



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 is in response to supplemental information provided by UPSIDE Foods, Inc. (UPSIDE) regarding the firm's consultation with the Food and Drug Administration (FDA, we) regarding a cultured animal cell food product and associated production process, designated as CCC 000002. We received the supplement on February 17, 2023. The supplement describes two additional substances used during production of UPSIDE's food product.

We previously responded to CCC 000002 on November 16, 2022. 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. Based on FDA's evaluation of the information UPSIDE presented to FDA, as well as other information available to the agency, we concluded in our response letter that we did not have any questions at that time regarding UPSIDE's conclusion 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.

In the supplement dated February 17, 2023, UPSIDE provides confidential commercial information describing two additional substances used during production of its food product, and provides the basis for its view that the use of either substance would not alter its safety conclusion described in CCC 000002. One substance is a nutrient intended for support of basic cell metabolism that has high structural similarity to a substance described in UPSIDE's original submission and is metabolized by the same pathway. The second substance is commonly used in food and is the subject of multiple FDA evaluations for a variety of uses in food at much higher levels than would result from UPSIDE's intended use in supporting a specific aspect of its adherent culture process. UPSIDE states that neither substance is intended to be present or have an ongoing technical effect in the cultured chicken cell material, and that any residual presence would be at very low levels that would not alter properties of the food relevant to safety or nutrition.

U.S. Food and Drug Administration  
Center for Food Safety & Applied Nutrition  
5001 Campus Drive  
College Park, MD 20740  
[www.fda.gov](http://www.fda.gov)

Based on the information UPSIDE has presented to FDA, we continue to 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.

We have added the supplement provided by UPSIDE to the supporting, corroborative information contained in a confidential appendix of CCC 000002.

A copy of this letter responding to the supplemental information regarding CCC 000002 is 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  
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Kristi Muldoon-Jacobs, Ph.D.  
Director, Acting  
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cc: Melissa Hammar  
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