

# United States Senate

WASHINGTON, DC 20510

July 21, 2011

Dr. Margaret A. Hamburg  
Commissioner  
Food and Drug Administration  
10903 New Hampshire Ave  
Silver Spring, MD 20993-0002

Dear Commissioner Hamburg:

We are increasingly concerned about the pace and apparent inaction at the Food and Drug Administration in finalizing standards for gluten-free labels on food. We believe this delay is creating unnecessary confusion for consumers and uncertainty for agricultural producers.

On August 2, 2004, the Food Allergen Labeling and Consumer Protection Act was signed into law with widespread, bipartisan support, passing the Senate by unanimous consent, and the House of Representatives by a voice vote. Section 206 of this bill required the Secretary of Health and Human Services to issue a proposed rule on gluten labeling within two years, and a final rule within four years. In January 2007, FDA issued its proposed rule. Since then, no final rule has been proposed or issued. It has since been seven years since Congress mandated that your agency address this issue, and more than four years since any significant action on this has been taken.

The regulatory uncertainty surrounding FDA's inaction has led to a proliferation of "gluten free" standards and labels provided by 3<sup>rd</sup> party groups. This creates confusion for consumers, and hesitancy amongst producers on what their requirements will be.

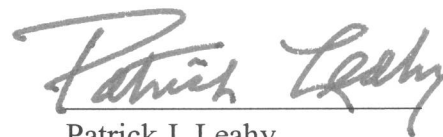
We ask that you provide us with an update on when FDA will promulgate a final rule, why FDA has taken so long to issue this rule, and if there are any legal or regulatory hurdles that have prevented the timely implementation of this legislation.

We look forward to your response and to working with you in the future.

Sincerely,



Ron Wyden  
United States Senator



Patrick J. Leahy  
United States Senator