



September 25, 2018

Dockets Management Staff  
(HFA-305)  
Food and Drug Administration  
5630 Fishers Lane  
Room 1061  
Rockville, MD 20852

**RE: Docket ID: FDA-2018-N-2155; Foods Produced Using Animal Cell Culture Technology;  
Public Meeting; Request for Comments**

To Whom It May Concern:

The National Cattlemen's Beef Association (NCBA) submits these comments in response to the Food and Drug Administration's (FDA) July 12, 2018 public meeting during which the proper model for regulatory oversight of meat food products derived from animal cell culture technology was discussed. Initiated in 1898, NCBA is the largest and oldest national trade association representing America's cattle farmers and ranchers, working to advance the economic, political, and social interests of its producer-members.

NCBA has a strong interest in ensuring reasonable, equitable, and science-based standards continue to serve as the basis for a comprehensive regulatory system over all meat food products, regardless of the production method. While the purported focus of FDA's public meeting was to examine the risks, hazards, and manufacturing methods of lab-grown meat food products, it was apparent that FDA entered this meeting with a pre-determined conclusion that FDA would have sole authority over these products. Such an unfortunate outcome would result in only cursory oversight of lab-grown meat food product by FDA in comparison with traditional meat food products which are subject to continuous inspection by experts appointed for that purpose by the Secretary of Agriculture.

NCBA remains extremely concerned by several FDA actions demonstrating a clear bias in favor of non-traditional food technologies and what can only be interpreted as the agency's intent to prioritize market entry for these products over ensuring the safety of our nation's food supply. NCBA is particularly concerned with comments from senior leaders within FDA, in which arbitrary benefits were attributed to these lab-grown products.

A statement dated June 15, 2018 from FDA Commissioner Scott Gottlieb, M.D. and Deputy Commissioner Anna Abram specifically references the appeal of cell-cultured technologies to "consumers motivated by animal welfare concerns," as well as the "commercial incentives, including environmental impact, for replacing traditional animal-derived materials."

NCBA wishes to remind the Food and Drug Administration that executive branch agencies are responsible for implementation of the laws and policies set forth by the legislative branch. Societal commentary on issues related to animal welfare and environmental sustainability are unrelated to FDA's responsibilities of ensuring food safety and consumer protection, and fall well beyond the purview of the laws FDA is responsible for enforcing.



As indicated by FDA, the use of animal cell culture technology as a method of food production and manufacturing raises many interesting issues from both technical and regulatory perspectives. However, NCBA believes that the appropriate agency to address these challenges must ultimately be the agency that has primary jurisdiction over lab-grown meat food products. The law governing oversight of meat food products is clear, and any fair reading of the law places lab-grown meat food products within the primary jurisdiction of the U.S. Department of Agriculture (USDA) as delegated to the Food Safety and Inspection Service (FSIS).

While it was unfortunate that USDA officials were completely excluded from the July 12<sup>th</sup> public meeting, despite the bipartisan objections of authorizing committees in Congress, NCBA was pleased to see the recent announcement of a joint USDA and FDA meeting scheduled for October 23-24 and looks forward to participating in that event.

NCBA is hopeful that USDA's effort to restart this process with the scheduling of a joint public meeting is a signal of recognition by the Food and Drug Administration that USDA has primary jurisdiction over all meat food products – lab-grown or conventional. NCBA strongly discourages FDA from taking any further action related to these products independent of the U.S. Department of Agriculture and the principal regulatory authority granted in law to the Secretary of Agriculture.

Thank you for the opportunity to submit these comments. Should you have questions or seek additional information, please contact Danielle Beck, NCBA Director of Government Affairs, by phone or email (202-879-9127 or [dbeck@beef.org](mailto:dbeck@beef.org)).

Respectfully,

A handwritten signature in black ink, appearing to read "W. A. Woodall", with a long horizontal stroke extending to the right.

Colin Woodall  
Senior Vice President, Government Affairs  
National Cattlemen's Beef Association