DEPARTMENT OF HEALTH AND HUMAN SERVICES

Administration for Children and Families

Submission for OMB Review; Comment Request

Title: Performance Measurement On-Line Tool (PMOTOOL).

OMB No.: New Collection.

Description: The Performance Measurement On-Line Tool (PMOTOOL) was designed by the Children's Bureau to collect data, in an automated format, from specified discretionary grants funded by the Children's Bureau. The data collected by this instrument will be submitted by individual discretionary grantees funded under the following programs: Abandoned Infants Assistance Program, Infant Adoption Awareness Program, Adoption Opportunities Program, Child Abuse and Neglect Program and the Child Welfare Training Program. Grantees will submit this information on semi-annual basis in conjunction with their semi-annual program progress report.

The purpose of this data collection is to assist the Children's Bureau in responding to the government wide performance effort to collect aggregate data over time to assess program progress on discretionary funded programs. The Performance Measurement ON–Line Tool (PMOTOOL) will focus on quantifiable outcome measures that are directly related to the expected social impact or public benefit of each federal program. These measurable outcomes will serve as evidence that the federally funded programs are making progress toward achieving broad, legislated program goals.

Respondents: Selected clusters of competitive grant program funded by the Children's Bureau.

Annual Burden Estimated:

Instrument	Number of respondents	Number of responses per respondent	Average burden hours per response	Total burden hours
Performance Measurement On-Line Tool.	Abandoned Infants Assistance Program Estimate 20.	2 per fiscal year	One hour per response field ..	Estimate 40.
Performance Measurement On-Line Tool.	Infant Adoption Awareness Program Estimate 6.	2 per fiscal year	One hour per response field ..	Estimate 12.
Performance Measurement On-Line Tool.	Adoption Opportunities Program Estimate 45.	2 per fiscal year	One hour per response field ..	Estimate 90.
Performance Measurement On-Line Tool.	Child Abuse and Neglect Program Estimate 30.	2 per fiscal year	One hour per response field ..	Estimate 60.
Performance Measurement On-Line Tool.	Child Welfare Training Program Estimate 40.	2 per fiscal year	One hour per response field ..	Estimate 80.

Estimated Total Annual Burden Hours: 282.

Additional Information: Copies of the proposed collection may be obtained by writing to the Administration for Children and Families, Office of Administration, Office of Information Services, 370 L'Enfant Promenade SW., Washington, DC 20447, Attn: ACF Reports Clearance Officer. All requests should be identified by the title of the information collection. Email address: *infocollection@acf.hhs.gov.*

OMB Comment: OMB is required to make a decision concerning the collections of information between 30 and 60 days after publication of this document in the **Federal Register**. Therefore, a comment is best assured of having its full effect if OMB receives it within 30 days of publication. Written comments should be sent directly to the following: Office of Management and Budget, Paperwork Reduction Project, Fax: 202–395–6974, Attn: Desk Officer for the Administration for Children and Families.

Robert Sargis,

Reports Clearance Officer.

[FR Doc. 2012–12704 Filed 5–24–12; 8:45 am]

BILLING CODE 4184–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2012–D–0429]

Guidance on Meetings With Industry and Investigators on the Research and Development of Tobacco Products; Availability

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is announcing the availability of a guidance for industry entitled ''Meetings with Industry and Investigators on the Research and Development of Tobacco Products.'' This guidance describes FDA's current policies and recommendations with respect to Agency meetings with tobacco manufacturers, importers, researchers, and/or investigators relating to their plans to conduct research to inform the regulation of tobacco products, or support the development or marketing of tobacco products. The guidance is intended to assist persons seeking a meeting with FDA to discuss the research and development of tobacco products. This guidance does not pertain to other types of meetings or meeting requests with Center for Tobacco Products (CTP) staff.

DATES: Submit either electronic or written comments on this guidance at any time. Submit comments on information collection issues under the Paperwork Reduction Act of 1995 (the PRA) by July 24, 2012 (see section III. Paperwork Reduction Act of 1995 in this document).

ADDRESSES: Submit written requests for single copies of the guidance entitled ''Meetings with Industry and Investigators on the Research and Development of Tobacco Products'' to the Center for Tobacco Products, Food and Drug Administration, 9200 Corporate Blvd., Rockville, MD 20850–3229. Send one self-addressed adhesive label to assist that office in processing your request or include a fax number to which the guidance document may be sent. See the **SUPPLEMENTARY INFORMATION** section for electronic access to the guidance document.

Submit electronic comments on the guidance to *http://www.regulations.gov.* Submit written comments, including comments on the proposed collection of information, to the Division of Dockets Management (HFA–305), Food and Drug Administration, 5630 Fishers Lane, rm. 1061, Rockville, MD 20852.

FOR FURTHER INFORMATION CONTACT: With regard to the guidance: Gerie Voss, Center for Tobacco Products, 9200 Corporate Blvd., Rockville, MD 20850,

1–877–287–1373, *gerie.voss@fda.hhs.gov.*

With regard to the proposed collection of information: Daniel Gittleson, Office of Information Management, Food and Drug Administration, 1350 Piccard Dr., PI50–400B, Rockville, MD 20850, 301–796–5156, *daniel.gittleson@fda.hhs.gov.*

SUPPLEMENTARY INFORMATION:

I. Background

FDA is announcing the availability of a guidance for industry entitled ''Meetings with Industry and Investigators on the Research and Development of Tobacco Products.'' This guidance is intended to assist tobacco manufacturers, importers, researchers, and investigators, and their representatives who seek meetings with staff of FDA's CTP relating to their plans to conduct research to inform the regulation of tobacco products or support the development or marketing of tobacco products. This guidance does not pertain to other types of meetings or meeting requests with CTP staff.

The Family Smoking Prevention and Tobacco Control Act (Tobacco Control Act) (Pub. L. 111–31) offers tobacco product manufacturers several pathways to obtain an order from FDA to authorize the marketing of a tobacco product before it may be introduced or delivered into interstate commerce. To provide assistance with these pathways to market particular products, FDA will meet with tobacco product manufacturers, importers, researchers, and investigators (or their representatives) where appropriate.

This guidance is intended to assist persons who seek guidance relating to their research to inform the regulation of tobacco products, or to support the development or marketing of tobacco products. In the guidance, the Agency discusses, among other things:

- What information FDA recommends persons include in such a meeting request,
- How and when to submit such a request, and
- What information FDA recommends persons submit prior to such a meeting.

II. Significance of Guidance

FDA is issuing this guidance as a level 2 guidance consistent with FDA's good guidance practices regulations (21 CFR 10.115). The guidance represents the Agency's current thinking on ''Meetings with Industry and Investigators on the Research and Development of Tobacco Products.'' It does not create or confer any rights for or on any person and does not operate to bind FDA or the public. An alternative approach may be used if such approach satisfies the requirements of the applicable statute and regulations.

III. Paperwork Reduction Act of 1995

Under the PRA (44 U.S.C. 3501–3520), Federal Agencies must obtain approval from the Office of Management and Budget (OMB) for each collection of information that they conduct or sponsor. ''Collection of information'' is defined in 44 U.S.C. 3502(3) and 5 CFR 1320(c) and includes Agency requests or requirements that members of the public submit reports, keep records, or provide information to a third party. Section 3506(c)(2)(A) of the PRA (44 U.S.C. 3506(c)(2)(A)) requires Federal Agencies to provide a 60-day notice in the **Federal Register** concerning each proposed collection of information before submitting the collection to OMB for approval. To comply with this requirement, FDA is publishing this notice of the proposed collection of information set forth in this document.

With respect to the following collection of information, FDA invites comments on these 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 on 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.

Guidance for Industry: Meetings With Industry and Investigators on the Research and Development of Tobacco Products

This guidance is intended to assist persons seeking to have a meeting with FDA on the research and development of tobacco products. This guidance document discusses, among other things: What information FDA recommends that persons include in a meeting request, how and when to submit a request, and what information FDA recommends that persons submit prior to the meeting.

This guidance describes two collections of information: (1) The submission of a meeting request containing certain information and (2) the submission of an information package in advance of the meeting. The purpose of this proposed information collection is to allow FDA to conduct meetings with tobacco manufacturers, importers, researchers, and investigators in an effective and efficient manner.

A. Meeting Requests

Section IV.E of the guidance sets forth FDA's recommendations for materials to be included in a request for a meeting with FDA to discuss the research and development of tobacco products. Under the guidance, FDA recommends that the following information be included in the meeting request:

1. Product name and FDA-assigned Submission Tracking Number (if applicable);
2. Product category (e.g., cigarettes, smokeless tobacco, etc.) (if applicable);
3. Product use (indicate for consumer use or for further manufacturing);
4. Contact information for individual or company requesting the meeting;
5. The type of meeting being requested;
6. A brief statement of the purpose of the meeting, which could include a discussion of the types of studies or data to be discussed at the meeting, the general nature of the primary questions to be asked, and where the meeting fits in the overall product development plans;
7. A draft list of the specific objectives/outcomes expected from the meeting;
8. A preliminary proposed agenda, including estimated amounts of time needed for each agenda item and designated speaker(s);
9. A draft list of specific questions, grouped by discipline;
10. A list of all individuals (including titles and responsibilities) who will attend the meeting on behalf of the tobacco product manufacturer, importer, researcher, or investigator;
11. The approximate date on which supporting documentation (i.e., the meeting information package) likely will be received by FDA; and
12. Suggested dates and times for the meeting (note that generally a meeting will be scheduled for approximately 1 to 1.5 hours).

This information will be used by the Agency to: (1) Determine the utility of the meeting, (2) identify Agency staff necessary to discuss proposed agenda items, and (3) schedule the meeting.

B. Information Packages

An individual submitting a meeting information package to FDA in advance of a meeting should provide summary information relevant to the product and supplementary information pertaining to any issue raised by the individual or

FDA to be discussed at the meeting. As stated in section IV.K of the guidance, FDA recommends that meeting information packages generally include updated information from the meeting request (see items 1 through 8 in section III.A of this document) and:

1. Chemistry, manufacturing, and control data summary (as applicable);

2. Preclinical data summary (as applicable);

3. Clinical data summary (as applicable);

4. Behavioral and product use data summary (as applicable);

5. User and nonuser perception data summary (as applicable); and

6. Investigational plans for studies and surveillance of the tobacco product, including a summary of proposed study protocols containing the following information (as applicable):

a. Study objective(s),

b. Study hypotheses,

c. Study design,

d. Study population (inclusion/exclusion criteria, comparison group(s)),

e. Human subject protection information, including Institutional Review Board information,

f. Primary and secondary endpoints (definition and success criteria),

g. Sample size calculation,

h. Data collection procedures,

i. Duration of followup and baseline and followup assessments, and

j. Data analysis plan(s).

The purpose of the information package is to provide Agency staff the opportunity to adequately prepare for the meeting, including the review of relevant data concerning the product. In the Agency's experience, reviewing such information is critical to achieving a productive meeting. For the information that was previously submitted in the meeting request, the information package should provide updated information that reflects the most current and accurate information available.

C. Description of Respondents

The respondents to this collection of information are manufacturers, importers, researchers, and investigators of tobacco products who seek to meet with FDA to discuss their plans regarding the development or marketing of a tobacco product.

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

TABLE 1—ESTIMATED ANNUAL REPORTING BURDEN[1]

Meeting requests and information packages	Number of respondents	Number of responses per respondent	Total annual responses	Average burden per response (in hours)	Total hours
Meeting Requests					
Combining and sending meeting request letters for manufacturers, importers, and researchers	67	1	67	10	670
Meeting Information Packages					
Combining and submitting meeting information packages for manufacturers, importers, and researchers	67	1	67	18	1,206
Collection Totals					1,876

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

FDA's estimate of the number of respondents for meeting requests in table 1 of this document is based on the number of meeting requests to be received over the next 3 years. In the first year of this collection, FDA estimates that 50 preapplication meetings will be requested. In year 2, FDA estimates that 100 meetings will be requested, especially as applications and reports for substantial equivalence, etc., are received and acted upon. Once the public knows more about submitting these applications in year 3, the request for meetings is expected to drop back to the year 1 rate of 50 per year. Thus, FDA estimates the number of manufacturers, importers, researchers, and investigators who are expected to submit meeting request requests in table 1 of this document to be 67 (50 year 1 requests + 100 year 2 requests + 50 year 3 requests divided by 3). The hours per response, which is the estimated number of hours that a respondent would spend preparing the information recommended by this guidance to be submitted with a meeting request is estimated to be approximately 10 hours each, and the total burden hours are 670 hours (10 hours preparation/mailing times 67 average respondents per year). Based on FDA's experience, the Agency expects it will take respondents this amount of time to prepare, gather, copy, and submit brief statements about the product and a description of the purpose and details of the meeting.

FDA's estimate of the number of respondents for compiling meeting information packages in table 1 of this document is based on 67 respondents each preparing copies of their information package and submitting them to FDA, for a total of 1,206 hours annually. The hours per response, which is the estimated number of hours that a respondent would spend preparing the information package as recommended by the guidance, is estimated to be approximately 18 hours per information package. Based on FDA's experience, the Agency expects that it will take respondents 1,206 hours of time (67 respondents times 18 hours) to gather, copy, and submit brief statements about the product, a description of the details of the anticipated meeting, and data and information that generally would already have been generated for the planned research and/or product development.

The total number of burden hours for this collection of information is 1,876 hours (67 hours to prepare and submit meeting requests and 1,206 hours to prepare and submit information packages).

IV. Comments

Interested persons may submit to the Division of Dockets Management (see **ADDRESSES**) either electronic or written comments regarding this document. It is only necessary to send one set of 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.

V. Electronic Access

Persons with access to the Internet may obtain an electronic version of this guidance document at *http://www.regulations.gov* or *http://www.fda.gov/TobaccoProducts/GuidanceComplianceRegulatoryInformation/default.htm.*

Dated: May 17, 2012.

Leslie Kux,

Assistant Commissioner for Policy.

[FR Doc. 2012–12775 Filed 5–24–12; 8:45 am]

BILLING CODE 4160–01–P

DEPARTMENT OF HOMELAND SECURITY

Office of the Secretary

Public Workshop: Privacy Compliance Workshop

AGENCY: Privacy Office, DHS.

ACTION: Notice Announcing Public Workshop.

SUMMARY: The Department of Homeland Security Privacy Office will host a public workshop, ''Privacy Compliance Workshop.''

DATES: The workshop will be held on June 20, 2012, from 8:30 a.m. to 4:30 p.m.

ADDRESSES: The workshop will be held in the conference center at the Federal Trade Commission Building located at 601 New Jersey Avenue NW., Washington, DC 20001.

FOR FURTHER INFORMATION CONTACT: Rebecca Richards, Privacy Office, Department of Homeland Security, Washington, DC 20528; by telephone 703–235–0780; by facsimile 703–235–0442; or by email at *PIA@dhs.gov.*

SUPPLEMENTARY INFORMATION: The Department of Homeland Security (DHS) Privacy Office will conduct a free public workshop open to all federal employees and contractors to provide in-depth training on the privacy compliance process at DHS. The morning session will consist of overview presentations, including the privacy compliance fundamentals, privacy and data security, and the privacy compliance life cycle. A learning lunch will provide attendees with the opportunity to interact with compliance experts at DHS. The afternoon sessions will cover advanced presentations, including the Paperwork Reduction Act, the Freedom of Information Act, Privacy Compliance Reviews, and program case studies.

Registration and Security: In order to facilitate security requirements of the FTC facility, attendees must register in advance for this workshop. Registration closes at 5:00 p.m., Friday, June 15, 2012. To register, please send an email to *privacyworkshop@hq.dhs.gov,* with ''PRIVComplianceWorkshop'' in the subject line, and include your full name, email address and organizational affiliation in the body of the email. Alternatively, you may call 703–235–0780 to register and to provide the Privacy Office with your full name and organizational affiliation.

All attendees who are employed by a federal agency will be required to show their federal agency employee photo identification badge to enter the building. Attendees who do not possess a federal agency employee photo identification badge will need to show a form of government-issued photo identification, such as a driver's license, in order to verify their previously-provided registration information.

The Privacy Office will only use your name for the security purposes of this specific workshop and to contact you in the event of a change to the workshop.

Special Assistance: The workshop site is fully handicapped accessible, with both the training rooms and restrooms situated on the ground floor.

Mary Ellen Callahan,

Chief Privacy Officer, U.S. Department of Homeland Security.

[FR Doc. 2012–12829 Filed 5–24–12; 8:45 am]

BILLING CODE 9110–9L–P

DEPARTMENT OF HOMELAND SECURITY

Federal Emergency Management Agency

[Internal Agency Docket No. FEMA–4022–DR; Docket ID FEMA–2012–0002]

Vermont; Amendment No. 9 to Notice of a Major Disaster Declaration

AGENCY: Federal Emergency Management Agency, DHS.

ACTION: Notice.

SUMMARY: This notice amends the notice of a major disaster for the State of Vermont (FEMA–4022–DR), dated September 1, 2011, and related determinations.

DATES: *Effective Date:* May 16, 2012.

FOR FURTHER INFORMATION CONTACT: Peggy Miller, Office of Response and Recovery, Federal Emergency Management Agency, 500 C Street SW., Washington, DC 20472, (202) 646–3886.

SUPPLEMENTARY INFORMATION: Notice is hereby given that, in a letter dated May 16, 2012, the President amended the cost-sharing arrangements regarding Federal funds provided under the authority of the Robert T. Stafford Disaster Relief and Emergency Assistance Act, 42 U.S.C. 5121 *et seq.* (the ''Stafford Act''), in a letter to W. Craig Fugate, Administrator, Federal Emergency Management Agency, Department of Homeland Security, under Executive Order 12148, as follows:

I have determined that the damage in certain areas of the State of Vermont resulting from Tropical Storm Irene during the period of August 27 to September 2, 2011, is of sufficient severity and magnitude that special cost sharing arrangements are warranted regarding Federal funds provided under the Robert T. Stafford Disaster Relief and Emergency Assistance Act, 42 U.S.C. 5121 et seq. (the ''Stafford Act'').

Therefore, I amend my declaration of September 1, 2011, to authorize Federal funds for all categories of Public Assistance at 90 percent of total eligible costs.

This adjustment to State and local cost sharing applies only to Public Assistance costs and direct Federal assistance eligible for such adjustments under the law. The Robert T. Stafford Disaster Relief and Emergency Assistance Act specifically prohibits a similar adjustment for funds provided for Other Needs Assistance (Section 408), and the Hazard Mitigation Grant Program (Section 404). These funds will continue to be reimbursed at 75 percent of total eligible costs.

(The following Catalog of Federal Domestic Assistance Numbers (CFDA) are to be used for reporting and drawing funds: 97.030, Community Disaster Loans; 97.031, Cora Brown Fund; 97.032, Crisis Counseling; 97.033, Disaster Legal Services; 97.034, Disaster Unemployment Assistance (DUA); 97.046, Fire Management Assistance Grant; 97.048, Disaster Housing Assistance to Individuals and Households In Presidentially Declared Disaster Areas; 97.049, Presidentially Declared Disaster Assistance—Disaster Housing Operations for Individuals and Households; 97.050 Presidentially Declared Disaster Assistance to Individuals and Households—Other Needs; 97.036, Disaster Grants—Public Assistance (Presidentially Declared Disasters); 97.039, Hazard Mitigation Grant.)

W. Craig Fugate,

Administrator, Federal Emergency Management Agency.

[FR Doc. 2012–12713 Filed 5–24–12; 8:45 am]

BILLING CODE 9111–23–P