

Congress of the United States
Washington, DC 20515

February 23, 2016

Acting Commissioner Dr. Stephen Ostroff
U.S. Food and Drug Administration
10903 New Hampshire Avenue
Silver Spring, MD 20993

Re: Docket Number FDA-2012-F-0480

Dear Acting Commissioner Ostroff,

As members of Congress who care deeply about the health of mothers and babies, we have followed with great interest the Citizens Petition filed in April 2012 calling for corn masa fortification. We urge the Food and Drug Administration (FDA) to take decisive action to reduce neural tube defects (NTDs) in the Hispanic community by allowing voluntary fortification of corn masa flour with folic acid, currently under agency consideration, if the stability study data proves folic acid can be added safely and stably. As you know, 14 countries already have successfully implemented fortification of corn masa flour. It was our understanding FDA had until January 17, 2016 to respond to the Citizens Petition, but has requested 90 additional days to respond.

When FDA authorized fortification of wheat and other types of flour in 1996, it served as the catalyst for a major public health victory. The Centers for Disease Control and Prevention (CDC) has reported that since fortification was implemented in 1998, the rate of NTDs across the United States has been reduced by 27 percent. That represents a reduction of nearly one-third in babies who would otherwise have suffered from spina bifida, anencephaly, or other NTDs, now born healthy instead. FDA deserves accolades for this significant improvement in our nation's health, and the agency should seize the opportunity to continue this proud tradition of promoting maternal and child health by reducing NTDs.

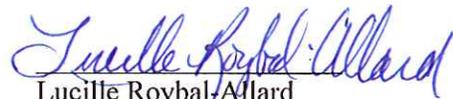
Despite these advances, however, opportunities for improvement remain. Preventable NTDs continue to occur in the United States, particularly among families in the Hispanic community. Public health experts hypothesize that these higher rates are linked to the fact that corn masa flour, the staple grain in the diet of most individuals of Hispanic descent, is still not fortified with folic acid. As such, we have followed with great interest the Citizens Petition filed in April 2012 calling for corn masa fortification. We recognize that FDA has exercised its option to take up to an additional 90 days to make a determination, and we look forward to FDA's decision by mid-April.

Fortifying corn masa flour will capitalize upon the landmark public health improvements that occurred with wheat flour fortification. We believe it is critical that childbearing women in the Hispanic American community and their families have the same access to this proven intervention for preventing devastating birth defects as all other American families. We therefore look forward to your timely decision on the Citizens Petition.

Sincerely,



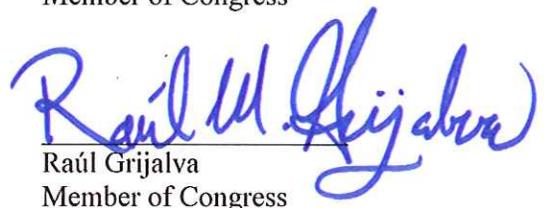
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Mario Diaz-Balart
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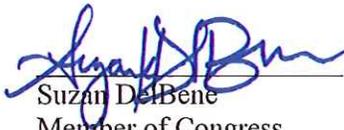
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Lloyd Doggett
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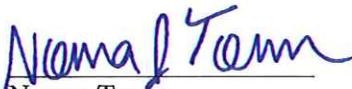
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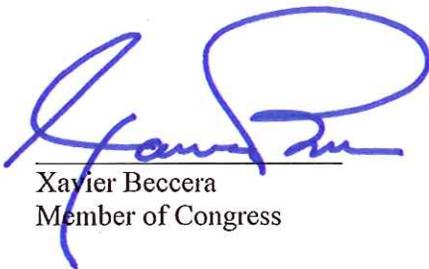
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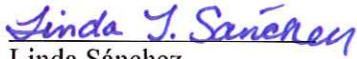
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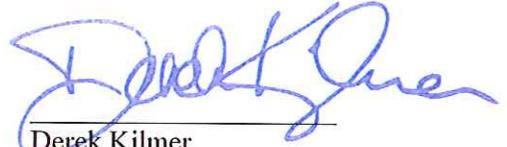
Juan Vargas
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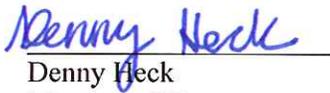
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Linda Sánchez
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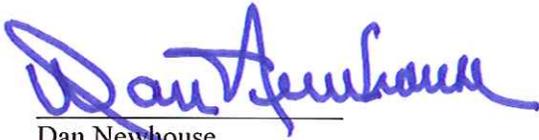
Derek Kilmer
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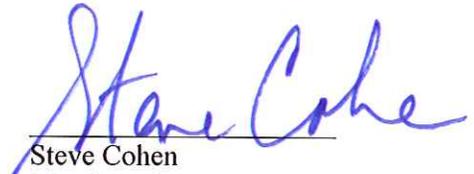
Denny Heck
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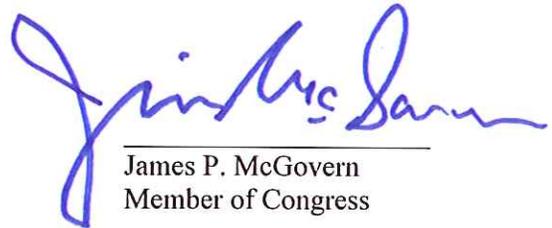
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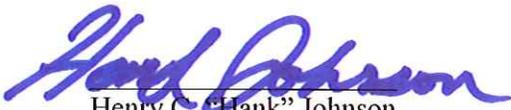
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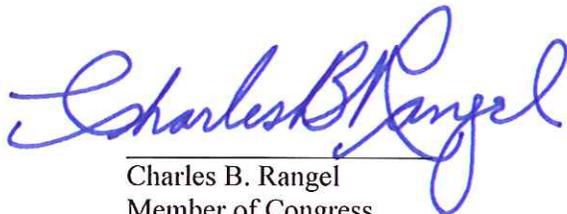
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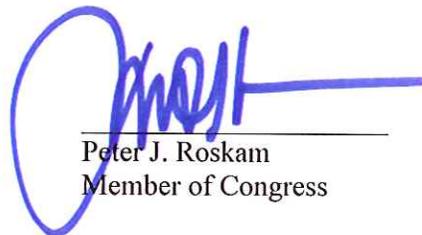
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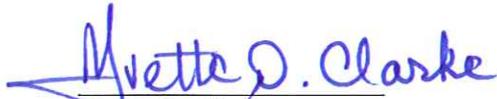


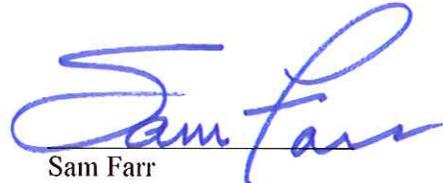
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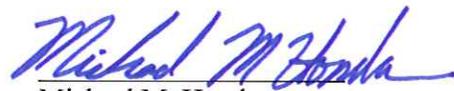


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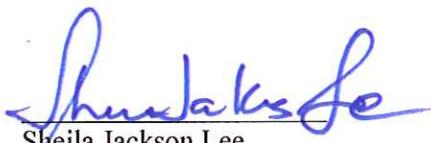

Sam Farr
Member of Congress

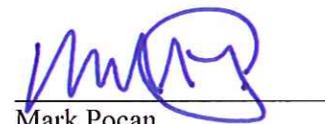

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