Dr. Elizabeth Hood
Director of Research and Development
GreenLab, Inc.
2713 Paula Drive
Jonesboro, AR 72404

RE: NPC 000019; Manganese-dependent peroxidase

Dear Dr. Hood:

This letter is in response to GreenLab, Inc.'s (formerly Infinite Enzymes, Inc.) early food safety evaluation of the protein, manganese-dependent peroxidase (MnP) from *Phanerochaete chrysosporium*, expressed in a new plant variety. GreenLab initially intends for MnP to be used in environmental detoxification and bioremediation efforts; however, you acknowledge in an email (March 31, 2022) the possibility that use of MnP may extend to food products in the future. You submitted GreenLab's evaluation to the Food and Drug Administration (FDA) under our guidance to industry, "Recommendations for the Early Food Safety Evaluation of New Non-Pesticidal Proteins Produced by New Plant Varieties Intended for Food Use."[1] We received GreenLab's evaluation on February 28, 2022. We received additional information from GreenLab on October 6 and November 23, 2022, and February 27, 2023. In this letter and in the guidance, the term "food" refers to both human and animal food. All materials relevant to this evaluation have been placed in a file designated NPC 000019. This file will be maintained in the Office of Food Additive Safety in the Center for Food Safety and Applied Nutrition.

Based on your early food safety evaluation, it is our understanding that GreenLab has concluded that the potential inadvertent presence in the food supply of low levels of MnP would not raise food safety concerns. We have completed our evaluation of your submission, and we have no questions at this time regarding GreenLab's conclusion.

In 1996, FDA issued guidance on consultation procedures for foods derived from new plant varieties.[1] The submission of an early food safety evaluation for a new protein is not meant to substitute for a biotechnology consultation or other appropriate regulatory process with FDA about food derived from a new plant variety. We anticipate that GreenLab will participate in appropriate regulatory review processes prior to marketing food derived from new plant

[1] Accessible from https://www.fda.gov/food/food-new-plant-varieties/consultation-programs-food-new-plant-varieties

varieties expressing MnP. We recommend that you contact CFSAN's Office of Food Additive Safety (premarkt@fda.hhs.gov) for human food use, and CVM's Division of Animal Food Ingredients (animalfood-premarket@fda.hhs.gov) for animal food use to discuss regulatory and safety considerations of intended use in food under the Federal Food, Drug, and Cosmetic Act.

Sincerely,

Mary D. Ditto -S

Digitally signed by Mary D. Ditto -S
Date: 2024.07.26 11:15:48 -04'00'

Mary D. Ditto, Ph.D.
Director
Division of Science and Technology
Center for Food Safety
and Applied Nutrition