

APPENDIX A

[Federal Register Volume 76, Number 127 (Friday, July 1, 2011)]
[Notices]
[Pages 38663-38666]
From the Federal Register Online via the Government Printing Office
[\[www.gpo.gov\]](http://www.gpo.gov)
[FR Doc No: 2011-16628]

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

[[Page 38664]]

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. 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.

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

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\

\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. Nayakankuppum, 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.

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.

\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.

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.

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

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 2x3 factorial design as follows:

[[Page 38665]]

Table 1--Proposed Design of Phase I (2 x 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

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.
[FR Doc. 2011-16628 Filed 6-30-11; 8:45 am]
BILLING CODE 4160-01-P