The undersigned organizations appreciate this opportunity to comment on how the Food and Drug Administration ("FDA") is implementing the reinspection and recall fee programs [Docket No. FDA-2011-N-0528]. We offer the following comments on improvements that should be undertaken in anticipation of the fiscal year 2013 fee schedule.

We believe FDA should ensure its methodology for setting the fees is fact-based and does not underprice the cost of a fully supported inspection. Congress included the reinspection and mandatory recall fees in the FDA Food Safety Modernization Act¹ ("FSMA") to free up resources for robust food safety oversight and to ensure that taxpayers do not bear costs created by industry misconduct. Reinspection-related costs are defined as "all expenses, including administrative expenses, incurred in connection with (i) arranging, conducting, and evaluating the results of reinspections; and (ii) assessing and collecting reinspection fees".²

During consideration of FSMA in Congress, our organizations questioned the estimated cost of inspections that FDA provided to the Congressional Budget Office ("CBO"). In response, FDA briefed our organizations on its analysis of inspection costs providing a detailed chart (attached) that shows the average inspection, in 2010, consumed 32.8 hours at a total cost of $9,778. This would suggest the proper hourly rate to recover all expenses for an inspection at that time was $298. The inflation adjusted cost estimate in the fee schedule is $224 per hour. While we do not have a detailed basis for the estimate FDA briefed us on, the discrepancy in hourly costs suggests FDA has used two different methodologies or has not included all expenses in its estimate for the fees. We urge FDA to review its methodology against the method used for providing an estimate to CBO and revise its fee schedule to ensure that all reinspection-related cost are recovered in the hourly rate. In addition, as FDA implements the preventive control

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requirements in FSMA the agency’s inspection activities will change. We urge FDA to reevaluate its methodology in the future based on changes to agency inspection activities.

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

Attachment