



Nicole K. Berzins  
MycoTechnology Inc  
3155 North Chambers Road  
Aurora, CO 80011

Re: GRAS Notice No. GRN 000794

Dear Ms. Berzins:

The Food and Drug Administration (FDA, we) is granting your request to cease our evaluation of GRN 000794, which we filed on July 26, 2018. We received your request in an email on October 30, 2018.

The subject of the notice is fermented shiitake, pea, and brown rice protein. The notice informs FDA of MycoTechnology's view that fermented shiitake, pea, and brown rice protein is GRAS, through scientific procedures, for use as an ingredient in foods where proteins are used, including but not limited to, dry blend beverage bases (e.g. smoothies, protein powder mixes), ready to drink beverages, baked goods and baking mixes, and soups and soup mixes, at levels ranging from 1% to 40%.

On October 1, 2018, we held a teleconference with you to discuss issues we identified during our evaluation of GRN 000794. On October 23, 2018, we sent you an email with a summary of several issues that GRN 000794 failed to address. We discussed that: 1) the notice lacks sufficient information about the identity of the notified substance, 2) the notice does not clearly describe the manufacturing process of the substance, 3) the notice does not provide a sufficient narrative about the safety of consumption of the shiitake mycelia and the notified substance.


We recommended that MycoTechnology request that we cease our evaluation of GRN 000794 to ensure sufficient time to address these issues, and we suggested that MycoTechnology meet with us before submitting a new notice. In your email dated October 30, 2018, you stated that MycoTechnology agreed with these suggestions.

U.S. Food and Drug Administration  
Center for Food Safety & Applied Nutrition  
5001 Campus Drive  
College Park, MD 20740  
[www.fda.gov](http://www.fda.gov)

In accordance with 21 CFR 170.275(b)(3), the text of this letter responding to GRN 000794 is accessible to the public at [www.fda.gov/grasnoticeinventory](http://www.fda.gov/grasnoticeinventory).

Sincerely,

Susan J.  
Carlson -S

 Digitally signed by Susan J.  
Carlson -S  
Date: 2018.11.09 15:55:57  
-05'00'

Susan J. Carlson, Ph.D.  
Director  
Division of Biotechnology  
and GRAS Notice Review  
Office of Food Additive Safety  
Center for Food Safety  
and Applied Nutrition