acetaminophen of the circumstances in which FDA intends to exercise enforcement discretion with regard to the liver warning required in the labeling.

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comment on any guidance at any time (see 21 CFR 10.115(g)(5)), to ensure that the Agency considers your comment on this draft guidance before it begins work on the final version of the guidance, submit either electronic or written comments on the draft guidance by September 4, 2012.

ADDRESSES: Submit written requests for single copies of the draft guidance to the Division of Drug Information, Center for Drug Evaluation and Research, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 51, rm. 2201,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. 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 See the **SUPPLEMENTARY INFORMATION** section for electronic access to the draft guidance document.

Submit electronic comments on the draft guidance to *http://www.regulations.gov.* Submit written comments to the Division of Dockets Management (HFA–305), Food and Drug Administration, 5630 Fishers Lane, Rm.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

FOR FURTHER INFORMATION CONTACT: Tina Walther, Center for Drug Evaluation and Research, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 51, rm. 5108, Silver Spring, MD 20993–0002, 301–796–5086.

SUPPLEMENTARY INFORMATION:

I. Background

FDA is announcing the availability of a draft guidance for industry entitled ''Organ-Specific Warnings: Internal Analgesic, Antipyretic, and Antirheumatic Drug Products for Over-the-Counter Human Use—Labeling for Products That Contain Acetaminophen.'' In the **Federal Register** of December 26, 2006 (71 FR 77314), FDA published a proposed rule on organ-specific warnings and related labeling for OTC IAAA drug products. In the **Federal Register** of April 29, 2009 (74 FR 19385), FDA published the final rule (2009 final rule). In the **Federal Register** of November 25, 2009 (74 FR 61512), FDA published a technical amendment to clarify several provisions in response to industry feedback. The 2009 final rule, as amended, changed some of the labeling requirements for OTC IAAA drug products to inform consumers about the risk of liver injury when using acetaminophen and the risk of stomach bleeding when using nonsteroidal anti-inflammatory drugs. It went into effect April 29, 2010.

The labeling for OTC IAAA products that contain acetaminophen and are labeled for adults only, must include the following liver warning:

> **Liver warning:** This product contains acetaminophen. Severe liver damage may occur if you take • more than [insert maximum number of daily dosage units] in 24 hours, which is the maximum daily amount [optional: ''For this product''] • with other drugs containing acetaminophen • 3 or more alcoholic drinks every day while using this product.

Although the currently proposed total daily dose of acetaminophen is 4,000 milligrams (mg), some OTC IAAA products that contain acetaminophen have directions for use that provide a maximum daily dose of acetaminophen for the product that is less than 4,000 mg. For example, for some OTC IAAA drug products that contain both acetaminophen and one or more other active ingredients, the maximum number of daily dosage units might be limited by an active ingredient other than acetaminophen, which could result in a maximum daily dose of acetaminophen that is less than 4,000 mg for that product. The optional statement, ''for this product,'' in the first bullet of the liver warning is intended to address these situations, by clarifying that the maximum number of daily dosage units for a product might not reflect the maximum daily dose of acetaminophen.

However, the Agency understands that in certain circumstances, despite this optional statement, the wording of the first bulleted warning might be interpreted as indicating that severe liver damage is associated with a total daily dose of acetaminophen that is less than 4,000 mg. This suggestion is not the intent of the requirement that the liver warning be included in the labeling. To address this potential confusion, the Agency intends to exercise enforcement discretion with respect to the liver warning required in the circumstances described in this draft guidance.

This 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 this topic. 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. 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. 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: June 21, 2012.

Leslie Kux,

Assistant Commissioner for Policy.

[FR Doc. 2012–16244 Filed 7–3–12; 8:45 am]

BILLING CODE 4160–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Health Resources and Services Administration

Agency Information Collection Activities: Proposed Collection: Comment Request

In compliance with the requirement for opportunity for public comment on proposed data collection projects (section 3506(c) (2) (A) of Title 44, United States Code, as amended by the Paperwork Reduction Act of 1995, Pub. L. 104–13), the Health Resources and Services Administration (HRSA) publishes periodic summaries of proposed projects being developed for submission to the Office of Management and Budget (OMB) under the Paperwork Reduction Act of 1995. To request more information on the proposed project or to obtain a copy of the data collection plans and draft instruments, email *paperwork@hrsa.gov* or call the HRSA Reports Clearance Officer at (301) 443–1984.

Comments are invited on: (a) The proposed collection of information for the proper performance of the functions of the Agency; (b) the accuracy of the Agency's estimate of the burden of the proposed collection of information; (c) ways to enhance 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.

Proposed Project: Health Center Controlled Networks (OMB No. 0915–xxxx)—[New]

One goal of the Health Resources and Services Administration (HRSA) is to ensure that all Health Center program grantees effectively implement health information technology (HIT) systems that enable all providers to become meaningful users of HIT, including Electronic Health Records (EHRs), and use those systems to increase access to care, improve quality of care, and reduce the costs of care delivered. The Health Center Controlled Network (HCCN) program serves as a major component of HRSA's HIT initiative to support these goals. The HCCN model focuses on the integration of certain functions and the sharing of skills, resources, and data to improve health center operations and care provision, and generating efficiencies and economies of scale. Through this grant, HCCNs will provide support for the adoption, implementation, and meaningful use of Health Information Technology (HIT) to improve the quality of care provided by existing Health Center Program grantees (i.e., Section 330 funded health centers) by engaging in the following program components:

• *Adoption and Implementation:* Assist participating health centers with effectively adopting and implementing certified EHR technology.

• *Meaningful Use:* Support participating health centers in meeting Meaningful Use requirements and accessing incentive payments under the Medicare and Medicaid Electronic Health Records Incentive Programs.

• *Quality Improvement:* Advance participating health centers' QI initiatives to improve clinical and operational quality, including Patient Centered Medical Home (PCMH) recognition.

HRSA plans to collect and evaluate network outcome measures. HRSA plans to require that HCCNs report such measures to HRSA in annual work plan updates as part of their annual, non-competing continuation progress reports through an electronic reporting system. The work plan updates will include information on grantees' plans and progress on the following:

• Adoption and Implementation of HIT (including EHR);

• Attainment of Meaningful Use Requirements; and

• Quality improvement measures (e.g., Healthy People 2020 clinical quality measures, PCMH recognition status, etc.).

The annual, non-competing continuation progress reports will describe each grantee's progress in achieving key activity goals such as quality improvement, data access and exchange, efficiency and effectiveness of network services, and the ability to track and monitor patient outcomes, as well as emerging needs, challenges and barriers encountered customer satisfaction, and plans to meet goals for the next year. Grantees will submit their work plan updates and annual, non-competing continuation progress report each fiscal year of the grant; the submission and subsequent HRSA approval of each report triggers the budget period renewal and release of each subsequent year of funding. The estimated total number of burden hours is 750.

The annual estimate of burden is as follows:

Instrument	Number of respondents	Responses per respondent	Total responses	Hours per response	Total burden hours
Work Plan Update	30	1	30	5	150
Annual Progress Report/Interim Evaluation Progress Report	30	1	30	20	600
Total	60				750

Email comments to *paperwork@hrsa.gov* or mail the HRSA Reports Clearance Officer, Room 10–29, Parklawn Building, 5600 Fishers Lane, Rockville, MD 20857. Written comments should be received within 60 days of this notice.

Dated: June 28, 2012.

Reva Harris,

Acting Director, Division of Policy and Information Coordination.

[FR Doc. 2012–16332 Filed 7–3–12; 8:45 am]

BILLING CODE 4165–15–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

Eunice Kennedy Shriver National Institute of Child Health & Human Development; Notice of Closed Meeting

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 meeting.

The meeting 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 contract proposal and the discussions could disclose confidential trade secrets or commercial property such as patentable material, and personal information concerning individuals associated with the contract proposal, the disclosure of which would constitute a clearly unwarranted invasion of personal privacy.

Name of Committee: National Institute of Child Health and Human Development Special Emphasis Panel; National Children's Study Vanguard 2.0.

Date: July 23, 2012.

Time: 8:00 a.m. to 5:00 p.m.

Agenda: To review and evaluate grant applications.

Place: Embassy Suites at the Chevy Chase Pavilion, 4300 Military Road NW., Washington, DC 20015.

Contact Person: Sathasiva B. Kandasamy, Ph.D., Scientific Review Officer, Division of Scientific Review, National Institute Of Child Health and Human Development, 6100 Executive Boulevard, Rockville, MD 20892–9304, (301) 435–6680, *skandasa@mail.nih.gov.*

This notice is being published less than 15 days prior to the meeting due to the timing limitations imposed by the review and funding cycle.

(Catalogue of Federal Domestic Assistance Program Nos. 93.864, Population Research; 93.865, Research for Mothers and Children; 93.929, Center for Medical Rehabilitation Research; 93.209, Contraception and Infertility Loan Repayment Program, National Institutes of Health, HHS)