DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2007–N–0451] (formerly Docket No. 2007N–0321)

Agency Information Collection Activities; Submission for Office of Management and Budget Review; 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 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. Due to an administrative error, this document is being republished.

DATES: Fax written comments on the collection of information by [*insert date 30 days after date of publication in the* **Federal Register**].

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: 202–395–6974, or e-mailed to *oira_submission@omb.eop.gov*. All comments should be identified with the OMB control number 0910–NEW and title ''Experimental Evaluation of the Impact of Distraction on Consumer Understanding of Risk and Benefit Information in Direct-to-Consumer Prescription Drug Broadcast

Advertisements.'' Also include the FDA docket number found in brackets in the heading of this document.

FOR FURTHER INFORMATION CONTACT: Elizabeth Berbakos, Office of Information Management (HFA–710), Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857, 301–796–3792.

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.

Experimental Evaluation of the Impact of Distraction on Consumer Understanding of Risk and Benefit Information in Direct-to-Consumer 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' Direct-to-Consumer (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 manner in which required risk information is presented in DTC ads has been recently addressed in the Food and Drug Administration Amendments Act of 2007 (FDAAA). Section 901(3) of FDAAA states that the major statement in DTC broadcast ads ''shall be presented in a clear, conspicuous and neutral manner.'' Further, the Secretary of Health and Human Services ''shall establish standards for determining whether the major statement is presented in such a manner.'' FDAAA does not define how the objective of ''clear, conspicuous, and neutral'' is to be achieved.

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. An attitude is simply

an association between an object and a degree of positivity or negativity. Thus, the impact of varying visual displays during the presentation of audio risks may be manifested in varying attitudes toward the brand. This is important because brand attitudes may be an important determinant of future behavior toward the brand. In contexts where product information is complex, initial impressions based on more subtle processes may have as significant an impact on behavioral tendencies as impressions based upon more ‘‘cognitively-effortful’’ factual information. Because visual cues are typically easier to process than verbal information, initial attitudes for this group are likely to be greatly influenced by these cues. Under many circumstances, people rely much less on facts that they know, such as the number of risks associated with, for example, ibuprofen, and much more on general feelings they have, such as strong positivity toward a brand, such as the Advil brand of ibuprofen. Compelling visuals during the audio risk presentation of DTC broadcast advertisements 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 that fulfills certain requirements (such as adequate provision statements, for example ‘‘See our ad in * * *’’) and limits claims of product use may appear. Providing verbatim text repetition of the risks required to be in the audio portion in broadcast ads may facilitate processing the risks, but only if viewers pay attention to the text. Viewers’ attention may be affected

by both the prominence of the textual information and the combined effects of text prominence and different visual information. The proposed study examines these associations.

A final purpose of this study is to provide FDA with information on defining the presentation of the major statement as ''clear, conspicuous, and neutral'' as required by FDAAA. 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 or ''neutral'' picture of the product.

This study will investigate the impact of visual distraction and the interplay of different sensory modalities (oral, visual) used to present risk and benefit information during a television prescription drug advertisement. Data from this study will provide useful information for FDA as it considers whether it is appropriate to develop guidance to help improve how broadcast ads present a prescription drug's risks and benefits. This study will also provide preliminary data on how FDA might interpret the ''clear, conspicuous, and neutral'' standard. The data should help us plan whether additional research is needed to develop the standards called for in FDAAA.

Overview: To investigate the overall and interactive role of visual images and text presentations during the audio presentation of risk information in television DTC ads, we will create a variety of ads for a new (fictitious) brand of high blood pressure medication. The ads will vary only in the type of information shown on screen during the presentation of required risk information (the ''major statement''). We will conduct pretesting to determine whether participants will view one version of the test ad two times or if the

test ad will be viewed in the context of other ads (''clutter reel''). Respondents will answer questions about the test ad, including information about product risks and benefits, whether they intend to ask the doctor about the product, basic comprehension of the risk and benefit information, and their general attitudes toward the product. This experimental design will allow for comparisons between conditions in a controlled presentation where only the visual information varies.

Design: The study includes two primary designs that, taken together, investigate three different variables.

A one-way, five condition design will examine the impact of degree of consistency between visuals presented during orally presented (audio) risk information. The visuals will be either very consistent, somewhat consistent, neutral, somewhat inconsistent, or very inconsistent with the audio risk information. The consistent conditions will visually reinforce the product risks by presenting the words of the risks on the screen as they are being spoken. The inconsistent conditions will reinforce the product's benefits by presenting visuals that suggest blood pressure being decreased from high to normal levels. The degree or magnitude of consistency will be manipulated by including fewer pieces of information, interspersed with images of the fictitious drug logo. A control or ''*neutral*'' condition will consist of showing the brand logo during the entire audio risk presentation.

The second design will be a two-way factorial design combining each level of one independent variable with each level of a second independent variable. The first variable consists of three levels of visual ''tone''—neutral, mildly positive, and highly positive. The second variable consists of three levels of prominence of ''supers''—level one, level two, and no super (control).

Because the control cell in each of the 2 designs will overlap (neutral, no supers), both designs together will amount to a total of 13 separate ‘‘cells’’ and corresponding versions of advertisements for the fictitious brand.

In a separate sub-experiment, five selected cells taken from across the two designs will assess implicit attitudes using the Attitude Misattribution Procedure (AMP). The questions asked of the participants in the AMP conditions will be reduced in number to account for the additional time needed to administer the AMP.

Eligible participants for the study (n=2,400, following pretesting) will be recruited from Synovate Inc.’s online Internet panel. They will be 40 years of age or older to increase the likelihood of including members of the population most likely to have high blood pressure. At least 30 percent of the recruited sample within each of the designs will have equal to or less than a high school education. The composition of participants in each format condition will be balanced with respect to gender (50% female, +/- 10%). Panel members who meet age and education requirements will not be screened further for disease condition.

Dependent Measures: The primary dependent variables are recall and comprehension of risk and benefit information. We will also investigate behavioral intention and attitudes toward the fictitious brand. In a separate sub-experiment using only five cells throughout both designs, we will use the AMP, in addition to some explicit measures, to collect implicit attitude measures that should not be affected by social desirability biases.

In the **Federal Register** of August 22, 2007 (72 FR 47051), FDA published a 60-day notice requesting public comment on the information collection provisions. Thirty commenters responded. In total, this amounted to

approximately 29 distinct comments that specifically referenced the study. Of these, 12 were not PRA related. As a result of the comments that were PRA-related, FDA made extensive modifications to the study's methodology and design. As reflected in these modifications, we agreed to do the following: Change from a mall-intercept to an Internet administered procedure, limit use of the AMP to a sub-experiment consisting of only five of the experimental conditions, add questions addressing the advertised (fictitious) drug's benefits, and make certain changes to the wording of the questions. Changing the administration procedure also allows us to double our sample size and test more conditions. In response to comments received both from the commenters and from our peer reviewers, we also decided to conduct significantly more pretesting than originally planned, to address the suggestion that the test ad should be embedded in a clutter reel of other ads and to test the validity of the stimulus manipulations (the mocked up advertisements). We disagreed, primarily because of time and complexity constraints, with suggestions to do the following: (1) Add more independent variables, (2) recruit a different set of participants, (3) change the use of Chinese characters in the (now more limited) AMP-measured conditions, (4) add certain additional dependent measures, (5) increase or decrease the number of behavioral intention questions (both were requested), (6) control for baseline attitudes (because this is not needed in an experimental design and we are using a fictitious drug for the stimulus materials), or (7) get industry approval and public comment on the mocked up ads.

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

TABLE 1.—ESTIMATED ANNUAL REPORTING BURDEN[1]

21 CFR Section	No. of Respondents	Annual Frequency per Response	Total Annual Responses	Hours per Response	Total Hours
21 U.S.C. 393(b)(2)(c) Screener, pretesting	1,600	1	1,600	.03	48

TABLE 1.—ESTIMATED ANNUAL REPORTING BURDEN[1]—Continued

21 CFR Section	No. of Respondents	Annual Frequency per Response	Total Annual Responses	Hours per Response	Total Hours
21 U.S.C. 393(b)(2)(c) Questionnaire, pretesting	800	1	800	.16	128
21 U.S.C. 393(b)(2)(c) Screener, study	4,800	1	4,800	.03	144
21 U.S.C. 393(b)(2)(c) Questionnaire, study	2,400	1	2,400	.25	600
Total					920

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

Dated: December 18, 2008.

Jeffrey Shuren,

Associate Commissioner for Policy and Planning.

[FR Doc. 08–????? Filed ??–??–08; 8:45 am]

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