U.S. FOOD & DRUG ADMINISTRATION
CENTER FOR FOOD SAFETY & APPLIED NUTRITION

Laura M. Plunkett, Ph.D., DABT
Bio Policy Solutions LLC
1127 Eldridge Pkwy, Suite 300-335
Houston, TX 77077-1528

Re: GRAS Notice No. GRN 001152

Dear Dr. Plunkett:

The Food and Drug Administration (FDA, we) is granting the request on behalf of Mushlabs to cease our evaluation of GRN 001152, which we filed on November 7, 2023. We received this request on March 19, 2024.

The subject of the notice is Phoenix oyster mushroom (*Pleurotus pulmonarius*) mycelia biomass for use as a source of protein and fiber in dairy alternatives (milk, cream, yogurt, ice cream, and processed cheese); meat alternatives; fish and seafood alternatives; and baked goods at maximum levels ranging from 10 to 25 g/100g. [1] The notice informs us of Mushlabs' view that these uses of Phoenix oyster mushroom mycelia biomass are GRAS through scientific procedures.

In an email dated January 26, 2024, and during a subsequent teleconference held on February 7, 2024, we informed you that we had concerns regarding deficiencies identified in the safety narrative, particularly regarding the data and information about the potential differential gene expression between the fruiting body and the mycelium and questions on how that may translate into a differential safety profile for consumption.

In accordance with 21 CFR 170.275(b)(3), the text of this letter responding to GRN 001152 is accessible to the public at www.fda.gov/grasnoticeinventory.

Sincerely,

Susan J. Carlson -S Digitally signed by Susan J. Carlson -S
Date: 2024.03.21 14:49:04 -04'00'

Susan J. Carlson, Ph.D.
Director
Division of Food Ingredients
Office of Food Additive Safety
Center for Food Safety
and Applied Nutrition

[1] Mushlabs states that Phoenix oyster mushroom mycelia biomass is not intended for use in infant formula, or in food products under the jurisdiction of the United States Department of Agriculture.