DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. 2007N–0321]

Agency Information Collection Activities; Proposed Collection; Comment Request; Experimental Evaluation of the Impact of Distraction on Consumer Understanding of Risk and Benefit Information in Direct-to-Consumer Prescription Drug Broadcast Advertisements

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is announcing an opportunity for public comment on a 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, including each proposed extension of an existing collection of information, and to allow 60 days for public comment in response to the notice. This notice solicits comments on a study of consumer evaluations of variations in communicating risk information in direct-to-consumer (DTC) prescription drug broadcast advertisements.

DATES: Submit written or electronic comments on the collection of information by October 22, 2007.

ADDRESSES: Submit electronic comments on the collection of information to: *http://www.fda.gov/dockets/ecomments* or *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: Elizabeth Berbakos, Office of the Chief Information Officer (HFA–250), Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857, 301–827–1482.

SUPPLEMENTARY INFORMATION:

I. Background

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 agencies to provide a 60-day notice in the **Federal Register** concerning each proposed collection of information, including each proposed extension of an existing collection of information, before submitting the collection to OMB for approval. To comply with this requirement, FDA is publishing notice of the proposed collection of information set forth in this document.

With respect to the following collection of information, FDA invites comments on these topics: (1) Whether the proposed collection of information is necessary for the proper performance of FDA's functions, including whether the information will have practical utility; (2) the accuracy of FDA's estimate of the burden of the proposed collection of information, including the validity of the methodology and assumptions used; (3) ways to enhance the quality, utility, and clarity of the information to be collected; and (4) ways to minimize the burden of the collection of information on respondents, including through the use of automated collection techniques, when appropriate, and other forms of information technology.

Experimental Evaluation of the Impact of Distraction on Consumer Understanding of Risk and Benefit Information in DTC Prescription Drug Broadcast Advertisements

Section 1701(a)(4) of the Public Health Service Act (42 U.S.C. 300u(a)(4)) authorizes FDA to conduct research relating to health information. Section 903(b)(2)(c) of the Federal Food, Drug, and Cosmetic Act (the act) (21 U.S.C. 393(b)(2)(c)) authorizes FDA to conduct research relating to drugs and other FDA regulated products in carrying out the provisions of the act.

FDA regulations require that advertisements that make claims about a prescription drug include a ''fair balance'' of information about the benefits and risks of advertised products, in terms of both content and presentation. Ads can present information in ways that can optimize or skew the relative balance of risks and benefits. Both healthcare providers and consumers have expressed concerns to FDA about the effectiveness of its regulation of manufacturers' DTC prescription drug advertising, especially as it relates to assuring balanced communication of risks compared with benefits.

One characteristic of DTC television broadcast ads is the use of compelling visuals. Many assert that the visuals present during the product risk presentation are virtually always positive in tone and often depict product benefits. A consistently raised question is whether advertising visuals of benefits interferes with consumers' understanding and processing of the risk information in the ad's audio or text.

The purpose of the proposed study is, in part, to determine whether the use of competing, compelling visual information about potential drug benefits interferes with viewers' processing and comprehension of risk information about drugs in DTC advertising or with their cognitive representations of the drugs. Positive visual images could influence the processing of risk-related information and the final representation of the advertised drug in multiple ways. First, compelling visuals could simply distract consumers from carefully considering and encoding the risk information. To the extent that compelling visuals cause them to attend to or to process risk information less, participants exposed to risk information with simultaneous compelling positive visuals should recall fewer risks (and perhaps fewer benefits) than do participants exposed to the risk information without the positive visuals. Second, compelling visuals may affect the way consumers think about the brand, specifically their attitudes toward the advertised brand (Ref. 1). An attitude is simply an association between an object and a degree of positivity or negativity. Attitudes can be important determinants of behavior; in some contexts, they may have more impact than factual information. That is, under many circumstances, people rely much less on facts that they know, such as the number of risks associated with ibuprofen, and much more on general feelings they have, such as strong positivity toward Advil. Compelling visuals in DTC advertising have the potential to lead a consumer to form a positive opinion of a drug for no other reason than that it is presented in the same context as positive images.

Another purpose of the present study is to examine the role of textual elements in the processing of risk information. Sponsors often place superimposed text (''supers'') onto the screen to clarify spoken information or to provide extra information that is not included in the audio. For example, information such as adequate provision

statements (''See our ad in...'') and limits to indication statements may appear. This text potentially has the power to distract viewers from the more important audio information, although only if viewers pay attention to the text. Likewise, providing verbatim repetition of the audio risks in text format may facilitate the processing of the risks. We will examine the added distraction or facilitation of the text in the present study in addition to the role of visual information.

We have limited data about how consumers perceive risk and benefit information in DTC broadcast ads as a function of exposure to different content and presentations. Therefore, we do not fully understand the influence of visual and textual factors on the conveyance of a balanced picture of the product.

This study will investigate the impact of visual distraction and the interplay of different sensory modalities (verbal, visual) used to present risk and benefit information during a television prescription drug advertisement. Data from this study will provide useful information to help improve how broadcast ads present a prescription drug's risks and benefits.

Design: This study will employ a between-subjects crossed 3 x 3 factorial design with two independent variables. The first independent variable represents the consistency of the disclosure of risk information between the audio and text (superimposed text, or ''supers'') portions of television ads. It will have three conditions: ''Reinforcing'' text, ''competing'' text, and a ''control'' condition with no text. We define ''reinforcing'' text as a verbatim repetition of the audio risk; ''competing'' text will include contextual information for understanding usage and will not contain risk or benefit information. The second independent variable is the consistency of background visuals with the audio presentation of risk information. It will have three conditions: Consistent visuals, neutral visuals, and inconsistent visuals.

Participants: Data will be collected using a mall-intercept protocol in multiple locations across the continental United States. Consumers over the age of 40 will be screened and recruited by the contractor to represent a range of education levels (some college or less vs. completed college or more). Because the task presumes basic reading abilities, all selected participants must speak English as their primary language and have reading glasses available as needed. In addition, due to the nature of one of our measures requiring a set of neutral stimuli, which we have designated as Chinese characters, it will be necessary for us to eliminate individuals who can read Chinese.

We chose to limit our investigation to one disease condition: High blood pressure. High blood pressure remains a significant public health concern but because there is little DTC promotion for high blood pressure treatment, participants should be less familiar with television ads for these types of drugs, reducing the potential influence of prior experience. Further, many older people have or are at risk for high blood pressure, which should facilitate recruitment.

Procedure: Participants will be shown one DTC ad for high blood pressure. Then a structured interview will be conducted with each participant to examine a number of important perceptions about the advertised product, including perceived riskiness of the drug, comprehension of risk and benefit information, perceived balance of risk and benefit information, and attitudes toward the drug product.

Because attitudes are often a strong determinant of behavior, we will investigate this dependent variable in two ways. First, we will use an implicit measure to determine whether participants have an overall positive or negative attitude toward the drug product. Implicit measurement of attitudes is a relatively new but well-validated process for understanding people's feelings toward particular entities (Ref. 1). The Affect Misattribution Procedure, in which participants are asked to respond to neutral characters (such as Chinese symbols) after viewing pictures of the object of interest, has been validated as an unobtrusive way to attain these measures. We expect attitudes toward the drug product to vary depending on each participant's experimental condition (i.e., whether they have adequately processed the risk information or not). This implicit method will be conducted after participants see the broadcast ad but before they are asked any other questions that might influence their responses. Second, we will assess attitudes and behavioral intentions using more traditional explicit measures, i.e. asking participants directly. Including both types of measures will allow us to further validate these measures in a DTC context.

Finally, demographic and health care utilization information will be collected. The entire procedure is expected to last approximately 15 minutes. A total of 1,020 interviews will be completed. This will be a one-time (rather than annual) information collection.

FDA estimates the burden of this collection of information as follows:

FDA estimates that 2,000 individuals will need to be screened to obtain a respondent sample of 1,020 for the study. The screener is expected to take 30 seconds, for a total screener burden of 16 hours. The 1,020 respondents in the study will then be asked to respond to a series of questions about the advertisement. The ad viewing and questionnaire are expected to take 15 minutes, for a study burden of 255 hours. The estimated total burden for this data collection effort is 271 hours. The respondent burden is provided in table 1 of this document:

TABLE 1.—ESTIMATED ANNUAL REPORTING BURDEN[1]

No. of Respondents	Annual Frequency per Response	Total Annual Responses	Hours per Response	Total Hours
2,000 (screener)	1	2,000	.008	16
1,020 (study)	1	1,020	.25	255
Total				271

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

II. References

The following reference has been placed on public display in the Division of Dockets Management (see **ADDRESSES**), and may be seen between 9 a.m. and 4 p.m., Monday through Friday.

1. Payne, B.K., C.M. Cheng, O. Govorun, et al., ''An Inkblot for Attitudes: Affect Misattribution as Implicit Measurement,'' *Journal of Personality and Social Psychology*, vol. 89 (3), pp. 277–293, 2005.

Dated: August 16, 2007.

Jeffrey Shuren,

Assistant Commissioner for Policy.

[FR Doc. E7–16603 Filed 8–21–07; 8:45 am]

BILLING CODE 4160–01–S

DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

National Institute on Deafness and Other Communication Disorders; Notice of Closed Meetings

Pursuant to section 10(d) of the Federal Advisory Committee Act, as amended (5 U.S.C. Appendix 2), notice is hereby given of the following meetings.

The meetings will be closed to the public in accordance with the provisions set forth in sections 552b(c)(4) and 552b(c)(6), Title 5 U.S.C., as amended. The grant applications and the discussions could disclose confidential trade secrets or commercial property such as patentable material, and personal information concerning individuals associated with the grant applications, the disclosure of which would constitute a clearly unwarranted invasion of personal privacy.

Name of Committee: National Institute on Deafness and Other Communication Disorders Special Emphasis Panel, T35 Short Term Institutionals Research Training.

Date: September 20, 2007.

Time: 11 a.m. to 12 p.m.

Agenda: To review and evaluate grant applications.

Place: National Institutes of Health, 6120 Executive Blvd., Rockville, MD 20852 (Telephone Conference Call).

Contact Person: Stanley C. Oaks, PhD, Scientific Review Administrator, Division of Extramural Activities, NIDCD, NIH, Executive Plaza South, Room 400C, 6120 Executive Blvd—MSC 7180, Bethesda, MD 20892–7180, 301–496–8683, *so14s@nih.gov.*

Name of Committee: National Institute on Deafness and Other Communication Disorders Special Emphasis Panel, Diseases of the Vestibular System.

Date: September 24, 2007.

Time: 11 a.m. to 2 p.m.

Agenda: To review and evaluate grant applications.

Place: National Institutes of Health, 6120 Executive Blvd., Rockville, MD 20852 (Telephone Conference Call).

Contact Person: Christine A. Livingston, PhD, Scientific Review Administrator, Division of Extramural Activities, National Institutes of Health/NIDCD, 6120 Executive Blvd.—MSC 7180, Bethesda, MD 20892, (301) 496–8683, *livingsc@mail.nih.gov.*

(Catalogue of Federal Domestic Assistance Program Nos. 93.173, Biological Research Related to Deafness and Communicative Disorders, National Institutes of Health, HHS)

Dated: August 14, 2007.

Jennifer Spaeth,

Director, Office of Federal Advisory Committee Policy.

[FR Doc. 07–4101 Filed 8–21–07; 8:45 am]

BILLING CODE 4140–01–M

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Substance Abuse and Mental Health Services Administration

Agency Information Collection Activities: Submission for OMB Review; Comment Request

Periodically, the Substance Abuse and Mental Health Services Administration (SAMHSA) will publish a summary of information collection requests under OMB review, in compliance with the Paperwork Reduction Act (44 U.S.C. Chapter 35). To request a copy of these documents, call the SAMHSA Reports Clearance Officer on (240) 276–1243.

Project: Independent Evaluation of the Community Mental Health Services Block Grant Program—NEW

The Substance Abuse and Mental Health Services Administration (SAMHSA), the Center for Mental Health Services (CMHS) administers the Community Mental Health Services Block Grant (CMHS BG). The Community Mental Health Services Block Grant was funded by Congress to develop community-based systems of care for adults with serious mental illness (SMI) and children with severe emotional disorders (SED), and has been the largest Federal program dedicated to improving community mental health services. States have latitude in determining how to spend their funds to support services for adults with SMI and children with SED. The only requirements outlined in the authorizing legislation for State receipt of CMHS BG funds are provisions to increase children's services, create a State mental health planning council, and to develop a State mental health plan to be submitted to the Secretary of Health and Human Services (HHS). The State mental health planning council is to comprise various State constituents including providers, administrators, and mental health services consumers. Each State plan must:

- Provide for the establishment and implementation of an organized community-based system of care for individuals with mental illness.
- Estimate the incidence and prevalence of adults with SMI and children with SED within the State.
- Provide for a system of integrated services appropriate for the multiple needs of children.
- Provide for outreach to and services for rural and homeless populations.
- Describe the financial and other resources necessary to implement the plan and describe how the CMHS BG funds are to be spent.

In addition, Congress included a maintenance-of-effort (MOE) requirement that a State's expenditures for community mental health services be no less than the average spent in the two preceding fiscal years.

The CMHS BG received an adequate rating on the OMB PART in 2003. Clearly in the follow up period to that assessment, one of the critical areas that must be addressed is the expectation that an independent and objective evaluation of the program is to be carried out initially and at regular intervals. In addition, the program evaluation has been designed to be of high quality, sufficient scope and unbiased (with appropriate documentation for each of these elements). In fact it is in addressing an evaluation of the program that critical elements of accountability and program performance are also identified and initially assessed. The rigor of the evaluation is seen in how it addresses the effectiveness of the program's impact with regard to its mission and long term goals. By legislative design the CMHS BG Program has previously focused on legislative compliance. Now it addresses the impact of the program nationally, over time, with a view to coming to terms with identified program deficiencies and the corresponding impact of proposed changes.

In this evaluation, a multi-method evaluation approach is being used to examine Federal and State performance with regard to the CMHS BG and its identified goals. This approach emphasizes a qualitative and quantitative examination of both the CMHS BG *process* (e.g., activities and outputs in the logic model) and system-level *outcomes* whereby Federal and State stakeholder perspectives on the CMHS BG, as captured through semi-structured interviews and surveys, are