listed in the Diagnostic and Statistical Manual of Mental Disorders—Fourth Edition (DSM-IV), published by the American Psychiatric Association, Washington D. C. (1994). Psychiatric disorders include anxiety disorders (e.g., acute stress disorder agoraphobia, generalized anxiety disorder, obsessive-compulsive**

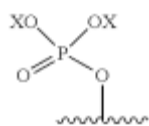
	<p>disorder, panic disorder, posttraumatic stress disorder, separation anxiety disorder, social phobia, and specific phobia), childhood disorders, (e.g., attention-deficit/hyperactivity disorder, conduct disorder, and oppositional defiant disorder), eating disorders (e.g., anorexia nervosa and bulimia nervosa), mood disorders (e.g., depression, bipolar disorder, cyclothymic disorder, dysthymic disorder, and <b>major depressive disorder</b>), personality disorders (e.g., antisocial personality disorder, avoidant personality disorder, borderline personality disorder, dependent personality disorder, histrionic personality disorder, narcissistic personality disorder, obsessive-compulsive personality disorder, paranoid personality disorder, schizoid personality disorder, and schizotypal personality disorder), psychotic disorders (e.g., brief psychotic disorder, delusional disorder, schizoaffective disorder, schizophreniform disorder, schizophrenia, and shared psychotic disorder), substance-related disorders (e.g., alcohol dependence, amphetamine dependence, cannabis dependence, cocaine dependence, hallucinogen dependence, inhalant dependence, nicotine dependence, opioid dependence, phencyclidine dependence, and sedative dependence), adjustment disorder, autism, delirium, dementia, multi-infarct dementia, learning and memory disorders (e.g., amnesia and age-related memory loss), and Tourette's disorder.</p> <p>2. ISHIER RAOTE (2007) “Serotonin Receptors in Neuobiology - Serotonin 2A (5-HT2A) Receptor Function: Ligand-Dependent Mechanisms and Pathways” <i>CRC Press/Taylor &amp; Francis</i>. ISBN 0849339774. Pages 104-132.</p> <p>From <b>Implications in Diseases: Given the extensive localization of this receptor to brain areas that mediate cognitive functions and social interaction, it suggests that the 5-HT2A receptor might be involved in diseases in which these functions are impaired. Disorders in which the 5-HT2A receptor seems to be involved range from</b> schizophrenia, <b>depression</b>, obsessive compulsive disorder (OCD), and attention deficit–hyperactivity disorder (ADHD), to eating disorders such as anorexia nervosa, to autism spectrum disorders.</p>
<p>47. The method of claim 44, wherein the central nervous system (CNS) disorder is treatment-resistant depression (TRD).</p>	
<p>48. The method of claim 44, wherein the central nervous system (CNS) disorder is generalized anxiety disorder (GAD).</p>	<p>1. U.S. Pat. App. Pub. No. US/11000534B1 “Deuterated derivatives of psilocybin and uses thereof” (Published 11 May 2021)</p> <p>From <b>Summary of the Invention: The compositions described herein comprise deuterated psilocybin and deuterated psilocin. In certain embodiments, the composition comprises a compound of Formula (I):</b></p>

(I)



or a pharmaceutically acceptable salt, prodrug, hydrate, or solvate thereof;

wherein R is selected from —OX or



each X is independently protium or deuterium; and at least one X is enriched for deuterium.

**From Definitions: Reference to deuterated psilocybin or deuterated psilocin herein (i.e., a compound of Formula (I)) or a pharmaceutically acceptable salt, prodrug, hydrate, or solvate thereof, includes all amorphous and polymorph forms.**

**From Detailed Description of Certain Embodiments of the Invention: In certain embodiments, a provided composition comprises one or more disintegrants or solubilizing agents, such as a cyclodextrin, or a carboxymethyl cellulose, calcium carboxymethyl cellulose, low-substituted hydroxypropyl cellulose, sodium croscarmellose, sodium carboxy starch, calcium carbonate, sodium carbonate and the like.**

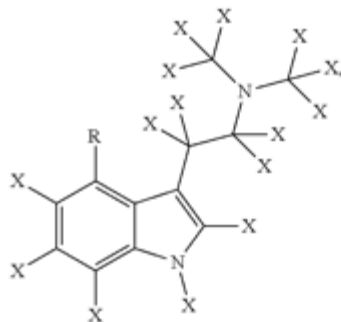
1. U.S. Pat. App. Pub. No. US/11000534B1 “Deuterated derivatives of psilocybin and uses thereof” (Published 11 May 2021)

**From Summary of the Invention: In certain embodiments, the percentage of the amount of the compound of Formula (I), or a pharmaceutically acceptable salt, prodrug, hydrate, or solvate thereof, relative to the total amount of psilocybin present in the composition ranges from about 1% to about 100%.**

**From Methods of Use and Uses: In certain embodiments, the disease is a psychiatric disorder. The term “psychiatric disorder” refers to a disease of the mind and includes diseases and disorders listed in the Diagnostic and Statistical Manual of Mental Disorders—Fourth Edition (DSM-IV), published by the American Psychiatric Association, Washington D. C. (1994). Psychiatric disorders include anxiety disorders (e.g., acute stress disorder agoraphobia, generalized anxiety disorder, obsessive-compulsive**

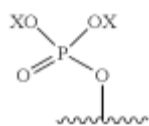
	<p>disorder, panic disorder, posttraumatic stress disorder, separation anxiety disorder, social phobia, and specific phobia), childhood disorders, (e.g., attention-deficit/hyperactivity disorder, conduct disorder, and oppositional defiant disorder), eating disorders (e.g., anorexia nervosa and bulimia nervosa), mood disorders (e.g., depression, bipolar disorder, cyclothymic disorder, dysthymic disorder, and major depressive disorder), personality disorders (e.g., antisocial personality disorder, avoidant personality disorder, borderline personality disorder, dependent personality disorder, histrionic personality disorder, narcissistic personality disorder, obsessive-compulsive personality disorder, paranoid personality disorder, schizoid personality disorder, and schizotypal personality disorder), psychotic disorders (e.g., brief psychotic disorder, delusional disorder, schizoaffective disorder, schizophreniform disorder, schizophrenia, and shared psychotic disorder), substance-related disorders (e.g., alcohol dependence, amphetamine dependence, cannabis dependence, cocaine dependence, hallucinogen dependence, inhalant dependence, nicotine dependence, opioid dependence, phencyclidine dependence, and sedative dependence), adjustment disorder, autism, delirium, dementia, multi-infarct dementia, learning and memory disorders (e.g., amnesia and age-related memory loss), and Tourette's disorder.</p> <p>2. ISHIER RAOTE (2007) “Serotonin Receptors in Neuobiology - Serotonin 2A (5-HT2A) Receptor Function: Ligand-Dependent Mechanisms and Pathways” <i>CRC Press/Taylor &amp; Francis</i>. ISBN 0849339774. Pages 104-132.</p> <p><b>From Implications in Diseases: Given the extensive localization of this receptor to brain areas that mediate cognitive functions and social interaction, it suggests that the 5-HT2A receptor might be involved in diseases in which these functions are impaired. Disorders in which the 5-HT2A receptor seems to be involved range from schizophrenia, depression, obsessive compulsive disorder (OCD), and attention deficit–hyperactivity disorder (ADHD), to eating disorders such as anorexia nervosa, to autism spectrum disorders.</b></p>
<p>49. The method of claim 44, wherein the central nervous system (CNS) disorder is social anxiety disorder.</p>	<p>1. U.S. Pat. App. Pub. No. US/11000534B1 “Deuterated derivatives of psilocybin and uses thereof” (Published 11 May 2021)</p> <p><b>From Summary of the Invention: The compositions described herein comprise deuterated psilocybin and deuterated psilocin. In certain embodiments, the composition comprises a compound of Formula (I):</b></p>

(I)



or a pharmaceutically acceptable salt, prodrug, hydrate, or solvate thereof;

wherein R is selected from —OX or



each X is independently protium or deuterium; and at least one X is enriched for deuterium.

From **Definitions: Reference to deuterated psilocybin or deuterated psilocin herein (i.e., a compound of Formula (I))** or a pharmaceutically acceptable salt, prodrug, hydrate, or solvate thereof, **includes all amorphous and polymorph forms.**

From **Detailed Description of Certain Embodiments of the Invention: In certain embodiments, a provided composition comprises one or more disintegrants or solubilizing agents, such as a cyclodextrin, or a carboxymethyl cellulose, calcium carboxymethyl cellulose, low-substituted hydroxypropyl cellulose, sodium croscarmellose, sodium carboxy starch, calcium carbonate, sodium carbonate and the like.**

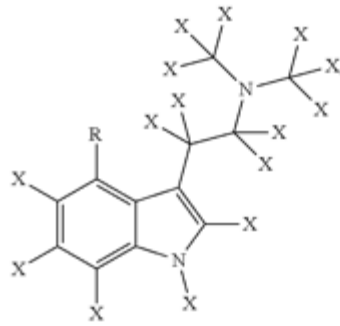
1. U.S. Pat. App. Pub. No. US/11000534B1 “Deuterated derivatives of psilocybin and uses thereof” (Published 11 May 2021)

From **Summary of the Invention: In certain embodiments, the percentage of the amount of the compound of Formula (I), or a pharmaceutically acceptable salt, prodrug, hydrate, or solvate thereof, relative to the total amount of psilocybin present in the composition ranges from about 1% to about 100%.**

From **Methods of Use and Uses: In certain embodiments, the disease is a psychiatric disorder. The term “psychiatric disorder” refers to a disease of the mind and includes diseases and disorders listed in the Diagnostic and Statistical Manual of Mental Disorders—Fourth Edition (DSM-IV), published by the American Psychiatric Association, Washington D. C. (1994). Psychiatric disorders include anxiety disorders (e.g., acute stress disorder agoraphobia, generalized anxiety disorder, obsessive-compulsive**

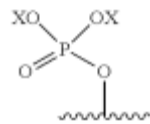
	<p>disorder, panic disorder, posttraumatic stress disorder, separation anxiety disorder, <b>social phobia</b>, and specific phobia), childhood disorders, (e.g., attention-deficit/hyperactivity disorder, conduct disorder, and oppositional defiant disorder), eating disorders (e.g., anorexia nervosa and bulimia nervosa), mood disorders (e.g., depression, bipolar disorder, cyclothymic disorder, dysthymic disorder, and major depressive disorder), personality disorders (e.g., antisocial personality disorder, avoidant personality disorder, borderline personality disorder, dependent personality disorder, histrionic personality disorder, narcissistic personality disorder, obsessive-compulsive personality disorder, paranoid personality disorder, schizoid personality disorder, and schizotypal personality disorder), psychotic disorders (e.g., brief psychotic disorder, delusional disorder, schizoaffective disorder, schizophreniform disorder, schizophrenia, and shared psychotic disorder), substance-related disorders (e.g., alcohol dependence, amphetamine dependence, cannabis dependence, cocaine dependence, hallucinogen dependence, inhalant dependence, nicotine dependence, opioid dependence, phencyclidine dependence, and sedative dependence), adjustment disorder, autism, delirium, dementia, multi-infarct dementia, learning and memory disorders (e.g., amnesia and age-related memory loss), and Tourette's disorder.</p> <p>2. ISHIER RAOTE (2007) “Serotonin Receptors in Neuobiology - Serotonin 2A (5-HT2A) Receptor Function: Ligand-Dependent Mechanisms and Pathways” <i>CRC Press/Taylor &amp; Francis</i>. ISBN 0849339774. Pages 104-132.</p> <p><b>From Implications in Diseases: Given the extensive localization of this receptor to brain areas that mediate cognitive functions and social interaction, it suggests that the 5-HT2A receptor might be involved in diseases in which these functions are impaired. Disorders in which the 5-HT2A receptor seems to be involved range from schizophrenia, depression, obsessive compulsive disorder (OCD), and attention deficit–hyperactivity disorder (ADHD), to eating disorders such as anorexia nervosa, to autism spectrum disorders.</b></p>
<p>50. The method of claim 44, wherein the central nervous system (CNS) disorder is obsessive-compulsive disorder (OCD).</p>	<p>1. U.S. Pat. App. Pub. No. US/11000534B1 “Deuterated derivatives of psilocybin and uses thereof” (Published 11 May 2021)</p> <p><b>From Summary of the Invention: The compositions described herein comprise deuterated psilocybin and deuterated psilocin. In certain embodiments, the composition comprises a compound of Formula (I):</b></p>

(I)



or a pharmaceutically acceptable salt, prodrug, hydrate, or solvate thereof;

wherein R is selected from —OX or



each X is independently protium or deuterium; and at least one X is enriched for deuterium.

From **Definitions: Reference to deuterated psilocybin or deuterated psilocin herein (i.e., a compound of Formula (I))** or a pharmaceutically acceptable salt, prodrug, hydrate, or solvate thereof, **includes all amorphous and polymorph forms.**

From **Detailed Description of Certain Embodiments of the Invention: In certain embodiments, a provided composition comprises one or more disintegrants or solubilizing agents, such as a cyclodextrin, or a carboxymethyl cellulose, calcium carboxymethyl cellulose, low-substituted hydroxypropyl cellulose, sodium croscarmellose, sodium carboxy starch, calcium carbonate, sodium carbonate and the like.**

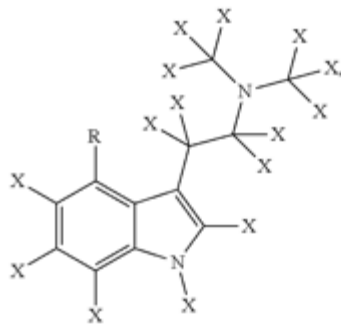
1. U.S. Pat. App. Pub. No. US/11000534B1 “Deuterated derivatives of psilocybin and uses thereof” (Published 11 May 2021)

From **Summary of the Invention: In certain embodiments, the percentage of the amount of the compound of Formula (I), or a pharmaceutically acceptable salt, prodrug, hydrate, or solvate thereof, relative to the total amount of psilocybin present in the composition ranges from about 1% to about 100%.**

From **Methods of Use and Uses: In certain embodiments, the disease is a psychiatric disorder. The term “psychiatric disorder” refers to a disease of the mind and includes diseases and disorders listed in the Diagnostic and Statistical Manual of Mental Disorders—Fourth Edition (DSM-IV), published by the American Psychiatric Association, Washington D. C. (1994). Psychiatric disorders include anxiety disorders (e.g., acute stress disorder agoraphobia, generalized anxiety disorder, obsessive-compulsive**

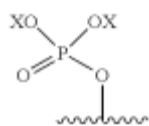
	<p>disorder, panic disorder, posttraumatic stress disorder, separation anxiety disorder, social phobia, and specific phobia), childhood disorders, (e.g., attention-deficit/hyperactivity disorder, conduct disorder, and oppositional defiant disorder), eating disorders (e.g., anorexia nervosa and bulimia nervosa), mood disorders (e.g., depression, bipolar disorder, cyclothymic disorder, dysthymic disorder, and major depressive disorder), personality disorders (e.g., antisocial personality disorder, avoidant personality disorder, borderline personality disorder, dependent personality disorder, histrionic personality disorder, narcissistic personality disorder, <b>obsessive-compulsive personality disorder</b>, paranoid personality disorder, schizoid personality disorder, and schizotypal personality disorder), psychotic disorders (e.g., brief psychotic disorder, delusional disorder, schizoaffective disorder, schizophreniform disorder, schizophrenia, and shared psychotic disorder), substance-related disorders (e.g., alcohol dependence, amphetamine dependence, cannabis dependence, cocaine dependence, hallucinogen dependence, inhalant dependence, nicotine dependence, opioid dependence, phencyclidine dependence, and sedative dependence), adjustment disorder, autism, delirium, dementia, multi-infarct dementia, learning and memory disorders (e.g., amnesia and age-related memory loss), and Tourette's disorder.</p> <p>2. ISHIER RAOTE (2007) “Serotonin Receptors in Neuobiology - Serotonin 2A (5-HT2A) Receptor Function: Ligand-Dependent Mechanisms and Pathways” <i>CRC Press/Taylor &amp; Francis</i>. ISBN 0849339774. Pages 104-132.</p> <p>From <b>Implications in Diseases: Given the extensive localization of this receptor to brain areas that mediate cognitive functions and social interaction, it suggests that the 5-HT2A receptor might be involved in diseases in which these functions are impaired. Disorders in which the 5-HT2A receptor seems to be involved range from schizophrenia, depression, obsessive compulsive disorder (OCD), and attention deficit–hyperactivity disorder (ADHD), to eating disorders such as anorexia nervosa, to autism spectrum disorders.</b></p>
<p>51. The method of claim 44, wherein the central nervous system (CNS) disorder is cluster headaches or migraine.</p>	<p>1. U.S. Pat. App. Pub. No. US/11000534B1 “Deuterated derivatives of psilocybin and uses thereof” (Published 11 May 2021)</p> <p>From <b>Summary of the Invention: The compositions described herein comprise deuterated psilocybin and deuterated psilocin. In certain embodiments, the composition comprises a compound of Formula (I):</b></p>

(I)



or a pharmaceutically acceptable salt, prodrug, hydrate, or solvate thereof;

wherein R is selected from —OX or



each X is independently protium or deuterium; and at least one X is enriched for deuterium.

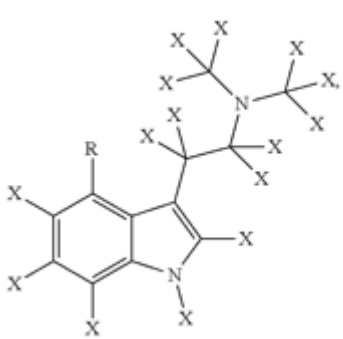
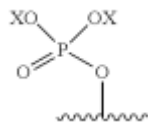
**From Definitions: Reference to deuterated psilocybin or deuterated psilocin herein (i.e., a compound of Formula (I)) or a pharmaceutically acceptable salt, prodrug, hydrate, or solvate thereof, includes all amorphous and polymorph forms.**

**From Detailed Description of Certain Embodiments of the Invention: In certain embodiments, a provided composition comprises one or more disintegrants or solubilizing agents, such as a cyclodextrin, or a carboxymethyl cellulose, calcium carboxymethyl cellulose, low-substituted hydroxypropyl cellulose, sodium croscarmellose, sodium carboxy starch, calcium carbonate, sodium carbonate and the like.**

1. U.S. Pat. App. Pub. No. US/11000534B1 “Deuterated derivatives of psilocybin and uses thereof” (Published 11 May 2021)

**From Summary of the Invention: In certain embodiments, the percentage of the amount of the compound of Formula (I), or a pharmaceutically acceptable salt, prodrug, hydrate, or solvate thereof, relative to the total amount of psilocybin present in the composition ranges from about 1% to about 100%.**

**From Methods of Use and Uses: In certain embodiments, the effective amount is effective in treating the disease. In certain embodiments, the effective amount is effective in preventing the disease. In certain aspects, the disease is a neurological disease. Further examples of neurological diseases include... migraine**

	<p>2. ISHIER RAOTE (2007) “Serotonin Receptors in Neuobiology - Serotonin 2A (5-HT2A) Receptor Function: Ligand-Dependent Mechanisms and Pathways” <i>CRC Press/Taylor &amp; Francis</i>. ISBN 0849339774. Pages 104-132.</p> <p>From <b>Implications in Diseases</b>: Given the extensive localization of this receptor to brain areas that mediate cognitive functions and social interaction, it suggests that the 5-HT2A receptor might be involved in diseases in which these functions are impaired. Disorders in which the 5-HT2A receptor seems to be involved range from schizophrenia, depression, obsessive compulsive disorder (OCD), and attention deficit-hyperactivity disorder (ADHD), to eating disorders such as anorexia nervosa, to autism spectrum disorders.</p>
<p>52. The method of claim 44, wherein the central nervous system (CNS) disorder is a substance use disorder.</p>	<p>1. U.S. Pat. App. Pub. No. US/11000534B1 “Deuterated derivatives of psilocybin and uses thereof” (Published 11 May 2021)</p> <p>From <b>Summary of the Invention</b>: The compositions described herein comprise deuterated psilocybin and deuterated psilocin. In certain embodiments, the composition comprises a compound of Formula (I):</p> <div style="text-align: center;">  <p>(I)</p> </div> <p>or a pharmaceutically acceptable salt, prodrug, hydrate, or solvate thereof;  wherein R is selected from —OX or</p> <div style="text-align: center;">  </div> <p>each X is independently protium or deuterium; and  at least one X is enriched for deuterium.</p> <p>From <b>Definitions</b>: Reference to deuterated psilocybin or deuterated psilocin herein (i.e., a compound of Formula (I)) or a pharmaceutically acceptable salt, prodrug, hydrate, or solvate thereof, <b>includes all amorphous and polymorph forms.</b></p> <p>From <b>Detailed Description of Certain Embodiments of the Invention</b>: In certain embodiments, a provided composition comprises one or more disintegrants or solubilizing agents, such as a cyclodextrin, or a</p>

**carboxymethyl cellulose, calcium carboxymethyl cellulose, low-substituted hydroxypropyl cellulose, sodium croscarmellose, sodium carboxy starch, calcium carbonate, sodium carbonate and the like.**

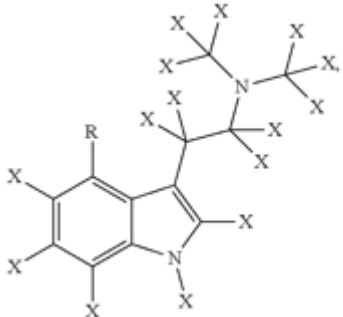
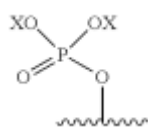
1. U.S. Pat. App. Pub. No. US/11000534B1 “Deuterated derivatives of psilocybin and uses thereof” (Published 11 May 2021)

**From Summary of the Invention: In certain embodiments, the percentage of the amount of the compound of Formula (I), or a pharmaceutically acceptable salt, prodrug, hydrate, or solvate thereof, relative to the total amount of psilocybin present in the composition ranges from about 1% to about 100%.**

**From Methods of Use and Uses: In certain embodiments, the disease is a psychiatric disorder. The term “psychiatric disorder” refers to a disease of the mind and includes diseases and disorders listed in the Diagnostic and Statistical Manual of Mental Disorders—Fourth Edition (DSM-IV), published by the American Psychiatric Association, Washington D. C. (1994). Psychiatric disorders include anxiety disorders (e.g., acute stress disorder agoraphobia, generalized anxiety disorder, obsessive-compulsive disorder, panic disorder, posttraumatic stress disorder, separation anxiety disorder, social phobia, and specific phobia), childhood disorders, (e.g., attention-deficit/hyperactivity disorder, conduct disorder, and oppositional defiant disorder), eating disorders (e.g., anorexia nervosa and bulimia nervosa), mood disorders (e.g., depression, bipolar disorder, cyclothymic disorder, dysthymic disorder, and major depressive disorder), personality disorders (e.g., antisocial personality disorder, avoidant personality disorder, borderline personality disorder, dependent personality disorder, histrionic personality disorder, narcissistic personality disorder, **obsessive-compulsive personality disorder, paranoid personality disorder, schizoid personality disorder, and schizotypal personality disorder**), psychotic disorders (e.g., brief psychotic disorder, delusional disorder, schizoaffective disorder, schizophreniform disorder, schizophrenia, and shared psychotic disorder), **substance-related disorders (e.g., alcohol dependence, amphetamine dependence, cannabis dependence, cocaine dependence, hallucinogen dependence, inhalant dependence, nicotine dependence, opioid dependence, phencyclidine dependence, and sedative dependence)**, adjustment disorder, autism, delirium, dementia, multi-infarct dementia, learning and memory disorders (e.g., amnesia and age-related memory loss), and Tourette's disorder.**

2. ISHIER RAOTE (2007) “Serotonin Receptors in Neuobiology - Serotonin 2A (5-HT<sub>2A</sub>) Receptor Function: Ligand-Dependent Mechanisms and Pathways” *CRC Press/Taylor & Francis*. ISBN 0849339774. Pages 104-132.

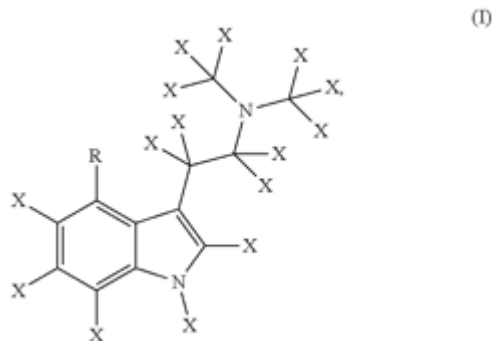
**From Implications in Diseases: Given the extensive localization of this receptor to brain areas that mediate cognitive functions and social interaction, it suggests that the 5-HT<sub>2A</sub> receptor might be involved in diseases in which these functions are impaired. Disorders in which the**

	<p><b>5-HT2A receptor seems to be involved range from schizophrenia, depression, obsessive compulsive disorder (OCD), and attention deficit-hyperactivity disorder (ADHD), to eating disorders such as anorexia nervosa, to autism spectrum disorders.</b></p>
<p>53. The method of claim 52, wherein the substance use disorder is alcohol use disorder.</p>	<p>1. U.S. Pat. App. Pub. No. US/11000534B1 “Deuterated derivatives of psilocybin and uses thereof” (Published 11 May 2021)</p> <p>From <b>Summary of the Invention: The compositions described herein comprise deuterated psilocybin and deuterated psilocin. In certain embodiments, the composition comprises a compound of Formula (I):</b></p> <p style="text-align: center;">(I)</p>  <p><b>or a pharmaceutically acceptable salt, prodrug, hydrate, or solvate thereof;</b>  <b>wherein R is selected from —OX or</b></p>  <p><b>each X is independently protium or deuterium; and at least one X is enriched for deuterium.</b></p> <p>From <b>Definitions: Reference to deuterated psilocybin or deuterated psilocin herein (i.e., a compound of Formula (I)) or a pharmaceutically acceptable salt, prodrug, hydrate, or solvate thereof, includes all amorphous and polymorph forms.</b></p> <p>1. U.S. Pat. App. Pub. No. US/11000534B1 “Deuterated derivatives of psilocybin and uses thereof” (Published 11 May 2021)</p> <p>From <b>Summary of the Invention: In certain embodiments, the percentage of the amount of the compound of Formula (I), or a pharmaceutically acceptable salt, prodrug, hydrate, or solvate thereof, relative to the total amount of psilocybin present in the composition ranges from about 1% to about 100%.</b></p> <p>From <b>Detailed Description of Certain Embodiments of the Invention: In certain embodiments, a provided composition comprises one or more disintegrants or solubilizing agents, such as a cyclodextrin, or a</b></p>

	<p><b>carboxymethyl cellulose, calcium carboxymethyl cellulose, low-substituted hydroxypropyl cellulose, sodium croscarmellose, sodium carboxy starch, calcium carbonate, sodium carbonate and the like.</b></p> <p>From <b>Methods of Use and Uses: In certain embodiments, the disease is a psychiatric disorder. The term “psychiatric disorder” refers to a disease of the mind and includes diseases and disorders listed in the Diagnostic and Statistical Manual of Mental Disorders—Fourth Edition (DSM-IV), published by the American Psychiatric Association, Washington D. C. (1994). Psychiatric disorders include</b> anxiety disorders (e.g., acute stress disorder agoraphobia, generalized anxiety disorder, obsessive-compulsive disorder, panic disorder, posttraumatic stress disorder, separation anxiety disorder, social phobia, and specific phobia), childhood disorders, (e.g., attention-deficit/hyperactivity disorder, conduct disorder, and oppositional defiant disorder), eating disorders (e.g., anorexia nervosa and bulimia nervosa), mood disorders (e.g., depression, bipolar disorder, cyclothymic disorder, dysthymic disorder, and major depressive disorder), personality disorders (e.g., antisocial personality disorder, avoidant personality disorder, borderline personality disorder, dependent personality disorder, histrionic personality disorder, narcissistic personality disorder, <b>obsessive-compulsive personality disorder, paranoid personality disorder, schizoid personality disorder, and schizotypal personality disorder</b>), psychotic disorders (e.g., brief psychotic disorder, delusional disorder, schizoaffective disorder, schizophreniform disorder, schizophrenia, and shared psychotic disorder), <b>substance-related disorders (e.g., alcohol dependence, amphetamine dependence, cannabis dependence, cocaine dependence, hallucinogen dependence, inhalant dependence, nicotine dependence, opioid dependence, phencyclidine dependence, and sedative dependence)</b>, adjustment disorder, autism, delirium, dementia, multi-infarct dementia, learning and memory disorders (e.g., amnesia and age-related memory loss), and Tourette's disorder.</p> <p>2. ISHIER RAOTE (2007) “Serotonin Receptors in Neuobiology - Serotonin 2A (5-HT2A) Receptor Function: Ligand-Dependent Mechanisms and Pathways” <i>CRC Press/Taylor &amp; Francis</i>. ISBN 0849339774. Pages 104-132.</p> <p>From <b>Implications in Diseases: Given the extensive localization of this receptor to brain areas that mediate cognitive functions and social interaction, it suggests that the 5-HT2A receptor might be involved in diseases in which these functions are impaired. Disorders in which the 5-HT2A receptor seems to be involved range from schizophrenia, depression, obsessive compulsive disorder (OCD), and attention deficit–hyperactivity disorder (ADHD), to eating disorders such as anorexia nervosa, to autism spectrum disorders.</b></p>
58. The method of claim 42, wherein the pharmaceutical	1. U.S. Pat. App. Pub. No. US/11000534B1 “Deuterated derivatives of psilocybin and uses thereof” (Published 11 May 2021)

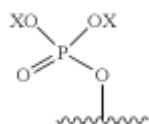
composition is administered orally to the subject.

From **Summary of the Invention: The compositions described herein comprise deuterated psilocybin and deuterated psilocin. In certain embodiments, the composition comprises a compound of Formula (I):**



**or a pharmaceutically acceptable salt, prodrug, hydrate, or solvate thereof;**

**wherein R is selected from —OX or**



**each X is independently protium or deuterium; and at least one X is enriched for deuterium.**

From **Definitions: Reference to deuterated psilocybin or deuterated psilocin herein (i.e., a compound of Formula (I)) or a pharmaceutically acceptable salt, prodrug, hydrate, or solvate thereof, includes all amorphous and polymorph forms.**

From **Detailed Description of Certain Embodiments of the Invention: In certain embodiments, a provided composition comprises one or more disintegrants or solubilizing agents, such as a cyclodextrin, or a carboxymethyl cellulose, calcium carboxymethyl cellulose, low-substituted hydroxypropyl cellulose, sodium croscarmellose, sodium carboxy starch, calcium carbonate, sodium carbonate and the like.**

From **Detailed Description of Certain Embodiments of the Invention: In certain embodiments, pharmaceutical excipients for an oral formulation include: diluents, such as, microcrystalline cellulose, starch, mannitol, calcium hydrogen phosphate anhydrous or co-mixtures of silicon dioxide, calcium carbonate, microcrystalline cellulose and talc**

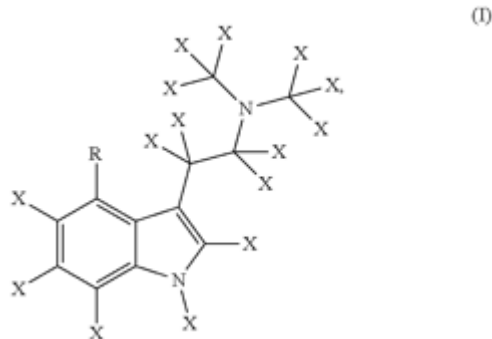
1. U.S. Pat. App. Pub. No. US/11000534B1 “Deuterated derivatives of psilocybin and uses thereof” (Published 11 May 2021)

From **Summary of the Invention: In certain embodiments, the percentage of the amount of the compound of Formula (I), or a pharmaceutically acceptable salt, prodrug, hydrate, or solvate thereof,**

	<p>relative to the total amount of psilocybin present in the composition ranges from about 1% to about 100%.</p> <p>From <b>Methods of Use and Uses</b>: In certain embodiments, the disease is a psychiatric disorder. The term “psychiatric disorder” refers to a disease of the mind and includes diseases and disorders listed in the <b>Diagnostic and Statistical Manual of Mental Disorders—Fourth Edition (DSM-IV)</b>, published by the American Psychiatric Association, Washington D. C. (1994). Psychiatric disorders include anxiety disorders (e.g., acute stress disorder agoraphobia, generalized anxiety disorder, obsessive-compulsive disorder, panic disorder, posttraumatic stress disorder, separation anxiety disorder, social phobia, and specific phobia), childhood disorders, (e.g., attention-deficit/hyperactivity disorder, conduct disorder, and oppositional defiant disorder), eating disorders (e.g., anorexia nervosa and bulimia nervosa), mood disorders (e.g., depression, bipolar disorder, cyclothymic disorder, dysthymic disorder, and major depressive disorder), personality disorders (e.g., antisocial personality disorder, avoidant personality disorder, borderline personality disorder, dependent personality disorder, histrionic personality disorder, narcissistic personality disorder, obsessive-compulsive personality disorder, paranoid personality disorder, schizoid personality disorder, and schizotypal personality disorder), psychotic disorders (e.g., brief psychotic disorder, delusional disorder, schizoaffective disorder, schizophreniform disorder, schizophrenia, and shared psychotic disorder), substance-related disorders (e.g., alcohol dependence, amphetamine dependence, cannabis dependence, cocaine dependence, hallucinogen dependence, inhalant dependence, nicotine dependence, opioid dependence, phencyclidine dependence, and sedative dependence), adjustment disorder, autism, delirium, dementia, multi-infarct dementia, learning and memory disorders (e.g., amnesia and age-related memory loss), and Tourette's disorder.</p> <p>2. ISHIER RAOTE (2007) “Serotonin Receptors in Neuobiology - Serotonin 2A (5-HT2A) Receptor Function: Ligand-Dependent Mechanisms and Pathways” <i>CRC Press/Taylor &amp; Francis</i>. ISBN 0849339774. Pages 104-132.</p> <p>From <b>Implications in Diseases</b>: Given the extensive localization of this receptor to brain areas that mediate cognitive functions and social interaction, it suggests that the 5-HT2A receptor might be involved in diseases in which these functions are impaired. Disorders in which the 5-HT2A receptor seems to be involved range from schizophrenia, depression, obsessive compulsive disorder (OCD), and attention deficit–hyperactivity disorder (ADHD), to eating disorders such as anorexia nervosa, to autism spectrum disorders.</p>
61. The method of claim 42, wherein the pharmaceutical	1. U.S. Pat. App. Pub. No. US/11000534B1 “Deuterated derivatives of psilocybin and uses thereof” (Published 11 May 2021)

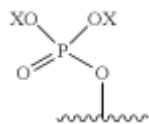
composition is administered to provide the compound of Formula (I) to the subject at a psychedelic dose of about 0.083 mg/kg to about 1 mg/kg.

From **Summary of the Invention: The compositions described herein comprise deuterated psilocybin and deuterated psilocin. In certain embodiments, the composition comprises a compound of Formula (I):**



**or a pharmaceutically acceptable salt, prodrug, hydrate, or solvate thereof;**

**wherein R is selected from —OX or**



**each X is independently protium or deuterium; and at least one X is enriched for deuterium.**

From **Definitions: Reference to deuterated psilocybin or deuterated psilocin herein (i.e., a compound of Formula (I)) or a pharmaceutically acceptable salt, prodrug, hydrate, or solvate thereof, includes all amorphous and polymorph forms.**

From **Detailed Description of Certain Embodiments of the Invention: In certain embodiments, a provided composition comprises one or more disintegrants or solubilizing agents, such as a cyclodextrin, or a carboxymethyl cellulose, calcium carboxymethyl cellulose, low-substituted hydroxypropyl cellulose, sodium croscarmellose, sodium carboxy starch, calcium carbonate, sodium carbonate and the like.**

1. U.S. Pat. App. Pub. No. US/11000534B1 “Deuterated derivatives of psilocybin and uses thereof” (Published 11 May 2021)

From **Summary of the Invention: In certain embodiments, the percentage of the amount of the compound of Formula (I), or a pharmaceutically acceptable salt, prodrug, hydrate, or solvate thereof, relative to the total amount of psilocybin present in the composition ranges from about 1% to about 100%.**

From **Methods of Use and Uses: In certain embodiments, the disease is a psychiatric disorder. The term “psychiatric disorder” refers to a disease of the mind and includes diseases and disorders listed in the Diagnostic and Statistical Manual of Mental Disorders—Fourth Edition (DSM-IV),**

published by the American Psychiatric Association, Washington D. C. (1994). Psychiatric disorders include anxiety disorders (e.g., acute stress disorder agoraphobia, generalized anxiety disorder, obsessive-compulsive disorder, panic disorder, posttraumatic stress disorder, separation anxiety disorder, social phobia, and specific phobia), childhood disorders, (e.g., attention-deficit/hyperactivity disorder, conduct disorder, and oppositional defiant disorder), eating disorders (e.g., anorexia nervosa and bulimia nervosa), mood disorders (e.g., depression, bipolar disorder, cyclothymic disorder, dysthymic disorder, and major depressive disorder), personality disorders (e.g., antisocial personality disorder, avoidant personality disorder, borderline personality disorder, dependent personality disorder, histrionic personality disorder, narcissistic personality disorder, obsessive-compulsive personality disorder, paranoid personality disorder, schizoid personality disorder, and schizotypal personality disorder), psychotic disorders (e.g., brief psychotic disorder, delusional disorder, schizoaffective disorder, schizophreniform disorder, schizophrenia, and shared psychotic disorder), substance-related disorders (e.g., alcohol dependence, amphetamine dependence, cannabis dependence, cocaine dependence, hallucinogen dependence, inhalant dependence, nicotine dependence, opioid dependence, phencyclidine dependence, and sedative dependence), adjustment disorder, autism, delirium, dementia, multi-infarct dementia, learning and memory disorders (e.g., amnesia and age-related memory loss), and Tourette's disorder.

**From Detailed Description of Certain Embodiments of the Invention:**  
**In another aspect, the pharmaceutical compositions described herein may be administered or consumed in a dose that is based on the weight of the subject. In one aspect, the pharmaceutical composition comprises an effective amount of about 0.05 mg/kg to about 2.0 mg/kg of the compound of Formula (I), or a pharmaceutically acceptable salt, prodrug, hydrate, or solvate thereof.**

2. ISHIER RAOTE (2007) "Serotonin Receptors in Neuobiology - Serotonin 2A (5-HT2A) Receptor Function: Ligand-Dependent Mechanisms and Pathways" *CRC Press/Taylor & Francis*. ISBN 0849339774. Pages 104-132.

**From Implications in Diseases: Given the extensive localization of this receptor to brain areas that mediate cognitive functions and social interaction, it suggests that the 5-HT2A receptor might be involved in diseases in which these functions are impaired. Disorders in which the 5-HT2A receptor seems to be involved range from schizophrenia, depression, obsessive compulsive disorder (OCD), and attention deficit-hyperactivity disorder (ADHD), to eating disorders such as anorexia nervosa, to autism spectrum disorders.**





UNITED STATES  
PATENT AND TRADEMARK OFFICE

P.O. Box 1450  
Alexandria, VA 22313 - 1450  
www.uspto.gov

## ELECTRONIC ACKNOWLEDGEMENT RECEIPT

APPLICATION #	RECEIPT DATE / TIME	ATTORNEY DOCKET #
<b>18/561,152</b>	<b>02/07/2025 10:16:49 AM Z ET</b>	

### Title of Invention

### Application Information

APPLICATION TYPE	PATENT #
CONFIRMATION #	FILED BY Jeremy Rolquin
PATENT CENTER # 69091568	FILING DATE 11/15/2023
CUSTOMER # -	FIRST NAMED INVENTOR
INTL. APPLICATION # -	INTL. FILING DATE -
CORRESPONDENCE ADDRESS -	AUTHORIZED BY -

### Documents

**TOTAL DOCUMENTS: 6**

DOCUMENT	PAGES	DESCRIPTION	SIZE (KB)
third-party-preissuance-submission.pdf	2	Third-Party Submission Under 37 CFR 1.290	44 KB
Concise-description-generated.pdf	2	Concise Description of Relevance	25 KB
Third-party-notification-request.pdf	1	Request for Notification of Non-compliant Third-Party Submission	13 KB
3PS.pdf	47	-	661 KB
3PS-3P.RELEVANCE.pdf (1-47)	47	Concise Description of Relevance	534 KB
3PS-3P.RELEVANCE.pdf (1-47)	47	Concise Description of Relevance	534 KB

Raote.pdf		28	-	615 KB
Raote-NPL.pdf	(1-28)	28	Non Patent Literature	610 KB

## Digest

DOCUMENT	MESSAGE DIGEST(SHA-512)
third-party-preissuance-submission.pdf	B307AC13014D6DAEE3EC20F8387045D752BA913716606EE0D207341CE73001D96925C99059EAB0862325EFC0FA9A11FFB44CA9C868D1A10779CE3416C2146628
Concise-description-generated.pdf	C532157F5B7B57A6C9A03BA05B6307568AAA0F3178B867D3B726EE0E5C7B525B9AC7777ABA9189CCAC8DA52ADDC5558002D557830BE152631548D992C0CE0759
Third-party-notification-request.pdf	9712AA1027AB19C1AE215BE69620E0694052ADD4F099C9220CA941790105A2F406950C67FBEBEC8B633B414373F0E36A096701F52912309BF92A4B758B41C321
3PS.pdf	7DED0265D7135F78A9B9AD6E18A5A4D2EE74BBF9EA96FDEACB97D55F1246F7A245527085961B46EF13198026B64E6422C396CD492DE67FD6DEC70D6F3DDE5002
3PS-3P.RELEVANCE.pdf	B6A04AB497B85CDC822F119158DF8A1446D2803E7A0EBF91D981AD0EF02A0E059F0F33E84FC4E9A82CF33809789AC848A8489F42549B0DE8016FD29481F08D8F
3PS-3P.RELEVANCE.pdf	76169CB844E6C1687DC6195C50E6EEEBA698DD0D212DA62E3ED34411518D563CC173383D3355029D1BC680AA13A7B3362DA7D431BB2E8B1EAC60C29B4F7A0EEB
Raote.pdf	C860222B74C7C770C799DC1C050078AE7A3CB78A0E7671B1D6AD5B5392ECFC3AB4B183C7BDFDB44A4B959A583ACB6631AEBEBFED8034B4C09348326CE20B6B9F
Raote-NPL.pdf	98E51BBE1533559823D01A5597C5F0DABCBDDA54DA3A313E2D91B643DBD60C9876A49E1ED2CCC0AA57F2EDFC6EC872919CE2A3CE123B1440A3A322E47AAFB1E0

This Acknowledgement Receipt evidences receipt on the noted date by the USPTO of the indicated documents, characterized by the applicant, and including page counts, where applicable. It serves as evidence of receipt similar to a Post Card, as described in MPEP 503.

### New Applications Under 35 U.S.C. 111

If a new application is being filed and the application includes the necessary components for filing date (see 37 CFR 1.53(b)-(d) and MPEP 506), a Filing Receipt (37 CFR 1.54) will be issued in due course and the date shown on this Acknowledgement Receipt will establish the filing date of the application

### National Stage of an International Application under 35 U.S.C. 371

If a timely submission to enter the national stage of an international application is compliant with the conditions of 35 U.S.C. 371 and other applicable requirements a Form PCT/DO/EO/903 indicating acceptance of the application as a national stage

submission under 35 U.S.C. 371 will be issued in addition to the Filing Receipt, in due course.

**New International Application Filed with the USPTO as a Receiving Office**

If a new international application is being filed and the international application includes the necessary components for an international filing date (see PCT Article 11 and MPEP 1810), a Notification of the International Application Number and of the International Filing Date (Form PCT/RO/105) will be issued in due course, subject to prescriptions concerning national security, and the date shown on this Acknowledgement Receipt will establish the international filing date of the application.