

Please Note: The contents of all submissions, regardless of format, will be available to the public upon request unless prohibited by law.

The draft of this review will be posted on AHRQ's EHC program Web site and available for public comment for a period of 4 weeks. If you would like to be notified when the draft is posted, please sign up for the email list at: <http://effectivehealthcare.AHRQ.gov/index.cfm/join-the-email-list1/>.

The Key Questions

Question 1

What is the comparative effectiveness of the various liver-directed therapies in patients with hepatocellular carcinoma (HCC) who are not otherwise candidates for surgical resection or transplantation with no evidence of extrahepatic disease regarding survival and quality of life?

Question 2

What are the comparative harms of the various liver-directed therapies in patients with HCC who are not otherwise candidates for surgical resection or transplantation with no evidence of extrahepatic disease regarding adverse events?

Question 3

Are there differences in comparative effectiveness of various liver-directed therapies in patients with HCC who are not otherwise candidates for surgical resection or transplantation for specific patient and tumor characteristics, such as age, gender, disease etiology, and Child-Pugh score?

Dated: April 19, 2012.

Carolyn M. Clancy,
AHRQ, Director.

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Centers for Disease Control and Prevention

[30Day-12-0010]

Agency Forms Undergoing Paperwork Reduction Act Review

The Centers for Disease Control and Prevention (CDC) publishes a list of information collection requests under review by the Office of Management and Budget (OMB) in compliance with the Paperwork Reduction Act (44 U.S.C. chapter 35). To request a copy of these requests, call (404) 639-7570 or send an email to omb@cdc.gov. Send written comments to CDC Desk Officer, Office of Management and Budget, Washington, DC or by fax to (202) 395-5806. Written comments should be received within 30 days of this notice.

Proposed Project

The National Birth Defects Prevention Study (NBDPS)—(0920-0010, Expiration 06/30/2012)—Extension—National Center on Birth Defects and Developmental Disabilities (NCBDDD), Centers for Disease Control and Prevention (CDC).

Background and Brief Description

CDC has been monitoring the occurrence of serious birth defects and genetic diseases in Atlanta since 1967 through the Metropolitan Atlanta Congenital Defects Program (MACDP). The MACDP is a population-based surveillance system for birth defects in the 5 counties of Metropolitan Atlanta. Its primary purpose is to describe the spatial and temporal patterns of birth defects occurrence and serves as an early warning system for new teratogens. In 1997, the Birth Defects Risk Factor Surveillance (BDRFS) study, a case-control study of risk factors for selected birth defects, became the National Birth Defects Prevention Study

(NBDPS). The major components of the study did not change.

The NBDPS is a case-control study of major birth defects that includes cases identified from existing birth defect surveillance registries in nine states, including metropolitan Atlanta. Control infants are randomly selected from birth certificates or birth hospital records. Mothers of case and control infants are interviewed using a computer-assisted telephone interview. The interview takes approximately one hour. A maximum of thirty-six hundred interviews are planned, 2,700 cases and 900 controls, resulting in a maximum interview burden of approximately 3,600 hours for all Centers.

Parents are also asked to collect cheek cells from themselves and their infants for DNA testing. The collection of cheek cells by the mother, father, and infant is estimated to take about 10 minutes per person. Each person will be asked to rub 1 brush inside the left cheek and 1 brush inside the right cheek for a total of 2 brushes per person. Collection of the cheek cells takes approximately 1-2 minutes, but the estimate of burden is 10 minutes to account for reading and understanding the consent form and specimen collection instructions and mailing back the completed kits. The anticipated maximum burden for collection of the cheek cells is 1,800 hours for all Centers.

Information gathered from both the interviews and the DNA specimens will be used to study independent genetic and environmental factors as well as gene-environment interactions for a broad range of carefully classified birth defects.

This request is submitted to obtain OMB clearance for three additional years.

There are no costs to the respondents other than their time. The total estimated annualized burden is 5,400 hours.

ESTIMATED ANNUALIZED BURDEN TABLE

Type of respondents	Form name	Number of respondents	Number of responses per respondent	Average burden per response (in hours)
Mothers	NBDPS mother questionnaire	3,600	1	1
Mothers, fathers, infants	Cheek Cell Specimen Collection	10,800	1	10/60

Kimberly S. Lane,

*Deputy Director, Office of Science Integrity,
Office of the Associate Director for Science,
Office of the Director, Centers for Disease
Control and Prevention.*

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA-2011-N-0902]

Agency Information Collection Activities; Submission for Office of Management and Budget Review; Comment Request; Prescription Drug Product Labeling; Medication Guide Requirements

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is announcing that a proposed collection of information has been submitted to the Office of Management and Budget (OMB) for review and clearance under the Paperwork Reduction Act of 1995 (the PRA).

DATES: Fax written comments on the collection of information by May 29, 2012.

ADDRESSES: To ensure that comments on the information collection are received, OMB recommends that written comments be faxed to the Office of Information and Regulatory Affairs, OMB, Attn: FDA Desk Officer, FAX: 202-395-7285, or emailed to oir_submission@omb.eop.gov. All comments should be identified with the OMB control number 0910-0393. Also include the FDA docket number found in brackets in the heading of this document.

FOR FURTHER INFORMATION CONTACT: Juanmanuel Vilela, Office of Information Management, Food and Drug Administration, 1350 Piccard Dr., PI50-400B, Rockville, MD 20850, 301-796-7651, juanmanuel.vilela@fda.hhs.gov.

SUPPLEMENTARY INFORMATION: In compliance with 44 U.S.C. 3507, FDA has submitted the following proposed collection of information to OMB for review and clearance.

Prescription Drug Product Labeling; Medication Guide Requirements (OMB Control Number 0910-0393)—Extension

FDA regulations require the distribution of patient labeling, called

Medication Guides, for certain prescription human drug and biological products used primarily on an outpatient basis that pose a serious and significant public health concern requiring distribution of FDA-approved patient medication information. These Medication Guides inform patients about the most important information they should know about these products in order to use them safely and effectively. Included is information such as the drug's approved uses, contraindications, adverse drug reactions, and cautions for specific populations, with a focus on why the particular product requires a Medication Guide. These regulations are intended to improve the public health by providing information necessary for patients to use certain medication safely and effectively.

The regulations contain the following reporting requirements that are subject to the PRA. The estimates for the burden hours imposed by the following regulations are listed in table 1 of this document:

- 21 CFR 208.20—Applicants must submit draft Medication Guides for FDA approval according to the prescribed content and format.
- 21 CFR 208.24(e)—Each authorized dispenser of a prescription drug product for which a Medication Guide is required, when dispensing the product to a patient or to a patient's agent, must provide a Medication Guide directly to each patient unless an exemption applies under 21 CFR 208.26.
- 21 CFR 208.26 (a)—Requests may be submitted for exemption or deferral from particular Medication Guide content or format requirements.
- 21 CFR 314.70(b)(3)(ii) and 21 CFR 601.12(f)—Application holders must submit changes to Medication Guides to FDA for prior approval as supplements to their applications.

In the **Federal Register** of December 21, 2011 (76 FR 79194), FDA published a 60-day notice requesting public comment on the proposed collection of information. FDA received the following comments:

(Comment 1) One comment states that FDA's hourly burden estimate of 3 minutes per Medication Guide for pharmacists to comply with the requirements is miscalculated, although more in line with current practices versus previous FDA estimates.

(Response) Because the comment did not indicate if the miscalculation was over- or under-estimated or provide alternative burden estimates for pharmacy time associated with distribution of a Medication Guide, we continue to use 3 minutes as the

estimated burden for pharmacists to distribute Medication Guides to patients.

(Comment 2) One comment said that there are distributor costs to comply with the Medication Guide requirements and FDA's estimate omits § 208.24(c), which provides that "Each distributor or packer that receives Medication Guides, or the means to produce Medication Guides, from a manufacturer under paragraph (b) of this section shall provide those Medication Guides, or the means to produce Medication Guides, to each authorized dispenser to whom it ships a container of drug product." The comment states that the December 21, 2011, notice of proposed information collection (76 FR 79194) does not include an estimate for the reporting requirements of § 208.24(c) and that the requirement should be included in FDA's assessment.

(Response) FDA has re-evaluated § 208.24(c) with regards to information collection burden on distributors and packers and determined that § 208.24(c) does not contain an additional collection of information subject to the reporting requirements of the PRA. A "collection of information" includes an Agency request or requirement that members of the public submit reports, keep records, or provide information to third parties or the public by or for an Agency. Therefore, the manufacturer is responsible for providing information to third parties (§ 208.24(a)), i.e., Medication Guides, and the distributor or packer distributes the Medication Guides with the shipment of drugs to the dispensers. Thus, § 208.24(c) is not subject to the reporting requirements of the PRA.

(Comment 3) One comment says that FDA should reassess the need to provide Medication Guides with each prescription refill and states there are situations where it is not necessary due to certain circumstances. The comment states that Medication Guides should be a tool to enhance the level of care to consumers, rather than a hindrance to pharmacists in their ability to provide quality patient care.

(Response) FDA agrees and directs the comment to the guidance made available to the public entitled "Medication Guides—Distribution Requirements and Inclusion in Risk Evaluation and Mitigation Strategies (REMS)." In this guidance, FDA articulates the circumstances under which FDA intends to exercise enforcement discretion regarding the requirement to provide Medication Guides in certain settings.