February 9, 2017

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

Submitted Electronically via Federal eRulemaking Portal (http://www.regulations.gov)

Re: Docket No. FDA-2017-N-6455. Agency Information Collection Activities; Proposed Collection; Comment Request; Guidance on Consultation Procedures: Foods Derived from New Plant Varieties.

Dear Sir or Madam:

The Biotechnology Innovation Organization (BIO) is pleased to submit these comments in response to the U.S. Food and Drug Administration's (FDA) request for public input on a notice published in the *Federal Register*[1] regarding information collection burdens associated with its "Guidance on Consultation Procedures: Foods Derived from New Plant Varieties." BIO is the world's largest trade association representing roughly 1,000 biotechnology companies, academic institutions, state biotechnology centers and related organizations across the United States and in more than 30 other nations. BIO members are involved in the research and development of innovative healthcare, agricultural, industrial and environmental biotechnology products. BIO represents many of the agricultural biotechnology product developers in North America, including companies developing products subject to the information collections described in this notice.

In 1986, the U.S. White House Office of Science and Technology Policy articulated general policies and principles for the oversight of certain products of agricultural biotechnology in a document entitled the "Coordinated Framework for the Regulation of Biotechnology" (the "Coordinated Framework").[2] FDA's role within the Coordinated Framework was described in a 1992 policy statement, *Foods Derived from New Plant Varieties,*[3] implementing the principles of the Coordinated Framework with respect to food and feed safety of plants and plant products. FDA's 1992 policy offers an explanation of the rationale it uses to formulate a science-based approach to safety reviews, and forms the basis of a voluntary process by which developers may consult with FDA regarding the safety of foods derived from new plant varieties before bringing such foods to market.[4] This consultation process is jointly administered by the Center for Food Safety and Nutrition (CFSAN) and the Center for Veterinary Medicine (CVM).

BIO applauds the work that FDA has undertaken to develop and enforce a sensible, science-based approach to the regulation of products of agricultural biotechnology. FDA's consultation process has worked well for nearly 30 years, and BIO members do not consider the current information collection

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[1] 82 FR 58619-58621 (December 13, 2017).
[2] OSTP. 1986. Coordinated Framework for Regulation of Biotechnology. 51 Fed. Reg. 23302, 23304
[3] FDA. 1992. Statement of Policy: Foods Derived from New Plant Varieties. 57 FR 22984-23005.
[4] FDA. 1997. *Consultation Procedures under FDA's 1992 Statement of Policy - Foods Derived from New Plant Varieties*. https://www.fda.gov/RegulatoryInformation/Guidances/ucm096126.htm

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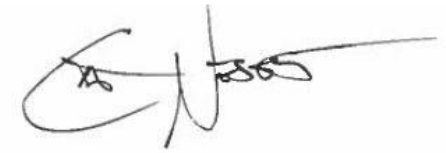
requests associated with the consultation process to be unduly burdensome. However, we strongly encourage FDA to identify mechanisms by which it can better incorporate its experience over time and, where possible, implement more efficient, streamlined review processes for those products similar to those the agency has reviewed in the past. USDA regulations, for example, include a streamlined "extension" process[5] for more efficient reviews of products of agricultural biotechnology sufficiently similar to those previously reviewed by the agency. FDA should consider implementation of similar mechanisms to parallel USDA's review process.

An additional, significant shortcoming of the premarket consultation process at FDA is that reviews independently conducted by CFSAN and CVM are partially, if not wholly, redundant with each other. This creates significant inefficiencies for the agency, as well as creating the possibility that reviews for similar food safety risks are implemented inconsistently across the two Centers. We encourage FDA to develop a less redundant review process (such as reciprocity if no material differences are identified) that better coordinates expertise across CFSAN and CVM into a single, efficient review.

Thank you for the opportunity to provide comments on information collection burdens related to FDA's new plant variety consultation process. Please feel free to contact me directly if you have any questions about our comments.

Sincerely,



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[5] 7 CFR 340.6(e)