



Keith Redenbaugh, Ph.D.
Senior Regulatory Manager
Verdeca LLC
202 Cousteau Place, Suite 200
Davis, CA 95618

RE: Biotechnology Notice File No. BNF 000155

Dear Dr. Redenbaugh:

This letter addresses Verdeca LLC's (Verdeca) consultation with the Food and Drug Administration (FDA) (Center for Food Safety and Applied Nutrition (CFSAN) and Center for Veterinary Medicine) on genetically engineered soybean, HB4 soybean. According to information Verdeca has provided, HB4 soybean is genetically engineered to express the *Helianthus annuus* (common sunflower) transcription factor HAHB4 protein. Verdeca states that expression of HAHB4 protein is intended to increase tolerance to various environmental stresses, thereby avoiding reduction of crop yield. All materials relevant to this consultation have been placed in a file designated BNF 000155. This file will be maintained in the Office of Food Additive Safety in CFSAN.

As part of bringing this consultation to closure, Verdeca submitted to FDA a summary of its safety and nutritional assessment of HB4 soybean, which FDA received on May 17, 2016. Verdeca submitted additional information, received by FDA on December 22, 2016, and May 8 and 10, 2017. These communications informed FDA of the steps taken by Verdeca 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 Verdeca has conducted, it is our understanding that Verdeca has concluded that human and animal food from HB4 soybean are not materially different in composition, safety, and other relevant parameters from soybean-derived human and animal food currently on the market, and that genetically engineered HB4 soybean 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 United States Department of Agriculture's (USDA) Agricultural Marketing Service with developing a national mandatory system for disclosing the presence of bioengineered material in human food. Producers, distributors, and marketers of HB4 soybean are responsible for following the requirements issued by USDA relevant to the labeling of their products.

Based on the information Verdeca has presented to FDA, we have no further questions concerning human and animal food derived from HB4 soybean at this time. However, as you

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

are aware, it is Verdeca'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 the text of this letter responding to BNF 000155, as well as a copy of the text of FDA's memorandum summarizing the information in BNF 000155, is available for public review and copying at <http://www.fda.gov/bioconinventory>.

Sincerely,

**Dennis M.
Keefe -S**

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