



James M. Ligon, Ph.D.
VP, Regulatory Affairs and Stewardship
Agrivida, Inc.
1023 Christopher Drive
Chapel Hill, NC 27517

RE: NPC 000018; AC1 glucanase

Dear Dr. Ligon:

This letter is in response to Agrivida's early food safety evaluation of the protein, AC1 glucanase,¹ expressed in new plant varieties under development. AC1 glucanase is intended for use to degrade nonstarch polysaccharide compounds in poultry and swine feed following consumption by the animal, thereby reducing the viscosity of the digesta. You submitted your 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" (available on the FDA internet site²). We received your evaluation on October 5, 2017. We received additional information from you on January 22, 2018. In this letter and in the guidance, the term "food" refers to both human and animal food. The administrative record for this evaluation has been placed in a file designated NPC 000018. 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 Agrivida has concluded that the potential inadvertent presence in the food supply of low levels of AC1 glucanase would not raise food safety concerns. We have completed our evaluation of your submission, and we have no questions at this time regarding Agrivida's conclusion.

In 1996, FDA issued guidance on consultation procedures for foods derived from new plant varieties (accessible from <http://www.fda.gov/GEplantfoods>). The submission of an early food safety evaluation for a new protein is not meant to substitute for a biotechnology consultation (or

¹ In its evaluation, Agrivida refers to the enzyme as Carbohydrase AC1. In a letter dated January 22, 2018, you state that you will instead refer to the enzyme as AC1 glucanase since its major enzymatic activity is β -1,4 endoglucanase.

² From the FDA home page at <http://www.fda.gov> – follow the hyperlink from the "Regulatory Information/Guidance Documents" topic and type "early food safety" in the Guidance Document search field.

other appropriate regulatory process) with FDA about food derived from a new bioengineered plant variety. We anticipate that Agrivida will participate in appropriate regulatory review processes prior to marketing food derived from new plant varieties expressing AC1 glucanase.

Sincerely,

**Susan J.
Carlson -S**

Digitally signed by Susan J. Carlson -S
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**Susan J. Carlson, Ph.D.
Director
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