Dated: June 30, 2010.

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Centers for Disease Control and Prevention

[30Day–10–09AL]

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 the CDC Reports Clearance Officer at (404) 639–5960 or send an e-mail to *omb@cdc.gov.* Send written comments to CDC Desk Officer, Office of Management and Budget, Washington, DC 20503 or by fax to (202) 395–5806. Written comments should be received within 30 days of this notice.

Proposed Project

The Green Housing Study: Environmental health impacts on women and children in low-income multifamily housing—New—National Center for Environmental Health (NCEH) and Agency for Toxic Substances and Disease Registry (ATSDR)/Centers for Disease Control and Prevention (CDC).

Background and Brief Description

This study directly supports the Healthy Homes' health protection goal of the Centers for Disease Control and Prevention (CDC). This investigation is also consistent with CDC's Health Protection Research Agenda, which calls for research to identify the major environmental causes of disease and disability and related risk factors.

The efficacy of green building design features in reducing allergens and toxic substances within the home has been assumed based on conventional wisdom. A better understanding is needed of the extent to which green-built, low-income housing actually reduces exposures to these compounds when compared to standard-built, low-income housing. In addition, this study may provide insight into how specific green building practices (e.g., use of low chemical-emitting paints and carpets) may influence levels of substances in the home (such as volatile organic compounds (VOCs). A study investigating these topics would provide a solid foundation upon which to explore green affordable housing's potential to promote healthy homes principles.

The title of this study has changed since publication of the initial 60-day **Federal Register** Notice (FRN); however, the goals remain the same. These goals will be accomplished in ongoing building renovation programs sponsored by the Department of Housing and Urban Development (HUD). In partnership with HUD, the CDC will leverage opportunities to collect survey and biomarker data from residents and to collect environmental measurements in homes in order to evaluate associations between green housing and health.

Participants will include pregnant women and children living in HUD-subsidized housing that has either been rehabilitated in a green (*e.g.,* case) or a traditional manner (*e.g.,* control) from study sites across the United States. The following are eligible for the study: (1) 688 children (age 7–12 years with asthma); (2) 688 children (less than or equal to 6 years); (3) 688 pregnant women; and (4) 688 mothers of the children enrolled. Pregnant women and children with asthma (ages 7–12 years) will donate blood samples (for assessment of allergy) and urine samples (for assessment of pesticide and VOC exposures). The children with asthma (ages 7–12 years) will be also tested for lung function and lung inflammatory markers. The length of follow-up is one year. Questionnaires regarding home characteristics and respiratory symptoms will be administered at 6-month intervals. Environmental sampling of the air and dust in the participants' homes will be conducted over a 1-year period (once in the home before rehabilitation (baseline I), and then at three time points after rehabilitation has been completed: Baseline II, 6 months, and 12 months). Environmental sampling includes measurements of air exchange rate, pesticides, VOCs, indoor allergens, fungi, temperature, humidity, and particulate matter.

Approximately 1,600 adults (800 mothers and 800 pregnant women) will complete the screening forms. We assume after screening, some women will not be eligible (an estimate of roughly 15%). With an anticipated loss to follow-up in our study of 20%, we will recruit 688 asthmatic children (age 7–12 years) and their mothers. We will also recruit 688 pregnant women. In addition, children age 0–6 years could also be enrolled if a household already has an enrolled participant. In summary, expected overall response rate could range from 69%–86% for each of the eligible types of women participating in the study from screening through the end of data collection. The number and type of respondents that will complete the questionnaires are as follows: (1) 688 mothers of enrolled children—from ages 0–6 yrs and/or children with asthma (ages 7–12 years) and (2) 688 pregnant women—with or without eligible children. All health and environmental exposure information about children will be provided by their mothers (*i.e.,* no children will fill out questionnaires). Children ages 0–6 years are only recruited if their enrolled mother is pregnant or their mother also has an enrolled child with asthma between the ages 7–12 years. The total estimated annual burden hours equals 3,878.

There is no cost to the respondents other than their time to participate in the study.

ESTIMATED ANNUALIZED BURDEN HOURS

Forms	Respondents	Number of respondents	Number of responses per respondent	Average burden per response (in hours)
Screening Questionnaire	Mothers of enrolled children/Pregnant Women.	1,600	1	10/60
Baseline Questionnaire (Home Characteristics)	Mothers of enrolled children/Pregnant Women.	1,376	1	15/60
Baseline Questionnaire (for Mother or Pregnant Women).	Mothers of enrolled children/Pregnant Women.	1,376	1	15/60

ESTIMATED ANNUALIZED BURDEN HOURS—Continued

Forms	Respondents	Number of respondents	Number of responses per respondent	Average burden per response (in hours)
Baseline Questionnaire (for Children with asthma 7–12 years).	Mothers of enrolled children.	688	1	15/60
Baseline Questionnaire (for Children 0–6 years)	Mothers of enrolled children.	688	1	15/60
3- and 9-month Phone contact	Mothers of enrolled children/Pregnant Women.	1,376	2	5/60
6- and 12-month Follow-up Questionnaire (for environment).	Mothers of enrolled children/Pregnant Women.	1,376	2	10/60
6- and 12-month Follow-up Questionnaire (for women)	Mothers of enrolled children/Pregnant Women.	1,376	2	10/60
6- and 12-month Follow-up Questionnaire (for Children with asthma 7–12 years).	Mothers of enrolled children.	688	2	10/60
6- and 12-month Follow-up Questionnaire (for children 0–6).	Mothers of enrolled children.	688	2	10/60
Time/Activity form (for Children with asthma 7–12 years).	Mothers of enrolled children.	688	4	5/60
Time/Activity form (for Children 0–6 years)	Mothers of enrolled children.	688	4	5/60
Time/Activity form (for Pregnant women or mothers)	Mothers of enrolled children/Pregnant Women.	1,376	4	5/60
Post-delivery questionnaire	Pregnant Women	688	1	5/60

Dated: June 30, 2010.

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2008–D–0434]

Guidance for Humanitarian Device Exemption Holders, Institutional Review Boards, Clinical Investigators, and Food and Drug Administration Staff; Humanitarian Device Exemption Regulation; Questions and Answers; Availability

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is announcing the availability of the guidance entitled "Humanitarian Device Exemption (HDE) Regulation: Questions and Answers." This guidance answers commonly asked questions about Humanitarian Use Devices (HUDs) and applications for HDEs.

DATES: Submit either electronic or written comments on this guidance at any time. General comments on agency guidance documents are welcome at any time.

ADDRESSES: Submit written requests for single copies of the guidance document entitled "Humanitarian Device Exemption (HDE) Regulation: Questions and Answers" to the Division of Small Manufacturers, International, and Consumer Assistance (DSMICA), Center for Devices and Radiological Health (CDRH), Food and Drug Administration, 10903 New Hampshire Ave., Bldg.66, rm. 4613, Silver Spring, MD 20993–0002 or to the Office of Communication, Outreach and Development (HFM–40), Center for Biologics Evaluation and Research (CBER), Food and Drug Administration, 1401 Rockville Pike, Rockville, MD 20852–1448. Send one self-addressed adhesive label to assist that office in processing your request, or fax your request to CDRH at 301–847–8149. The guidance may also be obtained by mail by calling CBER at 1–800–835–4709 or 301–827–1800. See the **SUPPLEMENTARY INFORMATION** section for information on electronic access to the guidance.

Submit electronic comments on the 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. Identify comments with the docket number found in brackets in the heading of this document.

FOR FURTHER INFORMATION CONTACT: Sheila Brown, Center for Devices and Radiological Health, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 66, rm. 1651, Silver Spring, MD 20993–0002, 301–796–6563, or Stephen Ripley, Center for Biologics Evaluation and Research (HFM–17), Food and Drug Administration, 1401 Rockville Pike, suite 200N, Rockville, MD 20852, 301–827–6210.

SUPPLEMENTARY INFORMATION:

I. Background

This guidance answers commonly asked questions about HUDs and applications for HDE authorized by section 510(m)(2) of the Federal Food, Drug and Cosmetic Act (the act) (21 U.S.C. 360(m)(2)). This update of the version issued in 2006 reflects additional requirements set forth in the Pediatric Medical Device Safety and Improvement Act of 2007 (Public Law 110–85). The Pediatric Medical Device Safety and Improvement Act of 2007 includes a provision requiring that all original HDE applications include both a description of any pediatric subpopulations that suffer from the disease or condition that the device is intended to treat, diagnose, or cure, and the number of affected pediatric patients (new section 515A(a)(2) of the act). It also amends section 520(m) of the act to exempt some HUDs from the prohibition on profit (new section 520(m)(6) of the act). Specifically, HDE applications indicated for use in pediatric patients that are approved on or after September 27, 2007, may be assigned an annual distribution number (ADN) and be sold for profit, subject to certain restrictions. Finally, the Pediatric Medical Device Safety and Improvement Act of 2007 includes a provision requiring that the agency provide guidance to Institutional Review Boards (IRBs) on the review of HUDs. This update of the HDE guidance