DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2012–N–0176]

Agency Information Collection Activities; Proposed Collection; Comment Request; Experimental Study: Examination of Corrective Direct-to-Consumer Television Advertising

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 ''Experimental Study: Examination of Corrective Direct-to-Consumer (DTC) Television Advertising.'' The proposed research will examine how corrective advertising may impact consumer misperceptions about prescription drug product safety and efficacy.

DATES: Submit either electronic or written comments on the collection of information by April 30, 2012.

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: Juanmanuel Vilela, Office of Information Management, Food and Drug Administration, 1350 Piccard Dr., PI50–400B, Rockville, MD 20850, 301–796–7651, *juanmanuel.vilela@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 Agencies to provide a 60-day notice in the **Federal Register** concerning each proposed 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 Study: Examination of Corrective DTC Television Advertising

I. Regulatory Background

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

II. Description

FDA regulations require prescription drug advertisements to contain accurate information about the benefits and risks of the drug advertised. When this is not the case, corrective advertising is designed to dissipate or correct erroneous beliefs resulting from a false claim (Refs. 1 and 2). Corrective advertising emerged in public debate in the United States in the 1970s as a hypothetical remedy for deceptive advertising, having first been proposed by Georgetown University law students in 1969 as a way of dispelling the effects of deceptive advertising (Ref. 3). Corrective advertising is one remedy FDA may request in response to false or misleading prescription drug promotion. In 2009, for example, Bayer HealthCare Pharmaceuticals produced and aired corrective DTC advertising for Yaz, a birth control pill, following a warning from FDA regarding misleading claims (Ref. 4). Despite these developments, researchers and policymakers currently lack exhaustive empirical literature regarding the various impacts of corrective DTC advertisements on prescription drug consumers. The current project will examine how variations in corrective advertising may impact consumers' misleading product beliefs.

III. Design and Method Overview

The study will involve three independent variables: Message exposure, similarity of original and corrective ads, and length of time between exposure to original and corrective ad in a medium prevalence medical condition (defined as between 5 percent and 10 percent of U.S. adult population). These variables will be examined in two phases. Participants will be recruited from an online Internet panel and will answer the survey questions online.

Phase 1 will vary the exposure to the messages (original ad alone versus original + corrective versus corrective ad alone). The goal of Phase 1 is to examine how exposure to a combination of original and corrective DTC advertisements affects message recall, message comprehension, perceived drug efficacy, perceived drug risk, and intentions to ask about or use the drug. Specifically, we will compare consumers who see both the original and corrective ad with those who see only the original ad, only the corrective ad, and neither ad.

TABLE 1—DESIGN OF PHASE 1: ORIGINAL EXPOSURE BY CORRECTIVE EXPOSURE

Exposure to Original ad	Exposure to Corrective ad	
	Yes	No
Yes		
No		(filler task only)

Phase 2 will examine the similarity of the corrective ad's theme and visual elements to those of the original ad (same ad elements versus some similar ad elements versus different ad elements) and the exposure delay (time) between viewing the original ad and the corrective ad (no delay versus 1 week delay versus 1 month delay). The purpose of Phase 2 is to examine whether a corrective advertisement's

ability to correct misinformation is related to (a) corrective ad similarity to the original ad and (b) time delay between original ad and corrective ad exposure.

We will vary these two characteristics to create a study with a 4x3 experimental design (see table 2).

TABLE 2—DESIGN OF PHASE 2: AD SIMILARITY BY EXPOSURE DELAY

Corrective ad similarity	Exposure delay		
	None	1 Week	1 Month
Same ad elements			
Some similar elements			
Different ad elements			
Control (Do not see corrective)			

Prior to conducting the main study, we will pretest the stimuli, questionnaires, and data collection process. The first set of pretests will focus on the stimuli, and its purpose will be to (a) ensure the stimuli display properly, (b) ensure participants perceive the stimuli as realistic, and (c) ensure participants notice the original and corrective messages in the ads. The second pretest will focus on the questionnaires and data collection process. Its purpose will be to (a) ensure that survey questions solicit responses that meet the study's analytic goals and (b) ensure data are captured and stored accurately for each question.

FDA estimates the burden of this collection of information as follows: 30 minutes in the pretests and each phase of the study, for a burden of 3,092 hours. This will be a one time (rather than annual) collection of information. The questionnaire is available upon request.

TABLE 3—ESTIMATED ANNUAL REPORTING BURDEN [1]

Activity	No. of respondents	No. of responses per respondent	Total annual responses	Average burden per response	Total hours
Pretests	1,250	1	1,250	0.5 (30 minutes)	625
Phase 1 Screener	3,228	1	3,228	0.033 (2 minutes)	108
Phase 1	1,000	1	1,000	0.5 (30 minutes)	500
Phase 2 Screener	10,768	1	10,768	0.033 (2 minutes)	359
Phase 2	3,000	1	3,000	0.5 (30 minutes)	1,500
Total	19,246				3,092

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

IV. 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.

1. Darke, P.R., L. Ashworth, and R.J.B. Ritchie, ''Damage From Corrective Advertising: Causes and Cures,'' *Journal of Marketing,* vol. 72, pp. 81–97, 2008.

2. Mazis, M.B. and J.E. Adkinson, ''An Experimental Evaluation of a Proposed Corrective Advertising Remedy,'' *Journal of Marketing Research,* vol. 13, pp. 178–183, 1976.

3. Mazis, M.B., D.L. McNeill, and K.L. Bernhardt, ''Day-After Recall of Listerine Corrective Commercials,'' *Journal of Public Policy & Marketing,* vol. 2, pp. 29–37, 1983.

4. Singer, N., *A Birth Control Pill That Promised Too Much,* New York Times, February 11, 2009, p. B1.

Dated: February 23, 2012.

Leslie Kux,

Acting Assistant Commissioner for Policy.

[FR Doc. 2012–4777 Filed 2–28–12; 8:45 am]

BILLING CODE 4160–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2011–N–0797]

Agency Information Collection Activities; Submission for Office of Management and Budget Review; Comment Request; State Enforcement Notifications

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.

DATES: Fax written comments on the collection of information by March 30, 2012.

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: 202–395–7285, or emailed to *oira_submission@omb.eop.gov.* All comments should be identified with the OMB control number 0910–0275. Also include the FDA docket number found in brackets in the heading of this document.

FOR FURTHER INFORMATION CONTACT: Denver Presley, II, Office of Information Management, Food and Drug Administration, 1350 Piccard Dr., PI50–400B, Rockville, MD 20850, 301–796–3793.

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.

State Enforcement Notifications—21 CFR 100.2(d) (OMB Control Number 0910–0275)—Extension

Section 310(b) of the Federal Food, Drug, and Cosmetic Act (the FD&C Act) (21 U.S.C. 337(b)) authorizes States to