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December 17, 2023

The Honorable Xavier Becerra
Secretary
Department of Health and Human Services
200 Independence Avenue, SW
Washington, D.C. 20201

The Honorable Robert M. Califf, MD
Commissioner of Food and Drugs
Food and Drug Administration
10903 New Hampshire Avenue
Building 32, Room 2346
Silver Spring, MD 20993

Dockets Management, FDA-2023-P-3942
Food and Drug Administration
5630 Fishers Lane, Room 1061
Rockville, MD 20852

Re: Comments on FDA Citizen Petition to Label Gluten as a Major Food Allergen
FDA Docket Number: FDA-2023-P-3942 ("Citizen Petition")

Dear Secretary Becerra and Commissioner Califf:

As the Heimbold Chair in International Law, Professor of Law; Professor of Medical Ethics & Health Policy; and Deputy Dean for International Programs at the University of Pennsylvania Carey Law School, I am writing to provide support for Celiac Journey's FDA Citizen Petition to require the labeling of Gluten on all food packages in the United States. As you surely know, Gluten labelling is required in 87 countries worldwide.[1] I believe that it is time for the US to become the 88th country to require such labelling.

The FDA has the legal responsibility and the authority to require the labeling of Gluten, a protein found in Wheat, Barley, Rye and most Oats. Today, only Wheat is required to be labeled, but Barley, Rye and Oats are not. By requiring the labeling of Gluten, the FDA will close a major food safety consumer protection gap that will improve the safety and quality of life for 3.3

[1] https://www.regulations.gov/document/FDA-2023-P-3942-0001

million Americans with Celiac, a potentially life-threatening and life-debilitating food allergy to Gluten.

The Citizen Petition clearly lays out the case for the labelling of Gluten. It requests that the FDA use its existing authority in the Food Allergen Labeling and Consumer Protection Act (21 U.S.C. § 343(x)) and issue a rule to: 1) require that all ingredients with Gluten be listed by name in the ingredient lists of all foods and; 2) add Gluten to the FDA's list of allergens in Sec. 555.250 of its Compliance Policy Guides Manual, "Statement of Policy for Labeling and Preventing Cross-contact of Common Food Allergens." The Petition points out that the FDA has clear legal authority to require such labelling, authority that was strengthened and clarified by the Food Allergen Labeling and Consumer Protection Act ("FALCPA"). Moreover, the FDA may require labeling pursuant to its authority to enforce the prohibition on misbranded foods in Section 403(a) of the FDCA. To protect the Celiac community, it is time for the FDA to require a clear statement of ingredients on food labels, e.g., "flour (from Rye)," "flour (from Barley)," and "flour (from Oats)."

Finally, the Citizen Petition correctly underscores that the FDCA confers broad authority on the FDA to effectuate the important public policy goals of the. Federal Food, Drug, and Cosmetic Act ("FDCA").[2] This authority is well-established and is supported by the public policy of protecting consumers by promoting honest and fair dealing where consumers have the right to know if there are potentially life-threatening food allergens in various food items.[3]

As you are aware, serious criticism is being aimed at the FDA for its reluctance to take meaningful action when it comes to labelling. As the Center for Science in the Public Interest recently stated,

> "Despite the need for periodic, evidence-based updates, FDA actions following the passage of FALCPA have been slow, piecemeal, and largely driven by advocacy from outside stakeholders, including CSPI. For example, the agency's only use of section 403(x) was in 2009, when the agency cited this section as one of several authorities supporting mandatory labeling of carmine/cochineal extract as an allergenic color additive, an action taken in response to a petition that CSPI had submitted 11 years earlier. More recently, FDA deliberated for six years on a 2014 petition from CSPI requesting that sesame be labeled as an allergen. While the agency eventually issued a draft guidance in November 2020 providing voluntary recommendations to manufacturers regarding sesame labeling, it never exercised its authorities under 403(x) or other provisions to require labeling and food safety controls for sesame."[4]

> Scholars have also weighed in on the side of FDA action. In a 2006 article "When Food Is Poison: The History, Consequences, and Limitations of the Food Allergen Labeling and Consumer Protection Act of 2004" published in the *Food & Drug Law Journal,* the author Laura Derr (under the supervision of the FDA's former chief counsel and Harvard Lecturer of Law Peter Barton Hutt) asserted that FALCPA "does not preclude FDA from

[2] 21 U.S.C.S. § 371(a).
[3] See, e.g., A. E. Staley Mfg. Co. v. Secretary of Agriculture, 120 F.2d 258, 260 (7th Cir. 1941).
[4] https://downloads.regulations.gov/FDA-2021-N-0553-1824/attachment_1.pdf

expanding via regulation the list of major allergens requiring identification under the FALCPA's labeling scheme."[5] Section 203(b) states that the labeling requirements established under new section 403(w) "do not prevent the Secretary from requiring labels or labeling changes for other food allergens that are not major food allergens."[6]

I urge you to carefully read the Citizen Petition, which carefully describes the health challenges facing those with Celiac Disease, and the importance of viewing those suffering from that disease as an underserved community of persons with a chronic disability[7] deserving of attention as a matter of equity (see President Biden's Executive Order 13985 on "Advancing Racial Equity and Support for Underserved Communities Through the Federal Government" (January 20, 2021)[8] and President Biden's Executive Order 14091 on "Further Advancing Racial Equity and Support for Underserved Communities Through the Federal Government." (February 16, 2023)[9]). By doing so, I am confident that you will agree with the view that people suffering from Celiac Disease deserve the full support of the government in their struggle for equal opportunity.[10]

I am respectfully requesting that the FDA change the voluntary gluten labeling rule to a mandatory labeling rule to keep 3.3 million Americans with Celiac safer. Thank you.

Sincerely,

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[5] "When Food is Poison," p.141, including footnotes 423-424.
[6] H.R. Rep. No. 108-608, at 18. (2004), https://www.congress.gov/108/crpt/hrpt608/CRPT-108hrpt608.pdf
[7] See Citizen Petition, Section VI, pages 63-87, https://downloads.regulations.gov/FDA-2023-P-3942-0001/attachment_1.pdf
[8] https://www.federalregister.gov/documents/2021/01/25/2021-01753/advancing-racial-equity-and-support-for-underserved-communities-through-the-federal-government
[9] https://www.federalregister.gov/documents/2023/02/22/2023-03779/further-advancing-racial-equity-and-support-for-underserved-communities-through-the-federal
[10] See Citizen Petition, Section V, pages 63-87, https://downloads.regulations.gov/FDA-2023-P-3942-0001/attachment_1.pdf