John M. Cordts
Cordts Consulting LLC
347 Matthew Flocco Drive
Newark, DE 19713

RE: Biotechnology Notification File No. BNF 000166

Dear Mr. Cordts:

This letter addresses Beijing DaBeiNong Biotechnology Co. Ltd.'s (DBNBC) consultation with the Food and Drug Administration (FDA, we) Center for Food Safety and Applied Nutrition (CFSAN) and Center for Veterinary Medicine (CVM) on grain from a genetically engineered corn variety, event DBN9936. According to information DBNBC has provided, DBN9936 corn is genetically engineered to express a Cry1Ab protein derived from *Bacillus thuringiensis* to confer resistance to lepidopteran insects and an EPSPS protein derived from *Agrobacterium* sp. strain CP4 as a selectable marker and to provide tolerance to glyphosate herbicides. The administrative record for this consultation has been placed in a file designated BNF 000166. This file will be maintained in the Office of Food Additive Safety in CFSAN.

As part of bringing this consultation to closure, DBNBC submitted to FDA a summary of its safety and nutritional assessment of the DBN9936 corn, which FDA received on May 4, 2018. DBNBC submitted additional information, received by FDA on March 5, 2019, March 26, 2019, and September 26, 2019. These communications informed FDA of the steps taken by DBNBC to ensure that this product complies with the legal and regulatory requirements that fall within FDA's jurisdiction. In its submission, DBNBC informed FDA that although DBN9936 corn is not currently intended for cultivation or marketing in the United States, it anticipates that human food products derived from DBN9936 corn may enter the U.S. food supply via imports from the country of production. Based on the safety and nutritional assessment DBNBC has conducted, it is our understanding that DBNBC has concluded that DBN9936 corn is not materially different in composition, safety, and other relevant parameters from corn currently on the market, and that genetically engineered DBN9936 corn does not raise issues that would require premarket review or approval by FDA.

In its submission, DBNBC stated that it expects the majority of DBN9936 corn grain will be consumed domestically in China, and a small portion will be exported to the United States in the form of processed foods, the vast majority of which will be for human consumption. DBNBC anticipates that animal food products containing a small amount of DBN9936 corn grain may be exported to the United States. Thus, CVM focused its evaluation on the potential safety and regulatory issues in the event that a limited amount of animal food products derived from

DBN9936 corn grain might be marketed in the United States.[1] Based on the information DBNBC has provided to FDA, CVM has no questions concerning the safety of intermittent low levels of DBN9936 corn grain in animal food. However, should the intended use of DBN9936 corn change to include widely marketing the corn or its byproducts as animal food in the United States, we recommend they contact CVM's Director for the Division of Animal Feeds, David Edwards at David.Edwards@fda.hhs.gov.

The United States Environmental Protection Agency (EPA) regulates plant-incorporated protectants (PIP), which include both the active and inert ingredients. DBN9936 corn contains a PIP, which is within the purview of EPA. DBNBC consulted with EPA and provided a copy of a message from EPA stating that the Cry1Ab protein in DBN9936 corn falls under the tolerance exemption for Cry1Ab at 40 CFR 174.511. DBNBC notes that the EPSPS protein in DBN9936 corn falls under the tolerance exemption for EPSPS at 40 CFR 174.523. It is DBNBC'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 DBN9936 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 DBN9936 corn are responsible for complying with the regulations issued by USDA relevant to the labeling of their products.

Based on the information DBNBC has presented to FDA, we have no further questions about DBNBC's current intended uses of DBN9936 corn in the United States. However, as you are aware, it is DBNBC'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 000166 and copies of FDA's memoranda summarizing the information in BNF 000166 are available to the public at http://www.fda.gov/bioconinventory.

Sincerely,

Dennis M. Keefe -S

Digitally signed by Dennis M. Keefe -S
Date: 2021.07.22 15:10:08 -04'00'

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

[1] FDA has explained the safety and regulatory issues in such situations in Guidance for Industry: Recommendations for the Early Food Safety Evaluation of New Non-Pesticidal Proteins Produced by New Plant Varieties Intended for Food Use, available at https://www.fda.gov/regulatory-information/search-fda-guidance-documents/guidance-industry-recommendations-early-food-safety-evaluation-new-non-pesticidal-proteins-produced.