



April 9, 2021

June Yao, Ph.D.  
Global Regulatory Lead  
Nuseed  
990 Riverside Parkway, Suite 140  
West Sacramento, CA 95605

Dear Dr. Yao:

This responds to your letter of March 26, 2021, regarding NS-B50027-4 canola. In your letter, you state that low levels of Nuseed's NS-B50027-4 canola have been detected in specific grain and seed lots in Montana and Washington states. Based on your description, our understanding is that these low levels of NS-B50027-4 canola are inadvertently present in these seeds. NS-B50027-4 canola is genetically engineered to enable biosynthesis of long chain polyunsaturated fatty acids (LCPUFAs), including docosahexaenoic acid (DHA) and eicosapentaenoic acid (EPA), through expression of several fatty acid desaturases and elongases in the seed. You explain that NS-B50027-4 canola is the subject of an ongoing voluntary premarket biotechnology consultation with FDA. Your letter states that human and animal food containing NS-B50027-4 canola does not present a food safety concern; that NS-B50027-4 canola seed, meal, and oil are comparable to those of conventional canola except for the intended changes to the fatty acid profile; and that the low levels of NS-B50027-4 canola inadvertently present in the food supply would result in a negligible difference in the composition of canola oil. You follow with a request for FDA's views on the safety of NS-B50027-4 canola when inadvertently present in food at low levels.

In its June 2006, "Guidance for Industry: Recommendations for the Early Food Safety Evaluation of New Non-Pesticidal Proteins Produced by New Plant Varieties Intended for Food Use,"<sup>1</sup> FDA explained that it believes that any food safety concern related to material from new plant varieties inadvertently present in the human and animal food supply at low levels would be limited to the potential that a new protein in food from the plant variety could cause an allergic reaction in susceptible people or could be a toxin in people or animals. The data and other information in your voluntary premarket biotechnology consultation on food from NS-B50027-4 canola establish that the new proteins expressed in NS-B50027-4 canola are not likely to be allergenic to humans and are not toxins to people or animals. Additionally, you state in your letter of March 26, 2021, that NS-B50027-4 canola seed, meal, and oil are comparable to those of conventional canola except for the intended changes to the fatty acid profile, and that the low levels of NS-B50027-4 canola inadvertently present in the food supply would result in a negligible difference in the composition of canola oil. Based on information supplied during your voluntary premarket biotechnology consultation for NS-B50027-4 canola and in your letter of March 26, 2021, FDA has no questions about the safety of NS-B50027-4 canola when

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<sup>1</sup> Guidance available at: <https://www.fda.gov/regulatory-information/search-fda-guidance-documents/guidance-industry-recommendations-early-food-safety-evaluation-new-non-pesticidal-proteins-produced>

**U.S. Food and Drug Administration**  
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inadvertently present in the food supply at low levels, as you have described.

While this letter addresses low levels of NS-B50027-4 canola inadvertently present in the human and animal food supply, FDA is continuing to evaluate your voluntary premarket biotechnology consultation on human and animal food from this variety. The biotechnology consultation process evaluates the full complement of food safety and regulatory issues based on the characteristics of the food for humans and animals, including potential unintended changes in the composition of the food.

Sincerely,

**Dennis M. Keefe -S**  
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**Dennis M. Keefe, Ph.D.**  
**Director**  
**Office of Food Additive Safety**  
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