March 14, 2017

Ms. Leslie Kux
Acting Deputy Commissioner for Policy, Legislation, and Analysis and
FDA Associate Commissioner for Policy
Food and Drug Administration
10903 New Hampshire Ave
Silver Spring, MD 20993-0002

Dear Ms. Kux:

The American Seed Trade Association (ASTA) and Biotechnology Innovation Organization (BIO) strongly support a coordinated U.S. Government approach to agriculture innovation as well as the engagement and leadership of the U.S. Government internationally to foster innovation and facilitate trade. We are also committed to providing Federal agencies with substantive and constructive input when requested through the Federal Register public comment process.

We note that on January 19, 2017, the Food and Drug Administration published two Federal Register notices on genome editing in plants and animals (*Genome Editing in New Plant Varieties Used for Foods: FDA-2016-N-4389* and *Regulation of Intentionally Altered Genomic DNA in Animals: FDA-2008-D-0394)*. The Request for Information for genome edited plants and the draft guidance for genome edited animals both raise important and complex issues that will require substantial contributions by commenters. Additionally, these Federal Register notices are interrelated with the U.S. Department of Agriculture (USDA) proposed regulation titled *Importation, Interstate Movement, and Release Into the Environment of Certain Genetically Engineered Organisms: APHIS-2015-0057-0016* to update their regulation of genetically engineered organisms under 7 CFR Part 340. USDA also published their proposed rule on January 19, 2017 and that comment period has now been extended to June 19, 2017.

A large number of organizations representing thousands of scientists, farmers, agribusinesses and food companies have requested that the comment period for both of the FDA dockets *Genome Editing in New Plant Varieties Used for Foods: FDA-2016-N-4389* and *Regulation of Intentionally Altered Genomic DNA in Animals: FDA-2008-D-0394* be extended to coincide with the end of the comment period for the USDA's *Importation, Interstate Movement, and Release Into the Environment of Certain Genetically Engineered Organisms: APHIS-2008-0076-001*6. Please see the attached letters sent to the individual dockets. For more information on the plant related request for information please contact Bernice Slutsky, Senior Vice President, Domestic and International Policy at ASTA at bslutsky@betterseed.org or 703-837-8140. For more information on the animal draft guidance, please contact Adrianne Massey, Managing Director, Science and Regulatory Affairs, BIO at amassey@bio.org or 202-962-9200.

Regards,

Andrew W. LaVigne
President and CEO
ASTA

Dana O'Brien
Executive Vice President
Food and Agriculture Section
BIO