

ONE HUNDRED THIRTEENTH CONGRESS
Congress of the United States
House of Representatives
COMMITTEE ON ENERGY AND COMMERCE
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May 22, 2014

The Honorable Margaret Hamburg, M.D.
Commissioner
U.S. Food and Drug Administration
10903 New Hampshire Avenue
Silver Spring, MD 20993

Dear Commissioner Hamburg:

We write to inform you of the significant concerns we share about the process the Food and Drug Administration (FDA) followed in issuing an interim final rule (IFR) on February 10, 2014, relating to quality and manufacturing standards for infant formula.¹

FDA last issued a proposal to revise several of these requirements in July 1996. After reviewing comments and engaging in a productive dialogue with industry stakeholders, successive periods for submitting comments on the proposed rule ultimately closed in September 2006. No additional regulatory actions have been taken in the nearly eight years since.

Without any notice, on February 10, 2014, FDA issued an IFR with an implementation date of July 10, 2014, including significant changes well outside the scope of the 1996 proposal. This is an unacceptable process and unworkable timeframe for implementation.

We ask that FDA postpone the implementation date of the IFR until the agency engages in a meaningful dialogue with Congress and industry about the need for—and the science and data behind—the changes proposed, and the feasibility of their implementation. Based on the small number of companies in this industry, any rash enforcement actions undertaken by the FDA could have significant impact on the availability of safe, nutritious, and affordable infant formula.

We appreciate your prompt attention to this matter.

Sincerely,

¹ See Current Good Manufacturing Practices, Quality Control Procedures, Quality Factors, Notification Requirements, and Records and Reports, for Infant Formula; Interim Final Rule, 79 *Federal Register* 7934 (Feb. 10, 2014).



Fred Upton
Chairman



Peter Welch
Member

cc: The Honorable Henry Waxman, Ranking Member