TABLE 2—ESTIMATED ANNUAL RECORDKEEPING BURDEN [1]

21 CFR Section	No. of recordkeepers	Annual frequency per recordkeeper	Total annual records	Hours per recordkeeper	Total hours
516.141	30	2	60	0.5	30
516.165	10	2	20	1	20
Total					50

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

Dated: November 29, 2010.

Leslie Kux,

Acting Assistant Commissioner for Policy.

[FR Doc. 2010–30316 Filed 12–2–10; 8:45 am]

BILLING CODE 4160–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2010–N–0266]

Agency Information Collection Activities; Submission for Office of Management and Budget Review; Comment Request; Study of Clinical Efficacy Information in Professional Labeling and Direct-to-Consumer Print Advertisements for Prescription Drugs

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 3, 2011.

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 e-mailed to *oira_submission@omb.eop.gov*. All comments should be identified with the OMB control number 0910-new and title "Study of Clinical Efficacy Information in Professional Labeling and Direct-to-Consumer (DTC) Print Advertisements for Prescription Drugs." Also include the FDA 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., PI50–400B, Rockville, MD 20850, 301–796–3792, *Elizabeth.Berbakos@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. Study of Clinical Efficacy Information in Professional Labeling and Direct-to-Consumer (DTC)

Print Advertisements for Prescription Drug—(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(b)(2)(c) of the Federal Food, Drug, and Cosmetic Act (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.

FDA regulations require that an advertisement that makes claims about a prescription drug include a "fair balance" of information about the benefits and risks of the advertised product, in terms of both content and presentation (21 CFR 202.1(e)(5)(ii)). In past research FDA has focused primarily on the risk component of the risk-benefit ratio. In the interest of thoroughly exploring the issue of fair balance, however, the presentation of effectiveness, or benefit, information is equally important.

The FD&C 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 this risk 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] Since FDA has an interest in fostering safe and proper use of prescription drugs, an activity that engages both risks and benefits, an in-depth understanding of consumers' processing of this information is central to this regulatory task.

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. In a content analysis of DTC advertising,[3] 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. For risk information, however, half the advertisements used data to describe side-effects, typically with lists of side-effects that generally occurred infrequently.

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 (aka "display") page of an advertisement, as well as the brief summary page. However, beyond the "balance" requirement limited guidance and research exists to direct or encourage sponsors to present benefit claims that are informative, specific, and reflect clinical effectiveness data.

The purpose of this project is to: (1) Understand how physicians process clinical efficacy information and how

[1] For prescription drugs and biologics, the FD&C Act requires advertisements to contain "information in brief summary relating to side effects, contraindications, and effectiveness" (21 U.S.C. 352(n)).

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

they interpret approved product label information,[4] (2) determine physician preferences for alternative presentations of clinical efficacy information in DTC advertising, and (3) examine how different presentations of clinical efficacy information in DTC advertising affect consumers' perceptions of efficacy and safety. Specifically, we are interested in how physicians and consumers make risk/benefit assessments and particularly, how consumers make such judgments in response to variations in the efficacy presentations in the "display" (first) page of a DTC print ad. A particular concern is whether certain presentations cause consumers to form skewed perceptions or unfounded risk/benefit tradeoffs. Therefore, we will investigate to what extent consumers, when provided with efficacy information, form perceptions that correspond with clinically-based physicians' assessments of the benefits, risks, and benefit/risk tradeoffs of the same drugs. These studies will inform FDA's thinking regarding how manufacturers may provide useful and non-misleading efficacy information in DTC print advertisements.

[4] As part of this effort, a qualitative mental models procedure was completed that helped us determine how physicians think about the efficacy of potential pharmaceutical options (OMB control no. 0910–0649).

Design Overview

This study will be conducted in two concurrent, independent parts. The first part will involve 2,500 consumers in an experimental examination of variations of the display page of print DTC ads for two fictitious drugs, closely approximating existing drugs for overactive bladder (OAB) and benign prostatic hyperplasia (BPH). In the second part, 600 general practitioners will review and evaluate a fictitious "approved" label for the same conditions. This design will allow us to compare consumers' perceptions of efficacy with a more objective measure of the true efficacy of the drug as measured by physician perceptions of clinical efficacy from labeling.

Consumer experiment. In this part of the study, women who have been diagnosed with or are at risk for OAB (self-designated based on relevant symptoms) will be recruited and will view one version of a DTC ad for a drug to treat OAB. Men who have been diagnosed with or are at risk for BPH (self-designated based on relevant symptoms) will be recruited and will view one version of a DTC ad for a drug to treat BPH. Although the two conditions are somewhat specific to gender (men can suffer from OAB but it is much more prevalent in women), they share many of the same symptoms and characteristics. These medical conditions afford us the ability to maintain various realistic manipulations of placebo level and type of claim, as explained below. The graphical elements and construction of the two ads will be comparable yet still realistic.

Consumers will be randomly assigned to see 1 of 12 DTC print ads within their respective medical condition and will answer questions about the effectiveness and safety of the fictitious drug advertised in them. These twelve experimental conditions will be created by examining three independent variables in the following manner: Type of claim (2 levels: Treatment, prevention), placebo rate (3 levels: High, low, none), and framing (2 levels: Single, mixed). Please note that the numbers describing efficacy seen in the following table are for illustration only. Actual numbers used will be determined by pretesting.

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		Treatment Claim Study		Prevention Claim Study	
		Frame		Frame	
		Single	Mixed	Single	Mixed
Placebo	High	• 30/100 on Drug X reduced urinary frequency and urgency • 20/100 without Drug X reduced urinary frequency and urgency	• 30/100 on Drug X reduced urinary frequency and urgency; 70/100 saw no improvement • 20/100 without Drug X reduced urinary frequency and urgency; 80/100 saw no improvement	• Diagnosed with bladder cancer on Drug X: 4/100 • Diagnosed with bladder cancer without Drug X: 5/100	• Diagnosed with bladder cancer on Drug X: 4/100; Not diagnosed with bladder cancer on Drug X: 96/100 • Diagnosed with bladder cancer without Drug X: 5/100; Not diagnosed with bladder cancer without Drug X: 95/100
	Low	• 30/100 on Drug X reduced urinary frequency and urgency • 3/100 without Drug X reduced urinary frequency and urgency	• 30/100 on Drug X reduced urinary frequency and urgency; 70/100 saw no improvement • 3/100 without Drug X reduced urinary frequency and urgency; 97/100 saw no improvement	• Diagnosed with bladder cancer on Drug X: 4/100 • Diagnosed with bladder cancer without Drug X: 9/100	• Diagnosed with bladder cancer on Drug X: 4/100; Not diagnosed with bladder cancer on Drug X: 96/100 • Diagnosed with bladder cancer without Drug X: 9/100; Not diagnosed with bladder cancer without Drug X: 91/100
	None	• 30/100 on Drug X reduced urinary frequency and urgency	• 30/100 on Drug X reduced urinary frequency and urgency; 70/100 saw no improvement	• Diagnosed with bladder cancer on Drug X: 4/100	• Diagnosed with bladder cancer on Drug X: 4/100; Not diagnosed with bladder cancer on Drug X: 96/100
Extra High Efficacy				• Diagnosed with bladder cancer on Drug X: 4/100 • Diagnosed with bladder cancer without Drug X: 15/100	• Diagnosed with bladder cancer on Drug X: 4/100; Not diagnosed with bladder cancer on Drug X: 96/100 • Diagnosed with bladder cancer without Drug X: 15/100; Not diagnosed with bladder cancer without Drug X: 85/100

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We will investigate variations of numerical presentation in two different types of claims: treatment and prevention. Treatment claims usually involve symptoms that may be alleviated by taking a given prescription drug. This type of claim is directly observable and somewhat testable by patients. If bothersome symptoms do not go away, a patient can return to the healthcare provider with this information and pursue additional options for treatment. In general, drugs that treat symptoms typically show substantial percentages of people who experience relief.

Prevention claims are important but due to their long-term nature, potentially harder to communicate. A drug that prevents a negative future event may not alleviate any symptoms

at all. Patients may feel no benefit from the drug and must trust their healthcare provider and the data, as much as they can process it, that the drug is providing a positive benefit for them. The nature of these claims is such that the event being prevented is relatively rare, and thus the numbers used to describe them are often very small. For example, a cholesterol drug that reduces the risk of heart attack from 3 out of 100 to 2 out of 100 may not seem objectively large, but has enormous consequences for millions of people and the healthcare system in general. We chose to test this type of claim to determine whether consumers are sensitive to the magnitude of the benefit in these clinically meaningful but objectively small and usually asymptomatic outcomes. While we will examine the current issues in both treatment and prevention claims, we do not intend to make comparisons between the two.

The second variable of interest is communication of a placebo rate. Three levels will be examined. In addition to testing a control condition with no placebo information, we will utilize a high and low placebo rate to better understand if and how consumers use placebo information. We see three possibilities: (1) People use placebo numbers correctly, such that the low placebo group demonstrates higher perceived efficacy than the high placebo group; (2) people use the placebo numbers as a peripheral cue to mean "science" so there are no differences between high and low placebo groups on perceived efficacy but both are higher than the no placebo group; and (3) people do not find the numbers meaningful or cannot process them, so the high and low groups do not differ from one another and they do not differ from the no placebo group. In an attempt to make our claims as realistic as possible, we will maintain fairly low rates of prevention in the prevention conditions. For this reason, in addition to the 12 cells in the table previously illustrated in this document, we will also have an additional control cell in which the effectiveness rates are quite high—higher than could reasonably be expected but high enough to be objectively noticeable (*e.g.,* risk of bladder cancer on Drug X, 4/100; risk of bladder cancer on placebo, 15/100). This additional condition will provide confidence that our research manipulations are operating as we expect.

Finally, we will examine the addition of *mixed* framing to the traditional use of a *single positive* frame in a DTC ad. Mixed framing provides the number of people who benefited and the number of people who did not benefit, whereas positive framing provides only the number of people who benefited. Only a few studies have actually measured this mixed approach [5] although risk communication guides recommend the use of mixed framing to create more accurate perceptions.[6] Although a completely balanced design would also include a negative framing condition (which would provide only the number of people who did not benefit), we feel it is unrealistic to create an ad that would suggest, for example, that "Drug X did not work for 70 percent of people in clinical trials," so we have chosen not to include negative framing in our investigation.

In this part of the project, we are most interested in consumers' perceived efficacy and safety, which we can then compare with ratings physicians will provide based on the prescribing information, described in the next section. We will also ask consumers questions to measure their accuracy with regard to claims, their recall of the information in the ad, and demographic questions that may influence their responses, such as knowledge about their medical condition and their level of numeracy.

Physician Study. Six hundred general practitioners [7] will participate in an Internet survey lasting no longer than 20 minutes. They will complete two tasks during this time. In the first task, they will evaluate a prescription drug label (also known as the *prescribing information,* written for healthcare practitioners) for one of the two fictitious drugs described in the consumer study below. To provide a match for the variations of information in the DTC ads the consumers will observe, physicians will be randomly assigned to see prescribing information that varies in terms of claim type, placebo rates in clinical trials, and the medical condition the drug treats (OAB or BPH).

As part of this task, we will obtain timing and sequence information on which sections of the label physicians examine. This will enable us to have a deeper understanding of physicians' processing of the prescribing information. We are not aware of existing literature on this topic. Additionally, physicians will answer questions about the efficacy and safety of the drug and quantitative questions about the benefit shown in the clinical studies (as described in the label). These questions have been designed such that they can be reasonably compared with the responses of consumers who will answer the same questions after viewing a corresponding DTC ad.

In the second task, physicians will see four versions of a print DTC ad for a fictitious product for high cholesterol and will rank the ads in order of how representative of the clinical data as the physicians know it the ads are and how useful they believe the ads would be for their patients.[8] The four versions will be selected to mirror the versions of the OAB/BPH drug that consumers will see in the consumer experiment (*i.e.,* low placebo, frame).

Thus, this research will provide us with a rich data set in order to address several questions: (1) How physicians process clinical efficacy information and how they use approved product label information, (2) how physicians' interpretations of clinical efficacy information relate to their preferences for alternative DTC ad presentations, and (3) which variations of information in DTC ads bring consumers closer to or farther away from the conclusions of the physicians regarding the same drugs.

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

The total respondent sample for this data collection is 3,400. We estimate the response burden to be 20 minutes in the first part and 15 minutes in the second part, for a burden of 906 hours.

In the **Federal Register** of June 16, 2010 (75 FR 34142), FDA published a 60-day notice requesting public comment on the proposed collection of information. No comments were received on the paperwork burden.

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

[5] For a literature review, see Moxey, A., D. O'Connell, P. McGettigan, et al., "Describing Treatment Effects to Patients: How They Are Expressed Makes a Difference," *Journal of General Internal Medicine,* 18, 948–959, 2003.

[6] Fagerlin, A., P.A. Ubel, D.M. Smith, et al., "Making Numbers Matter: Present and Future Research in Risk Communication," *American Journal of Health Behavior,* 31, S47–S56, 2007; Schwartz, L.M., S. Woloshin, H.G. Welch, "Risk Communication in Clinical Practice: Putting Cancer in Context," *Monograph of the National Cancer Institute,* 25, 124–133, 1999.

[7] Including internists, general practitioners, and family practitioners.

[8] To reduce burden, the physician sample will be split in this task, so that half of the physicians see the four ad versions with treatment claims and the other half see the four ad versions with prevention claims. Type of claim is described in greater detail in the consumer experiment section.

TABLE 1—TOTAL ESTIMATED ANNUAL REPORTING BURDEN [1]

21 CFR Section	Number of respondents	Annual frequency per response	Total annual responses	Hours per response	Total hours
Physician survey—pretest	100	1	100	.33	33
Physician survey—main study	600	1	600	.33	198
Consumer experiment—pretest	200	1	200	.25	50
Consumer experiment—main study	2,500	1	2,500	.25	625
Total					906

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

Dated: November 30, 2010.

Leslie Kux,

Acting Assistant Commissioner for Policy.

[FR Doc. 2010–30385 Filed 12–2–10; 8:45 am]

BILLING CODE 4160–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2010–N–0597]

Agency Information Collection Activities; Proposed Collection; Comment Request; Index of Legally Marketed Unapproved New Animal Drugs for Minor Species

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, including each proposed extension of an existing collection of information, and to allow 60 days for public comment in response to the notice. This notice solicits comments on the burden hours associated with indexing of legally marketed unapproved new animal drugs for minor species.

DATES: Submit either electronic or written comments on the collection of information by February 1, 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: Johnny 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, including each proposed extension of an existing 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.

Index of Legally Marketed Unapproved New Animal Drugs for Minor Species—21 CFR Part 516 (OMB Control Number 0910–0620)—Extension

The Minor Use and Minor Species Animal Health Act of 2004 (MUMS Act) amended the Federal Food, Drug, and Cosmetic Act (the FD&C Act) to authorize FDA to establish new regulatory procedures intended to make more medications legally available to veterinarians and animal owners for the treatment of minor animal species (species other than cattle, horses, swine, chickens, turkeys, dogs, and cats), as well as uncommon diseases in major animal species.

The MUMS Act added three new sections to the FD&C Act (sections 571, 572, and 573 (21 U.S.C. 360ccc, 360ccc–1, and 360ccc–2, respectively)). The final rule (72 FR 69108, December 6, 2007) implements section 572 of the FD&C Act, which provides for an index of legally marketed unapproved new animal drugs for minor species. Participation in any part of the MUMS program is optional so the associated paperwork only applies to those who choose to participate. The final rule specifies, among other things, the criteria and procedures for requesting eligibility for indexing and for requesting addition to the index as well as the annual reporting requirements for index holders.

Under the new subpart C of part 516 (21 CFR part 516, subpart C), § 516.119 provides requirements for naming a permanent-resident U.S. agent by foreign drug companies, and § 516.121 provides for informational meetings with FDA. Section 516.123 provides requirements for requesting informal conferences regarding agency administrative actions and § 516.125 provides for investigational use of new animal drugs intended for indexing. Provisions for requesting a determination of eligibility for indexing can be found under § 516.129 and provisions for subsequent requests for addition to the index can be found under § 516.145. A description of the