U.S. FOOD & DRUG ADMINISTRATION

Dr. David Douches
Professor, Potato Breeding and Genetics Program
Michigan State University
1066 Bogue Street
East Lansing, MI 48824

RE: Biotechnology Notification File No. BNF 000205

Dear Dr. Douches:

This letter addresses the Michigan State University Potato Breeding and Genetics Program's (MSU's) consultation with the Food and Drug Administration (FDA, we) (Human Foods Program (HFP) and Center for Veterinary Medicine (CVM)) on genetically engineered Kal91.3 potato. According to information MSU has provided, Kal91.3 potato is genetically engineered to express 1.) an RNAi cassette to silence expression of the vacuolar invertase gene *Vlnv*, leading to lower levels of reducing sugars in tubers, thereby preventing cold-induced sweetening, and 2.) the NPTII protein, conferring resistance to the antibiotics kanamycin and neomycin and utilized as a selection marker. The administrative record for this consultation has been placed in a file designated BNF 000205. This file will be maintained in the Office of Food Chemical Safety, Dietary Supplements, and Innovation in HFP.

As part of this consultation, MSU submitted to FDA a summary of its safety and nutritional assessment of Kal91.3 potato, which FDA received on September 15, 2025. MSU submitted additional information, received by FDA on December 19, 2025. These communications informed FDA of the steps taken by MSU 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 MSU has conducted, it is our understanding that MSU has concluded that human and animal food from Kal 91.3 potato are not materially different in composition, safety, and other relevant parameters from potato-derived human and animal food currently on the market, and that genetically engineered Kal 91.3 potato does not raise issues that would require premarket review or approval by FDA.

It is MSU's responsibility to obtain all appropriate clearances, including those from the United States Environmental Protection Agency and the United States Department of Agriculture, before marketing human or animal food derived from Kal91.3 potato.

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 Kal91.3 potato are responsible for complying with the regulations issued by USDA relevant to the labeling of their products.

U.S. Food and Drug Administration
Human Foods Program
5001 Campus Drive
College Park, MD 20740
www.fda.gov

Based on the information MSU has presented to FDA, we have no further questions concerning human or animal food derived from Kal91.3 potato at this time. However, as you are aware, it is MSU's continuing responsibility to ensure that foods marketed by MSU are safe, wholesome, and in compliance with all applicable legal and regulatory requirements. A copy of this letter responding to BNF 000205 and copies of FDA's memoranda summarizing the information in BNF 000205 will be made available to the public at https://www.fda.gov/bioconinventory.

Sincerely,

MARK A. HARTMAN -S

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Date: 2026.03.24 10:34:51 -04'00'

Mark A. Hartman
Director
Office of Food Chemical Safety,
Dietary Supplements, and Innovation
Human Foods Program