



November 4, 2024

Umailla Naeem
Laura MacCleery
UnidosUS
1126 16th St. NW #600
Washington, D.C. 20036

Via email to: ufatima@unidosus.org, lmaccleery@unidosus.org,

Re: Docket No. FDA-2024-P-2151

Dear Ms. Naeem and Ms. MacCleery,

This responds to your citizen petition dated May 07, 2024, under Docket No. FDA-2024-P-2151, requesting that the Food and Drug Administration (FDA) issue a regulation requiring a warning label on the principal display panel on all unfortified corn masa flour products and products made with corn masa (such as tortillas, tamales, pupusas, tortilla chips, etc.) alerting consumers that the product does not contain added folic acid and lack of folic acid increases the risk of neural tube defects. The warning should be required on the front of packages in a conspicuous font size and color. To meaningfully reach the Hispanic and Latino population, who are at the highest risk for neural tube defects, UnidosUS urges the FDA to require the warning label be present on unfortified corn masa foods in both English and Spanish.

Proposed Warning Label Language from the UnidosUS petition for use on principal display panel of a food:

In English:

"WARNING: The corn masa in this product is not fortified with folic acid. A lack of adequate folate before and during pregnancy increases the risk of serious birth defects."

In Spanish:

"ADVERTENCIA: Este producto no contiene ácido fólico. La falta de consumo de ácido fólico durante un embarazo, aumenta el riesgo de defectos de nacimiento en el cerebro y la columna vertebral del bebé."

We are advising you, in accordance with Title 21 of the *Code of Federal Regulations*, section 10.30(e)(2), that we have not been able to reach a decision on your petition within the first 180 days of its receipt, nor as of the date of this letter, because of other agency priorities and the

limited availability of resources. When we complete our review of your petition, we will notify you of our decision. If you have any questions, please let us know.

Sincerely yours,

Claudine Kavanaugh, Ph.D., MPH., RD
Director
Office of Nutrition
and Food Labeling
Nutrition Center
of Excellence