Weston A. Price Foundation
and
Farm and Ranch Freedom Alliance

July 6, 2011

Division of Dockets Management
HFA-305
Food & Drug Administration
5630 Fishers Lane, Rm 1061
Rockville, MD 20852

Re: Food and Drug Administration
Docket No. FDA-2011-N-0366
Request for Comment, 76 Fed. Reg. 30727 (May 26, 2011)

Dear FDA:

The Weston A. Price Foundation and the Farm and Ranch Freedom Alliance jointly submit these comments on inspection and enforcement under the FDA Food Safety Modernization Act.

The Weston A. Price Foundation (WAPF) is a nonprofit organization with members in every state and internationally. WAPF was founded in 1999 to disseminate the research of Dr. Weston Price, whose studies of isolated nonindustrialized peoples established the parameters of human health and determined the optimum characteristics of human diets. WAPF is dedicated to restoring nutrient-dense foods to the human diet through education, research and activism.

The Farm and Ranch Freedom Alliance (FARFA) is a non-profit organization headquartered in Texas with members in 45 states. FARFA advocates for farmers, ranchers, and homesteaders through public education and lobbying to assure their independence in the production and marketing of their food, and to prevent the imposition of unnecessary regulatory burdens that are not in the public interest. FARFA also advocates for consumers' access to information and resources to obtain healthy foods of their choice.

I. Enforcement authorities

The power to detain foods without judicial or administrative process is open to significant abuse, and the FDA should use its revised administration detention authority sparingly. The agency's focus should be on violations that pose genuine safety issues, not technical violations. Administrative detention should only be used when needed as a temporary measure to prevent harm to human or animal health while FDA goes through the appropriate process for either seizure or recall. Every effort should be made to determine as quickly as possible whether the food poses an actual health hazard or whether it should be released.

II. Frequency and Targeting of Facility Inspections

Clearly the federal government does not have the resources to inspect every facility as often as the FSMA calls for. It is critical that the FDA focus on prioritizing the facilities that pose the greatest risk of harm to human and animal health.

The criteria that should be considered include:

- The size of the facility: Facilities that sell fewer products pose a lower risk because they impact fewer people. Thus, large facilities should be ranked as higher risk than small facilities.
- The complexity and scope of the supply and distribution chain: The more complex the supply and distribution chain is, the greater the risk. Not only are there more opportunities for something to go wrong, but the difficulties in tracing, identifying, and correcting the problem increases exponentially as the number of businesses involved increase. Facilities with short supply and distribution chains pose a significantly lower risk. In essence, the fewer "hands" (including automated hands) that a food passes through, the lower risk it poses.
- Whether the facility is producing an ingredient or a final product: Facilities that produce ingredients for other foods pose a higher risk because of the scope of their impact. This is apparent from the scale of the 2008-2009 outbreak caused by Peanut Corporation of America, which produced peanut-based ingredients for approximately 4,000 manufactured foods. Similarly, tainted melamine in protein-based ingredients from China caused the widespread outbreak in over a hundred brands of pet food in 2007. In contrast, a facility that produces a final product for sale to consumers poses a lower risk because it will impact fewer people and because, if there is a problem, it is much more readily traced and addressed.
- The level of state and local inspections: A common factor in the major outbreaks of the last decade is that they often occur in facilities that had never been inspected by any health official, whether federal, state or local. Given the budget constraints faced by government agencies at every level, facilities that have been recently inspected by state or local authorities without apparent problems should be classified as lower risk for purposes of FDA inspections.

III. Conclusion

In adopting the Tester amendment and other provisions of the FSMA, Congress clearly established its intent to reject a one-size-fits-all approach and recognized that differences in scale and distribution are important. In developing regulations and guidance documents, FDA should respect both the specific exemptions created by the Tester amendment and the underlying intention. Local food producers are different from the long, complex, large-scale supply and processing chains that characterize the majority of the food supply. FDA should carefully consider the budget constraints that must be imposed due to the federal deficit and focus its regulatory and enforcement activities on the highest risk activities by large facilities, which impact the largest number of people.

Sincerely,

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