



May 19, 2025

Ms. Katie Davis
Senior Director, Regulatory Affairs
Cibus Inc.
6455 Nancy Ridge Drive
San Diego, CA 92121

RE: Biotechnology Notification File No. BNF 000184

Dear Ms. Davis:

This letter addresses Cibus Inc.'s (Cibus')¹ consultation with the Food and Drug Administration (FDA, we) (Human Foods Program (HFP) and Center for Veterinary Medicine (CVM)) on genetically engineered alfalfa with altered lignin profile (referred to by Cibus as IQ alfalfa; hereafter referred to as "altered lignin alfalfa"). According to information Cibus has provided, altered lignin alfalfa is genetically engineered to reduce the levels of syringyl (S) lignin and guaiacyl (G) lignin through gene editing. The administrative record for this consultation has been placed in a file designated BNF 000184. This file will be maintained in the Office of Food Chemical Safety, Dietary Supplements, and Innovation in HFP.

As part of this consultation, Cibus submitted to FDA a summary of its safety and nutritional assessment of altered lignin alfalfa, which FDA received on August 31, 2021. Cibus submitted additional information, received by FDA on August 9, 2023, October 4, 2023, and August 23, 2024. These communications informed FDA of the steps taken by Cibus 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 Cibus has conducted, it is our understanding that Cibus has concluded that human and animal food from altered lignin alfalfa are not materially different in composition, safety, and other relevant parameters from alfalfa-derived human and animal food currently on the market, and that altered lignin alfalfa does not raise issues that would require premarket review or approval by FDA.

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 altered lignin alfalfa are responsible for complying with the regulations issued by USDA relevant to the labeling of their products.

Based on the information Cibus has presented to FDA, we have no further questions concerning human or animal food derived from altered lignin alfalfa at this time. However, as you are aware,

¹ On August 9, 2023, the developer informed FDA about their name change from "Calyxt Inc." to "Cibus Inc." because of change in company ownership on June 1, 2023.

it is Cibus' continuing responsibility to ensure that foods marketed by the developer are safe, wholesome, and in compliance with all applicable legal and regulatory requirements. A copy of this letter responding to BNF 000184 and copies of FDA's memoranda summarizing the information in BNF 000184 will be made available to the public at
<https://www.fda.gov/bioconinventory>.

Sincerely,

MARK A.

HARTMAN

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Date: 2025.05.19 11:35:04 -04'00'

Mark A. Hartman

Director

Office of Food Chemical Safety,

Dietary Supplements, and Innovation

Human Foods Program