FDA expects that, although all sizes of business are eligible, small businesses and very small businesses are the firms most likely to be able to demonstrate a need to request an extension to the *trans* fat labeling deadline. The agency has already received three requests from businesses regarding the *trans* fat labeling compliance date of January 1, 2006. Because small businesses are more likely to submit requests for extensions, and most of the affected businesses are small, we use the number of small businesses as the base to calculate the reporting burden. The regulatory flexibility analysis of the *trans* fat final rule estimated that 11,180 small businesses will have to revise the label on their products as a result of the *trans* fat final rule. Given that only three businesses have submitted requests to FDA so far, FDA estimates that, in the first year following the issuance of the guidance, the total number of businesses that will request a labeling compliance extension from FDA can be estimated as approximately 0.5 percent of the number of small businesses, which equals 56.

FDA estimates that it will take one employee approximately 4 hours to put together a request to FDA and approximately 1 hour for a supervisor to look over the request before submitting it to the agency. Thus, each firm submitting a compliance extension request will need 5 hours of employee time to complete the request. Given that 56 businesses are expected to submit written requests in year one, the total burden hours for year one are 280.

In year two, FDA expects about one-half as many firms to request a labeling compliance extension. So for year two, 28 firms are expected to file a request for an extension to the labeling compliance date. Again, assuming that it will take 5 hours to complete each request, the total burden hours for year two will be 140.

Dated: August 26, 2005.

Jeffrey Shuren,

Assistant Commissioner for Policy.

[FR Doc. 05–17413 Filed 8–29–05; 2:49 pm]

BILLING CODE 4160–01–S

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

General Hospital and Personal Use Devices Panel of the Medical Devices Advisory Committee; Notice of Meeting

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

This notice announces a forthcoming meeting of a public advisory committee of the Food and Drug Administration (FDA). The meeting will be open to the public.

Name of Committee: General Hospital and Personal Use Devices Panel of the Medical Devices Advisory Committee.

General Function of the Committee: To provide advice and recommendations to the agency on FDA's regulatory issues.

Date and Time: The meeting will be held on September 27, 2005, from 8 a.m. to 5 p.m.

Location: Hilton Washington DC North/Gaithersburg, Ballroom, 620 Perry Pkwy., Gaithersburg, MD.

Contact Person: Scott Colburn, Center for Devices and Radiological Health (HFZ–480), Food and Drug Administration, 9200 Corporate Blvd., Rockville, MD 20850, 301–594–1287, ext. 177, or FDA Advisory Committee Information Line, 1–800–741–8138 (301–443–0572 in the Washington, DC area), code 3014512520. Please call the Information Line for up-to-date information on this meeting.

Agenda: The committee will hear a presentation on FDA's Critical Path Initiative. Subsequently, the committee will discuss and make recommendations regarding general issues related to the model used for validation testing to support a claim of decontamination of potentially transmissible spongiform encephalopathy (TSE)-contaminated surgical instruments. Background information for the topics, including the agenda and questions for the committee, will be available to the public 1 business day before the meeting, on the Internet at *http://www.fda.gov/cdrh/panelmtg.html*.

Procedure: Interested persons may present data, information, or views, orally or in writing, on issues pending before the committee. Written submissions may be made to the contact person by September 13, 2005. Oral presentations from the public will be scheduled for approximately 60 minutes at the beginning of deliberations and for approximately 30 minutes near the end of deliberations. Time allotted for each presentation may be limited. Those desiring to make formal oral presentations should notify the contact person before September 13, 2005, and submit a brief statement of the general nature of the evidence or arguments they wish to present, the names and addresses of proposed participants, and an indication of the approximate time requested to make their presentation.

Persons attending FDA's advisory committee meetings are advised that the agency is not responsible for providing access to electrical outlets.

FDA welcomes the attendance of the public at its advisory committee meetings and will make every effort to accommodate persons with physical disabilities or special needs. If you require special accommodations due to a disability, please contact AnnMarie Willliams at 240–276–0450, ext. 113, at least 7 days in advance of the meeting.

Notice of this meeting is given under the Federal Advisory Committee Act (5 U.S.C. app. 2).

Dated: August 23, 2005.

Scott Gottlieb,

Deputy Commissioner for Policy.

[FR Doc. 05–17412 Filed 8–31–05; 8:45 am]

BILLING CODE 4160–01–S

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Health Resources and Services Administration

Advisory Commission on Childhood Vaccines; Notice of Meeting

AGENCY: Health Resources and Services Administration, HHS.

ACTION: Notice; amendment.

SUMMARY: The Health Resources and Services Administration is amending a notice that appeared in the **Federal Register** of August 22, 2005 (70 FR 48962–48963) announcing an Advisory Commission on Childhood Vaccines meeting on September 14, 2005. The document announced that the public can join the meeting by attending in person or by audio conference call. The meeting will now be held by audio conference call only. This document amends the notice by changing the place of the meeting.

FOR FURTHER INFORMATION CONTACT: Ms. Cheryl Lee at 301–443–2124 or e-mail *clee@hrsa.gov*.

SUPPLEMENTARY INFORMATION: In FR Doc. 05–16502, beginning on page 48962 in the **Federal Register** of Monday, August 22, 2005, make the following amendment on page 48963 in the third paragraph: Change place of meeting to Audio Conference Call.

Dated: August 25, 2005.

Tina M. Cheatham,

Director, Division of Policy Review and Coordination.

[FR Doc. 05–17379 Filed 8–31–05; 8:45 am]

BILLING CODE 4165–15–P