Michael Weeks
US Registration Manager
Bayer CropScience LP
2 T.W. Alexander Drive
Research Triangle Park, NC 27709

RE: Biotechnology Notification File No. BNF 000157

Dear Mr. Weeks:

This letter addresses Bayer CropScience's (Bayer's) consultation with the Food and Drug Administration (FDA) (Center for Food Safety and Applied Nutrition (CFSAN) and Center for Veterinary Medicine) on genetically engineered canola, MS11. According to information Bayer has provided, MS11 canola is genetically engineered to express two proteins from *Bacillus amyloliquefaciens*: Barnase, an endoribonuclease that is intended to result in lack of viable pollen and thus, male sterility; and Barstar, an inhibitor of Barnase, used to enhance transformation efficiency. MS11 canola was also genetically engineered to express phosphinothricin acetyltransferase referred to as PAT/*bar* protein from *Streptomyces hygroscopicus*, which confers tolerance to the herbicide glufosinate ammonium. All materials relevant to this consultation have been placed in a file designated BNF 000157. This file will be maintained in the Office of Food Additive Safety in CFSAN.

As part of bringing this consultation to closure, Bayer submitted to FDA a summary of its safety and nutritional assessment of MS11 canola, which FDA received on August 26, 2016. Bayer submitted additional information, received by FDA on February 21, 2017 and February 22, 2017. These communications informed FDA of the steps taken by Bayer 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 Bayer has conducted, it is our understanding that Bayer has concluded that human and animal food from MS11 canola are not materially different in composition, safety, and other relevant parameters from canola-derived human and animal food currently on the market, and that genetically engineered MS11 canola does not raise issues that would require premarket review or approval by FDA.

On July 29, 2016, the National Bioengineered Food Disclosure Law (Public Law 114-216) charged the United States Department of Agriculture'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 MS11 canola are responsible for following the requirements issued by USDA relevant to the labeling of their products.

U.S. Food & Drug Administration
Center for Food Safety & Applied Nutrition
5001 Campus Drive
College Park, MD 20740

Based on the information Bayer has presented to FDA, we have no further questions concerning food and feed derived from MS11 canola at this time. However, as you are aware, it is Bayer'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 the text of this letter responding to BNF 000157, as well as a copy of the text of FDA's memorandum summarizing the information in BNF 000157, is available for public review and copying 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