DEPARTMENT OF HEALTH AND HUMAN SERVICES

NOV 3 1998

Raymond Dobert, Ph.D.
Regulatory Affairs Manager
Monsano Company, BB1K
700 Chesterfield Village Pky North
St. Louis, Missouri 63198

Jeff Stein, Ph.D.
Manager, Regulatory Affairs
Novartis Seeds, Inc.
3054 Cornwallis Road
Research Triangle Park, NC 27709

Dear Drs. Dobert and Stein:

This letter is in regard to your genetically modified sugar beet, line 77, about which you initiated a consultation with the Agency in June of 1998. According to Monsanto and Novartis, this new sugar beet variety has been rendered tolerant to the non-selective herbicide glyphosate through the expression of the 5-enolpyruvylshikimate-3-phosphate synthase gene derived from *Agrobacterium* sp. strain CP4 (CP4 EPSPS).

You submitted a summary of your safety and nutritional assessment of the new sugar beet variety on June 5, 1998. This communication informed FDA of the steps taken by Monsanto and Novartis to ensure that this product complies with those legal and regulatory requirements that fall within FDA's jurisdiction. Based on the safety and nutritional assessment you have conducted, it is our understanding that Monsanto and Novartis have concluded that the new sugar beet line is not materially different in composition, safety, or other relevant parameters from sugar beet varieties 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 consultation have been placed in a file that has been designated BNF0056 and that will be maintained in the Office of Premarket Approval.

Based on the information Monsanto and Novartis have presented to FDA, we have no further questions concerning the glyphosate-tolerant sugar beet, line 77, at this time. However, as you are aware, it is Monsanto's and Novartis' continued responsibility to ensure that foods the firms market 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
Center for Food Safety
and Applied Nutrition

cc: HFS-200 HFS-205 HFS-206 HFS-226 HFS-246 HFS-247 HFS-13 HFV-200
BNF 0056