

April 19, 2010

Submitted Via Electronic Mail  
Docket No. FDA-2004-N-0390

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

Dear Sir or Madam:

Re: Docket No. FDA-2004-N-0390 (formerly docket No. 2004N-0503); Agency Information Collection Activities; Proposed Collection; Comment Request; Guidance on Consultation Procedures: Foods Derived From new Plant Varieties

To whom it may concern:

These comments are submitted by the Biotechnology Industry Organization (BIO) in response to the February 18, 2010 announcement (the Notice) by the United States Food and Drug Administration (FDA or the Agency) soliciting comments on the information collection provisions of FDA's consultation procedures for foods derived from new plant varieties, including the information collection provisions in the guidance, "Consultation Procedures: Foods Derived From New Plant Varieties," and in Form FDA 3665, "Final Consultation For Food Derived From a New Plant Variety (Biotechnology Final Consultation)." 75 Fed. Reg. 7274. BIO appreciates this opportunity to provide these comments.

BIO is the world's largest biotechnology organization, providing advocacy, business development and communications services for more than 1,200 members worldwide. BIO members are involved in the research and development of innovative healthcare, agricultural, industrial and environmental biotechnology. Corporate members range from entrepreneurial companies developing their first product to Fortune 100 multinationals. We also represent state and regional biotechnology-derived associations, service providers to the industry, and academic centers.

BIO's members represent the majority of those entities subject to the information collection requests (ICR) that are the subject of this notice. BIO's member companies engaged in the development of biotechnology-derived commodity crops and other plants and organisms have acted under the regulatory oversight of FDA, along with the United States Department of Agriculture and the Environmental Protection Agency for over twenty years. Since that time, these products have yielded significant economic and environmental benefits, lowering both the costs and environmental impact of food, feed and fiber production in the United States and 24 other nations. This success has been grounded on the work that FDA and the other federal



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agencies overseeing this technology have conducted to ensure the safety of these products for the environment, as well as for the consuming public. BIO applauds the work that FDA has undertaken to develop and enforce a sensible, science-based approach to the regulation and development of these products.

As stated in the Notice, since 1992, when FDA issued its Statement of Policy: Foods Derived from New Plant Varieties, FDA has encouraged developers of new plant varieties, including those developed through biotechnology, to consult with FDA during the plant development process to discuss possible scientific and regulatory issues that might arise. BIO strongly supports the participation of its members in the consultation process, and every biotechnology-derived crop on the United States market today has undergone the consultation process.

With regards to the consultation process's ICR burden, BIO's members do not consider the current ICRs to be unduly burdensome, and recognize that the information collected assists FDA in reviewing the safety of food from biotechnology-derived crops. BIO members welcome the standardized format and ability to provide electronic information that Form FDA 3665 will provide. At the same time, the use of the new form and electronic submission of data and information for FDA's use should assure and acknowledge the protection of proprietary (non-CBI or trade secret) data and information submitted to FDA.

BIO looks forward to the opportunity to provide any additional information on this topic that FDA may request, and appreciates the opportunity to provide these comments in response to the Agency's Notice.

Sincerely,



Sharon Bomer Lauritsen  
Executive Vice President  
Food and Agriculture