



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

Re: Cell Culture Consultation Notification File: CCC 000039

Dear Mr. Shelley:

This letter is in response to supplemental information provided by Believer Meats (Believer, the firm) 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 000039. We received the supplement on September 4, 2025. The supplement describes the removal of a soy-derived enzyme¹ from production of the harvested cell material. On September 10, 2025, and September 18, 2025, Believer submitted a disclosable summary describing its removal of the soy-derived enzyme from the production process and clarified that this change has no impact on the safety of the harvested cell material.

We previously responded to CCC 000039 on July 24, 2025. 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 for use as human food. Based on FDA's evaluation of the information Believer 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 Believer's conclusion 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.

In the supplement dated September 4, 2025, Believer describes removing the soy-derived enzyme from its process and explains that removal of this enzyme is not expected to impact the safety or composition of the harvested cell material. The firm explains that this enzyme was the only media input derived from soy, or any other major food allergen as defined in the Food Allergen Labeling and Consumer Protection Act (FALCPA) and the Food Allergy Safety, Treatment, Education, and Research (FASTER) Act. As a result, by removing this soy-derived enzyme from the production process, the firm has eliminated the risk of allergenicity from soy. The firm reiterated that it has an allergen control program in place to mitigate the risk of cross-contamination from all nine major allergens identified in the FALCPA and FASTER

¹ In the July 24, 2025, CCC 000039 scientific memorandum, FDA referred to this as a "soy-derived protein."

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Acts (i.e., milk, egg, fish, crustacean shellfish, tree nuts, peanuts, wheat, soybeans, and sesame).

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

We have added the supplement provided by Believer, and all applicable amendments to the supplement, to the safety narrative submitted by Believer. A copy of the supplement, all applicable amendments, as well as a copy of this letter responding to the supplemental information regarding CCC 000039 are available to the public at [Human Food Made with Cultured Animal Cells Inventory](#).

Sincerely,

ANDREW J. ZAJAC -S
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Andrew J. Zajac
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