U.S. FOOD & DRUG ADMINISTRATION
Human Foods Program

Justin L. Kolbeck
Co-Founder & CEO
Wildtype, Inc.
953 Indiana Street
San Francisco, CA 94107

Re: Cell Culture Consultation CCC 000005

Dear Mr. Kolbeck:

This letter concludes Wildtype Inc.'s (Wildtype) consultation with the Food and Drug Administration (FDA, we) regarding a cultured animal cell food product and associated production process, designated as CCC 000005. The subject of CCC 000005 is cultured salmon (*Oncorhynchus kisutch*) cells of the mesenchymal lineage produced by the method described in CCC 000005, and harvested as a cell mass or paste. We will maintain the administrative record associated with CCC 000005 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 salmon 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 FDA's labeling requirements. We note that 21 CFR 102.5(a) outlines general principles that FDA considers when establishing a common or usual name for nonstandardized foods which Wildtype may want to consider. Issues associated with labeling and the common or usual name of a food are under the authority of the Office of Nutrition and Food Labeling (ONFL) in the Nutrition Center of Excellence. IFS did not consult with ONFL regarding the appropriate common or usual name for "cultured salmon cell material."

As part of bringing this consultation to closure, Wildtype submitted to FDA a summary of its safety assessment for the cultured salmon cell material, dated June 27, 2022, as well as supporting, corroborative information in a supplemental, confidential appendix, dated June 3, 2022. FDA accepted this final submission on June 27, 2022. Wildtype provided amendments on January 17, 2023, May 3, 2023, July 28, 2023, January 24, 2024, August 30, 2024, December 11, 2024, April 2, 2025, and April 11, 2025. These communications informed FDA of the steps taken by Wildtype to ensure that this food complies with the legal and regulatory requirements that fall within FDA's jurisdiction. Based on the safety assessment Wildtype has conducted, it is our understanding that Wildtype has concluded that foods comprised of or containing the cultured cellular material resulting from the production process defined in CCC 000005 are as safe as comparable foods produced by other methods and would not contain substances that adulterate the food.

Based on the information Wildtype 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 000005 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 Wildtype's conclusion that foods comprised of or containing cultured salmon cell material

resulting from the production process defined in CCC 000005 are as safe as comparable foods produced by other methods. However, as you are aware, it is Wildtype's continuing responsibility to ensure that foods it markets are safe, wholesome, and in compliance with all applicable legal and regulatory requirements. 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 Wildtype contact FDA.

Our evaluation of the nutrients used in the production of the cultured cellular material produced by the method described in CCC 000005 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. Companies marketing food products containing cultured salmon cell material are strongly advised to consult with ONFL in the Nutrition Center of Excellence within FDA's HFP to discuss any required or voluntary labeling.

A copy of this letter responding to CCC 000005 and of FDA's scientific memorandum summarizing the information in CCC 000005, as well as the safety narrative submitted by Wildtype, are available to the public at Human Food Made with Cultured Animal Cells Inventory.

Sincerely,

MARK A. HARTMAN -S

Digitally signed by MARK A. HARTMAN -S
Date: 2025.05.28 15:03:36 -04'00'

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