The undersigned members of the Safe Food Coalition and Make Our Food Safe appreciate this opportunity to comment on how the Food and Drug Administration ("FDA") should implement the fee adjustment provision in section 743(b)(2)(B)(iii) of the Federal Food, Drug, and Cosmetic Act ("FFDCA") [Docket No. FDA-2011-N-0529]. We believe that fees to recover the cost of reinspections and recalls conducted by the FDA should not be adjusted based on the size of the business alone. FDA should instead consider a waiver of fees under limited circumstances and only after the small business demonstrates compliance on reinspection. Additionally, no business should anticipate a reduced fee if it has shown such disregard for public safety that FDA had to execute a mandatory recall order.

I. Basis for Our Position.

In passing the Food Safety Modernization Act ("FSMA"), Congress placed obligations on food producers, processors and importers to implement preventive controls that ensure the safety of the food they produce and market.1 Facilities and importers that fail to implement adequate prevention measures are subject to fees that recover the costs FDA incurs in conducting

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reinspections and recalls. Congress also required FDA to consider the impact on small business of rules implementing various provisions in FSMA, including fee amounts. Section 743(b)(2)(B)(iii) of the FFDCA, as added by FSMA, requires FDA to publish “guidelines in consideration of the burden of fee amounts on small business…”, which “may include reduced fee amounts for small businesses.” FDA has requested comments on how it should implement this requirement in fiscal year 2013.

FDA in the past has correctly concluded that business size should not dictate whether compliance with food safety requirements is necessary, and we ask that the agency follow that principle in implementing the reinspection and recall fees. We believe such a position will best achieve the goal of establishing a preventive food safety system at FDA. It is important to note that section 743 of the FFDCA generally requires FDA to assess and collect fees that recover the full costs of conducting reinspections and mandatory recalls, while the specifics of the small business guidance are discretionary. Had Congress wished to require FDA to reduce or waive fees for small businesses it could have done that by adopting specific language similar to the fee waiver provisions in section 736(d)(1)(D) of the FFDCA. The approach Congress chose emphasizes that the fees are intended to free up resources for a system of robust food safety oversight by ensuring that taxpayers do not bear costs created by industry misconduct. In weighing the burden of these fees on small business, FDA’s overarching consideration should be how its administration of the fees can best protect public health.

II. Comments.

FDA asks for comments in three areas: (A) Is a fee reduction appropriate, (B) How should FDA define “small business”, and (C) What factors should be considered in reducing fees.

A. Fee Reductions Are Only Appropriate Under Narrow Circumstances.

We believe that a separate fee schedule based on size is not appropriate. This is because the fees are easily avoided by compliance with food safety requirements. Those requirements are already adjusted under FSMA to assist small businesses. Additionally, FDA would be limited in its ability to adjust such fees because section 743(b)(2)(B)(iii) of the FFDCA requires any adjustment to a fee schedule for small business to be done through notice and comment rulemaking.

The more acceptable method for reducing fees is a waiver of all or part of the fee on a case-by-case basis. This would ensure that the fees provide the strongest incentive for compliance while still meeting the intent of section 743(b)(2)(B)(iii) of the FFDCA. Waivers, however, are only acceptable if administered in a way that ensures consumers do not unnecessarily bear costs created by industry misconduct. Section 743(b)(2) of the FFDCA requires FDA to set fees at a level that recovers 100 percent of the costs of reinspection-related and mandatory recall activities that it conducts. FDA conducts these activities in response to identified noncompliance which puts public health and safety at risk, and in many cases under FSMA constitutes a prohibited act. For example, failure to comply with any part of the hazard analysis and preventive controls requirements in section 418 of the FFDCA is a prohibited act that is punishable by imprisonment and/or fines.3 In circumstances where the noncompliance

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3 FDA Food Safety Modernization Act § 103(e) (2011) (adding section 301(uu) to the list of prohibited acts in the Federal Food, Drug, and Cosmetic Act).
results from a clear disregard for the requirements of FSMA, neither partial nor full waivers should ever be considered.

1. Reinspection Fee Waivers Must Weigh Impact on Compliance and Consumers.

In deciding when to permit a waiver, FDA must consider the impact a fee reduction will have on the agency’s administration of a preventive food safety system. Since the agency sets the reinspection and recall fees on a basis of the hourly costs of a reinspection, each waiver will result in a reduction in resources otherwise available to conduct initial inspections. The damage done by a reduction in resources is compounded if the fee waivers are granted too broadly. This is mainly because the waiver in effect subsidizes misconduct. It may also provide an undeserved benefit to a violator, given that it is additive to the many provisions in FSMA that already reduce compliance costs for small and very small businesses.

Any burden fees impose on small businesses also must be weighed against the burden on consumers of compliance failures. An estimated 48 million Americans suffer from foodborne diseases each year that cause 130,000 hospitalizations and 3,000 deaths. Collectively consumers bear the burden of billions of dollars in medical bills, lost wages and lost quality of life. The burden on each individual suffering an illness can also be high. A severe case of salmonellosis requiring hospitalization may cost the victim in excess of $12,000. Hospitalization costs for approximately 2,000 people suffering an *E. coli* O157:H7 infection each year may range up to $6 million per case. Additionally, many survivors of the initial foodborne

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illness face a lifetime of health consequences including organ transplants and shortened life expectancy. In comparison, FDA has estimated the cost of an average domestic inspection at $9,800, a considerably lower amount for activities that will lead to better food safety compliance on the part of industry, and ultimately a better public health outlook for consumers. In considering how to manage the waiver program, FDA must give adequate weight to the impact that noncompliance has on innocent consumers, and the effect the waivers will have on FDA’s ability to implement and enforce the preventive-based nature of the law.

A better approach is the one FDA has already taken of providing for a discretionary waiver of all or part of a fee assessed against a small business. FDA announced that the fees established for fiscal year 2012 will apply to all businesses, but the agency may waive a fee based on considerations of severe economic hardship, the nature and extent of the underlying violation, and other relevant factors. We agree that with regard to the reinspection fee, leniency may be appropriate but only where, in addition to the considerations FDA announced, the violation is inadvertent (not part of a pattern of violations), the small business takes immediate corrective actions, and payment of the fee would impede the business’ efforts to maintain its food safety system. In such a situation, FDA should be able to waive all or part of the fee if reinspection finds the business has come into compliance.

2. FDA Should Never Waive Mandatory Recall Fees.

We do not agree that a waiver for the mandatory recall fee is ever appropriate. There is no reason for a waiver since a business may avoid the fee by conducting a voluntary recall. FDA may only collect the recall fee in situations where the business has refused to recall voluntarily a

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8 Id. USDA Economic Research Service.
9 FDA’s estimate of the cost of inspections in 2008 provided to consumer organizations (documentation on file).
food that presents a risk of serious adverse health consequences or death.\textsuperscript{11} Also, a business has the right to contest a recall order before it is issued. This means that mandatory recall not only represents a situation where a business has shown disregard for public safety, but a review of the evidence has confirmed the need for a recall. A business that refuses to comply with a mandatory recall order under these circumstances should not expect relief from the costs of its actions.

\textbf{B. FDA Should Develop a Narrow Small Business Definition for Purposes of Waiving Fees.}

Definitions of small business that FDA has adopted for other regulations, if applied in this case, may result in the fee waiver being available to a significant number of food facilities. The agency frequently follows the Small Business Administration’s definition that a small food manufacturing business is one with fewer than 500 employees.\textsuperscript{12} This definition, which would cover up to 78 percent of registered food facilities,\textsuperscript{13} is not appropriate here. Similarly, if FDA uses one of the definitions developed by the agency for other regulations, it may also result in a significant number of businesses falling under the definition. In the seafood HACCP rule, FDA discussed using $1 to $2 million in annual gross revenue to define a small business. Under that definition, it estimated 80 percent of seafood processors qualified as small businesses.\textsuperscript{14} FDA defines certain egg producers as very small based on having fewer than 3,000 egg-laying hens.\textsuperscript{15} The number of farms with fewer than 3,000 hens constitutes 93 percent of egg producers.\textsuperscript{16} If

\textsuperscript{11} Federal Food, Drug, and Cosmetic Act § 423 (1938).
\textsuperscript{12} See 21 C.F.R. § 1.368(a) (2011) for an example.
\textsuperscript{13} This is based on the ratio of businesses meeting the Small Business Administration criteria compared to the number of various types of food facilities registered with FDA.
\textsuperscript{15} Production, Storage and Transportation of Shell Eggs, 21 C.F.R. § 118.1(a), (2010).
\textsuperscript{16} Prevention of Salmonella Enteritidis in Shell Eggs During Production, Storage, and Transportation; Final Rule, 74 Fed. Reg. 33030, 33056 (Footnote 17), July 9, 2009.
FDA uses any of these definitions, it may become overburdened with waiver requests that if
granted would quickly undermine the value of the reinspection fee as a means of freeing up
resources for initial inspections.

FDA should adopt a definition of small business expressly for purposes of waiving fees
under FSMA. A single definition would keep the proliferation of definitions from creating
confusion in the industry that could hamper administration of the fee waiver program. A single
definition would also avoid creating a situation where a business can pick and choose among
different definitions of small business.

The definition FDA uses should only apply for the purpose of providing a threshold for
when a business may be eligible to request a fee waiver and that threshold should not be set at a
level such that the vast majority of businesses qualify. The conditions for granting the waiver
remain factors related to achieving compliance with food safety requirements that FDA should
weigh and balance in each situation.

C. Basis for Granting Waiver Should Promote Compliance with Food Safety
Requirements.

FDA should only grant waivers of the reinspection fee on a case-by-case basis and under
conditions that promote compliance with food safety requirements. Waivers should be based on
a full evaluation so that no single factor such as severe economic hardship constitutes a reason
for granting a waiver. In no case should a business be rewarded with an economic benefit from
noncompliance and then get a waiver from a reinspection fee necessitated by its violations. Such
a situation would reward businesses that are competing unfairly against others who are spending
their funds to comply. Instead, a small business should demonstrate that the violation was
inadvertent (and not part of a pattern of violations or undertaken to reap an economic benefit
from noncompliance), it has taken immediate corrective action, and the burden of the fee would
impact its ability to implement measures for continued compliance. FDA should then only grant the waiver after determining the small business has come into compliance so that doing so serves to advance the agency’s public health mission.

III. Conclusion

We agree with FDA’s current practice of establishing a single fee to recover 100 percent of the costs of reinspection-related activities, while providing for case-by-case consideration of a waiver. The waiver process, however, should not be available to any business that is subject to a mandatory recall fee. To establish when a small business may seek a waiver, FDA will need to define small business expressly for purposes of the fee waiver. The definition of small business in itself should not be a basis for granting a waiver. Instead, waivers should only be extended to small businesses in limited circumstances and when doing so promotes compliance with food safety requirements. We believe this approach is most consistent with FDA’s mission of protecting public health and at the same time complies with the intent of section 743(b)(2)(B)(iii) of the FFDCA.

Respectfully Submitted,

Center for Foodborne Illness Research & Prevention

Center for Science in the Public Interest

Consumer Federation of America

Consumers Union

Food & Water Watch

National Consumers League

STOP Foodborne Illness

The PEW Charitable Trusts