



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 000188

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, PY1203 corn. According to information Agrivida has provided, PY1203 corn is genetically engineered to express the Phy02 phytase enzyme as a source of phytase. The administrative record for this consultation has been placed in a file designated BNF 000188. 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 PY1203 corn, which FDA received on January 25, 2022. Agrivida submitted additional information, received by FDA on June 22, 2023, August 7, 2023 and April 6, 2024. 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 PY1203 corn is not intended for use in human food, Agrivida assessed the safety of PY1203 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 PY1203 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 PY1203 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 PY1203 corn is intended for use as a source of the Phy02 phytase enzyme to improve phosphorus utilization 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 PY1203 corn in poultry and swine food¹; and therefore, CVM does not intend to evaluate the information on PY1203 corn in BNF 000188. Should Agrivida change its

¹ In AGRN 32, CVM evaluated Agrivida's conclusion that the ground grain obtained from PY1203 corn to increase the digestibility of phytin-bound phosphorus or to increase phosphorus availability from phytate in swine feeds when used to provide 500-4500 phytase activity units (FTU)/kilogram (kg) complete feed, or poultry feeds when used to provide 25—6000 FTU/kg complete feed is generally recognized as safe.

intended uses to include other uses of PY1203 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 PY1203 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 PY1203 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 PY1203 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 000188 and copies of FDA's memoranda summarizing the information in BNF 000188 will be made available to the public at <https://www.fda.gov/bioconinventory>.

Sincerely,

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