U.S. FOOD & DRUG ADMINISTRATION

Patrick Garcia
United States Seeds Regulatory Affairs Leader
Pioneer Hi-Bred International, Inc.
P.O. Box 7062
8325 NW 62nd Avenue
Johnston, IA 50131

RE: Biotechnology Notification File No. BNF 000209

Dear Mr. Garcia:

This letter addresses Pioneer Hi-Bred International, Inc. (Pioneer)'s consultation with the Food and Drug Administration (FDA, we) (Human Foods Program (HFP) and Center for Veterinary Medicine (CVM)) on genetically engineered soybean, COR1591. According to information Pioneer has provided, COR1591 soybean is genetically engineered to express the PPO-1.5, DGT-28 EPSPS, AAD-12, and DSM-2 PAT proteins for tolerance to protoporphyrinogen oxidase (PPO)-inhibiting herbicides, glyphosate herbicide, certain phenoxy auxin herbicides such as 2,4-D, and glufosinate herbicide, respectively. The administrative record for this consultation has been placed in a file designated BNF 000209. This file will be maintained in the Office of Food Chemical Safety, Dietary Supplements, and Innovation in HFP.

As part of this consultation, Pioneer submitted to FDA a summary of its safety and nutritional assessment of COR1591 soybean, which FDA received on April 17, 2026. Pioneer submitted additional information, received by FDA on July 17, 2026, and July 29, 2026. 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 COR1591 soybean are not materially different in composition, safety, and other relevant parameters from soybean-derived human and animal food currently on the market, and that genetically engineered COR1591 soybean 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 COR1591 soybean.

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 COR1591 soybean 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 COR1591 soybean 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 000209 and copies of FDA's memoranda summarizing the information in BNF 000209 will be made available to the public at https://www.fda.gov/bioconinventory.

Sincerely,

MARK A. HARTMAN -S

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