Science Board to the Food and Drug Administration
FDA White Oak Campus, Building 31, The Great Room (Rm. 1503)
10903 New Hampshire Ave, Silver Spring, Maryland 20993
October 22, 2018

FINAL AGENDA

9:00 a.m. **Opening Introductions**
Mark McLellan, PhD, Science Board Chair

9:05 a.m. **Conflict of Interest**
Rakesh Raghuwanshi, MPH, Designated Federal Officer, Science Board, FDA

9:10 a.m. **Chief Scientist's Update**
RADM Denise Hinton, Chief Scientist, FDA

9:20 a.m. **Commissioner's Update**
Scott Gottlieb, MD, Commissioner of Food and Drugs, FDA

9:50 a.m. **Response to the Science Board's NARMS Review Report**
Patrick McDermott, PhD, Director, National Antibiotic Resistance Monitoring System

10:30 a.m. **Break**

10:45 a.m. **Introduction to Topics for Discussion**
Susan Mayne, PhD, Director, Center for Food Safety and Applied Nutrition, FDA

10:55 a.m. **Background Information on Animal Cell Culture and Food Safety**

12:00 p.m. **Lunch**

12:45 p.m. **CFSAN Session: Identification of potential hazards, and nutritional considerations, in the production of food derived from animal cell culture technologies**

Adventitious Agents in Source Materials and in Culture

Question: Could adventitious agents be plausibly introduced into culture from seed cells or culture materials that might pose risks to human health from a finished food product? If so, what are they, and what tools would be most effective at managing these risks?

Question: What does previous cell culture experience tell us about the potential for contamination during the culture process, scaling effects, and likelihood of risks to human health from a finished food product?

Added Substances: Culture Media and Structural Materials

Question: What kinds of substances used in cell culture media would be present in meaningful amounts in the finished food product, and are ordinary food ingredient evaluation procedures sufficient to ensure safety?

Question: What kinds of structural materials might be used to culture tissues, e.g. scaffolding, and are there any that could not be addressed by ordinary food ingredient safety assessment?

Science Board to the Food and Drug Administration
FDA White Oak Campus, Building 31, The Great Room (Rm. 1503)
10903 New Hampshire Ave, Silver Spring, Maryland 20993
October 22, 2018

FINAL AGENDA

Properties of Cultured Cells

Question: How likely is it that cultured animal cells could produce harmful substances as a result of errors in the culture process?

Question: What are the characteristic nutritional properties of foods produced by traditional techniques from animals such as cattle, swine, poultry, and fish; and what departures from these characteristics would be expected in food products of animal cell culture technology derived from their respective sources? Are these departures material with regard to nutritional or non-nutritional considerations?

3:30 p.m. **Open Public Hearing**

4:30 p.m. **Final Thoughts, and Closing Comments**
Mark McLellan, PhD, Science Board Chair