

Request for Comments: Written comments and/or suggestions from the public and affected agencies are invited on one or more of the following points: (1) Whether the proposed collection of information is necessary for the proper performance of the function of the agency, including whether the information will have practical utility; (2) The accuracy of the agency'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 those who are to respond, including the use of appropriate automated, electronic, mechanical, or other technological collection techniques or other forms of information technology.

Direct Comments to OMB: Written comments and/or suggestions regarding the item(s) contained in this notice, especially regarding the estimated public burden and associated response time, should be directed to the: Office of Management and Budget, Office of Regulatory Affairs,

OIRA_submission@omb.eop.gov or by fax to 202-395-6974, *Attention:* Desk Officer for NIH. To request more information on the proposed project or to obtain a copy of the data collection plans and instruments, contact Dr. Cathrine Sasek, Coordinator, Science Education Program, Office of Science Policy and Communications, National Institute on Drug Abuse, 6001 Executive Blvd, Room 5237, Bethesda, MD 20892, or call non-toll-free number (301) 443-6071; fax (301) 443-6277; or by e-mail to *csasek@nida.nih.gov*.

Comments Due Date: Comments regarding this information collection are best assured of having their full effect if received within 30-days of the date of this publication.

Dated: September 22, 2010.

Mary Affeldt,

Executive Officer, (OM Director, NIDA).
[FR Doc. 2010-24400 Filed 9-28-10; 8:45 am]

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Administration for Children and Families

Proposed Information Collection Activity; Comment Request

Proposed Projects

Title: Required Data Elements for Paternity Establishment Affidavits.

OMB No.: 0970-0171.

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.

Respondents: 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

Estimated Total Annual Burden Hours: 0

In compliance with the requirements of Section 506(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 22, 2010.

Robert Sargis,

Reports Clearance Officer.
[FR Doc. 2010-24212 Filed 9-28-10; 8:45 am]

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA-2010-D-0482]

Draft Guidance for Industry and Investigators on Safety Reporting Requirements for Investigational New Drug Applications and Bioavailability/Bioequivalence Studies; Availability

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is announcing the availability of a draft guidance for industry and investigators entitled "Safety Reporting Requirements for INDs and BA/BE Studies." This draft guidance is intended to help sponsors and investigators comply with the new requirements in the final rule entitled "Investigational New Drug Safety Reporting Requirements for Human Drug and Biological Products and Safety

Reporting Requirements for Bioavailability and Bioequivalence Studies in Humans,” published elsewhere in this issue of the **Federal Register**.

DATES: Although you can comment on any guidance at any time (see 21 CFR 10.115(g)(5)), to ensure that the agency considers your comment on this draft guidance before it begins work on the final version of the guidance, submit either electronic or written comments on the draft guidance by December 28, 2010.

ADDRESSES: Submit written requests for single copies of the draft guidance to the Division of Drug Information, Center for Drug Evaluation and Research, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 51, rm. 2201, Silver Spring, MD 20993-0002; or the Office of Communication, Outreach, and Development (HFM-40), Center for Biologics Evaluation and Research, Food and Drug Administration, 1401 Rockville Pike, suite 200N, Rockville, MD 20852-1448. Send one self-addressed adhesive label to assist that office in processing your requests. See the **SUPPLEMENTARY INFORMATION** section for electronic access to the draft guidance document.

Submit written comments to the Division of Dockets Management (HFA-305), Food and Drug Administration, 5630 Fishers Lane, rm. 1061, Rockville, MD 20852. Submit electronic comments on the draft guidance to <http://www.regulations.gov>.

FOR FURTHER INFORMATION CONTACT:

Janet Norden, Center for Drug Evaluation and Research, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 51, rm. 6324, Silver Spring, MD 20993-0002, 301-796-2500; or Laura Rich, Center for Biologics Evaluation and Research, Food and Drug Administration, 1401 Rockville Pike, suite 200N, Rockville, MD 20852-1448, 301-827-6210.

SUPPLEMENTARY INFORMATION:

I. Background

FDA is announcing the availability of a draft guidance for industry and investigators entitled “Safety Reporting Requirements for INDs and BA/BE Studies.” This draft guidance is intended to help sponsors and investigators comply with the new requirements for investigational new drug applications (IND) safety reporting and safety reporting for bioavailability (BA) and bioequivalence (BE) studies.

In the **Federal Register** of March 14, 2003 (68 FR 12406), FDA published a proposed rule to revise its regulations governing pre- and postmarket safety

reporting for human drug and biological products. To make rulemaking more manageable, the Agency decided to issue revisions to the pre- and postmarket safety reporting regulations in two separate rulemakings. The final rule, entitled “Investigational New Drug Safety Reporting Requirements for Human Drug and Biological Products and Safety Reporting Requirements for Bioavailability and Bioequivalence Studies in Humans,” published elsewhere in this issue of the **Federal Register**, revises the premarket regulations. The revisions in the final rule will improve the utility and quality of safety reports, expedite and strengthen FDA’s ability to review critical safety information, improve safety monitoring of human drug and biological products, better protect human subjects enrolled in clinical trials, and harmonize safety reporting internationally. The new requirements revise the definitions used for IND safety reporting, make clear when to submit IND safety reports, and subject BA and BE studies to safety reporting requirements.

The draft guidance was developed to accompany the publication of the final rule. The draft guidance provides examples and explanations of the definitions used for IND safety reporting, makes recommendations for determining when and how to submit a safety report, and provides advice on other safety reporting issues that have generated questions from sponsors and investigators.

The draft guidance is being issued consistent with FDA’s good guidance practices regulation (21 CFR 10.115). The draft guidance, when finalized, will represent the Agency’s current thinking on safety reporting requirements for INDs and BA/BE studies. 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 statutes and regulations.

II. 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. It is no longer necessary to send two copies of mailed 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.

III. Paperwork Reduction Act of 1995

This draft guidance contains information collection provisions that are subject to review by the Office of Management and Budget (OMB) under the Paperwork Reduction Act of 1995 (44 U.S.C. 3501-3520). The collection(s) of information in the draft guidance are estimated in section “VII. Paperwork Reduction Act of 1995” of the final rule entitled, “Investigational New Drug Safety Reporting Requirements for Human Drug and Biological Products and Safety Reporting Requirements for Bioavailability and Bioequivalence Studies in Humans” published elsewhere in this issue of the **Federal Register**.

IV. Electronic Access

Persons with access to the Internet may obtain the document at either <http://www.fda.gov/Drugs/GuidanceComplianceRegulatoryInformation/Guidances/default.htm> or <http://www.regulations.gov>.

Dated: September 23, 2010.

Leslie Kux,

Acting Assistant Commissioner for Policy.

[FR Doc. 2010-24295 Filed 9-28-10; 8:45 am]

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

National Cancer Institute; Notice of Closed Meetings

Pursuant to section 10(d) of the Federal Advisory Committee Act, as amended (5 U.S.C. App.), notice is hereby given of the following meetings.

The meetings will be closed to the public in accordance with the provisions set forth in sections 552b(c)(4) and 552b(c)(6), Title 5 U.S.C., as amended. The grant applications and the discussions could disclose confidential trade secrets or commercial property such as patentable material, and personal information concerning individuals associated with the grant applications, the disclosure of which would constitute a clearly unwarranted invasion of personal privacy.

Name of Committee: National Cancer Institute Special Emphasis Panel; Basic and Translational Oncology P01.

Date: September 30–October 1, 2010.

Time: 8 a.m. to 5 p.m.

Agenda: To review and evaluate grant applications.

Place: Bethesda North Marriott Hotel & Conference Center, 5701 Marinelli Road, Bethesda, MD 20852.

Contact Person: Shakeel Ahmad, PhD, Scientific Review Officer, Research Programs