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MEMORANDUM

From: Gary Jay Kushner
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Re: **USDA and FDA Announce Joint Oversight Over Cell Cultured Products**

On Friday, November 16, 2018, the U.S. Department of Agriculture (USDA) Secretary Perdue and U.S. Food and Drug Administration (FDA) Commissioner Gottlieb announced a joint regulatory framework to oversee cell cultured products. 1/ Under the proposed framework, FDA plans to oversee cell collection, cell banks, cell growth, and cell differentiation. USDA will oversee cell harvest, production, and labeling of food products derived from the cells of livestock and poultry. While the technical details of the framework remain undefined, the agencies have expressed their view that no legislation on the topic is necessary because the agencies have statutory authority to regulate cell cultured food products derived from livestock and poultry.

This announcement comes three weeks after USDA and FDA hosted a joint public meeting on the topic, and before comments on the meeting are due. The agencies also announced they continue to seek public comment on the issue and will extend the deadline to submit comments until December 26, 2018.

Background on Joint USDA and FDA Public Meeting

On October 23 and 24, 2018, the two agencies hosted a joint public meeting on the use of cell culture technology to develop products derived from livestock and poultry. Animal cell culture food technology refers to the controlled growth of animal cells from livestock, poultry, fish, and other animals, their subsequent differentiation into various cell types, and their collection and processing into food. The public meeting was called to expand upon and supplement a discussion and presentation by the Science Board to FDA, which took place on October 22, 2018. The background materials and recorded webcasts for both the public meeting and the Science Board meeting are available on USDA's and FDA's websites. 2/

1/ Press Announcement, Statement from USDA Secretary Perdue and FDA Commissioner Gottlieb on the regulation of cell cultured food products from cell lines of livestock and poultry (Nov. 16, 2018), available at: https://www.fda.gov/NewsEvents/Newsroom/PressAnnouncements/ucm626117.htm.

2/ Science Board to the FDA, 2018 Meeting Materials, available at: https://www.fda.gov/AdvisoryCommittees/CommitteesMeetingMaterials/ScienceBoardtotheFoodandDrugAdministration/ucm603756.htm; FSIS Past Meetings, USDA and FDA Joint Public Meeting on

Opening comments by USDA Secretary Sonny Perdue and FDA Commissioner Scott Gottlieb were encouraging and hopeful about the role cell culture technology and other innovations could play in the food supply in coming years. Secretary Perdue declared the meeting, which boasted over 600 registrants, "one of the more robust meetings we've had," and emphasized the important role informed and engaged stakeholders play as the agencies take on the challenge of establishing a regulatory framework that "encourages innovation and new technology while providing the responsibility of a public, safe, wholesome, and nutritious food supply" that is accurately labeled. He touted the need for a "clear and concise" framework with "bright lines" and a "clear understanding of the roles and responsibilities of both FDA and USDA in the production and commercialization of this new technology." To close his remarks, Secretary Purdue highlighted the demands of a growing population and the need to balance innovation and safety. He qualified that, while USDA follows "a whatever-it-takes and all-of-the-above" approach to feeding the growing population, "new proteins should be treated in the same fashion as . . . past products. . . there must be safe processing and safe production for consumers as well as safe innovation making sure that these things have no unsafe or unhealthy aspects to them."

Commissioner Gottlieb's comments focused on continued collaboration between FDA and USDA, noting "we fully anticipate that both [agencies] will have active roles in the regulatory oversight of cell cultured products." He traced the current discussion around cell cultured products to the first FDA-approved medical therapies and suggested the technology is now "at an interesting intersection of medical technology and food technology." He shared that he would "not be surprised to see cell cultured burgers on the menus in restaurants in the coming years."

Over the two days, each agency presented background information on its existing regulatory tools that could be useful in regulating this new technology. Throughout the day the agencies received a wide array of public comments from scientists, consumer advocacy groups, and industry stakeholders in both conventional and cell cultured food production.

Some key issued raised include:

- Naming considerations (*e.g.*, whether "lab-grown meat," "synthetic meat," "cell cultured meat," and others are appropriate terms for these products);

- The use and regulation of antibiotics in cell cultured products, including as compared to the use and regulation of antibiotics in conventionally produced meat and poultry products;

- Allergen considerations relating to potential allergic reactions to cell cultured products and the resulting need for accurate labeling;

- Microbiological food safety issues raised by layering techniques and cell cultured scaffolding designs;

- Sustainability; and

- International trade and regulatory concerns.

The public docket remains open until December 26, 2018 for the submission of written public comments. 3/

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the Use of Cell Culture Technology to Develop Products Derived from Livestock and Poultry, available at: https://www.fsis.usda.gov/wps/portal/fsis/newsroom/meetings/past-meetings.

3/ Docket number: FSIS-2018-0036.

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We will continue to monitor developments on USDA's and FDA's proposed frameworks relating to the use of cell cultured technology in food products. Please contact us if you have any questions.