Sally A. Catron
Registration Manager
Corteva Agriscience
7100 NW 62nd Avenue
P.O. Box 1000
Johnston, IA 50131

RE: Biotechnology Notification File No. BNF 000175

Dear Ms. Catron:

This letter addresses Pioneer Hi-Bred International, Inc.'s (Pioneer's) 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, DP23211 corn. According to information Pioneer has provided, DP23211 corn is genetically engineered to express: DvSSJ1 double-stranded RNA (dsRNA) and the IPD072Aa protein to confer resistance to western corn rootworm; phosphinothricin acetyltransferase (PAT) to provide tolerance to glufosinate ammonium herbicides; and phosphomannose isomerase (PMI) for use as a selectable marker. The administrative record for this consultation has been placed in a file designated BNF 000175. This file will be maintained in the Office of Food Additive Safety in CFSAN.

As part of this consultation, Pioneer submitted to FDA a summary of its safety and nutritional assessment of DP23211 corn, which FDA received on May 31, 2019. Pioneer submitted additional information, received by FDA on July 1, 2019 and April 26, 2021. These communications informed FDA of the steps taken by Pioneer to ensure that this product complies with the legal and regulatory requirements that fall within FDA's jurisdiction. Based on the safety and nutritional assessment Pioneer has conducted, it is our understanding that Pioneer has concluded that human and animal food from DP23211 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 DP23211 corn does not raise issues that would require premarket review or approval by FDA.

The United States Environmental Protection Agency (EPA) regulates plant-incorporated protectants (PIP), which include both the active and inert ingredients. DP23211 corn contains PIPs which are within the purview of EPA. It is Pioneer's responsibility to obtain all appropriate clearances, including those from EPA and the United States Department of Agriculture (USDA), before marketing human or animal food derived from DP23211 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 DP23211 corn are responsible for complying with the regulations issued by USDA relevant to the labeling of their products.

Based on the information Pioneer has presented to FDA, we have no further questions concerning human or animal food derived from DP23211 corn at this time. However, as you are aware, it is Pioneer'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 000175 and copies of FDA's memoranda summarizing the information in BNF 000175 will be made available to the public at https://www.fda.gov/bioconinventory.

Sincerely,

Kristi L. Muldoon Jacobs -S

Digitally signed by Kristi L. Muldoon Jacobs -S
Date: 2022.07.31 16:36:32 -04'00'

Kristi L. Muldoon Jacobs, Ph.D.
Acting Director
Office of Food Additive Safety
Center for Food Safety
and Applied Nutrition