



Human Foods Program

Marc Shelley
Believer Meats
171 N. Aberdeen St. Suite 400
Chicago, IL 60607

Re: Cell Culture Consultation 000039

Dear Mr. Shelley:

This letter concludes Believer Meats' (Believer) consultation with the Food and Drug Administration (FDA, we) regarding a cultured animal cell food product and associated production process, designated as CCC 000039. The subject of CCC 000039 is cultured chicken (*Gallus gallus domesticus*) cells with characteristics of fibroblasts, produced by the method described in CCC 000039, and harvested as a cell mass. We will maintain the administrative record associated with CCC 000039 in the Office of Food Chemical Safety, Dietary Supplements, and Innovation (OFCSDSI) within FDA's Human Foods Program (HFP).

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, Believer 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 May 21, 2024. FDA accepted this final submission on May 22, 2024. Believer provided amendments on October 4, 2024, November 5, 2024, January 15, 2025, March 7, 2025, March 20, 2025, May 28, 2025, June 9, 2025, and June 25, 2025. These communications informed FDA of the steps taken by Believer to ensure that this food complies with the legal and regulatory requirements that fall within FDA's jurisdiction. Based on the safety assessment Believer has conducted, it is our understanding that Believer has concluded that foods comprised of or containing the cultured cellular material resulting from the production process defined in CCC 000039 are as safe as comparable foods produced by other methods and would not contain substances that adulterate the food.

Based on the information Believer has presented to FDA, as well as other information available to the agency, we did not identify a basis for concluding that the production

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process as described in CCC 000039 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 Believer's conclusion that foods comprised of or containing cultured chicken cell material resulting from the production process defined in CCC 000039 are as safe as comparable foods produced by other methods. However, as you are aware, it is Believer'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 Believer contact FDA.

Our evaluation of the nutrients used in the production of the cultured cellular material produced by the method described in CCC 000039 considered only whether the levels of nutrients in the harvested cellular material are safe and not their impact on nutritional quality of the food supply. Questions related to the labeling of food under the jurisdiction of USDA should be directed to USDA's FSIS. Questions related to labeling of food under the jurisdiction of FDA should be directed to the Office of Nutrition and Food Labeling in the Nutrition Center of Excellence within FDA's Human Foods Program.

A copy of this letter responding to CCC 000039 and of FDA's scientific memorandum summarizing the information in CCC 000039, as well as the safety narrative submitted by Believer, are available to the public at [Human Food Made with Cultured Animal Cells Inventory](#).

Sincerely,

MARK A.

HARTMAN -S

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Mark Hartman
Director
Office of Food Chemical Safety, Dietary
Supplements, and Innovation
Human Foods Program

cc: Melissa Hammar
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