

Visitors will be notified as soon as approval has been obtained.

*Status:* The meeting is open to the public, limited only by the space available. The meeting space accommodates approximately 100 people.

**SUPPLEMENTARY INFORMATION:**

*Recommended Attendees:* Purchasing agents and buyers of construction and manufacturing machinery and equipment who believe “Buy Quiet” programs can be effectively and efficiently woven into existing procurement processes.

Construction and manufacturing employers who wish to investigate the cost effectiveness of “Buy Quiet” and determine how best to use the program to demonstrate best available engineering noise control technology is being deployed at their worksites.

Noise control engineers, product designers and manufacturers wishing to learn how best to gather and present noise level information and to provide necessary information to their customers in support of “Buy Quiet” programs.

Other safety and health professionals and employee representatives who want to assist in bringing “Buy Quiet” programs into the workplace.

*Format:* Day one will provide presentations from invited speakers. Day two will combine presentations with break-out sessions and roundtable discussions. The break-outs and roundtable will provide participants the opportunity to share relevant experiences and aspirations on process techniques for implementation, incentives and barriers for implementation, and research to practice products and partnerships.

**Note:** This workshop is not a sales event nor will exhibits of any kind be allowed. Any attendees who attempt to use this meeting for sales purposes will be asked to leave. This meeting is to explore methods for the development and implementation of “Buy Quiet” programs that meet the needs of the business community identified as part of the Construction and Manufacturing industry sectors.

*Contact Person For More Information:* Charles Hayden, NIOSH, MS-C27, Robert A. Taft Laboratories, 4676 Columbia Parkway, Cincinnati, Ohio 45226, telephone (513) 533-8152, E-mail [chayden@cdc.gov](mailto:chayden@cdc.gov).

Dated: October 12, 2011.

**John Howard,**

*Director, National Institute for Occupational Safety and Health, Centers for Disease Control and Prevention.*

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**DEPARTMENT OF HEALTH AND HUMAN SERVICES**

**Food and Drug Administration**

[Docket No. FDA-2011-N-0529]

**Burden of Food and Drug Administration Food Safety Modernization Act Fee Amounts on Small Business; Extension of Comment Period**

**AGENCY:** Food and Drug Administration, HHS.

**ACTION:** Notice; extension of comment period.

**SUMMARY:** The Food and Drug Administration (FDA) is extending the comment period to November 30, 2011, for the notice entitled, “Burden of Food and Drug Administration Food Safety Modernization Act Fee Amounts on Small Business; Request for Comments” that appeared in the **Federal Register** of August 1, 2011 (76 FR 45818). In that document, FDA announced the establishment of a docket to obtain information that would be used to formulate a proposed set of guidelines in consideration of the burden of fee amounts on small business, as set forth in the FDA Food Safety Modernization Act (FSMA). In particular, the Agency requested public comments on whether a reduction of fees or other consideration for small business was appropriate, and if so, what factors the Agency should consider for each. In addition, the Agency requested public comment on how small business should be defined or recognized. The Agency is taking this action in response to requests for an extension to allow interested persons additional time to submit comments.

**DATES:** Submit either electronic or written or comments by November 30, 2011.

**ADDRESSES:** Submit electronic comments to <http://www.regulations.gov>. Submit written comments to the Division of Dockets Management (HFA-305), Food and Drug Administration, 5630 Fishers Lane, Rm. 1061, Rockville, MD 20852.

**FOR FURTHER INFORMATION CONTACT:** Alexis Nazario-Negron, Office of Financial Management, Food and Drug Administration, 1350 Piccard Dr., Rm. 210E, Rockville, MD 20850, 301-796-7223, [Alexis.Nazario-Negron@fda.hhs.gov](mailto:Alexis.Nazario-Negron@fda.hhs.gov).

**SUPPLEMENTARY INFORMATION:**

**I. Background**

In the **Federal Register** of August 1, 2011 (76 FR 45818), FDA published a

notice with a 78-day comment period to request comments on the burden of FSMA fee amounts on small business. FSMA provides the Agency with authority under section 743 of the Federal Food, Drug, and Cosmetic Act (FD&C Act) to assess and collect fees, including those for costs associated with certain domestic and foreign facility reinspections, failure to comply with a recall order, and importer reinspections. The Agency is seeking public comment on what burdens these fees might impose on small business, and whether and how the Agency should alleviate such burdens. In particular, the Agency is seeking public comments on whether a reduction of fees or other consideration for small business is appropriate, and if so, what factors the Agency should consider for each. In addition, the Agency is seeking public comment on how small business should be defined or recognized. The Agency has received a request for an extension of the comment period. The request conveyed concern that the current 78-day comment period does not allow sufficient time to develop a meaningful or thoughtful response to the notice.

FDA has considered the request and is extending the comment period for the notice until November 30, 2011. The Agency believes that this extension allows adequate time for interested persons to submit comments without significantly delaying the development of a proposed set of guidelines in consideration of the burden of the fee amounts on small business, as required by section 743(b)(2)(B)(iii) of the FD&C Act.

**II. Request for Comments**

Interested persons may submit to the Division of Dockets Management (see **ADDRESSES**) either electronic or written comments on this document. It is only necessary to send one set of comments. It is no longer necessary to send two copies of mailed comments. Identify comments with the docket number found in brackets in the heading of this document. Received comments may be seen in the Division of Dockets Management between 9 a.m. and 4 p.m., Monday through Friday.

Dated: October 12, 2011.

**David Dorsey,**

*Acting Associate Commissioner for Policy and Planning.*

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