NATURAL HEALTH PRODUCT

MUSHROOMS

This monograph is intended to serve as a guide to industry for the preparation of Product Licence Applications (PLAs) and labels for natural health product market authorization. It is not intended to be a comprehensive review of the medicinal ingredients.

Notes

- Text in parentheses is additional optional information which can be included on the PLA and product label at the applicant’s discretion.
- The solidus (/) indicates that the terms and/or the statements are synonymous. Either term or statement may be selected by the applicant.

Date

December 8, 2015

Proper name(s), Common name(s) and Source material(s)

Table 1  Medicinal ingredients¹

<table>
<thead>
<tr>
<th>Proper name(s)</th>
<th>Common name(s)</th>
<th>Source material(s)</th>
</tr>
</thead>
</table>
| *Agaricus blazei*            | Himematsutake           | ▶ Fruiting body  
|                              |                         | ▶ Mycelia                                              |
|                              |                         | ▶ Cultured Mycelia                                     |
| *Auricularia auricula-judaе* | Jelly Ear               | ▶ Fruiting body  
|                              |                         | ▶ Mycelia                                              |
|                              |                         | ▶ Cultured Mycelia                                     |
| *Ganoderma applanatum*       | ▶ Artist’s conk         | ▶ Fruiting body  
|                              | ▶ Polypore aplanii      | ▶ Mycelia                                              |
|                              |                         | ▶ Cultured Mycelia                                     |
| *Ganoderma lucidum*          | As per NNHPD Reishi     | As per NNHPD Reishi                                    |
|                              | monograph               | monograph                                             |
| *Grifola frondosa*           | As per NNHPD Maitake    | As per NNHPD Maitake                                   |
|                              | monograph               | monograph                                             |
| *Hericium erinaceus*         | Lion’s Mane              | ▶ Fruiting body  
|                              |                         | ▶ Mycelia                                              |
|                              |                         | ▶ Cultured Mycelia                                     |
| *Inonotus obliquus*          | Chaga                   | ▶ Fruiting body  
|                              |                         | ▶ Mycelia                                              |
|                              |                         | ▶ Cultured Mycelia                                     |
| *Lentinula edodes*           | Shiitake                | ▶ Fruiting body  
<p>|                              |                         | ▶ Mycelia                                              |</p>
<table>
<thead>
<tr>
<th><strong>Mushrooms</strong></th>
<th><strong>Route(s) of administration</strong></th>
<th><strong>Dosage form(s)</strong></th>
<th><strong>Use(s) or Purpose(s)</strong></th>
</tr>
</thead>
</table>

**Route(s) of administration**

Oral

**Dosage form(s)**

- The acceptable pharmaceutical dosage forms include, but are not limited to, capsules, chewables (e.g. gummies, tablets), liquids, powders, strips or tablets.
- This monograph is not intended to include foods or food-like dosage forms such as bars, chewing gums or beverages.

**Use(s) or Purpose(s)**

Statement(s) to the effect of

*All products*

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A *Agaricus blazei* should be agaritine free. See specifications section for details.

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**Mushrooms**

<table>
<thead>
<tr>
<th><strong>Ophiocordyceps sinensis</strong></th>
<th><strong>Cultured Mycelia</strong></th>
<th><strong>Stroma</strong></th>
</tr>
</thead>
<tbody>
<tr>
<td>Dong chong xia cao</td>
<td>Cordyceps</td>
<td>Chinese Caterpillar Fungus</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th><strong>Paecilomyces hepali</strong></th>
<th><strong>Cultured Mycelia</strong></th>
<th><strong>Fa xiao chong cao jun fen</strong></th>
</tr>
</thead>
<tbody>
<tr>
<td>Cordyceps</td>
<td>Cultured Chinese Caterpillar Fungus Powder</td>
<td></td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th><strong>Schizophyllum commune</strong></th>
<th><strong>Split Gill fungus</strong></th>
<th><strong>Fruiting body</strong></th>
<th><strong>Mycelia</strong></th>
<th><strong>Cultured Mycelia</strong></th>
</tr>
</thead>
</table>

<table>
<thead>
<tr>
<th><strong>Trametes versicolor</strong></th>
<th><strong>Kawaratake</strong></th>
<th><strong>Turkey Tail</strong></th>
<th><strong>Yunzhi</strong></th>
<th><strong>Fruiting body</strong></th>
<th><strong>Mycelia</strong></th>
<th><strong>Cultured Mycelia</strong></th>
</tr>
</thead>
</table>

<table>
<thead>
<tr>
<th><strong>Tremella fuciformis</strong></th>
<th><strong>Silver ear</strong></th>
<th><strong>White Mushroom</strong></th>
<th><strong>Fruiting body</strong></th>
<th><strong>Mycelia</strong></th>
<th><strong>Cultured Mycelia</strong></th>
</tr>
</thead>
</table>

<table>
<thead>
<tr>
<th><strong>Wolfiporia extensa</strong></th>
<th><strong>As per NNHPD Poria Monograph</strong></th>
<th><strong>As per NNHPD Poria Monograph</strong></th>
<th><strong>As per NNHPD Poria Monograph</strong></th>
<th><strong>As per NNHPD Poria Monograph</strong></th>
</tr>
</thead>
</table>

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*As per NNHPD Poria Monograph*

Products containing Lentinula edodes fruiting body and/or (cultured) mycelia, a decocted fruiting body of Agaricus blazei, a decocted fruiting body of Hericium erinaceus, a decocted cultured mycelia of Paecilomyces hepali and/or a decocted stroma of Ophiocordyceps sinensis

- Source of antioxidants/Provides antioxidants that help fight/protect (cell) against/reduce (the oxidative effects of/the oxidative damage caused by/cell damage caused by) free radicals (De Sà-Nakanishi et al. 2014; Zheng et al. 2014; Han et al. 2013; Qi et al. 2013; Wang et al. 2011; Bisen et al. 2010; Xu et al. 2010).

Products containing Ganoderma lucidum, Grifola frondosa and/or Wolfiporia extensa

As per respective NNHPD monographs.

Products containing Ophiocordyceps sinensis stroma

Used in Traditional Chinese Medicine to help tonify and replenish the lungs and kidneys, and resolve phlegm (PPRC 2010; Liu et al. 2005; Bensky et al. 2004).

Products containing Paecilomyces hepali cultured mycelia

Used in Traditional Chinese Medicine to help tonify and replenish the lungs and kidneys, tonify essence, and replenish qi (PPRC 2010).

Products containing decocted fruiting body of Trametes versicolor

Used in Traditional Chinese Medicine to fortify the spleen to drain dampness and clear toxic heat (PPRC 2010).

Products containing decocted fruiting body of Tremella fuciformis

Used in Traditional Chinese Medicine to nourish the stomach yin, moisten the lungs and generate fluids; for yin deficiency with ascendant yang (Bensky et al. 2004).

Products containing fruiting body or (cultured) mycelium of Lentinula edodes

Used in Herbal Medicine to support the immune system (Hobbs 2003; Wasser 2002).

Dose(s)
Subpopulation(s)

Adults (≥ 18 years)

Quantity(ies)

Table 2  Acceptable Methods of Preparation and Dosing

<table>
<thead>
<tr>
<th>Proper name(s)</th>
<th>Method(s) of Preparation</th>
<th>Dose(s)</th>
</tr>
</thead>
<tbody>
<tr>
<td><em>Agaricus blazei</em></td>
<td>Decoction</td>
<td>Up to 9 g of dried mushroom per day</td>
</tr>
<tr>
<td><em>Auricularia auricula-judae</em></td>
<td>Decoction</td>
<td>Up to 15 g of dried mushroom per day</td>
</tr>
<tr>
<td></td>
<td>Powder, tincture, fluid extract</td>
<td>Up to 3.6 g of dried mushroom per day</td>
</tr>
<tr>
<td><em>Ganoderma applanatum</em></td>
<td>Decoction</td>
<td>Up to 30 g of dried mushroom per day</td>
</tr>
<tr>
<td></td>
<td>Powder, tincture, fluid extract</td>
<td>Up to 3.6 g of dried mushroom per day</td>
</tr>
<tr>
<td><em>Ganoderma lucidum</em></td>
<td>As per NNHPD Reishi monograph</td>
<td>As per NNHPD Reishi monograph</td>
</tr>
<tr>
<td><em>Grifola frondosa</em></td>
<td>As per NNHPD Maitake monograph</td>
<td>As per NNHPD Maitake monograph</td>
</tr>
<tr>
<td><em>Hericium erinaceus</em></td>
<td>Decoction</td>
<td>Up to 12 g of dried mushroom per day</td>
</tr>
<tr>
<td></td>
<td>Powder, tincture, fluid extract</td>
<td>Up to 2.8 g of dried mushroom per day</td>
</tr>
<tr>
<td><em>Inonotus obliquus</em></td>
<td>Powder, tincture, fluid extract, decoction</td>
<td>Up to 3.6 g of dried mushroom per day</td>
</tr>
<tr>
<td><em>Lentinula edodes</em></td>
<td>Decoction</td>
<td>Up to 16 g of dried mushroom per day</td>
</tr>
<tr>
<td></td>
<td>Powder, tincture, fluid extract</td>
<td>Minimum 6 g of dried mushroom per day for Herbal Medicine claim</td>
</tr>
<tr>
<td><em>Ophiocordyceps sinensis</em></td>
<td>Decoction</td>
<td>Up to 9 g of dried mushroom per day</td>
</tr>
<tr>
<td></td>
<td>Powder, tincture, fluid extract</td>
<td>Minimum 3 g of dried mushroom per day for Traditional Chinese Medicine (TCM) claim</td>
</tr>
<tr>
<td><em>Paecilomyces hepali</em></td>
<td>Decoction</td>
<td>Up to 9 g of dried mushroom per day</td>
</tr>
<tr>
<td></td>
<td>Powder, tincture, fluid extract</td>
<td>Minimum 3 g of dried mushroom per day for TCM claim</td>
</tr>
<tr>
<td>Medicinal Ingredient</td>
<td>Formulation</td>
<td>Powder, tincture, fluid extract</td>
</tr>
<tr>
<td>---------------------------</td>
<td>------------------------------</td>
<td>---------------------------------</td>
</tr>
<tr>
<td><strong>Schizophyllum commune</strong></td>
<td></td>
<td>Up to 3 g of dried mushroom per day</td>
</tr>
<tr>
<td></td>
<td></td>
<td>Minimum 1.5 g of dried mushroom per day for TCM claim</td>
</tr>
<tr>
<td></td>
<td></td>
<td>Up to 3.6 g of dried mushroom per day</td>
</tr>
<tr>
<td><strong>Trametes versicolor</strong></td>
<td></td>
<td>Up to 27 g of dried mushroom per day</td>
</tr>
<tr>
<td></td>
<td></td>
<td>Minimum 9 g of dried mushroom per day</td>
</tr>
<tr>
<td></td>
<td></td>
<td>Minimum 3 g of dried mushroom per day</td>
</tr>
<tr>
<td><strong>Tremella fuciformis</strong></td>
<td></td>
<td>Up to 9 g of dried mushroom per day</td>
</tr>
<tr>
<td></td>
<td></td>
<td>Minimum 3 g of dried mushroom per day</td>
</tr>
<tr>
<td></td>
<td></td>
<td>Minimum 1.5 g of dried mushroom per day for TCM claim</td>
</tr>
<tr>
<td><strong>Wolfiporia extensa</strong></td>
<td></td>
<td>As per NNHPD Poria Monograph</td>
</tr>
<tr>
<td></td>
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<td>As per NNHPD Poria Monograph</td>
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<tr>
<td></td>
<td></td>
<td>As per NNHPD Poria Monograph</td>
</tr>
</tbody>
</table>

1The following references have been consulted: PPRC 2010; Mori et al. 2009; Liu et al. 2008; Liu et al. 2005; Bensky et al. 2004; Hobbs 2003; Levy et al. 1998; MHPRC 1998; Ying 1987.

**Note**

Potency (optional) for each medicinal ingredient: up to 40% polysaccharides.

**Directions for use**

No statement required.

**Duration of use**

Statement(s) to the effect of

**Products containing Wolfiporia extensa**

As per NNHPD Poria monograph.

**Risk information**

Statement(s) to the effect of

Consult Table 3 to determine the required risk statements for each medicinal ingredient. The medicinal ingredients of Table 3 are associated with the numbered statements below. For products containing *Auricularia auricula-judae*, the caution and warning statement “If you are pregnant or breastfeeding, consult a health care practitioner prior to use” will not be needed as it will be covered by a contraindication for that subpopulation (statement #8).

**Caution(s) and warning(s)**

1. If you are pregnant or breastfeeding, consult a health care practitioner prior to use.
2. If claims related to reductions of symptoms are made: If symptoms persist or worsen, consult a health care practitioner.

3. Products providing ≥ 150 mg of dried *Grifola frondosa*, used as powder, tincture or fluid extract and/or ≥ 300 mg of dried *Grifola frondosa*, used as decoction, and/or ≥ 300 mg of dried *Agaricus blazei*: If you have diabetes, consult a healthcare practitioner prior to use (Brinker 2010; Firenzuoli *et al.* 2008; Hsu *et al.* 2007; Konno 2003, 2001).

4. If you are taking blood thinners (anti-coagulants), consult a health care practitioner prior to use (Bisen *et al.* 2010; Wasser 2005).

5. Products making TCM claims based on *Ophiocordyceps sinensis* or *Paecilomyces hepali*: If you have exterior pathogens/conditions, consult a health care practitioner prior to use (Bensky *et al.* 2004).

6. Products making TCM claims based on *Tremella fuciformis*: If you have cough from wind-cold, consult a health care practitioner prior to use (Bensky *et al.* 2004).

7. Products making TCM claims based on *Wolfiporia extensa*: If you have a yin deficiency, sunken Spleen qi, or cold from deficiency with spermatorrhea, consult a health care practitioner prior to use (Bensky *et al.* 2004; Chen and Chen 2004).

**Contraindication(s)**

8. If you are pregnant or breastfeeding, do not use this product.

**Known adverse reaction(s)**


10. Diuretic effect may occur (PPRC 2010).

### Table 3  Risk information

<table>
<thead>
<tr>
<th>Medicinal Ingredient</th>
<th>Risk Information</th>
</tr>
</thead>
<tbody>
<tr>
<td><em>Agaricus blazei</em></td>
<td>1, 3</td>
</tr>
<tr>
<td><em>Auricularia auricula-judae</em></td>
<td>8</td>
</tr>
<tr>
<td><em>Ganoderma applanatum</em></td>
<td>1</td>
</tr>
<tr>
<td><em>Ganoderma lucidum</em></td>
<td>2, 9</td>
</tr>
<tr>
<td><em>Grifola frondosa</em></td>
<td>3</td>
</tr>
<tr>
<td><em>Hericium erinaceus</em></td>
<td>1</td>
</tr>
<tr>
<td><em>Inonotus obliquus</em></td>
<td>1</td>
</tr>
<tr>
<td><em>Lentinula edodes</em></td>
<td>4, 9</td>
</tr>
<tr>
<td><em>Ophiocordyceps sinensis</em></td>
<td>1, 2, 5</td>
</tr>
<tr>
<td><em>Paecilomyces hepali</em></td>
<td>1, 2, 5</td>
</tr>
</tbody>
</table>
### Non-medicinal ingredients

Must be chosen from the current Natural Health Products Ingredients Database (NHPID) and must meet the limitations outlined in the database.

### Storage conditions

No statement required.

### Specifications

- The finished product specifications must be established in accordance with the requirements described in the Natural and Non-prescription Health Products Directorate Quality of Natural Health Products Guide.
- The medicinal ingredient must comply with the requirements outlined in the NHPID.
- The product must not contain any traces of agaritine.

### References cited


Chu KK, Ho SS, Chow AH. *Coriolus versicolor*: a medicinal mushroom with promising immunotherapeutic values. Journal of Clinical Pharmacology 2002;42(9):976-984.


Li SP, Su ZR, Dong TT, Tsim KW. The fruiting body and its caterpillar host of *Cordyceps sinensis* show close resemblance in main constituents and anti-oxidation activity. Phytomedicine 2002;9(4):319-324.


Wasser SP. Medicinal mushrooms as a source of antitumor and immunomodulating polysaccharides. Applied Microbiology and Biotechnology 2002;60(3):258-274.


References reviewed


Li SP, Su ZR, Dong TT, Tsim KW. The fruiting body and its caterpillar host of Cordyceps sinensis show close resemblance in main constituents and anti-oxidation activity. Phytomedicine 2002;9(4):319-324.


Ning X, Luo Q, Li C, Ding Z, Pang J, Zhao C. Inhibitory effects of a polysaccharide extract from the Chaga medicinal mushroom, *Inonotus obliquus* (higher Basidiomycetes), on the proliferation...


Stamets P. Controlling Zoonotic Disease Vectors from insects and arthropods using preconidial mycelium and extracts of preconidial mycelium from entomopathogenic fungi. US8753656 B2; 2014.


