Testing Communications on Medical Devices and Radiation-Emitting Products—(OMB Control Number 0910–New)

FDA is authorized by section 1003(d)(2)(D) of the Federal Food, Drug, and Cosmetic Act (the act) (21 U.S.C. 393(d)(2)(D)) to conduct educational and public information programs relating to the safety of regulated medical devices and radiation-emitting products. FDA must conduct needed research to ensure that such programs have the highest likelihood of being effective. Improving communications about medical devices and radiation-emitting products will involve many research methods, including individual indepth interviews, mall-intercept interviews, focus groups, self-administered surveys, gatekeeper reviews, and omnibus telephone surveys.

The information collected will serve three major purposes. First, as formative research it will provide critical knowledge needed about target audiences to develop messages and campaigns about medical device and radiation-emitting product use. Knowledge of consumer and health care professional decisionmaking processes will provide the better understanding of target audiences that FDA needs to design effective communication strategies, messages, and labels. These communications will aim to improve public understanding of the risks and benefits of using medical devices and radiation-emitting products by providing users with a better context in which to place risk information more completely.

FDA is requesting this collection of information based on prior recent experience with the various types of data collection methods described earlier. FDA is requesting this burden so as not to restrict the agency’s ability to gather information on public sentiment for its proposals in its regulatory and communications programs.


Leslie Kux,
Acting Assistant Commissioner for Policy.

TABLE 1.—ESTIMATED ANNUAL REPORTING BURDEN

<table>
<thead>
<tr>
<th>Section of the act</th>
<th>No. of Respondents</th>
<th>Annual Frequency per Response</th>
<th>Total Annual Responses</th>
<th>Hours per Response</th>
<th>Total Hours</th>
<th>Total Operating &amp; Maintenance Costs¹</th>
</tr>
</thead>
<tbody>
<tr>
<td>1003(d)(2)(D)</td>
<td>16,448</td>
<td>1</td>
<td>16,448</td>
<td>0.1739</td>
<td>2,860</td>
<td>$25,239</td>
</tr>
<tr>
<td>Total</td>
<td>16,448</td>
<td>1</td>
<td>16,448</td>
<td>0.1739</td>
<td>2,860</td>
<td>$25,239</td>
</tr>
</tbody>
</table>

¹ There are no capital costs associated with this collection of information.

Annually, FDA projects about 30 studies using a variety of research methods, and lasting an average of 0.17 hours each (varying from 0.08–1.5 hours). The operating and maintenance costs include contractor expenses for designing and conducting information collection activities, specifically, drawing samples, training interviewers, collecting and analyzing information, and reporting and disseminating findings. FDA estimates the burden of this collection of information based on prior recent experience with the various types of data collection methods described earlier. FDA is requesting this burden so as not to restrict the agency’s ability to gather information on public sentiment for its proposals in its regulatory and communications programs.

DEPARTMENT OF HEALTH AND HUMAN SERVICES
Administration for Children and Families
Modification to the Basic Center Program Funding Opportunity Announcement

Program Office: Administration on Children, Youth, & Families—Family & Youth Services Bureau.
Funding Opportunity Title: Basic Center Program.
Announcement Type: Modification.
CFDA Number: 93.623.
Due Date for Applications: 07/19/2010.

This is a Modification to the Basic Center Program Funding Opportunity Announcement (FOA), HHS–2010–ACF–ACYF–CY–0002, published to the ACF Grant Opportunities webpage on June 2, 2010, http://www.acf.hhs.gov/grants/open/foa/view/HHS-2010-ACF-ACYF-CY-0002. A modified FOA that incorporates the following changes was published to the ACF Grant Opportunities webpage on June 25, 2010. The application procedures are hereby modified.

Second, as initial testing, it will allow FDA to assess the potential effectiveness of messages and materials in reaching and successfully communicating with their intended audiences. Testing messages with a sample of the target audience will allow FDA to refine messages while still in the developmental stage. Respondents will be asked to give their reaction to the messages in either individual or group settings.

Third, as evaluative research, it will allow FDA to ascertain the effectiveness of the messages and the distribution method of these messages in achieving the objectives of the message campaign. Evaluation of campaigns is a vital link in continuous improvement of communications at FDA.

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

SUMMARY: The Family and Youth Services Bureau (FYSB) is accepting applications for the Basic Center Program (BCP), which is authorized by the Runaway and Homeless Youth Act to address Runaway and Homeless Youth (RHY) problems. BCPs provide an alternative for runaway and homeless youth who might otherwise end up with law enforcement or in the child welfare, mental health, or juvenile justice systems. Each BCP must provide runaway and homeless youth with a safe and appropriate shelter; individual, family, and group counseling, as appropriate; and aftercare.

The purpose of the modification is to correct information appearing in Section IV.2 Content and Form of Application Submission regarding application formatting and point deduction for noncompliance with FOA instructions.

Modification to the Published Announcement

Please delete the following under Section IV.2. Content and Form of Application Submission:

“Applicants that do not adhere to the prescribed format will have points deducted from the overall total after the grant review:
Program narrative (which includes Objective and Need for Assistance, Results and Benefits, Approach, Organizational Profile, Staff and Position Data, and Budget
FOR FURTHER INFORMATION CONTACT: Katherine Serrano, Center for Devices and Radiological Health, Food and Drug Administration 10903 New Hampshire Ave., Bldg. 66., rm 5613, Silver Spring, MD 20993–0002, 301–796–6652, e-mail: katherine.serrano@fda.hhs.gov.

SUPPLEMENTARY INFORMATION:

I. Background

In the Federal Register of June 17, 2010 (75 FR 34463), FDA published a notice announcing a public meeting that is intended to create a forum for interested stakeholders to discuss the agency’s oversight of laboratory developed tests. FDA announced in the notice that it is seeking input and requesting comments on this topic. The June 17, 2010, notice invited individuals interested in presenting to register by July 12, 2010. Registration to present at the public meeting is closed. All others are welcome to attend on a first-come, first-served basis.

Because of greater than anticipated response for attending the public meeting, FDA is announcing in this notice a new location for the public meeting.

II. New Location for the Public Workshop

The new location will be The Marriott Inn & Conference Center, University of Maryland University College (see ADDRESSES). Directions and information on parking, accommodations, and transportation options can be found at: http://www.marriott.com/travel/wasum-the-marriott-inn-and-conference-center-university-ofmaryland-university-college/.


Nancy Slade, Acting Associate Director for Regulations and Policy, Center for Devices and Radiological Health.

BILLING CODE 4182–04–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2010–N–0274]

Oversight of Laboratory Developed Tests; Public Meeting; Change of Meeting Location

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is announcing a change in location for the upcoming public meeting entitled “Oversight of Laboratory Developed Tests.” A new address is given for those attending the public meeting.

DATES: The public meeting will be held on July 19 and 20, 2010, from 8 a.m. to 5 p.m. each day.

ADDRESSES: The public meeting will be held at The Marriott Inn & Conference Center, University of Maryland University College, 3501 University Blvd. E, Hyattsville, MD 20783.