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Fact Sheet

Advocacy: the voice of small business in government

Advocacy Suggests Improvements to the Food and Drug Administration's Proposed Rule on the Sanitary Transportation of Human and Animal Food

On July 31, 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, suggesting improvements in the agency's Regulatory Flexibility Act analyses. A copy of Advocacy's comment letter may be accessed at www.sba.gov/advocacy.

On February 5, 2014, the FDA published a rule in the *Federal Register* (79 Fed. Reg. 7005) that proposed to establish requirements for shippers, carriers, by motor vehicle and rail vehicle, and receivers engaged in the transportation of food for humans and animals to use sanitary transportation practices to ensure the safety of the food they transport. FDA 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 commended the FDA for its inclusion of alternatives and exemptions designed to lessen the rule's impact on small entities. However, 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.

- Despite the lack of data, FDA chose to establish an exemption for affected entities that have annual revenues of less than $500,000. Advocacy noted that the exemption was inconsistent with the SBA size standards and the current data on small entities. The estimated average revenue for many of these firms under 500 employees (the SBA size standard) is over $6,000,000. Consequently, the inconsistency made it difficult for many small entities to comment on FDA's proposed revenue exemption level because they are unsure of how they fit into the rule and the small entity cost calculations since they may or may not be small depending on different definitions and criteria.

- The FDA noted in the IRFA that it could increase the threshold for the small entity exemption or even exempt all small entities. However, the FDA did not create a clear quantifiable basis to determine where this threshold is reasonable, or whether it should be raised or lowered. Therefore, Advocacy suggested that the FDA conduct further analyses in the Final Regulatory Flexibility Analysis (FRFA) to better disclose the impacts of various exemption levels on the small business exemption threshold.

- For more information, visit Advocacy's web page at http://www.sba.gov/advocacy/7312014-sanitary-transportation-human-and-animal-food, or contact Linwood Rayford at (202) 205-6533.