

November 12, 2019

Docket No. FDA-2018-N-2381

Center for Food Safety and Applied Nutrition (HFS-009)

Food and Drug Administration

5001 Campus Dr., College Park, MD 20740

Via <https://www.regulations.gov/docket?D=FDA-2018-N-2381>.

This letter provides comments to the U. S. Food and Drug Administration on the draft Nutrition Innovation Strategy, Docket FDA-2018-N-2381.

The Information Technology and Innovation Foundation (ITIF) is an independent, nonpartisan research and educational institute focusing on the intersection of technological innovation and public policy. Recognized as the world's leading think tank for science and technology policy, ITIF's mission is to formulate and promote policy solutions that accelerate innovation and boost productivity to spur growth, opportunity, and progress. With this letter, ITIF responds to the invitation for public comment contained in Docket No. FDA-2018-N-2381.

The Food and Drug Administration is to be commended for recognizing the importance to consumers of sound nutrition information, and for proposing “a comprehensive, multi-year FDA Nutrition Innovation Strategy that is designed to improve healthy dietary behavior and help reduce preventable death and disease related to poor nutrition” in service to that objective.¹ In presentations at the September 27 meeting, FDA laid out the history of food and drug laws Congress has passed to ensure consumers have accurate nutritional information and are protected from deceptive business practices.² Much of the policy conversation concerned issues associated with standards of identity (SOI).³ Yet in the voluminous documents prepared before and

¹Food and Drug Administration, “Horizontal Approaches to Food Standards of Identity Modernization; Public Meeting; Request for Comments,” Federal Register, August 29, 2019

<https://www.federalregister.gov/documents/2019/08/29/2019-18713/horizontal-approaches-to-food-standards-of-identity-modernization-public-meeting-request-for>.

²Food and Drug Administration, “Public Meeting on Horizontal Approaches to Food Standards of Identity Modernization,” September 27, 2019 <https://www.fda.gov/food/workshops-meetings-webinars-food-and-dietary-supplements/public-meeting-horizontal-approaches-food-standards-identity-modernization-09272019-09272019>.

³ Food and Drug Administration, “Public Meeting on Horizontal Approaches to Food Standards of Identity Modernization, Event Materials,” September 27, 2019 <https://www.fda.gov/food/workshops-meetings-webinars-food->

derived from the September 27 public meeting FDA seems to ignore the most salient example of abuse of SOI being used to mislead consumers today: the “NonGMO” label that has become widespread in recent years, now featured on allegedly 60,000 food products.⁴ The NonGMO label promulgated by the NonGMO project is the most egregious example of a misleading “absence claim” label (others include the “gluten free” claim on foods with no ingredients containing gluten).⁵ This was pointed out to FDA during the September 27 meeting by the National Milk Producers Federation.⁶

It has been demonstrated that the NonGMO label has no basis in science, is inescapably misleading, and clearly violates the laws Congress has provided to empower FDA to protect consumers.⁷ It is therefore not possible to establish a SOI for “GMOs” that would illuminate the invalidity of the “NonGMO” label. But FDA’s reticence on this has allowed the NonGMO Project and those companies that have chosen to be their accomplices to deploy the NonGMO label as a de facto SOI and in so doing mislead and defraud consumers.

Congress has historically recognized the general need for FDA to prevent misleading labels of this sort, and provided both instructions and funds to address the issue through the “Agricultural Biotechnology Education and Outreach Initiative; Public Meetings; Request for Comments” of 2017.⁸ FDA has recognized the improprieties intrinsic to the NonGMO project label and provided guidance on the topic that makes it clear such labels are inescapably misleading and therefore illegal.⁹ And yet the NonGMO project continues to flaunt the law.

and-dietary-supplements/public-meeting-horizontal-approaches-food-standards-identity-modernization-09272019-09272019#event-materials.

⁴ Non-GMO Project, “About”, website at <https://www.nongmoproject.org/about/>, accessed 11 November, 2019.

⁵ Information Technology and Innovation Foundation, “Citizen’s Petition,” http://www2.itif.org/2018-non-gmo-citizen-petition.pdf?_ga=2.52336297.1012461357.1573507294-1394096080.1536250378.

⁶ Food and Drug Administration, “PM Breakout 2 (Regency) - Consumer Expectations of Standardized Foods,” Federal Register, August 29, 2019 <https://www.fda.gov/media/132404/download>.

⁷ Information Technology and Innovation Foundation, “Citizen’s Petition,” http://www2.itif.org/2018-non-gmo-citizen-petition.pdf?_ga=2.52336297.1012461357.1573507294-1394096080.1536250378.

⁸ Food and Drug Administration, “Agricultural Biotechnology Education and Outreach Initiative; Public Meetings; Request for Comments,” Federal Register, October 13, 2017.

<https://www.federalregister.gov/documents/2017/10/13/2017-22172/agricultural-biotechnology-education-and-outreach-initiative-public-meetings-request-for-comments>.

⁹ Food and Drug Administration, “Guidance for Industry: Voluntary Labeling Indicating Whether Foods Have or Have Not Been Derived from Genetically Engineered Plants,” Federal Register, March 8, 2019.

<https://www.fda.gov/regulatory-information/search-fda-guidance-documents/guidance-industry-voluntary-labeling-indicating-whether-foods-have-or-have-not-been-derived>.

It is past time for FDA to take action to terminate the ongoing deception and exploitation of consumers by corporations that use such misleading labels in their marketing campaigns. Enforcement action is clearly overdue.

Thank you for the opportunity to provide comments on this proposal.

Sincerely,

/s/

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