

Advocacy Commends the Food and Drug Administration for Participating in Industry Food Safety Modernization Act Roundtables and Suggests Improvements to the Agency's Proposed Rule on Good Manufacturing Practices and Preventative Controls for Animal Foods

On April 8, 2014, the Office of Advocacy's Chief Counsel, Dr. Winslow Sargeant, sent a letter to the Food and Drug Administration's (FDA) Commissioner, Dr. Margaret Hamburg, commending the agency for its participation in industry-coordinated roundtables discussing various Food Safety Modernization Act rules. Dr. Sargeant also suggested improvements to the FDA's proposed rule on Current Good Manufacturing Practice and Hazard Analysis and Risk-Based Preventative Controls for Food for Animals. The letter also provided the FDA with small business concerns about the potential economic impacts associated with the rule. A copy of Advocacy's comment letter may be accessed at www.sba.gov/advocacy.

On October 29, 2013, the FDA published a rule in the *Federal Register* (78 Fed. Reg. 64736) that proposed to regulate the manufacturing, processing, packing, or holding of animal food in two ways. It would implement new current good manufacturing practice (CGMP) regulations, and it would include new preventative control provisions (i.e. written food safety plan and completion of hazard analysis) on animal food facilities. FDA also complied with the Regulatory Flexibility Act by concluding that the proposed rule would have a significant impact on a substantial number of small businesses, and the agency published an Initial Regulatory Flexibility Analysis (IRFA).

- Advocacy voiced concerns about the sufficiency of FDA's assumptions and conclusions relative to the rule's costs and benefits. The FDA did not appear to perform its usual cost/benefit quantitative analysis, and the agency admitted that due to a lack of data it couldn't quantify the benefits of the regulation.
- Advocacy was unable to determine the reason for the discrepancy in annualized cost estimates as presented in the proposed rule versus the PRIA. Advocacy noted that both the overall cost impacts of the rule as well as the cost impacts to small businesses in the "fewer than 500 persons" category are somewhat unclear and difficult to distinguish from the more detailed analysis of cost impacts to very small businesses. And, while the Preliminary Regulatory Impact Analysis provided adequate detail on impacts to very small businesses by compliance cost categories, the IRFA section could benefit from some additional clarification and consistency in presentation.
- Advocacy also informed the FDA about small business food industry concerns with the rule. For example, owners of small breweries and farmers voiced to Advocacy their concern that the proposed rule will have a significant economic impact on their businesses. Those entities indicated that the rule will require the craft brewing industry that donates or sells spent grain to local farms to feed livestock to comply with certain risk assessment, testing and recordkeeping requirements of the rule. The proposed rule indicates that the FDA does intend for the rule to cover breweries and distilleries that sell spent grains intended as food for animals, but it fails to analyze the impact of the provision on these small entities.
- For more information, visit Advocacy's web page at <http://www.sba.gov/advocacy/816/818281>, or contact Linwood Rayford at (202) 205-6533.