Neal Carter
Okanagan Specialty Fruits Inc.
P.O. Box 1533
Summerland, BC V0H 1Z0
CANADA

RE: Biotechnology Notification File No. BNF 000154

Dear Mr. Carter:

This letter addresses Okanagan Specialty Fruits Inc.'s (OSF'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 apple, NF872. According to information OSF has provided, NF872 apples are genetically engineered to contain reduced levels of four polyphenol oxidases through RNA interference. OSF states that this modification is intended to impart resistance to browning associated with slicing or bruising. NF872 apples were also engineered to express the neomycin phosphotransferase (NPTII) selectable marker for transformation. The administrative record for this consultation has been placed in a file designated BNF 000154. This file will be maintained in the Office of Food Additive Safety in CFSAN.

As part of bringing this consultation to closure, OSF submitted to FDA a summary of its safety and nutritional assessment of the NF872 apple, which FDA received on April 11, 2016. OSF submitted additional information, received by FDA on December 21, 2016, June 4, 2017, September 7, 2017, January 5, 2018, and March 9, 2018. These communications informed FDA of the steps taken by OSF 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 OSF has conducted, it is our understanding that OSF has concluded that human and animal food from NF872 apple are not materially different in composition, safety, and other relevant parameters from apple-derived human and animal food currently on the market, and that genetically engineered NF872 apple does not raise issues that would require premarket review or approval by FDA.

It is OSF'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 NF872 apple.

As always, it is a producer's or distributor's responsibility to ensure that labeling of the foods it markets meets applicable legal requirements, including disclosure of any material differences in the food. It is our understanding that NF872 apples may be used in various food applications. Depending on the particular food application, the non-browning aspect of the apples may be considered material information requiring disclosure under Sections 201(n) and 403(a)(1) of the Federal Food, Drug, and Cosmetic Act [21 U.S.C. § 321(n) and 343(a)(1)]. Companies marketing NF872 apples or products containing NF872 apples are advised to consult with CFSAN's Office

of Nutrition and Food Labeling, Food Labeling and Standards Staff, to discuss any required or voluntary labeling including statements relating to attributes of this apple and its non-browning properties or any other type of claim.

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 NF872 apple are responsible for complying with the regulations issued by USDA relevant to the labeling of their products.

Based on the information OSF has presented to FDA, we have no further questions concerning human or animal food derived from NF872 apple at this time. However, as you are aware, it is OSF'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 000154, as well as a copy of the text of FDA's memorandum summarizing the information in BNF 000154, is available for public review and copying at http://www.fda.gov/bioconinventory.

Sincerely,

Dennis M. Keefe -S

Digitally signed by Dennis M. Keefe -S
Date: 2019.04.25 14:48:56 -04'00'

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