U.S. FOOD & DRUG ADMINISTRATION

Human Foods Program

Laura Plunkett, Ph.D.
BioPolicy Solutions LLC
1127 Eldridge Parkway Suite 300-335
Houston, Texas 77077

Re: GRAS Notice No. GRN 001220

Dear Dr. Plunkett:

The Food and Drug Administration (FDA, we) is granting the request on behalf of Mushlabs GmbH (Mushlabs) that we cease our evaluation of GRN 001220. We received this request on August 14, 2025. We received Mushlabs's notice on September 12, 2024 and filed it on January 23, 2025. Mushlabs submitted amendments to the notice on June 4, 2025, June 19, 2025, July 29, 2025, and August 4, 2025, providing additional information on the organism, manufacturing method, specifications, intended uses, and dietary exposure.

The subject of the notice is mycelial biomass of *Pleurotus pulmonarius* (fungal protein) for use as an ingredient in meat analogs, processed cheese, ice cream, and baked goods at a level of up to 25% in the final food. The notice informs us of Mushlabs's view that these uses of fungal protein are GRAS through scientific procedures.

In an email on July 15, 2025, and a phone call on July 22, 2025, we communicated with you as Mushlabs's representative regarding additional information needed to support a GRAS conclusion. Complete and accurate dietary exposures to mycelial biomass, protein, and fiber from the intended uses of fungal protein are needed. Additionally, a narrative supporting the safety of the dietary exposure to fiber is needed.

We have ceased our evaluation of the notice at your request on behalf of Mushlabs's request. We remind Mushlabs of a manufacturer's responsibility to ensure the safety and regulatory status of the substances that it markets for use in food or that it uses in food. We also remind Mushlabs that the use of a substance in food that is not GRAS (and is not otherwise excluded from the definition of a food additive), must have pre-market approval by FDA for its use in food (21 CFR 170.30(g)). More information about the criteria for GRAS is available in our regulations (21 CFR part 170).

Your request on behalf of Mushlabs does not preclude Mushlabs from submitting a future GRAS notice with respect to the subject of this notice (21 CFR 170.260(b)). We recommend that Mushlabs address these issues to adequately support a GRAS conclusion. Finally, we remind Mushlabs of the signed statements and certification (part 1 of a GRAS notice, 21 CFR 170.225) by which Mushlabs agrees to make all data and information regarding its GRAS conclusion available to FDA upon request.

In accordance with 21 CFR 170.275(b)(3), the text of this letter responding to GRN 001220 is accessible to the public at www.fda.gov/grasnoticeinventory.

Sincerely,

Susan J. Carlson -S

Digitally signed by Susan J. Carlson -S
Date: 2025.08.15 17:54:23 -04'00'

Susan J. Carlson, Ph.D.
Director
Division of Food Ingredients
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