



Nicole Berzins
Director, Regulatory Affairs
UPSIDE Foods, Inc.
804 Heinz Ave.
Berkeley, CA 94710

Re: Cell Culture Consultation Notification File: CCC 000002

Dear Ms. Berzins:

This letter concludes UPSIDE Foods Inc.'s (UPSIDE) consultation with the Food and Drug Administration (FDA, we) regarding a cultured animal cell food product and associated production process, designated as CCC 000002. The subject of CCC 000002 is cultured chicken (*Gallus gallus*) cells with characteristics of muscle and connective tissue, produced by the method described in CCC 000002, and harvested as multicellular tissue for use as human food. We will maintain the administrative record associated with CCC 000002 in the Office of Food Additive Safety (OFAS) in the Center for Food Safety and Applied Nutrition.

Our use of the term “cultured chicken cell material” in this letter is not our recommendation of that term as an appropriate common or usual name for declaring the substance in accordance with the United States Department of Agriculture (USDA), Food Safety and Inspection Service’s (FSIS) labeling requirements. Under the March 2019 Formal Agreement, FSIS has oversight of issues associated with labeling and the common or usual name for cultured animal cell human foods that incorporate livestock or poultry cells.

As part of bringing this consultation to closure, UPSIDE submitted to FDA a summary of its safety assessment for the cultured chicken cell material, dated October 1, 2021, as well as supporting, corroborative information in a supplemental confidential appendix dated September 23, 2021. FDA accepted this final submission on October 6, 2021. UPSIDE provided amendments on March 30, 2022, September 16, 2022, September 30, 2022, and November 9, 2022. These communications informed FDA of the steps taken by UPSIDE to ensure that this food complies with the legal and regulatory requirements that fall within FDA’s jurisdiction. Based on the safety assessment UPSIDE has conducted, it is our understanding that UPSIDE has concluded that foods comprised of or containing the cultured cellular material resulting from the production process defined in CCC 000002 are as safe as comparable foods produced by other methods and would not contain substances that adulterate the food.

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

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mandatory system for disclosing the presence of bioengineered material in human food. Producers, distributors, and marketers of foods that contain cultured chicken cell material as defined by the production process described in CCC 000002 are responsible for complying with any USDA requirements relevant to the labeling of their products.

Based on the information UPSIDE has presented to FDA, as well as other information available to the agency, we did not identify a basis for concluding that the production process as described in CCC 000002 would be expected to result in food that bears or contains any substance or microorganism that would adulterate the food. We have no questions at this time regarding UPSIDE's conclusion that foods comprised of or containing cultured chicken cell material resulting from the production process defined in CCC 000002 are as safe as comparable foods produced by other methods. However, as you are aware, it is UPSIDE's continuing responsibility to ensure that foods it markets are safe, wholesome, and in compliance with all applicable legal and regulatory requirements, including those administered by FSIS. Should new production procedures, cell lines, or substances employed during production be used that could be relevant to the safety of the food, we strongly recommend that UPSIDE consult with FDA to ensure that food resulting from any modified production process is in compliance with all applicable laws and regulations.

A copy of this letter responding to CCC 000002 and of FDA's scientific memorandum summarizing the information in CCC 000002, as well as the safety narrative submitted by UPSIDE, are available to the public at

<https://www.cfsanappsexternal.fda.gov/scripts/fdcc/?set=AnimalCellCultureFoods>.

Sincerely,

Kristi L. Muldoon Jacobs -S Digitally signed by Kristi L. Muldoon Jacobs -S
Date: 2022.11.16 10:59:17 -05'00'

Kristi Muldoon-Jacobs, Ph.D.
Director, Acting
Office of Food Additive Safety
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cc: Melissa Hammar
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