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.

<table>
<thead>
<tr>
<th>Forms</th>
<th>Respondents</th>
<th>Number of respondents</th>
<th>Number of responses per respondent</th>
<th>Average burden per response (in hours)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Screening Questionnaire</td>
<td>Mothers of enrolled children/Pregnant Women.</td>
<td>1,600</td>
<td>1</td>
<td>10/60</td>
</tr>
<tr>
<td>Baseline Questionnaire (Home Characteristics)</td>
<td>Mothers of enrolled children/Pregnant Women.</td>
<td>1,376</td>
<td>1</td>
<td>15/60</td>
</tr>
<tr>
<td>Baseline Questionnaire (for Mother or Pregnant Women).</td>
<td>Mothers of enrolled children/Pregnant Women.</td>
<td>1,376</td>
<td>1</td>
<td>15/60</td>
</tr>
</tbody>
</table>
DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

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” 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 301–847–8199. 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:

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 512(m)(6) of the act). It also amends section 520(m) of the act to exempt some HUDs from the prohibition on profit (new section 515A(a)(2) of the act). This update of 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.

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