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CITIZEN PETITION

April 30, 2024

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

Submitted electronically

Re: Citizen petition for the U.S. Food and Drug Administration to require warning labels for unfortified corn masa flour and products made with corn masa as a labeled ingredient to prevent neural tube defects

To Whom It May Concern:

UnidosUS hereby submits this petition under 5 U.S.C. § 553(e), 21 C.F.R. § 10.30, and Section 403(a) of the Food, Drug, and Cosmetic Act, requesting that the Commissioner of Food and Drugs issue a regulation requiring a warning label on all unfortified corn masa flour products and products made with corn masa to alert consumers when a product does not contain adequate folic acid and that the lack of folic acid increases the risks of serious neural tube birth defects.

Specifically, we request that a warning label be required on the front of packages of corn masa flour, and products made with corn masa as a labeled ingredient, in a clear and conspicuous font and color and that the warning statement be contained in a visually distinctive box. Such a warning statement is urgently needed to inform all consumers who purchase corn masa flour and products made with corn masa of the critical public health risks posed by products that lack adequate levels of added folic acid.

UnidosUS is the nation's largest Hispanic[*] civil rights and advocacy organization.[†] In 2012, a coalition, including UnidosUS, and food industry and public health partners, petitioned the FDA

[*] The terms "Hispanic" and "Latino" are used interchangeably by the U.S. Census Bureau and throughout this document to refer to persons of Mexican, Puerto Rican, Cuban, Central and South American, Dominican, Spanish, and other Hispanic descent; they may be of any race. Our materials may also refer to this population as "Latinx" to represent the diversity of gender identities and expressions that are present in the community.

[†] Through its unique combination of expert research, advocacy, programs, and an Affiliate Network of nearly 300 community-based organizations across the United States and Puerto Rico, UnidosUS simultaneously challenges the social, economic, and political barriers to the success and wellbeing of Latinos at the national and local levels. For more than 50 years, UnidosUS has united communities and different groups seeking common ground through collaboration and that share a desire to make our country stronger.

to allow voluntary fortification of corn masa flour with folic acid up to 0.7 mg/lb.[1] The FDA approved this request in 2016, citing the risks to Latino children and families from a lack of fortification.[2] However, voluntary fortification has failed to lead to adequate industry uptake.[3] Most corn masa flour and corn masa products (such as corn chips, tortilla chips, pupusas, and tamales) remain unfortified seven years later, perpetuating a health equity gap and posing a serious but preventable risk to Latino infants of an increased incidence of serious birth defects.[4] Studies show that 0% of corn tortillas and just 14% of corn masa flour were fortified with folic acid in 2022.[5]

As a result, Hispanic women continue to have lower folic acid intake than their peers, putting their pregnancies at higher risk.[6] Recent data show Hispanic women and infants in the United States continue to suffer from disproportionately high rates of neural tube defects (NTDs) compared to non-Hispanic white and black women and infants.[7] NTDs result when the neural tube, which ultimately forms the brain and spine, fails to close properly during the first month of embryonic development.[8] The two most common NTDs are spina bifida and anencephaly.[9] Spina bifida occurs in approximately 1,510 births per year in the United States and causes physical and intellectual disabilities.[10] Anencephaly, which occurs in approximately 944 births per year, is invariably fatal.[11]

Numerous studies have demonstrated that consuming adequate amounts of folic acid (a synthetic form of folate, or vitamin B9) around the time of conception can significantly reduce the risk of NTDs.[12] Folate is an umbrella term referring to various forms of vitamin B9 found naturally in foods like leafy greens, citrus fruits, and beans.[13] Folic acid is a synthetic type of folate used in supplements and fortified foods like bread and some breakfast cereals.[14] Extensive scientific evidence demonstrates folic acid effectively prevents devastating neural tube birth defects when consumed prior to and early in pregnancy.[15] The Centers for Disease Control and Prevention (CDC) advises all women of reproductive age to supplement their dietary folate intake with 400 micrograms of folic acid daily from fortified foods or folic acid supplements.[16]

Folic acid helps to facilitate proper development and closure of the neural tube during the early stages of pregnancy.[17] For this reason, health experts, including the National Academies of Sciences, Engineering, and Medicine (NASEM), recommend that all women capable of becoming pregnant consume 400-800 mcg of folic acid daily from fortified foods or supplements, in addition to folate obtained from a varied diet.[18] Studies demonstrate that nearly half of all pregnancies in the United States are unintentional and that folic acid fortification is therefore essential in the diet well before the onset of pregnancy.[19] In particular, lower-income and Hispanic women and girls continue to have much higher rates of unintended pregnancy than do non-Hispanic white people and those with higher incomes.[20] According to the CDC, "[w]aiting until the first prenatal visit (typically, the 6th to 12th week of pregnancy) to start folic acid consumption will not prevent neural tube defects. Therefore, to help prevent neural tube defects, it is important for women to start folic acid consumption before pregnancy begins."[21]

Unfortunately, national survey data show that Hispanic women have lower average folic acid intake when compared to non-Hispanic white women.[22] In addition to the dietary reasons we identify here as the major cause, other reasons for lower folic acid intake can include less access to preconception counseling, reproductive and prenatal health care, and health care coverage; lower education and income levels; and cultural and language barriers.[23] Even after folic acid fortification of U.S. grain products began in 1998, Hispanic women continue to have higher rates of NTD-affected pregnancies compared to non-Hispanic white and black women, reflecting such differences, including differences in the diet of staple foods.[24]

The growing Latino population in the United States makes addressing NTD disparities an increasingly urgent public health priority. Many Hispanic immigrants come from Latin American countries where corn masa flour and related products (e.g., corn tortillas) fortification is mandatory, including Mexico, and other countries where fortification is voluntary, such as Costa Rica.[25] These immigrants may incorrectly assume corn masa products in the U.S. are similarly fortified with folic acid. Hispanics currently make up nearly 19.1% of the population and are projected to make up 26.9% of the U.S. population by 2060.[26] As the Latino population grows, so will the number of women and infants who are exposed to unfortified corn masa foods.

One intervention to increase folic acid intake in the Hispanic community is to fortify corn masa flour and products made with corn masa. Corn masa flour and products made with corn masa are staple ingredients in Latino cuisine, used to make foods like tortillas, tamales, pupusas, enchiladas, tostadas, and empanadas.[27] More than half of Hispanic women of reproductive age report consuming corn masa flour and corn masa flour products.[28] Adding this commonly consumed food to the list of fortified staples could significantly improve folic acid intake and reduce NTDs among this population.[29]

Because the decision of whether to fortify a product is currently voluntary, a warning statement is required to address the risks of unfortified foods. This request for a warning statement to inform Latinos and others of this risk is consistent with the White House National Strategy on Hunger, Nutrition, and Health, which emphasizes "foster[ing] environments that enable all people to easily make informed, healthy choices, increase access to healthy food…and invest in public education campaigns that are culturally appropriate and resonate with specific communities."[30]

A. Action Requested

To protect all women and babies, particularly Latino women and children, from preventable NTDs, UnidosUS hereby petitions the FDA to take the following action:

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 corn masa foods in both English and Spanish.

Proposed Warning Label Language 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."

UnidosUS intends to test these and other formulations of the warning statement with consumers to develop an empirical record of consumer understanding of the warnings, and we will share our findings and such evidence with the FDA.

B. Statement of Grounds

I. General Statement of Grounds

Requiring a warning label on unfortified corn masa flour and products made with corn masa is urgently needed to inform consumers that these products lack adequate folic acid to support neural tube defect prevention. Without clear on-package messaging, consumers may unknowingly increase the risk of babies being born with birth defects when they purchase unfortified corn masa foods, and they may not know to look for the scant few products on the marketplace that are fortified, even when they are available on the shelf.

The regulatory record on the fortification of corn masa flour supports this action. On April 15, 2016, the FDA amended the food additive regulations to allow the addition of folic acid to corn masa flour. This decision responded to a petition filed jointly by Gruma Corporation, the Spina Bifida Association, the March of Dimes Foundation, the American Academy of Pediatrics, and the National Council of La Raza (now UnidosUS).[31]

The petition requested allowing folic acid in corn masa flour at levels not to exceed 0.7 milligrams (mg) per pound.[32] According to the FDA decision, "[t]he petition requested this fortification to increase the folic acid intake for U.S. women of childbearing age who regularly consume products made from corn masa flour as a staple in their diet, including, in particular, women of Latin American descent (for example, Mexican Americans), to help reduce the incidence of neural tube defects (NTDs), which are birth defects affecting the spine, brain, and spinal cord."[33]

Following a safety review, the FDA concluded that the petitioned use of folic acid in corn masa flour at a level not to exceed 0.7 mg folic acid per lb. of corn masa flour is safe and would help increase folic acid intake among women who regularly consume corn masa flour products.[34] The FDA further concluded that folic acid is important for proper fetal development and neural tube defect prevention, citing the Centers for Disease Control and Prevention's recommendation that all women of childbearing age consume 0.4 mg of folic acid daily.

As the FDA observed in its regulatory notice,[35] corn masa flour is a staple ingredient in the diets of many Hispanic women of childbearing age. Unfortified corn masa flour and corn masa pose a risk of inadequate folic acid intake and a higher risk of neural tube defects in babies born to these women.

Voluntary fortification alone, as currently permitted by the FDA, has failed to adequately protect public health or provide sufficient transparency to consumers about the implications of choosing unfortified corn masa foods over fortified alternatives. While folic acid fortification of staple foods beginning in 1998 led to a 28% reduction in neural tube defects (NTDs) overall in the U.S., NTD rates remain higher among Hispanic infants compared to other groups.[36] This disparity persists because Hispanic women have lower folic acid intake, and most corn masa flour and corn masa flour products lack fortification.[37]

Despite corn masa being a dietary staple for over half of Hispanic women, just 14% of corn masa flour and 0% of corn tortillas contained added folic acid as of 2022.[38] National survey data indicate that prior to 1998, Black and Mexican American women had lower folate intake and blood folate levels compared to White women.[39] These gaps remain today.[40] Without clear on-package messaging, consumers cannot make fully informed decisions when purchasing corn masa foods, inadvertently increasing their risk of devastating birth defects. Requiring warning labels on unfortified corn masa products is vital to enable transparent, health-promoting choices.

In addition to federal action, states are also recognizing the critical need for folic acid fortification in corn masa flour. For example, California State Representative Joaquin Arambula recently introduced Assembly Bill 1830, which would mandate the addition of folic acid to corn masa flour products sold in the state by January 1, 2026.[41] This bill is particularly important for promoting health equity, as it aims to address the higher rates of neural tube defects among Hispanic women and their children. If enacted, the bill is projected to increase folic acid intake among Mexican Americans by nearly 20%, significantly decreasing the risk of neural tube defects.

Further evidence of the governmental consensus about the critical need and public health benefits of expanded corn masa flour fortification comes from the U.S. Department of Agriculture's recently finalized updates to the Special Supplemental Nutrition Program for Women, Infants, and Children (WIC) food packages. The updates to the WIC food packages add folic acid-fortified corn masa flour tortillas as an approved whole grain option, improving options for pregnant women and young children. However, the language specifies that this

provision will take effect “once [compliant products are] available in the marketplace,” highlighting the current lack of fortified corn masa flour and corn masa products.[42]

While helpful, more is needed to spur market-wide fortification by itself given that WIC beneficiaries will be likely to learn a product is excluded by WIC once they are already at the checkout. This underscores the need for coordinated policy efforts across agencies to realize the immense potential benefits of fortification. Requiring warning labels on unfortified corn masa packages represents a significant and feasible step to drive broader voluntary fortification and enhance consumer awareness. In tandem with updated WIC standards, a warning statement could lead to transformative public health gains, if it is finalized.

A mandatory warning label for unfortified corn masa flour and corn masa products will enable all consumers to make fully informed decisions and purchases aligned with public health recommendations. Evidence shows that on-package warnings improve consumer knowledge and steer choices toward healthier options. For example, a 2020 study found that sodium warning labels decreased purchases of high-sodium products by 6-8%.[43]

Similarly, a warning that corn masa foods lack adequate folic acid may prompt some shoppers to opt for fortified alternatives and motivate manufacturers to increase fortification rates. Transparently alerting consumers about health risks is a matter of fairness and could motivate industry changes that reduce risks on a population scale. In Chile, black stop-sign warnings on foods high in calories, saturated fat, sugar, and sodium led to significant reductions in those nutrients across the food supply.[44] Likewise, in Peru, on-package warnings on processed foods with high levels of sugar, saturated fat, sodium, and calories were followed by reductions in those nutrients in reformulated products.[45] Warning labels on corn masa products could similarly incentivize manufacturers to add folic acid to their products as a way to side-step the requirement for labeling. This would, in turn, expand choices of fortified masa foods and reduce neural tube defect risk for all consumers.

Requiring dual language warning labels in English and Spanish would ensure the information reaches all Hispanic consumers equally, regardless of English fluency. It would maximize public health impact among the target high-risk population. Spanish is the most widely spoken non-English language in U.S. homes, and decades of census data show the majority of Hispanics speak Spanish at home.[46] While English proficiency is rising over generations, nearly one-third of Hispanic adults are not English proficient.[47] Furthermore, studies show that Spanish-speaking Hispanics consume traditional Latino foods like corn tortillas more frequently than English-speaking Hispanics.[48] Spanish speakers are also less likely to take folic acid supplements.[49]

Furthermore, foreign-born and less acculturated Hispanics have an even higher underlying risk of having a child with a neural tube defect, when compared to U.S.-born Hispanic families.[50] Requiring dual warnings would help overcome disparities in folic acid intake and neural tube defect rates related to language preference and acculturation level.

Precedent exists for bilingual labeling requirements in U.S. law and FDA regulations, including as to drug warnings.[51] Dual language warnings are critical for informing and protecting the most vulnerable Hispanic subpopulations.

Corn masa flour and corn masa products also warrant a warning label due to the disproportionate impact of neural tube defects (NTDs) on the Latino population in the United States. Unlike many enriched grain products, corn masa flour was not included in the U.S. folic acid fortification standards implemented in the 1990s. However, corn masa-based foods like tortillas, tamales, and pupusas are staple foods for many Latinos, with over half of Hispanic women of childbearing age regularly consuming corn masa according to recent NHANES data.[52] With the Latino population in the United States rapidly increasing, now accounting for more than 19% of the total population as of 2023, warning labels on corn masa flour and corn masa products present a critical opportunity to address health disparities that will likely worsen if left unaddressed.[53]

A warning label on unfortified corn masa flour products is a targeted, cost-effective public health intervention to increase folic acid intake in a high-risk subpopulation and help reduce the ethnic disparity in NTD prevalence. Many Latino communities have limited access to or cultural preferences for alternative fortified foods, making corn masa flour a central target for increasing folic acid intake. Failing to address the lack of folic acid in these products perpetuates health disparities and disproportionately impacts a historically underserved community.

Given the severity of NTD rates among Latinos in the United States, the ubiquity of corn masa in the Latino diet, and the potential for broad public health benefits, a warning label on corn masa flour products represents a proactive step towards health equity. It serves as a cost-effective, direct way to inform consumers and promote the importance of folic acid fortification in a population overlooked by previous fortification efforts.

II. Statement of Legal Grounds

Section 403(a) of the Food, Drug, and Cosmetic Act (FFDCA), the FDA has ample authority to require a warning label. First, it can deem food misbranded if its labeling is false or misleading. Section 403(a) of the FFDCA states, in pertinent part, that a "food shall be deemed to be misbranded if its labeling is....misleading in any particular."

Section 201(n) of the FFDCA provides that "in determining whether the labeling...is misleading there shall be taken into account (among other things) not only representations made or suggested...but also the extent to which the labeling....fails to reveal... consequences which may result from the use of the article to which the labeling relates...under such conditions of use as are customary or usual." The FDA's regulations further provide that affirmative disclosure of material facts under those statutory requirements may be required through regulations. 21 C.F.R. 1.21(b).

The FDA also has previously indicated that it "has required special labeling in cases where information is necessary to ensure that consumers are aware of special health risks associated with consumption of a particular product." 61 Fed. Reg. 3117 (Jan. 30, 1996) at 3160. For example:

- The term "milk derivative" must follow the ingredient declaration of sodium caseinate when it is used in a food product labeled "non-dairy." 21 C.F.R. 101.4(d).
- Food labels must disclose the presence of FD&C Yellow No. 5 because of the "life-threatening nature of the reaction in those people who are sensitive to the dye." 45 Fed. Reg. 60419 (Sept. 12, 1980) at 60419.
- FDA requires a declaration of two additional color additives—carmine and cochineal extract—on the labels of all food and cosmetic products that contain them due to severe allergic reactions among a subset of consumers. 74 Fed. Reg. 207 (Jan. 5, 2009).
- In 1996, the FDA required a warning label on foods containing olestra because it causes gastrointestinal distress: "THIS PRODUCT CONTAINS OLESTRA. Olestra may cause abdominal cramping and loose stools. Olestra inhibits the absorption of some vitamins and other nutrients. Vitamins A, D, E, and K have been added." 21 C.F.R. 172.867(e). (The requirement for a notice on products containing olestra was revoked in 2003, in part because evidence gathered in consumer surveys after 1996 showed "a high degree of awareness among the public" about the effects of olestra. 68 Fed. Reg. 46363 (Aug. 5, 2003), 46387. Use of the ingredient also was largely discontinued by the food industry.)

Consistent with the above requirements, 21 CFR § 101.17 (Food labeling warning, notice, and safe handling statements) requires a wide range of warning statements regarding a host of specific hazards related to foods, including for the following warnings, many of which are clearly intended to protect children:

- Self-pressurized containers and the possibility of eye injury: WARNING—Avoid spraying in eyes. Contents under pressure. Do not puncture or incinerate. Do not store at a temperature above 120 °F. Keep out of reach of children.; WARNING—Use only as directed. Intentional misuse by deliberately concentrating and inhaling the contents can be harmful or fatal.
- High-protein foods: WARNING—Use only as directed. Intentional misuse by deliberately concentrating and inhaling the contents can be harmful or fatal.
- Dietary supplements containing iron or iron salts: WARNING: Accidental overdose of iron-containing products is a leading cause of fatal poisoning in children under 6. Keep this product out of reach of children. In case of accidental overdose, call a doctor or poison control center immediately.
- Foods containing psyllium husk: "NOTICE: This food should be eaten with at least a full glass of liquid. Eating this product without enough liquid may cause choking. Do not eat this product if you have difficulty in swallowing."
- Juices that have not been specifically processed to prevent, reduce, or eliminate the presence of pathogens: WARNING: This product has not been pasteurized and,

therefore, may contain harmful bacteria that can cause serious illness in children, the elderly, and persons with weakened immune systems.
- Shell eggs: SAFE HANDLING INSTRUCTIONS: To prevent illness from bacteria: keep eggs refrigerated, cook eggs until yolks are firm, and cook foods containing eggs thoroughly.

Such warnings demonstrate a wide range of considerations under the FDA's broad authority on misbranding, from handling and opening instructions to dietary obstructions, food safety, poisoning risks, and bacterial contamination. They also reflect practical considerations grounded in public health, as does the warning suggested in this petition.

Requiring a warning label on unfortified corn masa flour and corn masa products falls squarely within the FDA's authority, as the absence of such a warning renders the products misbranded by omission of material facts about the public health implications of choosing these products over fortified alternatives. Women of reproductive age should be empowered to identify gaps in their health and choose fortified foods or supplements to address those gaps.

Moreover, under Section 701(a) of the FD&C Act, the FDA has the authority to issue regulations for the efficient enforcement of the Act, including regulations requiring clear, accessible labeling to prevent consumer deception. Mandating warning labels for unfortified corn masa flour and corn masa products is a necessary regulatory measure to promote honesty and fair dealing in the interests of consumers, consistent with the FDA's statutory mandate.

Requiring such warning labels would not violate manufacturers' First Amendment rights. Mandatory disclosures like warning labels are evaluated under a legal standard that examines whether the compelled commercial speech: 1) is factual and uncontroversial, 2) reasonably relates to a legitimate government interest, and 3) is not unjustified or unduly burdensome.[54]

A simple warning statement that an unfortified corn masa product lacks adequate folic acid levels to support neural tube defect prevention would be factual, accurate, and non-ideological. Courts have already deemed that sodium warnings and calorie disclosures pass the legal test and are "factual and uncontroversial."[55] Preventing devastating birth defects is clearly a legitimate government interest, and a small, printed warning would not be unduly burdensome to implement.

Requiring bilingual English-Spanish warning labels on corn masa products would not be unprecedented. There is an existing precedent for dual language labeling requirements in FDA regulations and U.S. law. For example, the FDA's regulation on over-the-counter drug labeling specifies that if a drug product contains labeling in Spanish, the Drug Facts label must also be presented in Spanish.[56] The health inequities and inability to reach the consumers most at risk of this serious health outcome more than justify this reasonable measure to promote informed choice and safety among Spanish-speaking consumers.

If challenged in court, a properly drafted and well-grounded mandatory label for corn masa products would likely be analyzed under the controlling case, *Zauderer v. Office of Disciplinary*

Counsel, 471 U.S. 626 (1985). There, the Supreme Court held that commercial disclosure requirements, including warnings and disclaimers, are constitutional if they are (a) "reasonably related to the State's interest in preventing deception of consumers," (b) require purely factual, accurate, and uncontroversial information about the product or service itself, and (c) not "unjustified or unduly burdensome." Under the third prong, the government must show the problem it seeks to address is "real and not purely hypothetical." *See also* Milavetz v. U.S., 559 US 229 (2010); NIFLA v. Becerra 585 US 755 (2018).

Importantly, in *NIFLA*, the Court stated that it does not "question the legality of health and safety warnings long considered permissible, or purely factual and uncontroversial disclosures about commercial products." Critically, these holdings rulings do not mean that the government requires evidence that a compelled disclosure would resolve the issues identified by the disclosure. Instead, "governments are entitled to attack problems piecemeal," so a disclosure requirement need not solve "all facets of the problem it is designed to ameliorate."

Applying these factors, a safety warning on corn masa products would be clearly constitutional. First, the statements we suggest are uncontroversial assertions of fact concerning the presence or absence of folic acid fortification in a product and the risks associated with a lack of folate in the diet. Such a warning that an unfortified corn masa product lacks adequate folic acid levels to support neural tube defect prevention is factual, accurate, and non-ideological. It would convey the scientifically validated fact that folic acid is crucial for proper neural tube development during early pregnancy.

Courts have already deemed disclosures like sodium warnings and calorie counts as "factual and uncontroversial" under the *Zauderer* standard.[57] Warning labels for unfortified corn masa flour and corn masa products would similarly be grounded in nutritional science and policy, not opinion. Therefore, they would satisfy the first prong of the Zauderer test.

Second, the labeling requirement would be reasonably related to legitimate governmental interests in preventing serious birth defects in babies and promoting maternal and child health. Neural tube defects resulting from inadequate folic acid intake during early pregnancy continue to affect Hispanic infants at disproportionately high rates. Strong evidence, as described above, clearly establishes the public health need to inform consumers about risks related to folic acid deficiency. This clear disclosure furthers the government's compelling interest in reducing health disparities and preventable harm to mothers and children. Moreover, given that folate levels must be adequate before and at the beginning of pregnancy, ensuring that levels are high for populations through dietary fortification also qualifies as a legitimate interest. Indeed, it would be absurd for a court to find that pressurized cans and allergens are a legitimate state interest, while the prevention of fatal or severe birth defects in babies is not.

Third, the labeling requirement would not be unduly burdensome. Warning labels would directly inform all consumers of the risks of purchasing unfortified masa foods compared to fortified alternatives. The suggested language is clear about the impacts on individuals of reproductive age, while others who would not be affected would be free to disregard the

warning. The warnings would be of modest size, and only as long as needed to ensure clarity for consumers so they can make informed choices. Moreover, warning labels are a common, expected feature on food packages. They can be incorporated seamlessly into existing packaging and represent a tiny fraction of the available space for manufacturers' messaging. The warning also would not prevent manufacturers from otherwise advertising their products or overshadowing other messaging that may be on the packaging concerning the nature of the product.

In sum, we are presenting a narrowly targeted regulation that imposes no burden beyond what is needed to serve the government's legitimate public health interests in protecting infants from serious and avoidable birth defects. Therefore, under its clear statutory authority and considering First Amendment precedents, the FDA can lawfully mandate warning labels alerting consumers that unfortified corn masa flour and corn masa products lack adequate folic acid to protect against neural tube defects. This targeted labeling regulation will enable fully informed consumer choices in the marketplace.

Importantly, fortification is also safe and a well-established public health tool in the U.S. and globally. First, fortification under such a regulation would not approach any reasonable daily limit for folate. Folic acid added through enriched cereal grain fortification is less than the Recommended Daily Allowance (RDA) (400 mcg/day) in the U.S. Studies by the CDC demonstrate that cereal grain fortification provides about 150 mcg/day of folic acid in the U.S., which is 1/3 of the RDA. The level we seek is identical to that for wheat flour, and there is no evidence that has been a cause for health concerns or adverse effects.

Second, there is no evidence linking food fortification with adverse health outcomes. A 2018 study by Field and Stover conducted an extensive review of the safety of folic acid, including the concentration found in fortification programs, and found no evidence of risk.[58] Moreover, 81 countries have introduced mandatory folic acid fortification of flour, and all studies of the consequences show a clear reduction in the incidence of NTDs.[59]

III. Statement of Factual Grounds

The inadequacy of folic acid in corn masa flour represents a distinct and pressing dietary insufficiency that disproportionately affects the Latino population in the United States. Unlike many other nutrient deficiencies that may impact various segments of the population, the lack of folic acid fortification in this staple food product specifically and uniquely puts Latino women and their children at a higher risk for neural tube defects.

This disparity is particularly concerning given that corn masa flour is a cornerstone of many traditional Latino diets, making it a critical vehicle for delivering essential nutrients like folic acid. By targeting this specific dietary staple for fortification and warning labels, we have the opportunity to implement a focused, efficient public health intervention that directly addresses a major health inequity.

Fortifying corn masa flour with folic acid and requiring warning labels on unfortified products is a strategic, tailored approach to improving nutrition and birth outcomes in a historically underserved community. This targeted intervention has the potential to significantly reduce the unacceptable burden of neural tube defects among Latino families, promoting health equity and protecting the most vulnerable members of our society.

Voluntary corn masa fortification has failed to increase folic acid intake among Hispanic women as intended. When the FDA issued the voluntary fortification rule in 2016, it estimated median folic acid intake would increase from 164 to 206 mcg among Mexican American women.[60] However, data shows no increase occurred – median intake was still just 161 mcg in 2017-2018.[61] Two studies found minimal folic acid in corn masa products following the final rule. One study of Atlanta stores in 2017 found 0% of corn tortillas and only 10% of corn masa flours were fortified.[62] A 2019 social media campaign identified fortified folic acid in 0% of tortillas and 7% of flours.[63] A 2022 national marketplace analysis by the Centers for Science in the Public Interest showed similar findings: 0% of 476 corn tortillas and only 14% of 59 corn masa flour contained added folic acid.[64]

This starkly contrasts with the widespread fortification of 79% of wheat flours and 85% of wheat tortillas.[65] Evidence shows companies can add folic acid to corn masa, as demonstrated by the few doing so and Mexico's national fortification program.[66] Yet, voluntary action has failed to improve Hispanic women and infants' folic acid intake and reduce their disproportionate neural tube defect rates.

Blood folate concentration refers to the measurable amount of folate present in the bloodstream.[67] When a woman consumes folic acid from fortified foods or supplements, their blood folate levels rise. Achieving an adequate blood folate level helps reduce the risk of neural tube defects affecting an infant's brain and spine development . Folate builds up slowly in the body, requiring adequate intake for several months before pregnancy to reach protective levels.[68]

Once a woman is consuming 400 mcg of folic acid daily, it takes time to reach a blood folate concentration high enough to prevent devastating neural tube birth defects.[69] The CDC thus recommends women take 400 mcg of folic acid daily starting at least one month prior to pregnancy, in addition to consuming folate from fortified foods and a varied diet.[70]
A robust body of scientific evidence demonstrates that increasing folic acid consumption around the time of conception, through both fortified foods and supplements, leads to a major reduction in the risk of devastating neural tube defects (NTDs). Large observational studies show 50-80% lower NTD prevalence among women who consume adequate folic acid from fortified foods or supplements compared to those with inadequate intake.[71] After the fortification of grain products began in the U.S. in 1998, NTD rates dropped by approximately 35% nationwide.[72]

Similar reductions have been documented in many other countries following the initiation of folic acid fortification policies.[73] Promoting adequate folic acid intake through fortification of

corn masa flour and corn masa products could lead to a major decrease in the occurrence of these tragic birth defects, particularly among people of color.

C. Environmental Impact

Under 21 C.F.R § 10.30(3), petitioners must provide an environmental impact assessment or claim a categorical exclusion from such a requirement. The action requested herein is subject to a categorical exclusion under 21 C.F.R. §§ 25.30 (h) and 25.30(k), and therefore does not require the preparation of an environmental assessment. Further, the undersigned believe that the actions requested in this petition would have no environmental impact.

D. Economic Impact

Requiring fortification and labeling for corn masa products will impose minimal costs on manufacturers and consumers. Adding folic acid to corn masa flour only adds approximately $0.50 per ton, or less than five cents per person per year. Warning labels would have negligible costs since packaging changes routinely. An estimated $312-428 million would be saved each year from preventing 600-800 neural tube defects in the U.S.[74] The minor cost of warning labels is far outweighed by the benefits of preventing hundreds of life-altering neural tube defects annually and the attendant expense in both health care costs and human suffering.

Previous studies modeling the effects of food labeling and reformulation efforts have found that public health benefits outweighed the costs. Analysis of the 1990 Nutrition Labeling and Education Act found benefits exceeded costs by $1.7 to 6.8 billion.[75] The FDA's 2014 proposed changes to Nutrition Facts labeling were estimated to have net benefits of $2.7-6.8 billion.[76]

We recognize that printing packaging in two languages imposes additional costs on the industry. However, the health equities at stake and potential lives saved outweigh these modest costs. Manufacturers already engage in dual language labeling for marketing purposes on many products.[77] To achieve the FDA's mission of promoting and protecting public health for all Americans, the dual warnings are a reasonable and necessary measure.

The food industry could prevent hundreds of NTDs each year by fortifying corn masa flour and corn masa products with folic acid. UnidosUS urges the FDA to use its authority to make this simple change to protect maternal and child health. We welcome the opportunity to discuss this urgent petition.

E. Certification

The undersigned certify, that, to the best knowledge and belief of the undersigned, this petition includes all information and views on which the petition relies, and that it includes representative data and information known to the petitioners which are unfavorable to the petition. Correspondence related to the petition should be directed to Umailla Naeem (ufatima@unidosus.org) or Laura MacCleery (lmaccleery@unidosus.org).

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