DEPARTMENT OF HEALTH AND HUMAN SERVICES

Administration for Children and Families

Proposed Information Collection Activity; Comment Request

**Title:** Accomplishments of the Domestic Violence Hotline, Online Connections and Text (ADVHOCaT) Study.

**OMB No.:** New Collection.

**Description:** The National Domestic Violence Hotline (NDVH) and the National Dating Abuse Helpline or Love Is Respect (NDAH/LIR), which are supported by the Division of Family Violence Prevention and Services within the Family and Youth Services Bureau of the Administration for Children and Families (ACF), U.S. Department of Health and Human Services (HHS), serve as partners in the intervention, prevention, and resource assistance efforts of the network of family violence, domestic violence, and dating violence service providers.

In order to describe the activities and accomplishments of the NDVH and NDAH/LIR and develop potential new or revised performance measures, the Office of Planning, Research and Evaluation (OPRE), within ACF/HHS is proposing data collection activity as part of the Accomplishments of the Domestic Violence Hotline, Online Connections and Text (ADVHOCaT) Study.

**Respondents:** Individuals who access the NDVH and NDAH/LIR Web sites.

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**ANNUAL BURDEN ESTIMATES**

<table>
<thead>
<tr>
<th>Instrument</th>
<th>Total/annual number of respondents</th>
<th>Number of responses per respondent</th>
<th>Average burden hours per response</th>
<th>Annual burden hours</th>
</tr>
</thead>
<tbody>
<tr>
<td>NDVH/LIR Preference of Use Survey</td>
<td>5000</td>
<td>1</td>
<td>0.041 hours (150 seconds)</td>
<td>205</td>
</tr>
</tbody>
</table>

**Estimated Total Annual Burden Hours: 205 hours.**

In compliance with the requirements of Section 3506(c)(2)(A) of the Paperwork Reduction Act of 1995, the Administration for Children and Families is soliciting public comment on the specific aspects of the information collection described above. Copies of the proposed collection of information can be obtained and comments may be forwarded by writing to the Administration for Children and Families, Office of Planning, Research and Evaluation, 370 L’Enfant Promenade SW., Washington, DC 20447, Attn: OPRE Reports Clearance Officer. Email address: OPREinfocollection@acf.hhs.gov. All requests should be identified by the title of the information collection.

The Department specifically requests comments on (a) whether the proposed collection of information is necessary for the proper performance of the functions of the agency, including whether the information shall have practical utility; (b) the accuracy of the agency’s estimate of the burden of the proposed collection of information; (c) 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. Consideration will be given to comments and suggestions submitted within 60 days of this publication.

Karl Koerper,
Reports Clearance Officer.
[FR Doc. 2015–17687 Filed 7–17–15; 8:45 am]

BILLING CODE 4184–01–P

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**DEPARTMENT OF HEALTH AND HUMAN SERVICES**

**Food and Drug Administration**

[Docket No. FDA–2015–N–2406]

**Agency Information Collection Activities; Proposed Collection; Comment Request; Market Claims in Direct-to-Consumer Prescription Drug Print Ads**

**AGENCY:** Food and Drug Administration, HHS.

**ACTION:** Notice.

**SUMMARY:** The Food and Drug Administration (FDA) is announcing an opportunity for public comment on the proposed collection of certain information by the Agency. Under the Paperwork Reduction Act of 1995 (the PRA), Federal Agencies are required to publish notice in the Federal Register concerning each proposed collection of information and to allow 60 days for public comment in response to the notice. This notice solicits comments on research entitled, “Market Claims in Direct-to-Consumer Prescription Drug Print Ads.” This study will examine the impact of market claim information in direct-to-consumer (DTC) print advertising for prescription drugs.

**DATES:** Submit either electronic or written comments on the collection of information by September 18, 2015.

**ADDRESSES:** Submit electronic comments on the collection of information to http://www.regulations.gov. Submit written comments on the collection of information to the Division of Dockets Management (HFA–305), Food and Drug Administration, 5630 Fishers Lane, Rm. 1061, Rockville, MD 20852. All comments should be identified with the docket number found in brackets in the heading of this document.

**FOR FURTHER INFORMATION CONTACT:** FDA PRA Staff, Office of Operations, Food and Drug Administration, 8455 Colesville Rd., COLE–14526, Silver Spring, MD 20993–0002, PRAStaff@fda.hhs.gov.

**SUPPLEMENTARY INFORMATION:** Under the PRA (44 U.S.C. 3501–3520), Federal Agencies must obtain approval from the Office of Management and Budget (OMB) for each collection of information they conduct or sponsor. “Collection of information” is defined in 44 U.S.C. 3502(3) and 5 CFR 1320.3(c) and includes Agency requests or requirements that members of the public submit reports, keep records, or provide information to a third party. Section 3506(c)(2)(A) of the PRA (44 U.S.C. 3506(c)(2)(A)) requires Federal
The project consists of two parts; a main study and a followup study. Pretesting will be conducted to assess and identify problems with the questionnaire, stimuli, and procedures. Participants will be consumers who self-identify as having been diagnosed with diabetes. All participants will be 18 years of age or older. We will exclude individuals from the consumer sample who work in healthcare or marketing settings because their knowledge and experiences may not reflect those of the average consumer. Recruitment and administration of the study will take place over the Internet. Participation is estimated to take no more than 30 minutes.

In the main study, participants will be randomly assigned to view one of nine possible versions of an ad, as depicted in table 1. The two variables of interest are type of market claim (#1 Prescribed, New) and level of efficacy information (high, low, or none). Efficacy information will be operationalized in the form of simple quantitative information (for example, product X can provide 50 percent relief for up to 60 percent of patients). We will investigate memory, perception, and understanding of product risks and benefits; perception and understanding of the market claim; perception of product quality; perceptions of product acceptance by doctor, intention to seek more information about the product; and perceptions of trust/skepticism regarding product claims and the sponsor. To examine differences between experimental conditions, we will conduct inferential statistical tests such as analysis of variance. With the sample size described below, we will have sufficient power to detect small- to medium-sized effects in the main study.

TABLE 1—MAIN STUDY DESIGN TYPE OF MARKET CLAIM

<table>
<thead>
<tr>
<th>Efficacy Level Information:</th>
<th>#1 Prescribed</th>
<th>New</th>
<th>None (control)</th>
</tr>
</thead>
<tbody>
<tr>
<td>High</td>
<td>A</td>
<td>B</td>
<td>C</td>
</tr>
<tr>
<td>Low</td>
<td>D</td>
<td>E</td>
<td>F</td>
</tr>
<tr>
<td>None (control)</td>
<td>G</td>
<td>H</td>
<td>I</td>
</tr>
</tbody>
</table>

The followup study will examine the tradeoff between efficacy level and market share claim using decision analysis techniques. Participants will be asked to choose between two different DTC print ads over 48 trials. One set of DTC ads will feature the two claims from the main study. The other set of DTC ads will depict 48 different levels of product efficacy. Participants will be asked to choose one product on one or more dependent measures.

FDA estimates the burden of this collection of information as follows:
TABLE 2—ESTIMATED BURDEN ¹

<table>
<thead>
<tr>
<th>Activity</th>
<th>Number of respondents</th>
<th>Number of responses per respondent</th>
<th>Total annual respondents</th>
<th>Average burden per response</th>
<th>Total hours</th>
</tr>
</thead>
<tbody>
<tr>
<td>Sample outgo (pretests and main survey)</td>
<td>16,384</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Screener completes</td>
<td>1,638</td>
<td>1</td>
<td>1,638</td>
<td>.03 (2 minutes)</td>
<td>49</td>
</tr>
<tr>
<td>Eligible</td>
<td>1,556</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Completes, Pretest 1</td>
<td>252</td>
<td>1</td>
<td>252</td>
<td>.5 (30 minutes)</td>
<td>126</td>
</tr>
<tr>
<td>Completes, Pretest 2</td>
<td>252</td>
<td>1</td>
<td>252</td>
<td>.5 (30 minutes)</td>
<td>126</td>
</tr>
<tr>
<td>Completes, Main Study</td>
<td>108</td>
<td>1</td>
<td>108</td>
<td>.25 (15 minutes)</td>
<td>27</td>
</tr>
<tr>
<td>Completes, Pretest 3</td>
<td>216</td>
<td>1</td>
<td>216</td>
<td>.25 (15 minutes)</td>
<td>54</td>
</tr>
<tr>
<td>Completes, Followup Study</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Total</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td>630</td>
</tr>
</tbody>
</table>

¹ There are no capital costs or operating and maintenance costs associated with this collection of information.

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2010–N–0128]

Prescription Drug User Fee Act; Stakeholder Consultation Meetings on the Prescription Drug User Fee Act Reauthorization: Request for Notification of Stakeholder Intention To Participate

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice; request for notification of participation.

SUMMARY: The Food and Drug Administration (FDA) or Agency) is issuing this notice to request that public stakeholders—including patient and consumer advocacy groups, health care professionals, and scientific and academic experts—notify FDA of their intent to participate in periodic consultation meetings on the reauthorization of the Prescription Drug User Fee Act (PDUFA). The statutory authority for PDUFA expires in September 2017. At that time, new legislation will be required for FDA to continue collecting user fees for the prescription drug program. The Federal Food, Drug, and Cosmetic Act (the FD&C Act) requires that FDA consult with a range of stakeholders in developing recommendations for the next PDUFA program. The FD&C Act also requires that FDA hold discussions (at least every month) with patient and consumer advocacy groups during FDA’s negotiations with the regulated industry. The purpose of this request for notification is to ensure continuity and progress in these monthly discussions by establishing consistent stakeholder representation.

DATES: Submit notification of intention to participate in these series of meetings by August 28, 2015. Stakeholder meetings will be held monthly. It is anticipated that they will commence in September or October 2015.

ADDRESSES: Submit notification of intention to participate in monthly stakeholder meetings by email to PDUFAReauthorization@fda.hhs.gov. The meetings will be held at the FDA campus, 10903 New Hampshire Ave., Silver Spring, MD 20993.

FOR FURTHER INFORMATION CONTACT: Graham Thompson, Center for Drug Evaluation and Research, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 51, Rm. 1146, Silver Spring, MD 20993, 301–796–5003, FAX: 301–847–8443.

SUPPLEMENTARY INFORMATION:

I. Background

FDA is requesting that public stakeholders—including patient and consumer advocacy groups, health care professionals, and scientific and academic experts—notify the Agency of their intent to participate in periodic stakeholder consultation meetings on the reauthorization of PDUFA. PDUFA authorizes FDA to collect user fees from the regulated industry for the process for the review of human drugs. The authorization for the current program (PDUFA V) expires in September 2017. Without new legislation, FDA will no longer be able to collect user fees for future fiscal years to fund the human drug review process.

Section 736B(d) of the FD&C Act (21 U.S.C. 379h–2(d)) requires that FDA consult with a range of stakeholders, including representatives from patient and consumer groups, health care professionals, and scientific and academic experts, in developing recommendations for the next PDUFA program. FDA will initiate the reauthorization process by holding a public meeting on July 15, 2015, where stakeholders and other members of the public will be given an opportunity to

References

The following references have been placed on display in the Division of Dockets Management (see ADDRESSES) and may be seen by interested persons between 9 a.m. and 4 p.m., Monday through Friday, and are available electronically at http://www.regulations.gov.


Dated: July 15, 2015.

Leslie Kux,
Associate Commissioner for Policy.

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