have a significant economic impact on a substantial number of small entities. Therefore, we are not preparing an analysis for the RFA.

In addition, section 1102(b) of the Social Security Act (the Act) requires us to prepare a regulatory impact analysis if a rule may have a significant impact on the operations of a substantial number of small rural hospitals. This analysis must conform to the provisions of section 604 of the RFA. For purposes of section 1102(b) of the Act, we define a small rural hospital as a hospital that is located outside of a Metropolitan Statistical Area and has fewer than 100 beds. We have determined that this notice will not have a significant effect on the operations of a substantial number of small rural hospitals. Therefore, we are not preparing an analysis for section 1102(b) of the Act.

Section 202 of the Unfunded Mandates Reform Act of 1995 also requires that agencies assess anticipated costs and benefits before issuing any rule that may result in expenditures in any 1 year by State, local, or tribal governments, in the aggregate, or by the private sector, of $110 million. This notice has no consequential effect on State, local, or tribal governments or on the private sector.

Executive Order 13132 establishes certain requirements that an agency must meet when it publishes a rule that imposes substantial direct requirement costs on State and local governments, preempts State law, or otherwise has Federalism implications. This notice will not have a substantial effect on State or local governments. There are no other alternatives at this time.

In accordance with the provisions of Executive Order 12866, this notice was reviewed by the Office of Management and Budget.

Authority: Sections 1102 and 1871 of the Social Security Act (42 U.S.C. 1302 and 1395hh).

(Catalog of Federal Domestic Assistance Program No. 93.774, Medicare—Supplementary Medical Insurance Program)

Dated: May 17, 2005.

Mark B. McClellan,

Administrator, Centers for Medicare & Medicaid Services.

Approved: August 25, 2005.

Michael O. Leavitt,

Secretary.

[FR Doc. 05–17278 Filed 8–26–05; 9:46 am]

BILLING CODE 4120–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Administration for Children and Families

Family and Youth Services Bureau; Positive Youth Development State and Local Collaboration Demonstration Projects

AGENCY: Family and Youth Services Bureau, Administration for Children and Families (ACF), Department of Health and Human Services (HHS).

ACTION: Award announcement.

CFDA#: The Catalog of Federal Domestic Assistance (CFDA) number for this program is 93.623. The title is the Positive Youth Development State and Local Collaboration Demonstration Projects.

Legislative Authority: Grants for Runaway and Homeless Youth programs are authorized by the Runaway and Homeless Youth Act (title III of the Juvenile Justice and Delinquency Prevention Act of 1974), as amended by the Missing, Exploited, and Runaway Children Protection Act of 1999, (Pub. L. 106–71).

Amount of Award: $100,000 per grantee.

Project Period: 9/30/04–9/29/05.

SUMMARY: Notice is hereby given that a noncompetitive grant supplement is being made to the following state agencies: State of Nebraska Health & Human Services, University of Kentucky Research Foundation, State of Oregon, New York Office of Children & Family Services, State of Louisiana, Iowa Dept. of Human Rights Criminal & Juvenile Justice, Commonwealth of Massachusetts, Illinois Department of Human Services, Governor's Office for Children Youth & Families. The purpose of this supplement is to support collaborations between state-level agencies and local community jurisdictions regarding positive development opportunities available to young people as approved in their original planning grant.

FOR FURTHER INFORMATION CONTACT: Administration for Children and Families, Family and Youth Services Bureau, 330 C Street, SW., Washington, DC 20447, Courtney Workman—(202) 205–8657, *cworkman@acf.hhs.gov*.

Dated: August 22, 2005.

Joan E. Ohl,

Commissioner, Administration on Children, Youth and Families.

[FR Doc. 05–17371 Filed 8–31–05; 8:45 am]

BILLING CODE 4184–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. 2005N–0343]

Agency Emergency Processing Under Office of Management and Budget Review; Guidance for Requesting an Extension to Use Existing Label Stock After the Trans Fat Labeling Effective Date of January 1, 2006

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is announcing that a proposed collection of information has been submitted to the Office of Management and Budget (OMB) for emergency processing under the Paperwork Reduction Act of 1995 (the PRA). FDA is preparing a guidance document to notify the public of procedures being implemented by the agency to assist firms that wish to request, on a case-by-case basis upon an appropriate showing, an extension to use existing label stock after the effective date of the *trans* fat labeling final rule. This notice solicits comments on the proposed collection of information associated with the guidance document entitled ''Guidance for Requesting an Extension to Use Existing Label Stock After the *Trans* Fat Labeling Effective Date of January 1, 2006.''

DATES: Fax written comments on the collection of information by October 3, 2005. FDA is requesting approval of this emergency processing by September 8, 2005.

ADDRESSES: OMB is still experiencing significant delays in the regular mail, including first class and express mail, and messenger deliveries are not being accepted. To ensure that comments on the information collection are received, OMB recommends that comments be faxed to the Office of Information and Regulatory Affairs, OMB, Attn: Fumie Yokota, Desk Officer for FDA, FAX: 202–395–6974.

FOR FURTHER INFORMATION CONTACT: Peggy Robbins, Office of Management Programs (HFA–250), Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857, 301–827–1223.

SUPPLEMENTARY INFORMATION: FDA has requested emergency processing of this proposed collection of information under section 3507(j) of the PRA (44 U.S.C. 3507(j)) and 5 CFR 1320.13. FDA issued a final rule (the *trans* fat final rule) on July 11, 2003 (68 FR 41434) to

require food labels to bear the gram amount of trans fat without a percent Daily Value (% DV) directly under the saturated fat line on the Nutrition Facts panel (*http://www.cfsan.fda.gov/~acrobat/fr03711a.pdf*). The *trans* fat final rule amended paragraph (c)(2) of § 101.9 *Nutrition Labeling of Food* (21 CFR 101.9). The effective date for the *trans* fat final rule is January 1, 2006. However, FDA has been advised by some businesses that they may experience hardship in revising their labels in time to meet the compliance date for *trans* fat labeling. Therefore, the agency believes that it would be appropriate to consider, on a case-by-case basis upon an appropriate showing, whether to exercise enforcement discretion with respect to the January 1, 2006, effective date for *trans* fat labeling for some businesses, so that these businesses would have the option of using some or all of their existing label stock that does not comply with the *trans* fat final rule.

FDA intends to notify the public, in a level 1 guidance document issued under the good guidance practices regulation (21 CFR 10.115), of the factors it intends to consider in granting or denying such requests and the process businesses may use to request the agency's consideration for enforcement discretion on *trans* fat labeling requirements. At a later date, FDA will announce the availability of a guidance entitled ''Guidance for Requesting an Extension to Use Existing Label Stock After the *Trans* Fat Labeling Effective Date of January 1, 2006.'' The guidance will provide voluntary recommendations on the process for firms that wish to request an extension to use existing label stock after the effective date of the *trans* fat final rule.

Because this guidance involves a collection of information, the PRA is implicated. However, the delay associated with normal PRA clearance procedures can reasonably be anticipated to prevent or disrupt the collection of information during a time period within which businesses would be most likely to make the request for the use of existing label stock before the effective date of January 1, 2006. As a result, given the need for immediate action, FDA requests emergency processing of this collection of information request.

With respect to the following proposed collection of information, FDA invites comments on the following topics: (1) Whether the proposed collection of information is necessary for the proper performance of FDA's functions, including whether the information will have practical utility; (2) the accuracy of FDA's estimate of the burden of the proposed collection of information, including the validity of the methodology and assumptions used; (3) ways to enhance the quality, utility, and clarity of the information to be collected; and (4) ways to minimize the burden of the collection of information on respondents, including through the use of automated collection techniques, when appropriate, and other forms of information technology.

Title: Guidance for Requesting an Extension to Use Existing Label Stock After the *Trans* Fat Labeling Effective Date of January 1, 2006.

Description: This policy provides guidance to FDA and the food industry about when and how businesses may request that the agency consider enforcement discretion for the use of some or all existing label stock, that does not declare *trans* fat labeling in compliance with the *trans* fat final rule, on products introduced into interstate commerce on or after the January 1, 2006, effective date.

Industry Compliance With the *Trans* Fat Final Rule

The *trans* fat final rule affects almost all manufacturers of packaged, labeled food sold in the United States. FDA believes that most businesses, including small businesses, should not have difficulty meeting the January 1, 2006, effective date of the *trans* fat final rule. However, under certain circumstances some businesses may want to request that the agency consider an extension of time to use current labels that are not in compliance with the *trans* fat final rule. Therefore, the agency believes that it would be appropriate to consider, on a case-by-case basis, whether to exercise enforcement discretion on the January 1, 2006, effective date for *trans* fat labeling for some businesses that can make an appropriate showing.

The agency intends to consider the following factors in any request from a firm for the agency's exercise of enforcement discretion:

- Whether products contain 0.5 gram or less *trans* fat;
- The explanation of why the request is being made;
- The number of existing labels that the firm is requesting to use;
- The dollar amount associated with the number of existing labels to be used; and
- The estimate of the amount of time needed, not exceeding 12 months, to exhaust the number of existing labels the firm is requesting to use.

Requests may be considered at any time before or after the January 1, 2006, effective date of the *trans* fat final rule. Firms may submit their requests in writing to FDA's Center for Food Safety and Applied Nutrition. Firms are encouraged to keep this letter of request for their records and should make a copy available for inspection to any officer or employee of the FDA who requests it. FDA intends to use the information in the letter to make decisions about whether a firm's product is subject to FDA's enforcement discretion for the *trans* fat labeling requirements.

FDA estimates the burden of the collection of information as follows:

TABLE 1.—ESTIMATED ANNUAL REPORTING BURDEN[1]

Activity	No. of Respondents	Annual Frequency per Response	Total Annual Responses	Hours per Response	Total Hours
Written requests to FDA in year one	56	1	56	5	280
Written requests to FDA in year two	28	1	28	5	140
Onetime burden hours for years one and two					420

[1] There are no capital costs or operating and maintenance costs associated with this collection of information.

FDA estimates a 2-year time period during which these requests will be made following the issuance of this guidance. Beyond 2 years, FDA expects businesses to fully comply with the *trans* fat final rule, as it is unlikely that there will still be old labeling stock left to use.

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