to comments and suggestions submitted within 60 days of this publication.

Robert Sargis,

Reports Clearance Officer.

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2011–N–0457]

Agency Information Collection Activities; Submission for Office of Management and Budget Review; Comment Request; Experimental Study of Comparative Direct-to-Consumer Advertising

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 January 9, 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—New and title, ''Experimental Study of Comparative Direct-to-Consumer Advertising.'' Also include the FDA 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: In compliance with 44 U.S.C. 3507, FDA has submitted the following proposed collection of information to OMB for review and clearance.

Experimental Study of Comparative Direct-to-Consumer Advertising—(OMB Control Number 0910—New)

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(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.

Regulations specify that sponsors cannot make comparative efficacy claims in advertising for prescription drugs without substantial evidence, most often in the form of well-controlled clinical trials, to support such claims (21 CFR 202.1(e)(6)(ii); 21 CFR 314.126). FDA has permitted some comparisons based on labeled attributes, such as indication, dosing, and mechanism of action. When substantial evidence does not yet exist, sponsors have used communication techniques that invite implicit comparisons, such as making indirect comparisons, using comparative visuals, and using vaguer language. This study is designed to apply the existing comparative advertising literature to direct-to-consumer (DTC) advertising, where little research has been conducted to date.

Moreover, as part of the American Recovery and Reinvestment Act of 2009 (Pub. L. 111–5), the Agency for Healthcare Research and Quality is in the process of securing a large compendium of information on the comparative effectiveness of medical treatments in 14 priority medical conditions, including arthritis, cancer, dementia, depression, diabetes, and substance abuse (Ref. 1). As part of this process, they will fund a set of CHOICE (Clinical and Health Outcomes Initiative in Comparative Effectiveness) studies designed to explore comparative effectiveness. When this large project is completed, FDA will have additional information to consider when regulating DTC advertising. It is possible that more DTC advertising will be comparative in nature. In preparation for this change, FDA is embarking on the proposed research to ensure that it has adequate information to assess whether comparative DTC ads provide truthful and nonmisleading information to consumers.

A. Comparative Advertising

Comparative advertisements typically compare two or more named or recognizably presented brands of the same product category, although some comparative advertisements implicitly compare a product to other brands by making superiority statements (e.g., ''Only Brand A can be cooked in five minutes or less.''). These ads are frequently used for commercial products, such as electronics, food products, and automobiles.

Marketing and advertising studies have investigated the influence of comparative ads, particularly in contrast to noncomparative ads (Refs. 2 to 5). Research specifically investigating the effects of comparative advertising on consumer attitudes—including attitudes toward the ad, the brand, and product use—has produced mixed results (Refs. 4 and 6). The research findings on the superiority of comparative versus noncomparative ads on purchase intentions, however, have been more conclusive. Relative to noncomparative ads, comparative ads were shown to result in greater purchase intentions (Refs. 2 to 4 and7). Finally, other evidence suggests that there may be more potential for consumers to confuse brands when viewing comparative versus noncomparative ads. Brands advertised in a comparative format were shown to be more likely to be perceived as similar to the leading brand than brands advertised in a noncomparative format (Refs. 8 to 10).

B. Comparative Prescription Drug Advertisements

Despite extensive research on comparative advertising of consumer products and a limited number of studies on how DTC ads could help consumers compare drugs (Refs. 11 and 12), very little research has been conducted on comparative prescription drug advertisements (Ref. 13). Consequently, it is unclear whether these findings are applicable to comparative drug ads or how such claims influence consumers' perceived efficacy of advertised drugs.

Currently, most DTC ad comparisons focus on drug attributes, such as differences in dosing or administration method (see 21 CFR 314.126). Because few head-to-head clinical trials have been conducted, very few DTC ads include efficacy-based comparisons (Ref. 13). The present study aims to investigate how consumers interpret and react to DTC comparative drug ads. Specifically, the study will explore two types of drug comparisons in DTC ads: (1) Drug efficacy comparisons and (2) other evidence-based comparisons, such as dosing, mechanism of action, and indication. The study findings will inform FDA of relevant consumer issues relating to comparative DTC advertising.

C. Design Overview

The proposed research will occur in two concurrent phases. The goal of Phase I is to: (1) Explore how consumers understand and interpret print and

broadcast ads that explicitly compare the efficacy of two similar drugs; and (2) learn whether named comparisons are more likely than unnamed comparisons to promote accurate recall, comprehension, and perceptions. For the purposes of the research described here, named comparisons are ones in which the ad explicitly compares the drug's efficacy to another named medication (e.g., Drug A was shown to be more effective than Drug B at lowering high cholesterol). Unnamed comparisons are ones in which the ad implicitly compares the drug's efficacy to other medications (e.g., Compared to other medications, Drug A lowered cholesterol in more patients). These different types of comparisons will be examined in print and television ads and will include appropriate control conditions in a 2 (ad type: print or broadcast) x 3 (comparison type: named, unnamed, or none) design as shown below.

TABLE 1—DESIGN

Ad type	Named comparison	Unnamed comparison	Control group
Print Ad	Arm #1	Arm #3	Arm #5.
Broadcast Ad	Arm #2	Arm #4	Arm #6.

The goal of Phase II is to (1) determine if consumers infer that one drug is better or more effective than another from ads that include different types of drug label comparisons (*i.e.,* indication, dosing, mechanism of action, drug risk), and (2) if consumers consider switching medications based on these comparisons in advertisements. We will examine four types of drug comparisons that are currently being used in DTC prescription drug ads. An indication-to-indication comparison highlights the approved indications of the advertised drug and the comparator drug (e,g., Drug X is approved to prevent and treat osteoporosis; Drug B is approved to treat osteoporosis). Dosing comparisons are those that compare the dosing schedule or dosing characteristics of two drugs (e.g., You can take Drug A in pill form; Drug B must be injected in a medical office). Mechanism of action comparisons involve differences in the way the two drugs work (e.g., Drug A works by targeting the build up of fat in the arteries; Drug B works by targeting that fat and by disintegrating tangier cells in the esophagus). Finally, risk comparisons involve ads that compare the risk profiles of more than one drug or the specific risks of more than one drug (e.g., Drug A has been known to cause liver failure in rats; Drug B has not shown liver damage in rats).

We will also explore whether conveying these comparisons with visual images moderates these results. Half of the participants will examine a print ad and the other half will view a television ad. We propose two fully-factorial 2 (comparison type: named or unnamed) x 2 (visual: present or absent) x 4 (drug aspect: indication, dosing, mechanism of action, drug risk) designs, one for print ads and one for television ads, as shown below. This design also includes two appropriate control groups.

For print ads:

TABLE 2—DESIGN FOR PRINT ADS

Comparison type	Visual type	Indication	Dosing	Mechanism of action	Drug risks	Control group
Named	Visual	Arm #1	Arm #5	Arm #9	Arm #13	Arm #17.
Unnamed	Visual	Arm #2	Arm #6	Arm #10	Arm #14.	
Named	No Visual	Arm #3	Arm #7	Arm #11	Arm #15.	
Unnamed	No Visual	Arm #4	Arm #8	Arm #12	Arm #16.	

For television ads:

TABLE 3—DESIGN FOR TELEVISION ADS

Comparison type	Visual type	Indication	Dosing	Mechanism of action	Drug risks	Control group
Named	Visual	Arm #1	Arm #5	Arm #9	Arm #13	Arm #17.
Unnamed	Visual	Arm #2	Arm #6	Arm #10	Arm #14.	
Named	No Visual	Arm #3	Arm #7	Arm #11	Arm #15.	
Unnamed	No Visual	Arm #4	Arm #8	Arm #12	Arm #16.	

All parts of this study will be administered over the Internet. Participants will be randomly assigned to view one version of a DTC prescription drug print ad or a prescription drug television ad. Following their perusal of this document or video, they will answer questions about their recall and understanding of the benefit and risk information, their perceptions of the benefits and risks of the drug, and their intent to ask a doctor about the medication. The entire procedure is expected to last approximately 20 minutes. A total of 9,560 participants will be involved in the study. This will be a one-time (rather than annual) information collection.

In the **Federal Register** of July 1, 2011 (76 FR 38663), FDA published a 60-day notice requesting public comment on the proposed collection of information. FDA received two public comments. One commenter failed to attach any comment, and the other commenter discussed issues far outside the scope of the proposed research (*i.e.,* about morning-after contraception). Thus, the

design presented in this notice reflects only changes suggested by external peer reviewers and further discussion among research team members.

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

TABLE 4—ESTIMATED ANNUAL REPORTING BURDEN [1]

Activity	Number of respondents	Number of responses per respondent	Total annual responses	Average burden per response	Total hours
Screener	19,120	1	19,120	0.03 (2 min.)	637
Pretest	900	1	900	0.33 (20 min.)	300
Main Study	8,660	1	8,660	0.33 (20 min.)	2,887
Total					3,824

[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 (HFA–305), Food and Drug Administration, 5630 Fishers Lane, rm. 1061, Rockville, MD 20852, and may be seen by interested persons between 9 a.m. and 4 p.m., Monday through Friday. (FDA has verified the Web site addresses, but FDA is not responsible for any subsequent changes to the Web sites after this document publishes in the **Federal Register.**)

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4. Grewal, D., S. Kavanoor, E.F. Fern, et al., ''Comparative Versus Noncomparative Advertising: A Meta-Analysis,'' *Journal of Marketing,* vol. 61, pp. 1–15, 1997.
5. Priester, J.R., J. Godek, D.J. Nayakankuppum, et al., ''Brand Congruity and Comparative Advertising: When and Why Comparative Advertisements Lead to Greater Elaboration,'' *Journal of Consumer Psychology,* vol. 14, pp. 115–123, 2004.
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8. Droge, C. and R.Y. Darmon, ''Associative Positioning Strategies Through Comparative Advertising: Attribute Versus Overall Similarity Approaches,'' *Journal of Marketing Research,* vol. 24, pp. 377–388, 1987.
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11. Schwartz, L.M., S. Woloshin, and H.G. Welch, ''Using a Drug Facts Box to Communicate Drug Benefits and Harms: Two Randomized Trials.'' *Annals of Internal Medicine,* vol. 150, pp. 516–527, 2009.
12. Hauber, A.B., A.F. Mohamed, F.R. Johnson, et al., ''Treatment Preferences and Medication Adherence of People With Type 2 Diabetes Using Oral Glucose-Lowering Agents,'' *Diabetic Medicine: A Journal of the British Diabetic Association,* vol. 26, pp. 416–424, 2009.
13. Mitra, A., J. Swasy,, and K. Aikin, ''How Do Consumers Interpret Market Leadership Claims in Direct-to-Consumer Advertising of Prescription Drugs?'' *Advances in Consumer Research,* vol. 33, pp. 381–387, 2006.

Dated: December 5, 2011.

Leslie Kux,

Acting Assistant Commissioner for Policy.

[FR Doc. 2011–31609 Filed 12–8–11; 8:45 am]

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2011–N–0769]

Notice of Listing of Members of the Food and Drug Administration's Senior Executive Service Performance Review Board

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is publishing a list of members who may be named to serve on FDA's Senior Executive Performance Review Board or Panels, which oversee the evaluation of performance appraisals of FDA's Senior Executive Service (SES) members. The Civil Service Reform Act of 1978 requires that the appointment of Performance Review Board Members be published in the **Federal Register.**

FOR FURTHER INFORMATION CONTACT: Mary Wathen, Office of Management Programs, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 1, rm. 4310, Silver Spring, MD 20993, (301) 796–8848.

SUPPLEMENTARY INFORMATION: The Civil Service Reform Act of 1978 (5 U.S.C. 4314(c)(4)) (Public Law 95–454) requires that the appointment of Performance Review Board Members be published in the **Federal Register.** The following persons may be named to serve on FDA's Performance Review Board or Panels.

SES	Non-SES
Jeanne Anson	Dennis Baker
Deborah Autor	Norman Baylor
Jane Axelrad	Nega Beru
Lawrence Bachorik	Gail Costello
Glenda Barfell	Lawrence Deyton