



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:

The purpose of this letter is to correct for the record an erroneous statement regarding the agency responsible for oversight of labeling of the cultured animal cell food product discussed in CCC 000001. This statement is found on page 81 of the safety assessment GOOD Meat, Inc. (GOOD Meat) submitted to the Food and Drug Administration (FDA, we) on March 4, 2022, regarding a cultured animal cell food product and associated production process, designated as CCC 000001.

GOOD Meat's discussion of labeling authority in Section 6.2.7 Description of Labeling on page 81 of the March 4, 2022, safety assessment states that "As per the joint memo issued by FDA and the USDA on March 7, 2019, labeling of the cultured chicken would be regulated by FDA and the finished cultured chicken meat product consisting of a combination of food ingredients and food additives would be regulated by the USDA." This statement incorrectly attributes regulatory authority for labeling of products derived from cultured cells of poultry to FDA. The March 7, 2019, Formal Agreement Between FDA and USDA Regarding Oversight of Human Food Produced Using Animal Cell Technology Derived from Cell Lines of USDA-Amenable Species<sup>1</sup> states that United States Department of Agriculture (USDA) Food Safety and Inspection Service (FSIS) will "Require that the labeling of human food products derived from the cultured cells of livestock and poultry be preapproved and then verified through inspection, as required by FSIS regulations."

FDA thus notes the factual error on page 81 of GOOD Meat's March 4, 2022, safety assessment and clarifies that USDA-FSIS oversees labeling of human food products derived from the cultured cells of livestock and poultry, including the unprocessed cellular material from the point of harvest forward.

We previously responded to CCC 000001 on March 21, 2023. Based on FDA's evaluation of the information GOOD Meat 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 GOOD Meat's conclusion that foods comprised of or containing the cultured cellular material resulting from the production

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<sup>1</sup> [Formal Agreement Between FDA and USDA Regarding Oversight of Human Food Produced Using Animal Cell Technology Derived from Cell Lines of USDA-amenable Species | FDA](#)

process defined in CCC 000001 are as safe as comparable foods produced by other methods and would not contain substances that adulterate the food. This correction does not involve facts related to safety and thus does not alter the basis for our conclusion that we have no questions regarding GOOD Meat’s safety assessment; therefore, our conclusion remains unchanged at this time.

A copy of this letter is available to the public at <https://www.cfsanappsexternal.fda.gov/scripts/fdcc/?set=AnimalCellCultureFoods>.

Sincerely,

**Mary D.**  
**Ditto -S**

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Mary Ditto, Ph.D.  
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