Sally A. Catron
Registration Manager
Pioneer Hi-Bred International, Inc.
7100 NW 62nd Avenue, P.O. Box 1000
Johnston, IA 50131

RE: Biotechnology Notification File No. BNF 000171

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) on genetically engineered maize (corn), DP202216 corn. According to information Pioneer has provided, DP202216 corn is genetically engineered for enhanced grain yield potential and herbicide tolerance to glufosinate-ammonium herbicides. Enhanced grain yield potential is conferred through increased and extended expression of the *Zea mays* ZMM28 transcription factor, which has been associated with plant vigor, photosynthetic capacity, and nutrient utilization. Tolerance to glufosinate-ammonium herbicides is conferred through expression of a *Streptomyces viridochromogenes*-derived phosphinothricin acetyltransferase (also referred to as "PAT"). The administrative record for this consultation has been placed in a file designated BNF 000171. 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 DP202216 corn, which FDA received on November 15, 2018. Pioneer submitted additional information, received by FDA on November 27, 2018; July 2 and November 5, 2019; January 23, April 13 and 14, 2020; and February 2, 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 DP202216 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 DP202216 corn does not raise issues that would require premarket review or approval by FDA.

It is Pioneer'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 DP202216 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. Producers,

distributors, and marketers of DP202216 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 DP202216 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 000171 and copies of FDA's memoranda summarizing the information in BNF 000171 are will be made available to the public at http://www.fda.gov/bioconinventory.

Sincerely,

Dennis M. Keefe -S

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