Press Release

Nammex Files Citizen Petition Requesting FDA Actions on Mushroom Product Labeling

Gibsons, BC, Canada (June 13, 2023) – North American Reishi Ltd ("Nammex"), the premier North American supplier of Certified Organic Functional Mushroom Extracts, has filed a Citizen Petition with FDA requesting the Agency to address the mislabeling of dietary supplements and functional foods as "mushroom" or containing "mushrooms" when they contain other fungal parts, and do not contain "mushrooms" as claimed, or fail to disclose added grain ingredients.

For many years, Nammex has been advocating for full transparency in product labeling and urging companies in the industry to identify ingredients from fungi according to the part of the fungal organism from which they are derived, consistent with FDA's labeling requirement for botanicals. While there has been some, although limited progress, in light of ambiguity in FDA's labeling regulations and compliance policies, Nammex Founder Jeff Chilton decided that it was time to raise public awareness and request guidance as well as increased attention from FDA to ensure industry compliance.

"Given the explosive growth the mushroom category is undergoing and entry of new companies marketing products with fungal ingredients that may not be aware of the regulatory requirements, it made sense to undertake this action now. We hope to raise awareness of the mislabeling problem that exists today in the US, and obtain FDA regulatory guidance on the labeling of mushrooms and other fungal ingredients to ensure truth-in-labeling," Jeff said. "When consumers buy a product labeled as "mushroom", they should feel confident that they are getting a genuine mushroom product."

According to Nammex's regulatory counsel, Holly Bayne of the Law Office of Bayne & Associates, "Citizen Petitions provide a public forum through which interested parties can request FDA to issue or amend a regulation or take other administrative action. As the petition has made clear, remedial action from FDA is warranted, including revisions to the Agency's compliance policies to ensure foods and dietary supplements containing fungal ingredients are accurately labeled and not misbranded. We look forward to engaging with FDA on this important issue."

The petition asks FDA to correct ambiguity in the dietary supplement labeling regulations to clarify that proper listing of ingredients from fungi on product labels includes identification of the part of the fungal organism from which the ingredient is derived. Nammex also requests that FDA issue industry guidance regarding the proper labeling of fungal ingredients, including a

Glossary of Mycological terms. Further, Nammex requests that FDA increase regulatory enforcement to ensure foods and dietary supplements containing fungal ingredients are accurately labeled, and take appropriate action against products labeled as "mushroom" when they do not contain mushrooms as claimed, but contain other fungal parts, such as mycelium, and fail to identify the presence of grain in the product.

The Agency has 180 days to respond to the petition. Nammex intends to keep the industry informed though out the process.

About Nammex

Since 1989, Nammex has pioneered the cultivation of organic mushrooms and development of high quality mushroom extracts to support consumer health and wellness. For over 30 years, Nammex has been a leader in advancing the scientific understanding of mushroom extracts and commercial use of scientifically validated analytical methods for quality control testing of fungal products. Nammex's mushroom extracts and concentrates are produced under rigorous quality standards, including : growing mushrooms naturally using organic practices, processing the mushrooms following cGMP standards, QC testing in qualified laboratories, and yearly audits of farm and factory. Nammex founder and President Jeff Chilton has deep, longstanding relationships with China's top researchers and growers of medicinal mushrooms.
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