total estimated annualized burden hours are 10,832.

ESTIMATED ANNUALIZED BURDEN TABLE

Type of respondent	Form name	No. of respondents	No. of responses per respondent	Average burden per response (in hours)
Hospital Chief Executive Officer	Hospital Induction (NHAMCS–101)	482	1	1
Ancillary Service Executive	Freestanding ASC Induction (NHAMCS–101FS).	200	1	1.5
Ancillary Service Executive	Ambulatory Unit Induction (NHAMCS–101U)	1,779	1	1
Physician/Registered Nurse/Medical Record Clerk.	ED Patient Record form NHAMCS–100 (ED)	225	100	7/60
Physician/Registered Nurse/Medical Record Clerk.	OPD Patient Record form NHAMCS–100 (OPD).	128	200	6/60
Physician/Registered Nurse/Medical Record Clerk.	ASC Patient Record Form NHAMCS–100 (ASC).	208	100	6/60
Medical Record Clerk	Pulling and re-filing Patient Records (ED, OPD, and ASC).	425	133	1/60
Physician/Physician Assistant/Nurse Practitioner/Nurse Midwife.	Cervical Cancer Screening Supplement (CCSS) (NHAMCS–906).	255	1	15/60

Dated: June 15, 2009.

Maryam I. Daneshvar,

Acting Reports Clearance Officer, Office of the Chief Science Officer, Centers for Disease Control and Prevention.

[FR Doc. E9–14553 Filed 6–19–09; 8:45 am]

BILLING CODE 4163–18–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2009–N–0263]

Agency Information Collection Activities; Proposed Collection; Comment Request; Experimental Study of Presentation of Quantitative Effectiveness Information to Consumers in Direct-to-Consumer Television and Print Advertisements for Prescription Drugs

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 Presentation of Quantitative Effectiveness Information to Consumers in Direct-to-Consumer (DTC) Television and Print Advertisements for Prescription Drugs. This study is designed to communicate quantitative information about product benefits in DTC print and television ads.

DATES: Submit written or electronic comments on the collection of information by [*August 21, 2009*

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

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 Presentation of Quantitative Effectiveness Information to Consumers in Direct-to-Consumer (DTC) Television and Print Advertisements for Prescription Drugs—New

The Federal Food, Drug, and Cosmetic Act (the act) requires that manufacturers, packers, and distributors (sponsors) who advertise prescription human and animal drugs, including biological products for humans, disclose in advertisements certain information about the advertised product's uses and risks.[1] By its nature, the presentation of

[1] For prescription drugs and biologics, section 502 of the act requires advertisements to contain ''information in brief summary relating to side effects, contraindications, and effectiveness'' (21 U.S.C. 352(n)).

[2] See Swartz, L., S. Woloshin, W. Black, et al., The Role of Numeracy in Understanding the Benefit of

this information is likely to evoke active trade-offs by consumers, i.e., comparisons with the perceived risks of not taking treatment, and comparisons with the perceived benefits of taking a treatment.[2] FDA has an interest in fostering safe and proper use of prescription drugs, an activity that engages both risks and benefits. Therefore, an examination of ways to improve consumers' understanding of this information is central to this regulatory task.

Under the act, FDA engages in a variety of communication activities to ensure that patients and health care providers have the information they need to make informed decisions about treatment options, including the use of prescription drugs. FDA regulations (21 CFR 201.57) describe the content of required product labeling, and FDA reviewers ensure that labeling contains accurate and complete information about the known risks and benefits of each drug.

FDA regulations require that prescription drug advertisements that make (promotional) claims about a product also include risk information in a ''balanced'' manner (21 CFR 202.1(e)(5)(ii)), both in terms of the content and presentation of the information. This balance applies to both the front, display page of an advertisement, as well as including the brief summary page. However, beyond the ''balance'' requirement there is limited guidance and research to direct or encourage sponsors to present benefit claims that are informative, specific, and reflect clinical effectiveness data.

Research and guidance to sponsors on how to present benefit and efficacy information in prescription drug advertisements is limited. For example, ''benefit claims,'' broadly defined, appearing in advertisements are often presented in general language that does not inform patients of the likelihood of efficacy and are often simply variants of an ''intended use'' statement. One content analysis of DTC advertising by Woloshin and Schwartz (2001)[3] found that information about product benefits and risks is often presented in an unbalanced fashion. The researchers classified the ''promotional techniques'' used in the advertisements. Emotional appeals were observed in 67 percent of the ads while vague and qualitative benefit terminology was found in 87 percent of the ads. Only 9 percent contained data. However, for risk information, half the advertisements used data to describe side-effects, typically with lists of side-effects that generally occurred infrequently. Similarly, a content analysis by Frosch et al. (2007)[4] found that only a small proportion of product-claim ads gave specific information about the population prevalence of the medical condition being advertised. The authors criticize DTC for presenting ''best-case scenarios that can distort and inflate consumers' expectations about what prescription drugs can accomplish'' (Froch et al., 2007, p. 12) without disclosing how many consumers are likely to experience that benefit.

Some research has proposed that providing quantitative information about product efficacy enables consumers to make better choices about potential therapy. One possible format (termed the ''drug facts'' box by its creators) for this information has recently received attention.[5] In these studies, the drug facts box format contained information about the product's efficacy and safety in terms of rate (how many people in the clinical trial experienced a benefit or side effect compared to placebo). As expected, this study showed that consumers who were provided efficacy information used it. Participants receiving efficacy information (without other potentially valuable information about the drug) were more likely to correctly choose the product with the higher efficacy than consumers who saw the brief summary that did not contain this information.

Although these results are intriguing, additional research is necessary to uncover important information about how consumers understand effectiveness information about prescription drug products from DTC advertisements. For example, the research to date does not address whether simply adding efficacy rate information and qualitative summations to a consumer-friendly brief summary would enable consumers to find and report the correct answer, or if the presentation of information in a chart format itself increases comprehension.

Further, these data cannot address the best way in which to convey numerical information; percents were used but another format, such as frequencies, may be more effective at communicating quantitative information. Previous research shows that individuals have great difficulty processing numerical concepts (e.g., Beyth-Marom, 1982; Bowman, 2002; Cohen, Ferrell, and Johnson, 2002).[6] A few studies have attempted to determine what different formats make these concepts least troublesome (e.g., Fagerlin, Wang, and Ubel, 2005; Lipkus, 2007),[7] however, most research into the communication of numerical concepts concentrates on risk information. We are not aware of research looking into the integration of quantitative information about effectiveness or benefits into the body of the advertisement itself. The addition of this information may help consumers make better healthcare decisions, provided they can understand it.

It is also not known if ways of communicating product efficacy work equally well across print and television DTC media. To our knowledge, research on presenting quantitative information in risk communication has been conducted exclusively with static modalities. The ideal format for presenting quantitative information may vary as a function of presentation. The amount of mental processing capacity each individual can devote to understanding a message varies depending on how long individuals have to look at the material and whether the material is self-paced or presented at an uncontrollable speed. As a result, some forms of quantitative information may lend themselves to print, rather than broadcast. This particular understanding is crucial to the risk-benefit tradeoff that patients must make with the consultation of a health care professional in order to achieve the best health outcomes.

The proposed study will examine: (1) Various ways of communicating

Screening Mammography, *Annals of Internal Medicine*, 127(11), 966–72, 1997.

[3] Woloshin, S. and L. Schwartz, Direct to Consumer Advertisements for Prescription Drugs: What Are Americans Being Told, *Lancet*, 358, 1141–46, 2001.

[4] Frosch, D.L., P.M. Krueger, R.C. Hornik, et al., Creating Demand for Prescription Drugs: A Content Analysis of Television Direct-to-Consumer Advertising, *Annals of Family Medicine*, 5(1), 6–13, 2007.

[5] Schwartz, L.M., S. Woloshin, H.G. Welch, The Drug Facts Box: Providing Consumers With Simple Tabular Data on Drug Benefit and Harm, *Medical Decision Making*, 27, 655–692, 2007; Schwartz, L.M., S. Woloshin, H.G. Welch, Communicating Drug Benefits and Harms With a Drug Facts Box: Two Randomized Trials, *Annals of Internal Medicine*, 150, 516–527, 2009; Woloshin, S., L.M. Schwartz, H.G. Welch, The Value of Benefit Data in Direct-to-Consumer Drug Ads, *Health Affairs, Suppl Web Exclusives*, W4–234–245, 2004.

[6] Beyth-Marom, R., How Probable is Probable? A Numerical Translation of Verbal Probability Expressions, *Journal of Forecasting*, 1, 257–269, 1982; Bowman, M.L., The Perfidity of Percentiles, *Archives of Clinical Neuropsychology*, 17, 295–303, 2002; Cohen, D.J., J.M. Ferrell, N. Johnson, What Very Small Numbers Mean, *Journal of Experimental Psychology: General*, 131, 424–442, 2002.

[7] Fagerlin, A., C. Wang, P.A. Ubel, Reducing the Influence of Anecdotal Reasoning on People's Health Care Decisions: Is a Picture Worth a Thousand Statistics? *Medical Decision Making*, 25, 398–405, 2005; Lipkus, I., Numeric, Verbal, and Visual Formats of Conveying Health Risks: Suggested Best Practices and Future Recommendations, *Medical Decision Making*, 27, 697–713, 2007.

quantitative efficacy in DTC print ads and (2) whether the findings translate to DTC television ads.

Design Overview: This study will be conducted in two concurrent parts; one examining quantitative information in DTC print advertisements and the other examining such information in DTC television advertisements. Three factors will be examined: Drug efficacy, visual format, and type of statistic. Drug efficacy (low versus high) is defined by a quantifiable, objective metric that can be conveyed in graphical representations of the drug versus the comparator reference drug (in this case, placebo). ''High'' efficacy is noticeably better than the placebo, whereas ''low'' efficacy is minimally better than the placebo. Visual format is defined as various methods through which efficacy can be visually represented. We have chosen to investigate three different formats: Bar graph, pictograph, and pie chart. Type of statistic is defined as the type of statistical information conveyed: Frequency, relative frequency, or percentage. These factors will be combined in a partially crossed factorial design as follows:

TABLE 1.—TYPE OF VISUAL FORMAT X TYPE OF STATISTIC CONVEYED X EFFICACY LEVEL

		Type of Visual Format			
Type of Statistic	Efficacy Level	None	Pie Chart	Bar Chart	Pictograph
Frequency	High Efficacy	✓	✓	✓	✓
	Low Efficacy	✓	✓	✓	✓
Percentage	High Efficacy	✓	✓	✓	N/A
	Low Efficacy	✓	✓	✓	N/A
Combination Frequency + Percentage	High Efficacy	✓	N/A	N/A	N/A
	Low Efficacy	✓	N/A	N/A	N/A
Relative Frequency	High Efficacy	✓	N/A	N/A	N/A
	Low Efficacy	✓	N/A	N/A	N/A
Relative Frequency + Absolute Rate	High Efficacy	✓	N/A	N/A	N/A
	Low Efficacy	✓	N/A	N/A	N/A
None	N/A	✓	N/A	N/A	N/A

The test product will be for the treatment of high cholesterol and modeled on an actual drug used to treat that condition (such as Lipitor©). The product labeling will be used as the reference for defining the high- and low-efficacy levels and the objective metrics for clinical performances. Because both parts of the study will run concurrently, experimental conditions will be identical in both the print and television portions.

Participants will read or view one ad version. After reading the ad, participants will make a series of judgments about the drug. The mean difference between the low- and high-efficacy condition will serve as the baseline for testing whether this difference varies across various graphical presentations, with the exception of the No Information (control) condition. In other words, our analyses will involve two steps. In step 1, within each format, we will test whether participants were able to distinguish between low- and high-efficacy drugs. In step 2, within each efficacy level, we will test whether participants' estimates of efficacy differ across formats and examine the accuracy of these estimates.

Interviews are expected to last no more than 20 minutes. A total of 4,500 participants will be involved in the 2 parts of the study. This will be a one time (rather than annual) collection of information.

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

The total respondent sample for this data collection is 4,500 (2,225 in each part). We estimate the response burden to be 20 minutes, for a burden of 1,485 hours.

The response burden chart is listed in table 2 of this document.

TABLE 2.—ESTIMATED ANNUAL REPORTING BURDEN[1]

21 CFR Section	No. of Respondents	Annual Frequency per Response	Total Annual Responses	Hours per Response	Total Hours
	4,500	1	4,500	.33	1,485
Total	4,500	1	4,500	.33	1,485

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

Dated: June 15, 2009.

Jeffrey Shuren,

Associate Commissioner for Policy and Planning.

[FR Doc. E9–14501 Filed 6–19–09; 8:45 am]

BILLING CODE 4160–01–S

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Administration for Children and Families

Submission for OMB Review; Comment Request

Title: Cross-Site Evaluation of the Infant Adoption Awareness Training Program for Projects Initially Funded in Fiscal Year 2006–NEW.

OMB No.: New Collection.

Description: The Administration for Children and Families (ACF), Childrens Bureau (CB), will conduct the Cross-Site Evaluation of the Infant Adoption Awareness Training Program (IAATP). Title XII, subtitle A, of the Childrens Health Act of 2000 (CHA) authorizes the Department of Health and Human Services to make Infant Adoption Awareness Training grants available to national, regional, and local adoption organizations for the purposes of developing and implementing programs that train the staff of public and non-profit private health service organizations to provide adoption information and referrals to pregnant women on an equal basis with all other courses of action included in non-directive counseling of pregnant women. Participants in the training include individuals who provide pregnancy or adoption information and those who will provide such services after receiving the training, with Title X (relating to voluntary family planning projects), section 330 (relating to community health centers, migrant health centers, and centers serving homeless individuals and residents of public housing), and CHA-funded school-based health centers, receiving priority to receive the training. A total of six organizations were awarded IAATP funding in 2006.

Section 1201(a)(2)(A) of the IAATP legislation requires grantees to develop and deliver trainings that are consistent with the Best Practice Guidelines for Infant Adoption Awareness Training. The IAATP guidelines address training goals, basic skills, curriculum and training structure. A complete description of the guidelines is available at *http://www.acf.hhs.gov/programs/cb/programs_fund/discretionary/iaatp.htm.*

In addition, grantees are required to conduct local evaluation of program outcomes and participate in the national evaluation of the extent to which IAATP training objectives are met. The Infant Adoption Awareness Training Program: Trainee Survey is the primary data collection instrument for the national cross-site evaluation. Respondents will complete the survey prior to receiving training and approximately 90 days after the training to assess the extent to which trainees demonstrate sustained gains in their knowledge about adoption, and to determine the impact of the training on their subsequent work with pregnant women.

1. Do health care workers who participate in the IAATP training: Demonstrate enhanced knowledge, attitudes, skills, and behaviors with respect to adoption counseling following completion of the program? Provide adoption information to pregnant women on an equal basis with other pregnancy planning options? Demonstrate enhanced awareness of community adoption-related resources and refer expectant mothers to them as needed?

2. Are trainees more confident about discussing all three pregnancy planning options (parenting, abortion, and adoption) in a non-directive counseling style than they were prior to participating in the training? Cross-site evaluation data will be collected on an annual basis throughout the five-year funding period. Pre-test and follow-up versions of the survey are expected to require approximately 10 to 15 minutes to complete. Estimated response time for the follow-up survey includes time for respondents to access the Web-based survey, complete the survey online, and electronically submit the survey. Respondents will not need to implement a recordkeeping system or compile source data in order to complete the survey. Where possible, fields in the follow-up version of the survey will be pre-filled with static data from the respondents pre-test (*e.g.,* demographics, agency type) in order to further expedite completion of the survey and minimize respondent burden.

Respondents: Infant Adoption Awareness Program Trainees.

ANNUAL BURDEN ESTIMATES

Instrument	Number of respondents	Number of responses per respondent	Average burden hours per response	Total burden hours
IAATP: Trainee Survey Pre-Test Administration	1,200	1	0.15	180
IAATP: Trainee Survey Follow-Up Administration	1,200	1	0.10	120

Estimated Total Annual Burden Hours: 300.

Additional Information

Copies of the proposed collection may be obtained by writing to the Administration for Children and Families, Office of Administration, Office of Information Services, 370 L'Enfant Promenade, SW., Washington, DC 20447, Attn: ACF Reports Clearance Officer. All requests should be identified by the title of the information collection. E-mail address: *infocollection@acf.hhs.gov.*

OMB Comment

OMB is required to make a decision concerning the collection of information between 30 and 60 days after publication of this document in the **Federal Register**. Therefore, a comment is best assured of having its full effect if OMB receives it within 30 days of publication. Written comments and recommendations for the proposed information collection should be sent directly to the following:

Office of Management and Budget, Paperwork Reduction Project, Fax: 202–395–6974, Attn: Desk Officer for the Administration for Children and Families.