Patricia Miranda, Ph.D.
Regulatory Affairs Manager
Bioceres Inc.
Ocampo 210 Bis
2000 Rosario, Sante Fe
ARGENTINA

RE: Biotechnology Notification File No. BNF 000170

Dear Dr. Miranda:

This letter addresses Bioceres Inc.'s 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 wheat, IND-ØØ412-7 wheat. According to information Bioceres has provided, IND-ØØ412-7 wheat is genetically engineered to express the *HaHb4* gene to confer increased tolerance to environmental stress and the *bar* gene to confer tolerance to glufosinate-based herbicides. The administrative record for this consultation has been placed in a file designated BNF 000170. This file will be maintained in the Office of Food Additive Safety in CFSAN.

As part of this consultation, Bioceres submitted to FDA a summary of its safety and nutritional assessment of the IND-ØØ412-7 wheat, which FDA received on September 17, 2018. Bioceres submitted additional information, received by FDA on October 25, 2018, October 23 and December 22, 2020, and October 25, 2021. These communications informed FDA of the steps taken by Bioceres to ensure that this product complies with the legal and regulatory requirements that fall within FDA's jurisdiction. In its submission, Bioceres informed FDA that although IND-ØØ412-7 wheat is not currently intended for cultivation or marketing in the United States, it anticipates that processed food products derived from IND-ØØ412-7 wheat may enter the U.S. food supply via imports from the country of production. Based on the safety and nutritional assessment Bioceres has conducted, it is our understanding that Bioceres has concluded that IND-ØØ412-7 wheat is not materially different in composition, safety, and other relevant parameters from wheat currently on the market, and that genetically engineered IND-ØØ412-7 wheat does not raise issues that would require premarket review or approval by FDA.

In its submission, Bioceres states that IND-ØØ412-7 wheat is intended solely for cultivation in Argentina or South America, and there is no plan to grow IND-ØØ412-7 wheat in the United States. Bioceres anticipates that the presence of IND-ØØ412-7 wheat in food in the United States would be limited to processed products, which derive from the wheat grain. The majority of wheat grain is used for human food. Thus, CVM focused its evaluation on the potential safety and regulatory issues in the event that a limited amount of animal food products derived from

IND-ØØ412-7 wheat might be marketed in the United States.[1] Based on the current information Bioceres has provided to FDA, CVM has no questions concerning the safety of intermittent low levels of IND-ØØ412-7 wheat in animal food. However, should Bioceres or distributers of IND-ØØ412-7 wheat intend to market the wheat or its byproducts as animal food in the United States, we recommend that they contact CVM's Division of Animal Food Ingredients.

It is Bioceres' 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 IND-ØØ412-7 wheat.

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 IND-ØØ412-7 wheat are responsible for complying with the regulations issued by USDA relevant to the labeling of their products.

Based on the information Bioceres has presented to FDA, we have no further questions about Bioceres' current intended uses of IND-ØØ412-7 wheat in the United States at this time. However, as you are aware, it is Bioceres' 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 000170 and copies of FDA's memoranda summarizing the information in BNF 000170 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 -S
Date: 2022.06.22 16:22:34 -04'00'

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

[1] FDA has explained the safety and regulatory issues in such situations in Guidance for Industry: Recommendations for the Early Food Safety Evaluation of New Non-Pesticidal Proteins Produced by New Plant Varieties Intended for Food Use, available at https://www.fda.gov/regulatory-information/search-fda-guidance-documents/guidance-industry-recommendations-early-food-safety-evaluation-new-non-pesticidal-proteins-produced.