



Eitan Fischer
Mission Barns
1155 Bryant Street
San Francisco, CA 94103

Re: Cell Culture Consultation ooooo8

Dear Mr. Fischer:

This letter concludes Mission Barns' consultation with the Food and Drug Administration (FDA, we) regarding a cultured animal cell food product and associated production process, designated as CCC ooooo8. The subject of CCC ooooo8 is cultured pork (*Sus scrofa domesticus*) cells with characteristics of adipocytes, produced by the method described in CCC ooooo8, and harvested as a cell mass or paste. We will maintain the administrative record associated with CCC ooooo8 in the Innovative Foods Staff (IFS) in the Office of Food Chemical Safety, Dietary Supplements, and Innovation (OFCSDI) within FDA's Human Foods Program (HFP).

The use of the term "cultured pork 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.¹

As part of bringing this consultation to closure, Mission Barns submitted to FDA a summary of its safety assessment for the cultured pork cell material, dated May 25, 2022, as well as supporting, corroborative information in a supplemental, confidential appendix, dated March 16, 2022. FDA accepted this final submission on June 27, 2022. Mission Barns provided amendments on March 6, 2023, June 5, 2023, August 23, 2023, September 26, 2023, October 26, 2023, October 31, 2023, November 6, 2023, December 11, 2023, January 31, 2024, June 3, 2024, July 8, 2024, September 25, 2024, October 24, 2024, November 13, 2024, December 24, 2024, February 11, 2025, February 18,

¹ Regulatory oversight of Mission Barns' cultured pork cell material transfers from FDA to USDA-FSIS at harvest. FDA and USDA divide primary regulation of meat products made from livestock based on the amount of meat, or cultured animal cell material, in the final, formulated product. FDA regulates meat products that contain 3% or less raw meat, less than 2% cooked meat, 30% or less fat, tallow, or meat extract. USDA regulates products that contain 3% or more raw meat, 2% or more cooked meat, or more than 30% fat, tallow, or meat extract.

2025, and February 19, 2025. These communications informed FDA of the steps taken by Mission Barns to ensure that this food complies with the legal and regulatory requirements that fall within FDA's jurisdiction. Based on the safety assessment Mission Barns has conducted, it is our understanding that Mission Barns has concluded that foods comprised of or containing the cultured cellular material resulting from the production process defined in CCC ooooo8 are as safe as comparable foods produced by other methods and would not contain substances that adulterate the food.

Based on the information Mission Barns 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 ooooo8 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 Mission Barns' conclusion that foods comprised of or containing cultured pork cell material resulting from the production process defined in CCC ooooo8 are as safe as comparable foods produced by other methods. However, as you are aware, it is Mission Barns' 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 Mission Barns contact FDA.

Our evaluation of the nutrients used in the production of the cultured cellular material produced by the method described in CCC ooooo8 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 Food Safety and Inspection Service. 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 ooooo8 and of FDA's scientific memorandum summarizing the information in CCC ooooo8, as well as the safety narrative submitted by Mission Barns, are available to the public at [Human Food Made with Cultured Animal Cells Inventory](#).

Sincerely,

MARK A.

HARTMAN

Digitally signed by
MARK A. HARTMAN -S

Date: 2025.03.07
09:36:33 -05'00'

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

cc: Melissa Hammar
Acting Director, Regulations Development Staff
USDA/FSIS/OPPD/RDS
USDA South Building
Room 6067
1400 Independence Ave. SW
Washington, DC 20250-3700