



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

RE: Biotechnology Notification File No. BNF 000167

Dear Dr. Ligon:

This letter addresses Agrivida, Inc.'s (Agrivida) consultation with the Food and Drug Administration (FDA, we) (Center for Food Safety and Applied Nutrition (CFSAN) and Center for Veterinary Medicine (CVM)) on genetically engineered corn, event PY203. According to information Agrivida has provided, PY203 corn is genetically engineered to express the phytase enzyme Phy02 derived from *Escherichia coli* strain K-12. The administrative record for this consultation has been placed in a file designated BNF 000167. This file will be maintained in the Office of Food Additive Safety in CFSAN.

As part of bringing this consultation to closure, Agrivida submitted to FDA a summary of its safety and nutritional assessment of PY203 corn, which FDA received on June 19, 2018. This assessment 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. Ground grain from PY203 corn is intended for use as a source of a phytase enzyme when added to animal food.¹ In its submission, Agrivida informed FDA that PY203 corn is not intended for other uses in food; however, it anticipates that low levels of PY203 corn, or food products derived from it, may enter the food supply inadvertently. Based on the safety and nutritional assessment Agrivida has conducted, it is our understanding that Agrivida has concluded that human and animal food from PY203 corn are not materially different in composition, safety, and other relevant parameters from corn-derived human and animal food currently on the market, and that genetically engineered PY203 corn does not raise issues that would require premarket review or approval by FDA.

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 PY203 corn.

As always, it is a producer's or distributor's responsibility to ensure that labeling of the foods it markets meets applicable legal requirements, including disclosure of any material differences in the food. In evaluating the common or usual name appropriate for animal food ingredients derived from PY203 corn, CVM considered that this new corn variety is genetically engineered


¹ Agrivida submitted to CVM Generally Recognized As Safe notices AGRN 21 and 27 regarding its conclusions about the use and regulatory status of the Phy02 enzyme in ground PY203 corn grain in poultry and swine diets, respectively.

to express the Phy02 phytase enzyme in its grain, and that Agrivida has concluded that the corn grain and forage are compositionally comparable to those from conventional corn varieties. When used in poultry or swine food according to the intended conditions of use described in AGRNs 21 or 27, respectively, CVM recognizes the name “phytase” as the common or usual name for the Phy02 phytase enzyme in PY203 corn grain. CVM recognizes that for all other uses of PY203 corn and derived products in animal food, “corn” is the appropriate name (for example, “flaked corn” and “dehydrated corn plant”).

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. Producers, distributors, and marketers of PY203 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 concerning human or animal food derived from PY203 corn at this time. 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 000167 and copies of FDA’s memoranda summarizing the information in BNF 000167 are available to the public at <http://www.fda.gov/bioconinventory>.

Sincerely,

**Dennis M.
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Dennis M. Keefe, Ph.D.
Director
Office of Food Additive Safety
Center for Food Safety
and Applied Nutrition