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Dated: June 27, 2011.

Leslie Kux,

Acting Assistant Commissioner for Policy.

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No FDA–2011–N–0457]

Agency Information Collection Activities; Proposed Collection; 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 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 the Experimental Study of Comparative Direct-to-Consumer (DTC) Advertising. This study is designed to explore how consumers understand and interpret DTC ads that explicitly compare the efficacy, dosing, and risks, among other items, of two similar drugs whether comparisons are named or unnamed.

DATES: Submit either electronic or written comments on the collection of information by August 30, 2011.

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: Elizabeth Berbakos, Office of Information Management, Food and Drug Administration, 1350 Piccard Dr., P150–400B, Rockville, MD 20850, 301–796–3792, Elizabeth.Berbakos@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 of Comparative Direct-to-Consumer (DTC) Advertising Regulatory Background—(OMB Control No. 0910–New)

Section 1701(a)(4) of the Public Health Service Act (42 U.S.C. 300u(a)(4)) authorizes the Food and Drug Administration (FDA) to conduct research relating to health information. Section 903(b)(2)(c) of the Federal Food, Drug, and Cosmetic Act (the FD&C 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 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 U.S.C. 202.1(e)(6)(ii); 21 U.S.C. 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 may use 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 DTC advertising, where little research has been conducted to date.

Moreover, as part of the American Recovery and Reinvestment Act of 2009 (ARRA), the Agency for Healthcare Research and Quality (AHRQ) 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.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.² 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.³ 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.⁴ 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.⁵

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,⁶ very little research has been conducted on comparative prescription drug advertisements.⁷ 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.⁸ Because few head-to-head clinical trials have been conducted, very

few DTC ads include efficacy-based comparisons;⁹ however, this may change given the current national focus on comparative effectiveness research. Given the growing opportunities for comparative prescription drug advertising, 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

This study will be conducted in two concurrent parts with random assignment to experimental condition. The goal of Phase I is to: (a) Explore how consumers understand and interpret ads that explicitly compare the efficacy of two similar drugs; and (b) learn whether including the name of the comparison drug affects comprehension and perceptions. We have defined named comparisons as ads that explicitly compare the drug’s efficacy to another named medication. An example of this is: “Drug A was shown to be more effective than Drug B at lowering high cholesterol.” We have defined unnamed comparisons as ads that implicitly compare the drug’s efficacy to other medications. An example of this is: “Compared to other medications, Drug A lowered cholesterol in more patients.” The control condition will not include a comparison to another drug.

We will explore the issue of named versus unnamed comparisons in print ads and television ads in a 2×3 factorial design as follows:

¹ <http://www.ahrq.gov/fund/cerfactsheets/>. Last accessed May 23, 2011.

² Ang, S. H., and S. B. Leong (1994), “Comparative advertising: superiority despite interference?”, *Asia Pacific Journal of Management*, 11(1), 33–46; Demirdjian, Z. S. (1983), “Sales effectiveness of comparative advertising: An experimental field investigation,” *Journal of Consumer Research*, 10, 362–364; Grewal, D., S. Kavanoor, E. F. Fern; C. Costley, and J. Barnes (1997), “Comparative versus noncomparative advertising: a meta-analysis,” *Journal of Marketing*, 61(4), 1–15; Priester, J. R., J. Godek, D.J. Nayankuppum, and K. Park (2004), “Brand congruity and comparative advertising: When and why comparative advertisements lead to greater elaboration,” *Journal of Consumer Psychology*, 14(1/2), 115–123.

³ See, for example, Grewal, D., S. Kavanoor, E. F. Fern, C. Costley, and J. Barnes (1997), “Comparative versus noncomparative advertising: A meta-analysis,” *Journal of Marketing*, 61(4), 1–15; Rogers, J. C., and T. G. Williams, (1989), “Comparative advertising effectiveness: Practitioners’ perceptions versus academic research findings,” *Journal of Advertising Research*, 29(5), 22–37.

⁴ Ang, S. H., S. B. Leong (1994), “Comparative advertising: superiority despite interference?”, *Asia Pacific Journal of Management*, 11(1), 33–46; Demirdjian, Z. S. (1983), “Sales effectiveness of comparative advertising: An experimental field investigation,” *Journal of Consumer Research*, 10, 362–364; Grewal, D., S. Kavanoor, E. F. Fern, C. Costley, and J. Barnes (1997), “Comparative versus noncomparative advertising: a meta-analysis,” *Journal of Marketing*, 61(4), 1–15; Miniard, P. W., M. J. Barone, R. L. Rose, and K. C. Manning (1994), “A re-examination of the relative persuasiveness of comparative and noncomparative advertising,” *Advances in Consumer Research*, 21(1), 299–303.

⁵ Droge, C. and R. Y. Darmon (1987), “Associative positioning strategies through comparative advertising: Attribute versus overall similarity approaches,” *Journal of Marketing Research*, 24, 377–388; Gorn, G. J. and C.B. Weinberg (1984), “The impact of comparative advertising on perception and attitude: Some positive findings,” *Journal of Consumer Research*, 11, 719–727; Iyer, E. S. (1988), “The influence of verbal content and relative newness on the effectiveness of comparative advertising,” *Journal of Advertising*, 17(3), 15–21.

⁶ See, for example, Schwartz, L. M., S. Woloshin, and H. G. Welch (2009), “Using a drug facts box to communicate drug benefits and harms: two randomized trials,” *Annals of Internal Medicine*, 150(8), 516–527; Hauber, A. B., A. F. Mohamed, F. R. Johnson, and H. Falvey (2009), “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*, 26(4), 416–424.

⁷ Mitra, A., J. Swasy, and K. Aikin (2006), “How do consumers interpret market leadership claims in direct-to-consumer advertising of prescription drugs?”, *Advances in Consumer Research*, 33, 381–387.

⁸ Applications for FDA Approval to Market a New Drug, 21 CFR 314.126. (2008), retrieved from http://edocket.access.gpo.gov/cfr_2008/aprqr/pdf/21cfr314.126.pdf.

⁹ Mitra, A., J. Swasy, and K. Aikin (2006), “How do consumers interpret market leadership claims in direct-to-consumer advertising of prescription drugs?”, *Advances in Consumer Research*, 33, 381–387.

TABLE 1—PROPOSED DESIGN OF PHASE I (2 × 3)

Type of Ad	Labeling of Comparison Drug		
	Named	Unnamed	Control
Print			
Television			

The goal of Phase II is to determine how ads that include evidence-based comparisons are understood by consumers. These ads often compare factual characteristics from the drug labels (e.g., dosing, mechanism of action). These characteristics do not necessarily affect drug efficacy, yet consumers may infer that one drug is better or more effective than another. We will examine four such comparisons: Indication, dosing,

mechanism of action, and risk. In this phase, we also examine the salience of the comparison drug by manipulating whether the comparison drug is named in the ad or not. In this case, an example of a named comparison is: “Drug A is taken only once a month, unlike Drug B, which you have to take every day.” An example of a relevant unnamed comparison is: “Drug A is the only medication that treats both high cholesterol and high blood pressure.”

Finally, we will explore whether the presence of a visual aid alters the understanding of these presentations. The control condition will not include a comparison to another drug.

These factors will be combined in a (2[type of ad] × 2[labeling of comparison drug] × 2[presence of visual] × 4[type of comparison] + 2[controls]) factorial design. For ease of illustration, the design is shown separately for print and television ads.

Table 2.--Proposed design of Phase II for print ads (2 x 2 x 4 + 1)

Labeling of Comparison Drug	Presence of Visual	Type of Comparison			
		Indication	Dosing	MOA*	Risk
Named	Visual				
	No Visual				
Unnamed	Visual				
	No Visual				

*MOA = Mechanism of Action

+

Control

Table 3.--Proposed design of Phase II for television ads (2 x 2 x 4 + 1)

Labeling of Comparison Drug	Presence of Visual	Type of Comparison			
		Indication	Dosing	MOA*	Risk
Named	Visual				
	No Visual				
Unnamed	Visual				
	No Visual				

*MOA = Mechanism of Action

+

Control

In both phases, we will examine the effects of these manipulated variables on several dependent measures, including perceived benefit and risk, comprehension of benefit and risk information, and behavioral intentions. We will also include demographic variables (such as gender and education level), and other variables such as

health knowledge as covariates to determine if they have any influence on the measures of interest.

The sample will include approximately 8,000 participants who have been diagnosed with osteoarthritis (Phase I) or high cholesterol (Phase II). The protocol will take place via the Internet. Participants will be randomly assigned to view one print or one

television ad for a fictitious prescription drug that treats either osteoarthritis or high cholesterol and will answer questions about it. The entire process is expected to take no longer than 20 minutes. This will be a one time (rather than annual) collection of information.

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

TABLE 4—ESTIMATED ANNUAL REPORTING BURDEN¹

Activity	No. of respondents	No. of responses per respondent	Total annual responses	Average burden per response	Total hours
Screener	16,000	1	16,000	.03 (2 min.)	480
Pretest	600	1	600	.33 (20 min.)	200

TABLE 4—ESTIMATED ANNUAL REPORTING BURDEN ¹—Continued

Activity	No. of respondents	No. of responses per respondent	Total annual responses	Average burden per response	Total hours
Main Study	8,000	1	8,000	.33 (20 min.)	2,640
Total					3,320

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

Dated: June 28, 2011.
Leslie Kux,
Acting Assistant Commissioner for Policy.
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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA-2011-N-0012]

Food and Drug Administration (FDA) and Marine Environmental Sciences Consortium/Dauphin Island Sea Lab Collaboration (U19)

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is announcing the availability of grant funds for the support of a cooperative agreement between the Center for Food Safety and Applied Nutrition (CFSAN) and the Marine Environmental Sciences Consortium/Dauphin Island Sea Lab (DISL). The goal of the DISL is marine science education, basic and applied marine science research, coastal zone management policy, and educating the general public.

- DATES:** Important dates are as follows:
1. The application due date is August 1, 2011.
 2. The anticipated start date is September, 2011.
 3. The opening date is the date the Funding Opportunity is published in the **Federal Register**.
 4. The expiration date is August 2, 2011.

FOR FURTHER INFORMATION AND ADDITIONAL REQUIREMENTS CONTACT:

Scientific/Programmatic Contact

Robert Dickey, Office of Food Safety, Gulf Coast Seafood Laboratory, One Iberville Dr., PO. D1-1, rm. 122 (HFS 400), Dauphin Island, AL 36528,. Tele.: 251-690-3368; e-mail: *Robert.Dickey@fda.hhs.gov*.

Grants Management Contact

Gladys Melendez-Bohler, Office of Acquisition and Grant Services (OAGS), Food and Drug Administration, 5630 Fishers Lane, rm. 1078, Rockville, MD 20857, Tele.: 301-827-7175; e-mail: *Gladys-Melendez-Bohler@fda.hhs.gov*.

For more information on this funding opportunity announcement (FOA) and to obtain detailed requirements, please refer to the full FOA located at <http://www.fda.gov/Food/NewsEvents/default.htm>.

SUPPLEMENTARY INFORMATION:

RFA-FD-11-015; 93.103.

A. Background

This FOA issued by the FDA/Office of Food Safety is soliciting a sole source grant application from the Dauphin Island Sea Lab (DISL). FDA is authorized to enforce the Federal Food, Drug, and Cosmetic Act (the FD&C Act) as amended (21 U.S.C. 301 *et seq.*). In fulfilling its responsibilities under the FD&C Act, FDA among other things, directs its activities toward promoting and protecting the public health by ensuring the safety and security of foods (Appendix A). To accomplish its mission, FDA must stay abreast of the latest developments in research and also communicate with stakeholders about complex scientific and public health issues. Increased development of research, education and outreach partnerships with the Marine Environmental Science Consortium-Dauphin Island Sea Lab (DISL) will greatly contribute to FDA's mission.

The DISL is one of Alabama's most valuable assets and adds immeasurably to the quality of life in the state and beyond. The DISL network of 21 institutions enrolls students worldwide in degree programs delivered in classrooms, laboratories, education centers, and online. The DISL's nationally ranked programs, leading-edge research collaborations, and innovative business partnerships provide an environment to support diverse multidisciplinary exchanges with FDA. The scientific, public health and policy expertise within FDA provide opportunities for collaborations

that support the DISL mission and strategic themes to provide access to high-quality education, research discovery, and knowledge-based services responsive to both the promises and demands of the state and the nation in the new century.

B. Research Objectives

FDA Gulf Coast Seafood Laboratory (GCSL) and the Marine Environmental Science Consortium of the DISL (the Parties) have a shared interest in scientific progress in the diverse disciplines that directly and indirectly affect seafood safety and human and animal health. The Parties also endorse scientific training for faculty, students and staff to foster a well-grounded foundation in interdisciplinary fields in which academia and government share mutual interest.

The cooperative agreement will establish terms of collaboration between FDA and DISL to support these shared interests that can be pursued through programs of collaborative research, public outreach, cooperative international initiatives, disciplinary training, and exchange of scientists and staff, including a program of graduate student internships.

The types of activities expected to develop from this agreement include:

- Exchanges between university faculty and staff and FDA scientists and staff;
- Educational opportunities for qualified students (graduate), staff members and faculty members in the Parties' laboratories, classroom and offices;
- Joint meetings for education and research;
- Research collaborations;
- Cooperative international activities including outreach; and
- Sharing of unique facilities and equipment for increased cost efficiencies for scientific endeavors;
- Promulgation and communication of identified collaborative efforts through appropriate means;
- Adjunct, affiliates and research facility appointments for appropriate FDA professional staff, provided that appointment of such candidates will advance specific programmatic