



October 18, 2000

Kent A. Croon  
Regulatory Affairs Manager  
Monsanto Company  
700 Chesterfield Parkway North  
St. Louis, Missouri 63198

Dear Dr. Croon:

This is in regard to Monsanto's consultation with the Food and Drug Administration (FDA) (Center for Veterinary Medicine and Center for Food Safety and Applied Nutrition) on its genetically modified Roundup Ready® NK603 corn. According to Monsanto, this new line is modified for herbicide tolerance through the expression of the 5-enolpyruvylshikimate-3-phosphate synthase gene (EPSPS) isolated from *Agrobacterium tumefaciens* sp. CP4. The CP4 EPSPS gene encodes the 5-enolpyruvylshikimate-3-phosphate synthase, which confers tolerance to glyphosate (Roundup®) herbicide.

As part of bringing the consultation regarding this product to closure, Monsanto submitted a summary of its safety and nutritional assessment of the genetically modified Roundup Ready® NK603 corn on February 28, 2000. This communication informed the FDA of the steps taken by Monsanto 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 Monsanto has conducted, it is our understanding that Monsanto has concluded that the Roundup Ready® NK603 corn grain and forage derived from the new variety, are not materially different in composition, safety, and other relevant parameters from corn grain and forage currently on the market and that it does not raise issues that would require premarket review or approval by FDA. All materials relevant to this notification have been placed in a file designated BNF 0071. This file will be maintained in the Office of Premarket Approval.

Based on the information Monsanto has presented to FDA, we have no further questions concerning grain and forage from the Roundup Ready® NK603 corn at this time. However, as you are aware, it is Monsanto's continued responsibility to ensure that foods marketed by the firm are safe, wholesome, and in compliance with all applicable legal and regulatory requirements.

Sincerely yours.

/s/

Alan M. Rulis, Ph.D.  
Director  
Office of Premarket Approval