routes, including inhalation, ingestion, and to a lesser degree absorption through the skin. Several observational human studies have reported an association between exposure to certain phthalates and adverse developmental and reproductive effects. The ubiquitous presence of phthalates in the environment and the potential consequences of human exposure to phthalates have raised concerns, particularly in vulnerable populations such as pregnant women and infants.

Although the currently available human data are limited, the Agency has determined that there is evidence that exposure to DBP and DEHP from pharmaceuticals presents a potential risk of developmental and reproductive toxicity. While it is recognized that drug products may carry inherent risks, DBP and DEHP are used as excipients, and safer alternatives are available. Therefore, the Agency recommends avoiding the use of DBP and DEHP as excipients in CDER-regulated drug and biologic products.

These recommendations apply to CDER-regulated drug and biologic products that are under development (i.e., investigational new drugs), nonapplication products (e.g., over the counter monograph products), and both marketed approved products and those currently under review for marketing consideration (i.e., new drug applications, abbreviated new drug applications, and biologics license applications).

There are alternatives to DBP and DEHP for use as excipients in CDER-regulated products. Manufacturers with products that contain DBP or DEHP should consider alternative excipients and determine if the alternative excipient they plan to use has been used in similar CDER-approved products and at what level.

The Inactive Ingredients Database provides information on excipients present in FDA-approved drug products, and this information can be helpful in developing drug products. As manufacturers reformulate their products, the listings for DBP and DEHP will be removed from the Inactive Ingredients Database.

This guidance is being issued consistent with FDA's good guidance practices regulation (21 CFR 10.115). The guidance represents the Agency's current thinking on limiting the use of certain phthalates as excipients in CDER-regulated 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 statutes and regulations.

II. Comments

Interested persons may submit either written comments regarding this document to the Division of Dockets Management (see **ADDRESSES**) or electronic comments to *http://www.regulations.gov.* 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, and will be posted to the docket at *http://www.regulations.gov.*

III. The Paperwork Reduction Act of 1995

This guidance refers to previously approved collections of information found in FDA regulations. These collections of information 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) and have been approved under OMB control numbers 0910–0014 and 0910–0001.

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: November 30, 2012.

Leslie Kux,

Assistant Commissioner for Policy.

[FR Doc. 2012–29461 Filed 12–5–12; 8:45 am]

BILLING CODE 4160–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Health Resources and Services Administration

Agency Information Collection Activities: Submission to OMB for Review and Approval; Public Comment Request

ACTION: Notice.

SUMMARY: In compliance with section 3506(c)(2)(A) of the Paperwork Reduction Act of 1995 (44 U.S.C. Chapter 35), the Health Resources and Services Administration (HRSA) will submit an Information Collection Request (ICR) to the Office of Management and Budget (OMB). Comments submitted during the first public review of this ICR will be provided to OMB. OMB will accept further comments from the public during the review and approval period. To request a copy of the clearance requests submitted to OMB for review, email *paperwork@hrsa.gov* or call the HRSA Reports Clearance Office at (301) 443–1984.

Information Collection Request Title: Health Center Controlled Networks (OMB No. 0915-xxxx) NEW

Abstract: 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 (EHR), 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 to generate efficiencies and economies of scale. Through this grant, HCCNs will provide support for the adoption, implementation, and meaningful use of 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 EHR Incentive Programs.
- *Quality Improvement (QI):* 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 also 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
• QI 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 1662.

Burden Statement: Burden in this context means the time expended by persons to generate, maintain, retain, disclose, or provide the information requested. This includes the time needed to review instructions; to develop, acquire, install and utilize technology and systems for the purpose of collecting, validating and verifying information, processing and maintaining information, and disclosing and providing information; to train personnel and to be able to respond to a collection of information; to search data sources; to complete and review the collection of information; and to transmit or otherwise disclose the information. The total annual burden hours estimated for this ICR are summarized in the table below.

The annual estimate of burden is as follows:

Form name	Number of respondents	Responses per respondent	Total responses	Hours per response	Total burden hours
Work Plan Update	30	1	30	10.9	327
Annual Progress Report/Interim Evaluation Progress Report	30	1	30	44.5	1,335
Total	30				1,662

ADDRESSES: Submit your comments to the desk officer for HRSA either by email to *OIRA_submission@omb.eop.gov* or by fax to 202–395–5806. Please direct all correspondence to the ''attention of the desk officer for HRSA.''

Deadline: Comments on this ICR should be received within 30 days of this notice.

Dated: November 29, 2012.

Bahar Niakan,

Director, Division of Policy and Information Coordination.

[FR Doc. 2012–29496 Filed 12–5–12; 8:45 am]

BILLING CODE 4165–15–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

Proposed Collection; Comment Request (60-Day FRN): The Agricultural Health Study: A Prospective Cohort Study of Cancer and Other Disease Among Men and Women in Agriculture (NCI)

Summary: In compliance with the requirement of Section 3506(c)(2)(A) of the Paperwork Reduction Act of 1995, for opportunity for public comment on proposed data collection projects, the National Institutes of Health (NIH) will publish periodic summaries of proposed projects to be submitted to the Office of Management and Budget (OMB) for review and approval.

Written comments and/or suggestions from the public and affected agencies are invited to address 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) The quality, utility, and clarity of the information to be collected; and (4) 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.

To submit comments in writing, request more information on the proposed project, or to obtain a copy of the data collection plans and instruments, contact: Jane Hoppin, Sc.D., Epidemiology Branch, National Institute of Environmental Health Sciences, NIH, 111 T.W. Alexander Drive, PO Box 12233, MD A3–05, Research Triangle Park, NC 27709, or call non-toll-free number 919–541–7622, or email your request, including your address to: *hoppin1@niehs.nih.gov*.

Comments regarding this information collection are best assured of having their full effect if received within 60 days of the date of this publication.

Proposed Collection: The Agricultural Health Study: A Prospective Cohort Study of Cancer and Other Disease Among Men and Women in Agriculture, 0925–0406, Expiration Date 5/31/2013—REVISION—National Institute of Environmental Health Sciences (NIEHS), National Institutes of Health (NIH).

Need and Use of Information Collection: The purpose of this information collection is to continue and complete updating the occupational and environmental exposure information as well as medical history information for licensed pesticide applicators and their spouses enrolled in the Agricultural Health Study. This represents a request to complete phase IV (2013–2015) of the study and to continue and complete the buccal cell collection and the Study of Biomarkers of Exposures and Effects in Agriculture (BEEA). The primary objectives of the study are to determine the health effects resulting from occupational and environmental exposures in the agricultural environment. The phase IV follow up data will be collected by using one of three methods of the cohort member's choosing: self-administered computer assisted web survey (CAWI); self-administered paper-and-pen (Paper/pen); or an interviewer administered computer assisted telephone interview (CATI). Proxy interviews for those cohort members unable to complete the follow up will be completed by using one of the three methods as well. Secondary objectives include evaluating