

**Congress of the United States**  
**Washington, DC 20515**

August 4, 2015

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

Dear Commissioner Ostroff,

We are writing to request your attention to a number of concerns regarding the Proposed Rule for Current Good Manufacturing Practice (CGMP) and Hazard Analysis and Risk-Based Preventive Controls for Animal Food. As you know, The Food Safety and Modernization Act (FSMA) encompassed major reforms to our nation's food safety practices, and gave the FDA authority to promulgate regulations that would allow for flexibility in the production and distribution of safe animal feed and pet food. However, there remains serious concerns that the FDA's current proposed regulations are overly burdensome and costly and do not provide the intended flexibility component for livestock feed facilities.

On behalf of Georgia agribusiness, we urge the FDA to actively address several issues to ensure the final rule will allow facilities to adopt livestock feed safety practices that are practical and effective for their specific, individual operations. Our recommendations include changes to the CGMP requirement, the Risk-Based Preventative Controls process, a final cost-benefit analysis, and implementation of a staggered compliance schedule for the forthcoming final rule. We strongly request your attention to these four recommendations.

1. The proposed rule only makes one overall set of CGMP requirements. We recommend that the FDA make a clear distinction between the current CGMP for human food and another appropriate set of CGMP applicable to the livestock feed industry. The basic food composition, serving differences, and the innate differences in the level of hygienic standards between food products and animal feed products support our reasoning for establishing separate CGMP requirements.
2. We appreciate the FDA's dedication to reducing and eliminating hazards to food products through a preventative controls process. However, we ask that the FDA, again, provide a modified preventative controls process or exemption for facilities who only produce livestock feed. Specifically, we support the FDA's supplemental revision that defines a "significant hazard"

process of identifying significant hazards within business operations. We believe that only those hazards which rise to the level of significant hazard should be subject to the preventive control regulations which will require thorough management controls including monitoring, corrections or corrective actions, validation, and record keeping. Given the associated risks and high costs for compliance, this exemption provision seems entirely appropriate.

3. The FDA's Preliminary Regulatory Impact Analysis (PRIA) has a wide range of compliance costs, with an increasing and significant economic impact on small and very small business entities. If a final, more limited rule is created, then the cost of compliance to the animal feed and pet food industry would greatly decrease. Additionally, the PRIA does not quantify the benefits of the proposed rule. Without determining both costs and benefits, the analysis is not complete, nor does it give the associated parties confidence in the final analysis. We believe it is important to have clear evidence that the costs of implementing the proposed rule are worth the anticipated benefits.
4. We request that the FDA provide a sufficient time period for facilities to meet obligations following the publication of the final regulation. Since the CGMPs regulations will establish new baseline requirements for all affected livestock feed facilities, a staggered compliance schedule would provide the necessary time for affected facilities to fully implement programs to comply with the CGMPs regulation and the preventive controls regulation. Therefore we recommend a three year compliance period for very small businesses, two year period for small business, and a one year compliance period for all other larger businesses to apply proper CGMP regulations. If affected facilities have an appropriate amount of time for CGMP compliance, then facilities will be able to lay a strong foundation of best practices which will aid facilities implementing the written animal feed and pet food safety plans required under the preventive controls regulation. As such, we recommend that FDA apply a compliance time frame for the preventative controls regulation of four years for very small businesses, three years for small business, and two years for larger businesses.

We support the FDA's efforts to ensure that all pet and animal feed are safely produced and distributed. With the recommendations that we have submitted on behalf of the livestock industry, we believe that an appropriate and safe rule can be achieved. Thank you for your consideration and thank you in advance for your response.

Sincerely,



Johnny Isakson

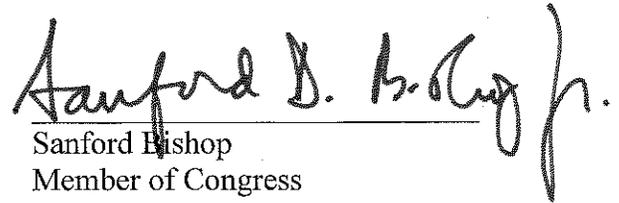
United States Senator

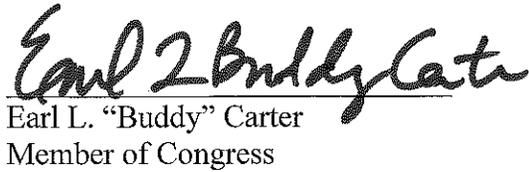


David Perdue

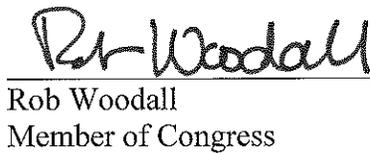
United States Senator

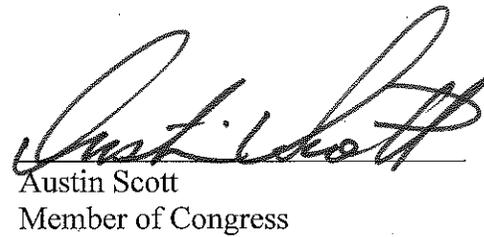
  
Lynn Westmoreland  
Member of Congress

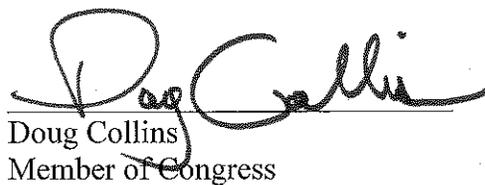
  
Sanford Bishop  
Member of Congress

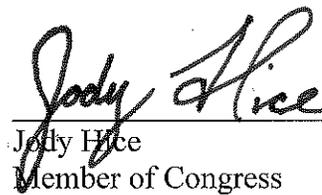
  
Earl L. "Buddy" Carter  
Member of Congress

  
Tom Price, M.D.  
Member of Congress

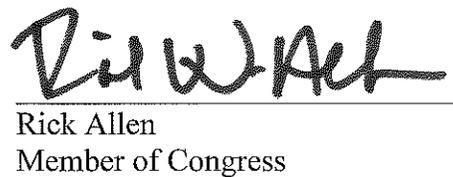
  
Rob Woodall  
Member of Congress

  
Austin Scott  
Member of Congress

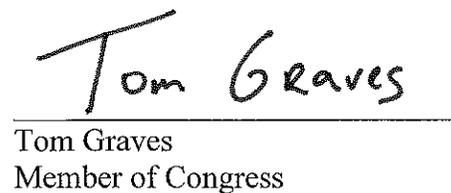
  
Doug Collins  
Member of Congress

  
Jody Hice  
Member of Congress

  
Barry Loudermilk  
Member of Congress

  
Rick Allen  
Member of Congress

  
David Scott  
Member of Congress

  
Tom Graves  
Member of Congress