March 13, 2017

Division of Dockets Management (HFA-305)
Food and Drug Administration
5630 Fishers Lane, Rm. 1061
Rockville, MD 20852

Re: *FDA-2008-D-0394: Regulation of Intentionally Altered Genomic DNA in Animals; Draft Guidance for Industry; Notice of Availability*[1]

To whom it may concern:

Thank you for the opportunity to provide comments to the Food and Drug Administration (FDA) on the 19 January 2017 draft revisions to FDA Guidance for Industry (GFI) #187. For a number of reasons, as noted below, we are requesting additional time to complete these comments. We request an extension of the comment period until at least June 19, 2017. Our request is consistent with, and furthers, the spirit and text of the Administration's recent Executive Orders and guidance aimed at a measured approach to new regulations and guidance[2].

First, FDA is seeking comments on five questions, four of which ask for empirical evidence. The scientific literature on the impacts of genomic changes on 1) the structure and function of the genome; 2) cell biology; 3) phenotypic expression of genetic information; and 4) associated risks, or lack thereof, is extensive. Members of the public and other stakeholders who want to provide empirical evidence to assist FDA in developing a science-based, risk-based regulatory system likely require more time to conduct a thorough literature review.

Second, an extension would foster greater coordination between the three regulatory agencies that participated in development of the White House Office of Science and Technology Policy (OSTP) January 4, 2017 update[3] of the *Coordinated Framework for the Regulation of Biotechnology* (Coordinated Framework)[4]. The Coordinated Framework update was accompanied by development of a *National Strategy for Modernizing the Regulatory System for Biotechnology Products* (the Strategy)[5], which provides a process for regular review of the agencies' regulation of biotechnology products.

The Coordinated Framework update and the Strategy reaffirmed the widely-accepted principles of good regulation articulated in the Coordinated Framework and in Executive

[1] 82 Fed. Reg. 6561 (Jan. 19, 2017).
[2] Regulatory Freeze Pending Review (Jan. 20, 2017), https://www.whitehouse.gov/the-press-office/2017/01/20/memorandum-heads-executive-departments-and-agencies; Implementation of Regulatory Freeze (Jan. 24, 2017), https://www.whitehouse.gov/the-press-office/2017/01/24/implementation-regulatory-freeze; Executive Order, Reducing Regulation and Controlling Regulatory Costs (Jan. 30, 2017), https://www.whitehouse.gov/the-press-office/2017/01/30/presidential-executive-order-reducing-regulation-and-controlling.
[3] Modernizing the Regulatory System for Biotechnology Products: Final Version of the 2017 Update to the Coordinated Framework for the Regulation of Biotechnology, https://obamawhitehouse.archives.gov/sites/default/files/microsites/ostp/2017_coordinated_framework_update.pdf; Increasing the Transparency, Coordination, and Predictability of the Biotechnology Regulatory System (Jan. 4, 2017), https://obamawhitehouse.archives.gov/blog/2017/01/04/increasing-transparency-coordination-and-predictability-biotechnology-regulatory.
[4] Executive Office of the President, Office of Science and Technology Policy, Coordinated Framework for Regulation of Biotechnology, 51 Fed. Reg. 23,302 (June 26, 1986), http://www.aphis.usda.gov/brs/fedregister/coordinated_framework.pdf.
[5] https://obamawhitehouse.archives.gov/sites/default/files/microsites/ostp/biotech_national_strategy_final.pdf.

Orders and White House memos that are rooted in those principles[6]. Additionally in those documents, the FDA, the Environmental Protection Agency (EPA) and the Department of Agriculture (USDA) committed to:

- Operating their programs in a coordinated fashion;
- Clarifying their policies for the regulation of products derived from genome editing techniques;
- Maintaining efficient and predictable regulatory practices; and
- Using a risk-based approach to distinguish biotechnology products that require a certain level of oversight from those that do not.

A foundational principle of the Coordinated Framework is that similar products with comparable risks should be treated similarly by regulatory agencies. On 19 January 2017, USDA published a proposed rule, *Importation, Interstate Movement, and Release Into the Environment of Certain Genetically Engineered Organisms,* to update its regulation of genetically engineered organisms under 7 CFR Part 340[7]. Comments for this proposed rule are currently due on June 19, 2017[8]. In this draft regulation, USDA proposes an approach to regulating certain products of genome editing. FDA's goal in revising the existing GFI #187 is to clarify how it plans to regulate animal products of genome editing. Because of the interrelationship between USDA's Part 340 proposal and the proposed revision to GFI #187, we believe that it would be appropriate to harmonize the comment period for these proposals. Such harmonization would also be consistent with agency good guidance practices set forth by the Office of Management and Budget (OMB) in 2007[9].

Third, we note that on 19 January 2017, FDA also released a request for input on its approach to possibly regulating genome editing in plants*, FDA-2016-N-4389; Genome Editing in New Plant Varieties Used for Foods; Request for Comment*[10]. To facilitate regulatory coordination and consistency for similar products, we are also requesting (via a separate letter) an extension of that comment period until at least June 19, 2017.

Fourth, the process for updating the Coordinated Framework included a solicitation for a report from the National Academy of Sciences (NAS) on appropriate regulation of products of genome editing. That report, *Preparing for the Future Products of Biotechnology*, was released on March 9, 2017. Extending the comment period would also provide additional time for stakeholders to review and analyze the report and incorporate or address any relevant conclusions or findings in their comments, in keeping with FDA's request for scientific evidence to support comments submitted on revisions to GFI #187.

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[6] Executive Order 12866, Regulatory Planning and Review, 58 Fed. Reg. 51,735 (Oct. 4, 1993), https://www.archives.gov/files/federal-register/executive-orders/pdf/12866.pdf; Executive Order 13422, Further Amendment to Executive Order 12866 (Jan. 23, 2007), https://www.gpo.gov/fdsys/pkg/FR-2007-01-23/pdf/07-293.pdf; Principles for Regulation and Oversight of Emerging Technologies (Mar. 11, 2011), https://cms.dot.gov/sites/dot.gov/files/docs/ETIPC%20Memo%203-11-2011.pdf; Regulatory Freeze Pending Review (Jan. 20, 2017), https://www.whitehouse.gov/the-press-office/2017/01/20/memorandum-heads-executive-departments-and-agencies; Implementation of Regulatory Freeze (Jan. 24, 2017), https://www.whitehouse.gov/the-press-office/2017/01/24/implementation-regulatory-freeze; Executive Order, Reducing Regulation and Controlling Regulatory Costs (Jan. 30, 2017), https://www.whitehouse.gov/the-press-office/2017/01/30/presidential-executive-order-reducing-regulation-and-controlling.

[7] 82 Fed. Reg. 7008 (Jan. 19, 2017).

[8] 82 Fed. Reg. 10,312 (Feb. 10, 2017), which extends the comment period to that date.

[9] OMB No. M-07-07, Final Bulletin for Agency Good Guidance Practices (Jan. 18, 2007), https://www.nhtsa.gov/sites/nhtsa.dot.gov/files/m07-07.pdf; OMB No. M-07-13, Implementation of Executive Order 13422 and the OMB Bulletin on Good Guidance Practices (Apr. 25, 2007), https://georgewbush-whitehouse.archives.gov/omb/memoranda/fy2007/m07-13.pdf; OMB/OIRA website, https://www.reginfo.gov/public/jsp/Utilities/faq.jsp.

[10] 82 Fed. Reg. 6564 (Jan. 19, 2017).

The undersigned organizations strongly support a robust commitment to science, research and agricultural innovation by the U.S. government so that scientists, farmers and ranchers have access to the best tools for driving innovation and job growth, and consumers continue to have access to a wide variety of safe and affordable food. These same organizations also strongly support active engagement by the U.S. government with our global trading partners to secure as much alignment in regulatory policies as possible, so that trade in U.S. commodities and global movement of seed and animal reproductive materials are not hindered or disrupted. Granting an extension will help us provide thoughtful and harmonized comments to both FDA and USDA on proposed regulatory frameworks for foods, plants and animals derived from genome editing techniques.

Sincerely,

American Farm Bureau Federation
Agricultural Retailers Association
American Seed Trade Association
American Soybean Association
Biotechnology Innovation Organization
FASS, Inc.[11]
National Association for the Advancement of Animal Science
National Association of Wheat Growers
National Corn Growers Association
National Cotton Council
National Council of Farmer Cooperatives
National Association of State Departments of Agriculture
Samuel Roberts Noble Foundation

cc. Leslie Kux, FDA Associate Commissioner for Policy and Acting Deputy Commissioner for Policy, Legislation, and Analysis
Laura Epstein, Center for Veterinary Medicine
Grail Sipes, Center for Drug Evaluation and Research Organization
Diane Maloney, Center for Biologics Evaluation and Research Organization
Lauren Silvis, Center for Devices and Radiological Health Organization
Jason Dietz, Center for Food Safety and Applied Nutrition
Kathleen Jones, Center for Veterinary Medicine

[11] formerly the Federation of Animal Science Societies