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.

Additional Criteria and Procedures for Classifying OTC Drugs as Generally Recognized as Safe and Effective and Not Misbranded—New

In the **Federal Register** of January 23, 2002 (67 FR 3060), we established regulations in § 330.14 (21 CFR 330.14) providing additional criteria and procedures for classifying OTC drugs as generally recognized as safe and effective and not misbranded (2002 TEA final rule). The regulations in § 330.14 state that OTC drug products introduced into the U.S. market after the OTC drug review began and OTC drug products without any marketing experience in the United States can be evaluated under the monograph process if the conditions (e.g., active ingredients) meet certain "time and extent" criteria outlined in § 330.14(b). The regulations allow a "time and extent" application (TEA) to be submitted to us by any party for our consideration to include new conditions in the OTC drug monograph system. TEAs must provide evidence described in § 330.14(c) demonstrating that the condition is eligible for inclusion in the monograph system. (Section 330.14(d) specifies the number of copies and address for submission of a TEA.) If a condition is found eligible, any interested parties can submit safety and effectiveness information as explained in § 330.14(f). Safety and effectiveness data include not only the data and information listed in 21 CFR 330.10(a)(2) (§ 330.14(f)(1)) but also a listing of all serious adverse drug experiences that may have occurred (§ 330.14(f)(2)) as well as an official or proposed compendial monograph (§ 330.14(i)).

In the 2002 TEA final rule, we estimated that 50 TEAs would be submitted to us annually by approximately 25 respondents (67 FR 3060 at 3073). We also estimated that the time required for preparing and submitting each TEA would be approximately 480 hours. We continue to believe that a respondent will spend approximately 480 hours preparing a TEA, but we no longer expect to receive 50 TEAs annually. Since 2003, we have received a total of 16 TEAs from 12 respondents. This is equivalent to 2.3 TEAs annually from 1.7 respondents. We now estimate that we will receive 2 TEAs annually from 2 respondents (see table 1 of this document).

We also estimated in the 2002 TEA final rule that we would receive three safety and effectiveness submissions for each condition found eligible for further consideration under a TEA (67 FR 3060 at 3072). We estimated that we would receive 90 submissions of safety and effectiveness data annually. And, we estimated that it would take approximately 800 hours to prepare and submit each safety and effectiveness submission. We believe that each submission, including serious adverse drug experiences and a compendial monograph, will take approximately 800 hours to complete (see table 1 of this document). However, we do not believe the estimated number of submissions is accurate. During the 8 years that have elapsed since publication of the 2002 TEA final rule, we have found 14 ingredients eligible under the TEA process and have received 16 submissions of safety and effectiveness data from 9 respondents. Therefore, we now estimate that we will receive two submissions of safety and effectiveness data annually from two respondents.

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

TABLE 1—ESTIMATED ANNUAL REPORTING BURDEN

21 CFR Section	Number of respondents	Annual frequency per response	Total annual responses	Hours per response	Total hours
330.14(c) and (d)[1]	2	1	2	480	960
330.14(f) and (i)[2]	2	1	2	800	1,600
Total					2,560

[1] TEA.
[2] Safety and effectiveness submission, including adverse events and compendial monograph.

Dated: October 3, 2010.

Leslie Kux,

Acting Assistant Commissioner for Policy.

[FR Doc. 2010–25375 Filed 10–7–10; 8:45 am]

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Administration for Children and Families

[OMB No. 0970–0171]

Proposed Information Collection Activity; Comment Request

Proposed Projects

Title: Required Data Elements for Voluntary Establishment of Paternity Affidavits.

Description: Section 466(a)(5)(C)(iv) of the Social Security Act (the Act) requires States to develop and use an affidavit for the voluntary acknowledgement of paternity. The affidavit for the voluntary acknowledgement of paternity must include the minimum requirements specified by the Secretary under section 452(a)(7) of the Act. The affidavits will be used by hospitals, birth record agencies, and other entities participating in the voluntary paternity establishment program, that collect information from parents of children that are born out of wedlock.

Respondents: Parents of children that are born out of wedlock provide the required information to State and Tribal IV–D agencies, hospitals, birth record agencies and other entities participating

in the voluntary paternity establishment program.

ANNUAL BURDEN ESTIMATES

Instrument	Number of respondents	Number of responses per respondent	Average burden hours per response	Total burden hours
None	1,167,097	1	.166	193,738

Estimated Total Annual Burden Hours: 193,738.

In compliance with the requirements of Section 3506(c)(2)(A) of the Paperwork Reduction Act of 1995, the Administration for Children and Families is soliciting public comment on the specific aspects of the information collection described above. Copies of the proposed collection of information can be obtained and comments may be forwarded 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. *E-mail address: infocollection@acf.hhs.gov.* All requests should be identified by the title of the information collection.

The Department specifically requests comments on: (a) Whether the proposed collection of information is necessary for the proper performance of the functions of the agency, including whether the information shall have practical utility; (b) the accuracy of the agency's estimate of the burden of the proposed collection of information; (c) the quality, utility, and clarity of the information to be collected; and (d) ways to minimize the burden of the collection of information on respondents, including through the use of automated collection techniques or other forms of information technology. Consideration will be given to comments and suggestions submitted within 60 days of this publication.

Dated: September 29, 2010.

Robert Sargis,

Reports Clearance Officer.

[FR Doc. 2010–25023 Filed 10–7–10; 8:45 am]

BILLING CODE 4184–01–M

DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

Plan To Develop a Genetic Testing Registry at the National Institutes of Health; Public Meeting; Request for Comments

AGENCY: National Institutes of Health, HHS.

ACTION: Notice of public meeting; request for comments.

SUMMARY: The National Institutes of Health is announcing a public meeting to gather stakeholder perspectives on its plan to develop the Genetic Testing Registry. The meeting will provide a forum for interested stakeholders to provide comments on specific aspects of the plan.

Date and Time: The public meeting will be held November 2, 2010, from 9 a.m. to 12 p.m.

Location: The public meeting will be held at the Walter E. Johnson Convention Center, Room 147, 801 Mount Vernon Place, NW., Washington, DC 20001. For directions, please contact the Convention Center at 202–249–3000 or refer to the following Web site: *http://www.dcconvention.com/.*

Special accommodations: Anyone planning to attend the meeting who needs special assistance, such as sign language interpretation or other reasonable accommodations, is asked to contact Cathy Fomous (see Contacts section) by October 26, 2010.

Registration: If you wish to attend the public meeting, please register by October 27, 2010. Registration is free and on a first-come, first-served basis. Pre-registration can be completed online at *http://oba.od.nih.gov/gtr/gtr_meetings.html.* Persons without Internet access may call Ms. Nicole Numbers at 301–650–8660. Onsite registration will be based on space availability.

Requests for Oral Presentations: Interested persons who would like to make oral comments during the meeting will be given 5 minutes to do so if they submit their request by October 27, 2010, to Cathy Fomous. Send requests by e-mail to *cfomous@od.nih.gov*; by fax to 301–496–9839; or via postal service to Cathy Fomous, Ph.D., Office of Biotechnology Activities, National Institutes of Health, 6705 Rockledge Dr., Suite 750, Bethesda, MD 20892. The request should include the commenter's name, title, affiliation, address, e-mail address, and telephone number. All requests should indicate which questions outlined below in the section on Public Meeting Focus will be addressed. Depending on the number of individuals and organizations that submit requests to make oral remarks, the allotted time may be expanded or shortened to provide all interested parties an opportunity to present.

Written Comments: Interested persons who cannot attend the meeting may submit written comments on the questions outlined below. Comments should be submitted to Cathy Fomous via e-mail, fax, or postal service using the above contact information. The comment period for written comments closes on November 12, 2010.

Contacts: For questions about the meeting logistics, please contact Ms. Nicole Numbers at *numbers@palladianpartners.com* or 301–650–8660. For special accommodations or questions about the meeting agenda and public comments, please contact Cathy Fomous, Ph.D., NIH Office of Biotechnology Activities at *cfomous@od.nih.gov* or 301–496–9838.

SUPPLEMENTARY INFORMATION:

I. Background

Advances in the knowledge of genetic factors involved in health and disease have been accompanied by a rapid rise in the availability of genetic tests, including those tests that diagnose or assess the risk for disease, provide prognostic information, and guide the selection of drug therapies and dosing. Although more than 2,000 genetic tests are available, there is no public resource that provides centralized information about the availability and scientific basis of these tests.

On March 18, 2010, the National Institutes of Health (NIH) announced its intent to develop the Genetic Testing