



Kathryna Ang  
Senior Manager, Regulatory Affairs  
GOOD Meat, Inc.  
300 Wind River Way  
Alameda, CA 94501

Re: Cell Culture Consultation Notification File: CCC 000001

Dear Ms. Ang:

This letter concludes GOOD Meat, Inc.'s (GOOD Meat) consultation with the Food and Drug Administration (FDA, we) regarding a cultured animal cell food product and associated production process, designated as CCC 000001. The subject of CCC 000001 is cultured chicken (*Gallus gallus*) cells with characteristics of fibroblasts, produced by the method described in CCC 000001, and harvested as a cell mass or paste. We will maintain the administrative record associated with CCC 000001 in the Office of Food Additive Safety in the Center for Food Safety and Applied Nutrition.

The 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, GOOD Meat submitted to FDA a summary of its safety assessment for the cultured chicken cell material, as well as supporting, corroborative information in a supplemental confidential appendix, both dated March 4, 2022. FDA accepted this final submission on March 10, 2022. GOOD Meat provided amendments on July 8, 2022, August 4, 2022, September 14, 2022, and March 2, 2023. These communications informed FDA of the steps taken by GOOD Meat to ensure that this food complies with the legal and regulatory requirements that fall within FDA’s jurisdiction. Based on the safety assessment GOOD Meat has conducted, it is our understanding that GOOD Meat has concluded that foods comprised of or containing the cultured cellular material resulting from the production process defined in CCC 000001 are as safe as comparable foods produced by other methods and would not contain substances that adulterate the food.

Based on the information GOOD Meat 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 000001 would be expected to result in food that bears or contains any substance or microorganism that would adulterate the food. We

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have no questions at this time regarding GOOD Meat’s conclusion that foods comprised of or containing cultured chicken cell material resulting from the production process defined in CCC 000001 are as safe as comparable foods produced by other methods. However, as you are aware, it is GOOD Meat’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 GOOD Meat 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 000001 and of FDA’s scientific memorandum summarizing the information in CCC 000001, as well as the safety narrative submitted by GOOD Meat, are available to the public at <https://www.cfsanappsexternal.fda.gov/scripts/fdcc/?set=AnimalCellCultureFoods>.

Sincerely,

Kristi L. Muldoon Jacobs  Digitally signed by Kristi L. Muldoon  
Jacobs -S  
Date: 2023.03.20 11:11:18 -04'00'

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

cc: Melissa Hammar  
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