## **Commercial Labeling of Medicinal Mushroom Products**

## By Jeff Chilton, Guest Contributor

Medicinal mushrooms are fungal organisms sold as health foods, nutritional supplements, so-called nutraceuticals, and, on occasion, cosmetics ingredients. They are part of an extensive natural health products category in Asia, where traditional Chinese medicine has utilized mushroom preparations for thousands of years. China is the historical site of shiitake mushroom (*Lentinula edodes*, Marasmiaceae) cultivation, which is reported to have originated in the 12th century. Today, China is responsible for 85% of the world's mushroom production.<sup>1</sup>

The estimated worldwide market value of medicinal mushrooms was \$6 billion in 1999, and \$18 billion in 2014.<sup>2,3</sup> Over the last 25 years the market for these products has expanded greatly in North America, and, today, just about every dietary supplement company has one or more mushroom-related formulations in their product line. In light of this growth trajectory, medicinal mushrooms are destined to become a much bigger product category.

Category growth is likely to attract increased scrutiny by the US Food and Drug Administration (FDA) and other governmental bodies. It is, therefore, more important than ever to properly define medicinal mushrooms and ensure that products meet ingredient labeling



requirements. This also raises ethical and liability issues for companies that may be selling products that do not conform to FDA standards for product authenticity. It is well known that different parts of the same plant may contain varying levels of active compounds. Likewise, depending on the stage of growth or parts used, fungi may contain different levels of distinct medicinal constituents as well. This is an important consideration for traditional healers and herbalists, as well as commercial entities, all of which want to be certain that the medicinal values and benefits they seek are in fact present. This is also why the FDA requires the "plant part" to be listed in the Supplement Facts panel for all botanical (and fungal) ingredients in dietary supplements.

Few companies realize that medicinal mushrooms as a category encompass more than just mushrooms. A mushroom is just one stage of these fungal organisms' life cycles. Most of the particular fungal organisms that are generally referred to as medicinal mushrooms belong to a taxonomic grouping called basidiomycetes. The genera *Ophiocordyceps* (family: Ophiocordycipitaceae) and *Cordyceps* (family: Cordycipitaceae) are exceptions and belong to the ascomycetes.<sup>4</sup>

Understanding the life cycle of a basidiomycete helps to define its respective components. What is commercially referred to as a medicinal mushroom is actually four distinct parts of a basidiomycete: mushroom, mycelium, sclerotium, and spore.

It is fitting to start with the spore, which is the beginning and end of the basidiomycete life cycle. Similar in function to a seed, fungal spores will germinate when environmental conditions are favorable. The germinating spore produces a hypha, a threadlike tube that spreads and branches in every direction. When multiple spores germinate and their hyphae grow together, a root-like network called a mycelium is formed.<sup>4</sup>

Mycelium is considered the vegetative stage of the basidiomycete.<sup>5</sup> In nature, one rarely sees the mycelium because it is naturally embedded in its food source, what is often referred to as the "substrate." Using the secretion of enzymes to digest its substrate, the mycelium grows in and feeds off of a diverse menu of dead organic matter, such as trees, woody debris, fallen leaves, and annual plants of all kinds. Fungal mycelium is one of nature's premier recyclers and is especially adept at breaking down cellulosic materials.

When environmental conditions are conducive, a fertile mycelium will produce a mushroom. The mushroom is defined as a specialized reproductive structure. A mushroom can be separated further into parts such as the stem, cap, gills or pores, and spores, but other than spores, this level of differentiation has not yet been commercially promoted or supported by consistent scientific analyses. That may change in the future as more research is conducted on these specific parts of the mushroom, and certainly companies are free to differentiate using this subset.

Vegetative mycelium can also form a dense and often hardened, irregular mass called a sclerotium. This sclerotium is considered a means for many fungi to survive environmental extremes such as freezing. When conditions improve, sclerotia provide food reserves for the production of fruiting bodies. Two important medicinal basidiomycetes are used in the sclerotial form: chaga (*Inonotus obliquus*, Hymenochaetaceae) and poria (*Wolfiporia extensa*, Polyporaceae). Although these are commonly called "mushrooms," they are classified more accurately as sclerotium or mycelium.

The mushroom and mycelium are similar in that both are composed of hyphae, but they are meaningfully different in structure, composition, and function. Mycelium is the "vegetative body" of a fungal organism, whereas the mushroom is considered the "fruiting body."<sup>6</sup> Mushroom and mycelium are not synonymous — an important and necessary distinction. For example, with respect to *Ganoderma lucidum* (Ganodermataceae), one can correctly say "reishi mycelium" or "Ganoderma mycelium," but it is incorrect to say "reishi mushroom mycelium" since these are separate parts. Therefore, per existing regulation, it is not permissible for a company to have a product label that says "reishi mushroom" when the ingredients are primarily reishi mycelium or reishi spores. So one must be certain of the stage of the fungal organism that is being sold and label it accordingly.

Since mycelium is often propagated using grain as a substrate, many basidiomycete products consist of inoculated grain — what some call a "biomass." The overwhelming majority of these products are marketed and labeled as mushrooms. This is a classic case of mislabeling since there are no mushrooms (in the true sense of the word, as just noted above) in these products. Furthermore, the presence of the grain needs to be listed on the label as an ingredient since these biomass products are not 100% pure mycelium but new and novel products. For example, it may be necessary to label a product as "reishi mycelium biomass," rather than "reishi mycelium," especially if the amount of mycelium is less than the residual grain. The actual amount of mycelium in the biomass can be readily tested by ergosterol analysis, and the grain residue can be measured by a starch test.<sup>7-9</sup> If the grain is not listed as an ingredient of this mycelium biomass product, it could reasonably be considered an adulterant.

In the case of a blend of different basidiomycete stages, proper labeling would state the percentage of each stage that was included. One could not simply say mycelium, mushroom, and spore. Some biomass manufacturers claim mushroom inclusion due to the presence of mushroom primordia. Primordia are not actual mushrooms, but simply the initial mycelium mass that, over time, becomes a mushroom.

In 1976, the FDA issued a statement in its Compliance Policy Guide, Section 585.525: Mushroom Mycelium – Fitness for Food; Labeling. It states: "Any food in which mushroom mycelium [sic] is used should be labeled to state that fact. Labeling should not suggest or imply that the food contains mushrooms."<sup>6</sup> It could not be clearer.

In conclusion, proper labeling of medicinal basidiomycete products is an issue that cannot be ignored. With five primary fungal ingredients in the marketplace — mushroom, pure mycelium, mycelium on grain biomass, sclerotium, and spore preparations — proper labeling is more essential than ever for manufacturers to know what they are selling. Just as important, practitioners and consumers need to know exactly what they are buying.

Jeff Chilton started growing mushrooms commercially in 1973. In 1983, he co-authored the highly acclaimed book The Mushroom Cultivator (Agarikon Press, 1983). In the 1980s, he operated a commercial mushroom spawn laboratory, and, in 1989, he started one of the first medicinal mushroom businesses in North America. His company, Nammex, sells certified organic basidiomycete raw materials. Contact Mr. Chilton by email at jeff@nammex.com.

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