Dear Sir or Madam:

The Grocery Manufacturers Association (GMA) takes this opportunity to comment on the Food and Drug Administration’s (FDA’s) Federal Register notice on the above referenced docket that is responsive to Section 107 of the FDA Food Safety Modernization Act (FSMA or “the Act”), and announces user fee rates for Fiscal Year (FY) 2014. The new hourly, per person rates for FY 2014 are $237 if domestic travel is required and $302 if foreign travel is required.

GMA is the voice of more than 300 leading food, beverage, and consumer product companies that sustain and enhance the quality of life for hundreds of millions of people in the United States and around the globe. Founded in 1908, GMA and its member companies are committed to meeting the needs of consumers through product innovation, responsible business practices, and effective public policy solutions developed through a genuine partnership with policymakers and other stakeholders. In keeping with our founding principles, GMA helps its members produce safe products through a strong and ongoing commitment to scientific research, testing, and evaluation. We ensure that our members have the very best and latest scientific knowledge available so they can provide consumers with the products, tools, and information they need to achieve a healthy diet and an active lifestyle. The $2.1 trillion food, beverage, and consumer packaged goods industry employs 14 million U.S. workers, and contributes over $1 trillion in added value to the nation's economy.

GMA notes that, unlike when FSMA-authorized reinspeetion fee rates were first published in 2011 or when they were raised in 2012, FDA did not solicit comments on the above-referenced Federal Register notice announcing the most recent hike in reinspeetion fee rates, nor did it
indicate that it intends to consider such comments in advance of its implementation of these fees. Nevertheless, we feel it important to resubmit our prior comments and reiterate our reservations and concerns about elements of the formula FDA continues to use to calculate these fees.

It is fortunate that FDA, for reasons explained in the Federal Register notice, has not yet begun to invoice firms for or collect fees for reinspection. We are very concerned, however, that once firms do start receiving invoices for reinspection services, they will be surprised by the dollar amount the Agency says must be reimbursed. We support FDA’s delay in billing firms for reinspection until mandated guidance is issued. We also strongly encourage the Agency to consider and address our concerns about the fee rates in the interim.

We have previously objected to FDA’s use, for purposes of calculating reinspection fee rates, of the same model the Agency used for user fees authorized under the Prescription Drug User Fee Act (PDUFA) and Medical Device User Fee and Modernization Act (MDUFMA) to recover the total costs of expedited review and approval functions. We continue to believe that model is inappropriate for establishing fees under FSMA. Reinspection of food facilities to assure compliance with food safety-related regulatory requirements is fundamentally a different type of activity than review and approval of new drugs or medical devices for manufacturers. Unlike PDUFA and MDUFMA, where inclusion of indirect costs were justified because the Agency had to hire hundreds of new employees and build an entirely new infrastructure to review new product applications, food facility reinspections are conducted by existing FDA employees, not new ones, and they operate within an existing infrastructure.

According to our calculations, if the FDA used more appropriate procedures for capturing direct costs along with appropriate costs for supporting staff, the fee rates would be much more compatible with rates that would be charged by companies for the same type of service.

We believe that a multiplier of 1.3 would be typical for generating total compensation for an individual based upon his/her base salary. Using this figure, total compensation for an FDA investigator making $100,000 per year would be $130,000. If we use the 1600 hours available for assignment per year that FDA relies on, then the hourly rate for this investigator would be $81.25 per hour. (If the salary is divided by the 2080 hours for which the investigator is paid per year, the true hourly rate would be $62.50 per hour.) If we multiply these hourly rates by the 1.43 fully supported cost factor the Agency uses to account for the 7 FTE’s in the field, the hourly rates would be $116.19 for 1600 hours (or $89.38 for 2080 hours). There is a significant difference between $116.19, using FDA’s 1600 hours for calculation, and $221 that FDA has calculated as its hourly cost for reinspection exclusive of domestic or foreign travel costs. Interestingly, the base salary for an FDA investigator required to reach the $221 hourly cost using the formula we describe above would be nearly $190,000, which seems at odds with a report issued in 2012 that showed nearly 80% of ORA staff make less than $100,000 per

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1 $100,000 investigator salary * 1.3 factor for benefits / 1600 hours available for inspection according to FDA = $81.25 per hour * 1.43 factor for support staff = $116.19 per hour
We believe that the major cause for this disparity is FDA’s use of the PDUFA/MDUFMA model for total cost recovery for the program.

As we have previously commented, the FDA reinspection fee rates stand in stark contrast to the current $69.36 per hour rate that the USDA Food Safety and Inspection Service charges inspected meat and poultry establishments for reimbursement for overtime inspection service. Also, we continue to believe that the FDA reinspection fee rates include activities or program costs that are totally unrelated to reinspection performance. We respectfully request that the Agency provide much more transparency about the elements of its rate calculations. Only with a much more granular depiction of program costs can we begin to understand why these rates are so high.

**Background**

On November 30, 2011, GMA provided comments responsive to Docket No. FDA-2011-N-0528, which focused specifically on the FDA’s new reinspection and recall-related fee authorities. A copy of these comments is attached for ready reference. These comments supported and supplemented oral statements provided at the public meeting held on June 6, 2011, written comments submitted to the Agency on July 6, 2011, and positions and questions shared during an industry meeting with FDA officials at the Chamber of Commerce on October 28, 2011. We were disappointed that the comments and concerns expressed by GMA and other industry groups were, for the most part, not addressed in the August 1, 2012 *Federal Register* Notice announcing fee rates for FY 2013.

In comments dated October 31, 2012, GMA reiterated our concerns in a submission to Docket No. FDA-2012-N-0799. A copy of those comments is also attached. Despite submission of multiple comments and statements, our concerns remain and we have received no indication, either in *Federal Register* notice preamble discussion or in any other form of feedback, from the Agency that our comments have been duly considered. Our main recommendations to the FDA are repeated below. Details of our concerns for each issue are expressed in our prior comments, which, as noted, are attached.

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4 Food and Drug Administration; Food Safety Modernization Act Domestic and Foreign Facility Reinspection, Recall, and Importer Reinspection Fee Rates for Fiscal Year 2013; 76 Fed. Reg. 45820 (August 1, 2011).

5 We acknowledge that the Agency did act on our expressed concern that domestic travel should not be included in the rate to be billed for foreign reinspections.
Summary of Prior GMA Recommendations

- FDA should reveal the specific benefits and operating costs used in fee calculations and explain the relevance of these costs to reinspection activities.

- Recovery of reinspection expenses should be limited to direct costs for Agency employees’ time; indirect costs should not be included. Furthermore, the cost of providing employee benefits such as paid holidays, annual leave, sick leave and the cost for time spent for generalized support functions not directly associated with reinspection activities should not be included in user fee rate calculations. When calculating hourly reinspection rates, if benefit hours are to be subtracted from total hours, then the cost of these benefits should also be subtracted from the total costs.

- In consideration of the fact that many food facilities are subject to both FDA and USDA jurisdiction, we suggest that FDA harmonize its fee calculation formula with FSIS's approach to provide consistency between food regulatory agencies. Additionally, consideration should be given to the impact of elevated fees on international agreements.

- When calculating base operating costs, FDA should use only those costs for activities common to both domestic and foreign reinspections. Additionally, the FDA should be transparent in specifying how these costs directly relate to reinspection activities, through publication on the Agency website or in the Federal Register.

- FDA should clarify its plans to use or not to use state inspectors to conduct reinspections. If state regulators are to be used, the Agency should detail how it plans to incorporate state inspection costs into the reinspection fee calculation.

- FDA should clearly define the process for communication between the Agency and firms undergoing reinspection. Regular communication should take place with the firm to inform them of the status of the reinspection. Invoices for reinspection fees should itemize the number of hours spent by Agency personnel in-plant, in-office and in-transit. Once FDA has completed its reinspection process, the formal closure of the reinspection process should be clearly communicated in writing to the firm. FDA should provide contact information in the event the firm desires to contact the Agency regarding the status of a reinspection. FDA also should establish a dispute resolution process to address questions or concerns about billing issues.

- FDA should inform industry about the percentage of past inspections that were classified as OAI and benchmark future inspections to this same level. The number of reinspections as a proportion of total inspections should remain consistent with historical norms. The Agency should not perform more
reinspections now solely due to the fact that associated expenses can be recovered. These fees are authorized only for recoupment—not for revenue generation. FDA also should be sensitive to not “running up fees,” allocating only the number of staff necessary to ensure that corrective actions have been appropriately implemented.

*          *         *

In conclusion, GMA hopes FDA will give serious consideration to our views on the Agency’s calculation of FY 2014 rates for reinspection services. Despite prior verbal assurances that the Agency would respond to our concerns about reinspection fee rates, this has not yet occurred. We still would welcome an opportunity to further discuss these important issues with FDA.

Sincerely,

Leon Bruner, DVM, Ph.D.
Senior Vice President for Scientific and Regulatory Affairs &
Chief Science Officer

Attachments:
- GMA comments dated October 31, 2012 submitted to Docket No. FDA-2012-N-0799
Dear Sir or Madam:

The Grocery Manufacturers Association (GMA) appreciates the opportunity to comment on the FDA Federal Register notice on the above referenced docket that is responsive to Section 107 provisions of the FDA Food Safety Modernization Act (FSMA or “the Act”) and announces user fee rates for fiscal year 2012. GMA is the voice of more than 300 leading food, beverage, and consumer product companies that sustain and enhance the quality of life for hundreds of millions of people in the United States and around the globe.

Founded in 1908, GMA and its member companies are committed to meeting the needs of consumers through product innovation, responsible business practices, and effective public policy solutions developed through a genuine partnership with policymakers and other stakeholders. In keeping with our founding principles, GMA helps its members produce safe products through a strong and ongoing commitment to scientific research, testing, and evaluation. We ensure that our members have the very best and latest scientific knowledge available so they can provide consumers with the products, tools, and information they need
to achieve a healthy diet and an active lifestyle. The $2.1 trillion food, beverage, and consumer packaged goods industry employs 14 million U.S. workers, and contributes over $1 trillion in added value to the nation's economy.

GMA has previously noted its belief that thoughtful application of the Agency’s broad new inspection mandate and compliance authorities under the FSMA can enhance the safety of the Nation’s food supply. These provisions are critical to protecting public health and safety and to ensuring consumers’ confidence in foods and brands and they must be implemented properly.

These GMA comments focus specifically on the Agency’s new authority to collect fees. They support and supplement oral statements provided at the FDA public meeting held on June 6, follow-up written comments submitted to the Agency on July 6, and positions and questions shared with FDA officials during an industry meeting with FDA officials at the Chamber of Commerce on October 28, 2011.

Prior GMA Comments on Reinspection Fees

GMA has previously commented that:

- Reinspection fees should apply only when physical reinspection of a facility is necessary to follow up on inspection results classified as Official Action Indicated (OAI) for food safety reasons
- The frequency of reinspections should be consistent with past Agency practice and should not be increased in order to collect fees
- The Agency should not use its authority to levy reinspection fees as a punitive measure or a means of increasing revenue
- FDA should communicate with a facility about the status of any reinspection, so that facilities are aware whether compliance has been achieved to the Agency’s satisfaction
- Firms should be made aware in advance, in writing and prior to reinspection, that they will be billed for any reinspection costs
- The Agency should be transparent about its fee schedule and clearly define what costs would be assessed
- FDA should clearly articulate whether or not and how costs would be impacted when state inspectors conduct reinspections on behalf of FDA
- FDA should clarify how it intends to apply fees in the context of examination of products offered for entry by importers, as this is not clear from the statute
- FDA should describe if, and if so how, it intends to apply fees in the context of reinspection of foreign facilities
- If FDA intends to conduct and to assess fees for reinspections in foreign facilities as is provided for in the Act, then the Agency should make clear the factors it uses to establish those fees and its legal basis for imposition of such fees
We appreciate FDA’s consideration of these prior comments and note that several of our suggestions were reflected in the Agency’s August 1 Notice announcing the user fees. Based on guidance and questions and answers released by the Agency on September 30, some of our issues and concerns have been addressed or at least held in abeyance for further consideration before fees are levied. We appreciate the Agency’s recent declaration\(^1\) that “FDA intends to assess a facility reinspection fee in circumstances where the initial facility inspection begins on or after October 1, 2011.” We also commend the Agency for its decision not to institute fees for import reinspections until multiple questions and concerns have been addressed.

However, we continue to have major concerns about the high hourly rates that the Agency intends to use in calculating reimbursable costs for domestic and foreign facility reinspections. We also reemphasize the need for transparency and consistency and the need for consideration of the burden these fees will have on small businesses.

**Hourly Rate Calculations**

Under FSMA, FDA is authorized to establish fees for certain domestic and foreign facility reinspections, mandatory recall orders, and certain importer reinspections to capture 100 percent of the costs of each activity. Such fees are to be used solely to pay for the costs of each activity for which the fee was incurred. FDA states in the *Federal Register* notice referenced above that this is most reasonably done by dividing the total funds allocated to the elements of FDA primarily responsible for carrying out the activities for which fees are being collected by the total FTEs allocated to those activities.

Several items appear problematic with this proposed procedure for calculating fees. Although FDA was directed to base its fee on 100 percent of the costs of reinspection related activities, FDA has instead elected to base its fee on the salary, benefits, and operating costs of the Agency program that conducts reinspections as a minor element of the myriad of functions performed. While certain benefits and operating costs are specified as being included in FDA’s fee calculation, the specific nature of these benefits and operating costs are not revealed.

In calculating hourly rates, FDA also derives direct work hours per year by subtracting time allotted for paid holidays, annual leave, sick leave, training, and meetings from a total of 2080 work hours per year. Thus, the resulting hourly rate calculation includes the benefits cost of paid holidays, annual leave, sick leave, training, and meetings. However, we do not believe these indirect benefit costs are directly associated with reinspection or recall activities and as such they should not be borne by firms that are subject to reinspection.

\(^1\) Guidance for Industry: Implementation of the Fee Provisions of Section 107 of the FDA Food Safety Modernization; September 2011; [http://www.fda.gov/Food/GuidanceComplianceRegulatoryInformation/GuidanceDocuments/FoodSafety/ucm274176.htm](http://www.fda.gov/Food/GuidanceComplianceRegulatoryInformation/GuidanceDocuments/FoodSafety/ucm274176.htm)
Reinspection of food facilities is fundamentally a different type of activity than the expedited review and approval functions for which user fees are authorized under the Prescription Drug User Fee Act (PDUFA) and the Medical Device User Fee and Modernization Act (MDUFMA) that FDA is using as its model for establishing fees under FSMA. We know of no evidence that suggest the Food Safety Modernization Act intended for the Agency to base its reinspection fees on recovery of both direct and indirect costs of the program rather the direct costs for the reinspection activities.

When compared to fees charged by other agencies, the FDA hourly costs appear significantly and disproportionately large. For example, the USDA-FSIS calculation for the 2011 base time rate per hour per program employee for overtime and holiday inspection services is $53.92 compared to the FDA published rate of $224.00. Especially for the many GMA members that operate dual jurisdiction processing establishments that manufacture both FDA and FSIS-inspected products, this disparity of costs for similar though not identical services seems untenable.

FDA calculates the foreign hourly rate by adding the average cost for foreign travel to the domestic rate. However because operating costs included in the domestic rate were not itemized, it is unclear if some of these domestic operating costs are irrelevant to foreign reinspection activities and thus should be deducted from the foreign reinspection rate.

GMA Recommendations

To address these noted concerns, GMA offers the following suggestions:

Fee Methodology

• The fees ultimately charged to firms for reinspection activities should be based on the actual costs incurred by the Agency for the reinspection of a firm. This could also help to address the small business burden issue as it would be expected that reinspection activities associated with a small business would have lower direct costs than those for larger firms.

• The fee schedule that FDA publishes in the Federal Register should be based principally on the salary of those federal investigators primarily responsible for conducting reinspection or for mandatory recall related activities. Under this procedure the actual fees ultimately charged to firms during a reinspection or recall should better reflect the actual cost of the specific reinspection or mandatory recall associated with that firm.

• Operating costs not associated with reinspections should not be included in the hourly rate calculation.

• Facilities should not be billed for travel time, as this is an indirect cost. Charging for travel time will unfairly penalize foreign facilities located overseas and domestic facilities in rural areas.
Out-of-pocket travel expenses (e.g., hotel, airfare), whether domestic or foreign, if invoiced, should be separately itemized specifically for each reinspection on an as incurred basis and not built into the hourly rate.

FDA should clarify how it intends to apportion the recovery of travel costs in situations where unrelated reinspections of multiple firms are performed during a single trip (domestic or foreign) or when other non-reimbursable activities are conducted during the trip.

FDA should clarify whether it plans to use third parties (such as state health inspectors) to conduct reinspections and if so, how it plans to calculate reinspection fees based on actual third party costs.

FDA should be aware that the published hourly fees to be charged to importers and US agents of foreign facilities will likely be seen as disproportionately expensive for foreign suppliers (or discriminatory under the WTO Agreement on Sanitary and Phytosanitary Measures, Article 2.3) and, consequently, may trigger World Trade Organization (WTO) or other international repercussions, such as retaliatory measures or a lack of international cooperation on issues of interest to the US.

In consideration of the fact that many food facilities manufacture products that are subject to both FDA and USDA jurisdiction, we suggest that FDA harmonize its fee calculation formula with FSIS’s approach to provide consistency between food regulatory agencies.

**Transparency**

FDA investigators should always keep the facility informed of any significant findings, as the inspection is being conducted. Any non-compliance that results in an Official Action Indicated (OAI) designation and that is considered by FDA to be materially related to food safety should be promptly and clearly communicated to the firm. Firms subject to reinspection fees should be notified in advance and in writing of any specific food safety violation(s) found by FDA during an initial inspection.

FDA should clearly communicate in writing the status and potential total costs of the reinspection to domestic facilities, importers and US agents of foreign facilities subject to reinspection fees at some designated frequency (e.g., monthly).

Once FDA has completed its reinspection process, the formal closure of the reinspection process should be clearly communicated in writing to the firm.

FDA should provide contact information in the event the firm desires to contact the Agency regarding the status of a reinspection.

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2 "Members shall ensure that their sanitary and phytosanitary measures do not arbitrarily or unjustifiably discriminate between Members where identical or similar conditions prevail, including between their own territory and that of other Members. Sanitary and phytosanitary measures shall not be applied in a manner which would constitute a disguised restriction on international trade."
GMA strongly encourages FDA to publish information about the average and range of hours required to complete reinspections (for issues of greater and of lesser relative concern) and for facilities of various sizes. Specifically, it would be helpful if FDA posted on its website information summarizing hypothetical reinspection fees that could be anticipated for larger and for smaller firms that might undergo reinspection for OAI situations of greater and of lesser relative significance. We believe this information, could be gleaned from existing Agency files for prior reinspections, and that its availability would greatly assist industry to anticipate the potential financial liabilities associated with reinspections.

Consistency

- FDA should inform industry of the percentage of inspections in the past that were classified as OAI and benchmark future inspections to this same level.
- The number of reinspections as a proportion of total inspections should remain consistent with historical norms.
- The Agency should not now perform more reinspections solely due to the fact that associated expenses can be recovered. These fees are authorized only for recoupment--not for revenue generation.
- FDA should take precautions not to financially burden the food industry with additional costs. For reinspections, the Agency should allocate the minimum staff for the minimum time necessary to assure that corrective actions have been appropriately implemented.

Reinspection Basis

- FDA should be clear as to how broadly or narrowly it will interpret findings of non-compliance that trigger subsequent reinspection and associated fees.
- For example, if a foreign supplier is put on Import Alert because an initial inspection revealed the presence of an undeclared allergen in Food “A,” and the firm subsequently exports Food “B” with the same undeclared allergen, would that trigger a reinspection with associated costs for the importer?
- Would reinspection fees be levied if Food “B” was determined to contain a different rather than the same undeclared allergen?

Small Business Considerations

- FDA needs to consider the financial impact and burden that reinspection fees could have on small businesses.
- For example, in a scenario where FDA conducts a reinspection of a facility using 4 inspectors over a 4-day period (at 8 hours of work per day), the resulting cost would total to almost $30,000, plus travel and other out-of-pocket expenses. Under the current fee schedule, reinspection fees could lead to the closure of small businesses.
Reinspection Fees for Imports

While GMA has not herein addressed in detail our concerns about the fees or the mechanism for assessment for reinspection fees for imported products, we wish to note our concurrence with the points made on this subject in comments submitted by a coalition of industry associations, namely the American Frozen Foods Institute, the American Bakers Association, the Grocery Manufacturers Association, the National Confectioners Association, and the National Fisheries Institute, which are also being filed on November 30.

In conclusion, GMA appreciates the opportunity to provide our views on the provisions of the FSMA that authorize FDA to collect fees from industry. We look forward to the prospect of holding future discussions with FDA on these important issues and stand ready to assist the Agency with its FSMA implementation efforts.

Sincerely,

Leon Bruner, DVM, Ph.D.
Senior Vice President Science and Regulatory Affairs

Attachments:

Appendix A – PowerPoint presentation delivered at FDA public meeting on June 6, 2011
Appendix B – GMA comments submitted to FDA on July 6, 2011
October 31, 2012

Division of Dockets Management (HFA-305)
Food and Drug Administration
5630 Fishers Lane, Room 1061
Rockville, MD 20852

Re: Docket No. FDA–2012–N–0799; Food and Drug Administration; Food Safety Modernization Act Domestic and Foreign Facility Reinspection, Recall, and Importer Reinspection Fee Rates for Fiscal Year 2013; Federal Register Notice; (77 FR 45636); August 1, 2012

Dear Sir or Madam:

The Grocery Manufacturers Association (GMA) appreciates the opportunity to comment on the FDA Federal Register notice on the above referenced docket that is responsive to Section 107 of the FDA Food Safety Modernization Act (FSMA or “the Act”) and announces user fee rates for Fiscal Year (FY) 2013. The new hourly, per person rates for FY 2013 are $221 if domestic travel is required and $289 if foreign travel is required. GMA is the voice of more than 300 leading food, beverage, and consumer product companies that sustain and enhance the quality of life for hundreds of millions of people in the United States and around the globe.

Founded in 1908, GMA and its member companies are committed to meeting the needs of consumers through product innovation, responsible business practices, and effective public policy solutions developed through a genuine partnership with policymakers and other stakeholders. In keeping with our founding principles, GMA helps its members produce safe products through a strong and ongoing commitment to scientific research, testing, and evaluation. We ensure that our members have the very best and latest scientific knowledge available so they can provide consumers with the products, tools, and information they need to achieve a healthy diet and an active lifestyle. The $2.1 trillion food, beverage, and consumer packaged goods industry employs 14 million U.S. workers, and contributes over $1 trillion in added value to the nation’s economy.
On November 30, 2011, GMA provided comments responsive to Docket No. FDA-2011-N-0528\(^1\), which focused specifically on the Agency’s new reinspection and recall-related fee authorities. A copy of these comments is attached for ready reference. These comments supported and supplemented oral statements provided at the public meeting held on June 6, 2011, written comments submitted to the Agency on July 6, 2011, and positions and questions shared during an industry meeting with FDA officials at the Chamber of Commerce on October 28, 2011. We are disappointed that the comments and concerns expressed by GMA and other industry groups were, for the most part, not addressed in the August 1, 2012 Federal Register Notice.

We appreciate that FDA has revised the methodology for calculation of fee rates for FY 2013 by separating out domestic travel rates. However, we continue to have many of the same major concerns articulated in our November 30, 2011 comments to the Agency. These concerns, to which the Agency has not yet responded, include the following:

1. While certain employee benefits and program operating costs are included in FDA’s fee calculation, the specific benefits and operating costs are not revealed.

   **GMA Recommendation:** FDA should reveal the specific benefits and operating costs used in fee calculations and explain the relevance of these costs to reinspection activities.

2. Under FSMA, FDA was authorized to establish fees for certain domestic and foreign facility reinspections, recall orders, and certain importer reinspections to capture 100 percent of the costs of each activity. Such fees are to be used solely to pay for the costs of each activity for which the fee was incurred. The Agency stated in the Federal Register that this is most reasonably done by dividing the total funds allocated to the elements of FDA primarily responsible for carrying out the activities for which fees are being collected by the total FTEs (full-time equivalents) allocated to those activities.\(^2\)

This is the model FDA employed for recovering the total costs for the expedited review and approval functions for which user fees are authorized under the Prescription Drug User Fee Act (PDUFA) and Medical Device User Fee and Modernization Act (MDUFMA). However, we believe that this model is inappropriate for establishing fees under FSMA. Reinspection of food facilities to assure compliance with regulatory requirements is fundamentally a different type of activity than review and approval of new drugs or medical devices for manufacturers. Unlike PDUFA and MDUFMA, where inclusion of indirect costs were justified because the Agency had to hire hundreds of new

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\(^1\) Food and Drug Administration; Food Safety Modernization Act Domestic and Foreign Facility Reinspection, Recall, and Importer Reinspection Fee Rates for Fiscal Year 2013; Federal Register Notice; (76 FR 45820); August 1, 2011.

\(^2\) 76 FR 45820.
employees and build an entirely new infrastructure to review new product applications, 
food facility re-inspections are conducted by existing FDA employees, not new ones, and 
they are operating within an existing infrastructure.

The FTE cost per hour upon which FDA has calculated its FY 2013 re-inspection fee rates 
includes overhead expenses such as human resources, information technology, 
administrative support, program management, and legal counsel. However, Section 107 
of FSMA only permits FDA to collect the direct costs (“100 percent of the costs of the 
re-inspection-related activities”), rather than indirect costs that include expenses such as 
overhead. Thus, re-inspection fees are intended solely to recoup the direct costs of the 
time spent directly by Agency personnel arranging, conducting, evaluating re-inspections 
and for assessing and collecting re-inspection fees. We are unaware of any evidence that 
suggests Congress, in adopting FSMA, intended the Agency to base its re-inspection fees 
on recovery of both direct and indirect costs of the program.

Furthermore, in calculating hourly rates, FDA computes direct work hours per year by 
subtracting time allotted for paid holidays, annual leave, sick leave, training, and 
meetings from a total of 2080 work hours per year. Thus, contrary to the Agency’s 
authorization to establish fees for recovery of direct costs, the resulting hourly rate 
calculation includes the indirect benefit costs of paid holidays, annual leave, sick leave, 
training and meetings.

We believe that FDA may properly collect 100 percent of re-inspection-related direct 
costs incurred by those Agency personnel performing specified re-inspection-related 
activities. The true “cost” of these re-inspections is simply the direct cost of the 
employees’ time that is redirected from routine activities to a re-inspection of a facility to 
assure compliance has been achieved following a finding of non-compliance materially 
related to a food safety requirement that was documented as OAI during a prior 
inspection. No indirect costs are involved. Especially when compared to the inspection-
related fees assessed by a sister agency (see discussion below), we believe that including 
the indirect costs significantly bloats the hourly amounts in ways that are simply 
inappropriate.

**GMA Recommendation:** Recovery of re-inspection expenses should be limited to 
direct costs for Agency employees’ time; indirect costs should not be included.
Furthermore, the cost of providing employee benefits such as paid holidays, annual 
leave, sick leave and the cost for time spent for generalized support functions not 
directly associated with re-inspection activities should not be included in user fee rate 
calculations. When calculating hourly re-inspection rates, if benefit hours are to be 
subtracted from total hours, then the cost of these benefits should also be subtracted 
from the total costs.
3. When compared to fees charged by other agencies, the FDA hourly costs appear significantly and disproportionately large. For example, the FY 2012 base time rate per hour per program employee for reimbursed inspection services by the US Department of Agriculture’s Food Safety and Inspection Service (FSIS) is $54.24 compared to the FDA published rate of $221. For the many GMA members that operate dual jurisdiction processing establishments, which manufacture both FDA and FSIS-inspected products, this disparity of costs for similar though not identical services is unjustifiable. Additionally, the published hourly fees to be charged to importers and US agents of foreign facilities are disproportionately expensive for foreign suppliers. If this is due to use of different calculation methodologies for foreign versus domestic reinspections, it may trigger World Trade Organization (WTO) or other international repercussions, such as a lack of international cooperation on issues of interest to the US.

**GMA Recommendation:** In consideration of the fact that many food facilities are subject to both FDA and USDA jurisdiction, we suggest that FDA harmonize its fee calculation formula with FSIS's approach to provide consistency between food regulatory agencies. Additionally, consideration should be given to the impact of elevated fees on international agreements.

4. FDA calculates the foreign hourly rate by adding the average cost for foreign travel to the domestic rate. However because operating costs included in the domestic rate were not revealed, it is unclear if some of these (domestic) operating costs are irrelevant to, and thus should be deducted from, activities involving foreign reinspections.

**GMA Recommendation:** When calculating base operating costs, FDA should use only those costs for activities common to both domestic and foreign reinspections. Additionally, the FDA should be transparent in specifying how these costs directly relate to reinspection activities, through publication on the Agency website or in the Federal Register.

5. It is unclear from the information provided to-date whether or not the Agency intends to use state inspectors to conduct reinspection activities.

**GMA Recommendation:** FDA should clarify its plans to use or not to use state inspectors to conduct reinspections. If state regulators are to be used, the Agency should detail how it plans to incorporate state inspection costs into the reinspection fee calculation.

6. According to information posted on the FDA website, a reinspection fee may be assessed if FDA conducts a reinspection to evaluate corrective actions following a previous FDA inspection of the same facility that was classified Official Action Indicated (OAI) and FDA determined the non-compliance was materially related to a food safety
requirement. However, there is no published process on how FDA intends to communicate the reinspection status, from initiation to closure, to a firm undergoing reinspection. Additionally, it is unclear how a firm can discuss and/or dispute billing issues (e.g., fee calculation errors, invoice accuracy) with the Agency, if necessary.

**GMA Recommendation:** FDA should clearly define the process for communication between the Agency and firms undergoing reinspection. Regular communication should take place with the firm to inform them of the status of the reinspection. Invoices for reinspection fees should itemize the number of hours spent by Agency personnel in-plant, in-office and in-transit. Once FDA has completed its reinspection process, the formal closure of the reinspection process should be clearly communicated in writing to the firm. FDA should provide contact information in the event the firm desires to contact the Agency regarding the status of a reinspection. FDA also should establish a dispute resolution process to address questions or concerns about billing issues.

**Additional GMA recommendations:** FDA should inform industry about the percentage of past inspections that were classified as OAI and benchmark future inspections to this same level. The number of reinspections as a proportion of total inspections should remain consistent with historical norms. The Agency should not perform more reinspections now solely due to the fact that associated expenses can be recovered. These fees are authorized only for recoupment—not for revenue generation. FDA also should be sensitive to not “running up fees,” allocating only the number of staff necessary to ensure that corrective actions have been appropriately implemented.

In conclusion, GMA appreciates the opportunity to provide our views on the Agency’s calculation of FY 2013 rates for reinspection services. We look forward to the prospect of holding future discussions with FDA on these important issues.

Sincerely,

[Signature]

Leon Bruner, DVM, Ph.D.
Senior Vice President
For Scientific and Regulatory Affairs
and Chief Science Office