



January 10, 2025

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

RE: Biotechnology Notification File No. BNF 000181

Dear Dr. Ligon:

This letter addresses Agrivida, Inc.'s (Agrivida's) consultation with the Food and Drug Administration (FDA, we) (Human Foods Program (HFP) and Center for Veterinary Medicine (CVM)) on genetically engineered corn, FG259 corn. According to information Agrivida has provided, FG259 corn is genetically engineered to express the AC1 beta-glucanase enzyme as a source of AC1 beta-glucanase. The administrative record for this consultation has been placed in a file designated BNF 000181. This file will be maintained in the Office of Food Chemical Safety, Dietary Supplements, and Innovation in HFP.

As part of this consultation, Agrivida submitted to FDA a summary of its safety and nutritional assessment of FG259 corn, which FDA received on December 3, 2020. Agrivida submitted additional information, received by FDA on February 22, 2021, August 30, 2022, and May 11, 2023. These communications informed FDA of the steps taken by Agrivida to ensure that this product complies with the legal and regulatory requirements that fall within FDA's jurisdiction.

Although FG259 corn is not intended for use in human food, Agrivida assessed the safety of FG259 corn if present in human food. Based on the safety and nutritional assessment Agrivida has conducted, it is HFP's understanding that Agrivida has concluded that FG259 corn is not materially different in composition, safety, and other relevant parameters from corn-derived human food currently on the market, and that genetically engineered FG259 corn does not raise issues that would require premarket review or approval by FDA if present in human food.

In its submission, Agrivida stated that the FG259 corn is intended for use as a source of the AC1 beta-glucanase enzyme when added to poultry and swine diets. CVM has already evaluated Agrivida's Generally Recognized as Safe conclusion for the intended use of ground grain from FG259 corn in poultry<sup>1</sup> and swine<sup>2</sup> food; and therefore, CVM does not intend to evaluate the

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<sup>1</sup> In AGRN 31, CVM evaluated Agrivida's conclusion that the ground grain obtained from FG259 corn to decrease the viscosity of digesta in poultry consuming feed containing high amounts of soluble non-starch polysaccharides when used to provide 200-500 beta-glucanase activity units per kg of complete feed is generally recognized as safe.

<sup>2</sup> In AGRN 50, CVM evaluated Agrivida's conclusion that the ground grain obtained from FG259 corn in swine feed at a use rate of 50-500 glucanase activity units per kg of complete feed is generally recognized as safe.

information on FG259 corn in BNF 000181. Should Agrivida change its intended uses to include other uses of FG259 corn in animal food in the United States, we recommend Agrivida contact CVM's Division of Animal Food Ingredients.

It is Agrivida's responsibility to obtain all appropriate clearances, including those from the United States Environmental Protection Agency and the United States Department of Agriculture (USDA), before marketing human or animal food derived from FG259 corn.

On July 29, 2016, the National Bioengineered Food Disclosure Law (Public Law 114-216) charged the USDA's Agricultural Marketing Service with developing a national mandatory system for disclosing the presence of bioengineered material in human food. Food manufacturers, importers, and retailers of FG259 corn are responsible for complying with the regulations issued by USDA relevant to the labeling of their products.

Based on the information Agrivida has presented to FDA, we have no further questions at this time concerning FG259 corn if present in human food. However, as you are aware, it is Agrivida's continuing responsibility to ensure that foods marketed by the firm are safe, wholesome, and in compliance with all applicable legal and regulatory requirements. A copy of this letter responding to BNF 000181 and copies of FDA's memoranda summarizing the information in BNF 000181 will be made available to the public at <https://www.fda.gov/bioconinventory>.

Sincerely,

MARK A.  
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Mark Hartman  
Director  
Office of Food Chemical Safety,  
Dietary Supplements, and Innovation  
Human Foods Program