



Neal Carter
President and CEO
Okanagan Specialty Fruits Inc.
15304 Prairie Valley Road
Summerland, BC V0H 1Z8
CANADA

RE: Biotechnology Notification File No. BNF 000192

Dear Mr. Carter:

This letter addresses Okanagan Specialty Fruits Inc.'s (OSF) consultation with the Food and Drug Administration (FDA, we) (Center for Food Safety and Applied Nutrition (CFSAN) and Center for Veterinary Medicine (CVM)) on genetically engineered apple, PG451. According to information OSF has provided, PG451 apple is genetically engineered to suppress the expression of four members of polyphenol oxidase gene family using RNA interference. OSF states that this modification is intended to impart resistance to browning associated with slicing or bruising. PG451 apple is 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 000192. This file will be maintained in the Office of Food Additive Safety in CFSAN.

As part of this consultation, OSF submitted to FDA a summary of its safety and nutritional assessment of PG451 apple, which FDA received on May 25, 2022. OSF submitted additional information, received by FDA on February 5, 2024. 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 PG451 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 PG451 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 PG451 apple.

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

As always, it is a producer's or distributor's responsibility to ensure that labeling of the foods it markets meets applicable legal requirements. It is our understanding that PG451 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 PG451 apple or products containing PG451 apple are advised to consult with CFSSAN's Office of Nutrition and Food Labeling, Division of Food Labeling and Standards, to discuss any required or voluntary labeling under the Federal Food, Drug, and Cosmetic Act including statements relating to attributes of this apple such as nonbrowning 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. Food manufacturers, importers, and retailers of PG451 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 PG451 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 this letter responding to BNF 000192 and copies of FDA's memoranda summarizing the information in BNF 000192 will be made available to the public at <https://www.fda.gov/bioconinventory>.

Sincerely,

Kristi L. Muldoon Jacobs -S

Digitally signed by Kristi L. Muldoon Jacobs
Date: 2024.09.19 15:25:19 -04'00'

Kristi L. Muldoon Jacobs, Ph.D.
Director
Office of Food Additive Safety
Center for Food Safety
and Applied Nutrition