ESTIMATED ANNUALIZED BURDEN TABLE

Type of survey	Number of respondents	Number of responses/respondent	Average burden/response (in hours)	Total burden hours
Questionnaire for conference registrants/attendees	1,000	1	15/60	250
Focus groups	80	1	1	80
Web-based	1,000	1	20/60	333
Other customer surveys	400	1	15/60	100
Total				763

Dated: December 8, 2005.

Joan F. Karr,

Acting Reports Clearance Officer, Centers for Disease Control and Prevention.

[FR Doc. E5–7382 Filed 12–14–05; 8:45 am]

BILLING CODE 4163–18–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. 2005N–0016]

Agency Information Collection Activities; Submission for Office of Management and Budget Review; Comment Request; Evaluation of Consumer-Friendly Formats for Brief Summary in Direct-to-Consumer Print Advertisements for Prescription Drugs: Study 1

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 17, 2006.

ADDRESSES: OMB is still experiencing significant delays in the regular mail, including first class and express mail, and messenger deliveries are not being accepted. 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: Fumie Yokota, Desk Officer for FDA, FAX: 202–395–6974.

FOR FURTHER INFORMATION CONTACT: Karen Nelson, Office of Management Programs (HFA–250), Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857, 301–827–1482.

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.

Evaluation of Consumer-Friendly Formats for Brief Summary in Direct-to-Consumer (DTC) Print Advertisements for Prescription Drugs: Study 1

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 (the 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 act. Under the act, a drug is misbranded if it's labeling or advertising is false or misleading. In addition, section 502(n) of the act (21 U.S.C. 352(n)) specifies that advertisements for prescription drugs and biological products must provide a true statement of information ''* * * in brief summary * * *'' about the advertised product's ''* * * side effects, contraindications and effectiveness * * *.'' Generally, the display text of an advertisement presents a fair and balanced disclosure of the product's indication and benefits and the product's side effects and contraindications. The prescription drug advertising regulations (§ 202.1(e)(3)(iii) (21 CFR 202.1(e)(3)(iii))) specify that the information about risks must include each specific side effect and contraindication from the advertised drug's approved labeling. The regulation also specifies that the phrase ''side effect and contraindication'' refers to all of the categories of risk information required in the approved product labeling written for health professionals, including the Warnings, Precautions, and Adverse Reactions sections. Thus, every risk in an advertised drug's approved labeling must be addressed to meet these regulations.

In recent years, FDA has become concerned about the adequacy of the brief summary in DTC print advertisements. Although advertising of prescription drugs was once primarily addressed to health professionals, consumers increasingly have become a primary target audience, and DTC advertising has dramatically increased in the past few years. Results of the FDA 2002 survey on DTC advertising (available at *http://www.fda.gov/cder/ddmac/researchka.htm*) provide some information regarding the extent to which consumers read these ads and the brief summary that accompanies the main ad—41 percent of respondents in 2002 reported they do not usually read any of the brief summary. Use of the brief summary is a function of whether they have an interest in the condition; about 45 percent of those having a particular interest in the advertised drug read all or almost all of the brief summary.

Because the regulations do not specify how to address each risk, sponsors can use discretion in fulfilling the brief summary requirement under § 202.1(e)(3)(iii). Frequently, sponsors print in small type, verbatim, the risk-related sections of the approved product labeling (also called the package insert, professional labeling, or prescribing information). This labeling is written for health professionals, using medical terminology. FDA believes that while this is one reasonable way to fulfill the brief summary requirement for print advertisements directed toward health professionals, this method may be difficult for consumers to understand.

Consumers may use the brief summary for many purposes, such as to learn about new treatments, to compare with OTC medications, to form a benefit-risk judgment, to make brand comparison, to generate questions for their healthcare provider, and to verify promotional claims. All of these possible uses contribute to achieving more informed healthcare decisions.

These different uses likely involve different mental processing strategies, therefore a balanced assessment of possible changes in the format and content of the brief summary is necessary. FDA's objectives for communicating important information

and sponsors' discretion in choosing what specific information to include requires an understanding of the range of consumer uses of the brief summary.[1] Thus, as a first step in assessing content and format options for the brief summary, this research will investigate the nature of consumers' goals when they read prescription drug print advertisements, and the relative usefulness of the information topics presented.

This study will be the first in a series of studies examining the format and content of the brief summary in DTC print advertisements. This first study will consider the full context of the ''side effect, contraindications, and effectiveness'' information presented in prescription drug advertisements, in terms of what consumers are trying to learn from the entire ad, including the display (or main) page and the brief summary, and what about each is useful. In addition, the research will directly consider caregivers, another important audience for prescription drug advertising.

This study will employ a between-subjects crossed factorial design using a mall-intercept protocol. The factors will be medical condition (high cholesterol versus obesity versus asthma versus allergies) and riskiness (high versus low) of the drug. Consumers will be screened to be either currently diagnosed with one of the previously mentioned conditions or currently giving care to someone who has been diagnosed. Participants will be shown one ad. For example, an ad for a high risk drug for asthma or an ad for a low risk drug for high cholesterol. Then a structured interview will be conducted with each participant to examine a number of important perceptions about the brief summary, including perceived riskiness of the drug, ratings of individual sections in the brief summary information, and perceived usefulness of brief summary information. Finally, demographic and health care utilization information will be collected to verify the generalizability of the sample. Participants will be offered a $5 incentive for their time. A total of 420 participants will be involved. This will be a one time (rather than annual) collection of information.

In the **Federal Register** of February 8, 2005 (70 FR 6691), FDA announced the availability of the draft guidance and requested comments for 60 days on the information collection. Two comments were received. Both comments included statements of support for the research itself.

A. Comments To Be Adopted

In the original proposal, our stimulus ad displayed a prescription drug that was available in a new patch form. We proposed this administration mechanism because we required a legitimate advertising draw that was not safety or efficacy based and thought a new administration form would solve these issues. Comment 1 expressed concern that because the patch is a less common mode of administration than the typical pill, such a novel product might alter individuals' normal search behavior and skew our results. The comment suggested that we present a drug with the standard administration form, a pill. With consideration, we have decided to drop the patch delivery mechanism and instead feature a ''once-weekly'' dosing regimen as a differentiation point in the advertisement. We feel this dosing claim will be realistic, interesting, not confounded with safety or efficacy, and should avoid potential problems related to less common administration mechanisms.

In the notice, we had proposed examining education level by blocking respondents by those who have attended some college or less and those who have attended some college or more. Comment 2 suggested that we segment education level further than proposed, and that we specifically add more ''high school or less'' individuals. We agree that education is an important variable that may influence key responses, and will measure finer segments of education. Additionally, we will ensure that a minimum of 30 percent of our sample has a high school degree or lower.

Comment 2 also noted that to reflect reality we should ensure a mix of respondents within the diagnosed population who are currently being treated and those who have yet to be treated. Although we do not have the resources to screen and solicit subjects and control on this variable, we plan to inquire as to participants' prescription and nonprescription drug usage and aim for a blend of individuals currently being treated and those yet to be treated.

We concur with the comment's concern that participants be recruited in a manner that does not bias their responses. We plan to use blinded recruitment so that respondents do not know exactly why they were chosen for the study, the nature of the interview, or the purpose of the research, as suggested by comment 2.

Comment 1 suggested that the main body of our stimulus ad fulfill all of the regulatory requirements for a truthful, fair, and balanced ad. The final stimulus ad has been evaluated by reviewers in the Division of Drug Marketing, Advertising and Communications for compliance with all applicable regulations.

B. Comments To Be Adopted With Modifications

The proposed mock brief summary contained a wide variety of topics culled from a review of existing brief summaries and from the input of focus groups. Comment 1 suggested that we remove all sections in our mock brief summary not currently required by regulation. We considered this suggestion and agree that some sections may be removed at this stage in the research. For example, a section on ''Lab Test Abnormalities'' may not be useful to consumers during initial exposure to a brand in a magazine read-through, as simulated in our study. However, the main purpose of our first study is to determine how people use the brief summary and what sections people find more or less useful. In order to fully assess this question, we feel that we must include sections that are not currently required.

It is reasonable to assume that people use the brief summary to decide whether to talk to their doctor about the advertised drug. This may be a reasonable assumption; however, people may also use the brief summary to verify claims on the main page, to compare the advertised drug to another, or to keep on hand as a reference. Until we know how people use the brief summary, we cannot assume that certain sections are irrelevant. Moreover, without testing this assumption, we cannot assume that the sections currently required by regulation are the only valuable sections. Those sections currently required by law (e.g., warnings, precautions, contraindications, adverse events) are also those that consumers are likely to find most useful, and will always be placed in the first column in our mock brief summaries. Nevertheless, we find it impossible to fully address our research question without including other sections.

In balancing the tradeoff between the realism of the magazine-reading situation and the need for experimenter control, our original proposal had left the issue of mode of presentation open. Both comments suggested that it would be valuable to measure the amount of time each participant spends reading

[1] For other FDA research investigating the relationship between consumer processing and issues of format and content, see Levy, Fein and Schucker, ''Performance Characteristics of Seven Nutrition Label Formats,'' *Journal of Public Policy and Marketing*, (Spring) 15(1), 1–15, 1996.

the main page and the brief summary page of the display ads. After much discussion we have decided to initially present the stimulus ad on a computer screen. Participants will be presented with a page or two of instructions and their reading speed will be tracked when they click the option to move to the next page. Then they will be presented with the test ad as well as two other filler ads, at least one of which will have two pages; a ''front'' and a ''back.'' These ads will enable us to determine basic reading speeds as well as comparative speeds between the main page and brief summary page and between the test ad and other ads. Given the importance of the reading time variable, we have chosen to exercise more experimental control to assess reading times and page-switching (via computer-based recording of times and switching) rather than present the test ad in a magazine mock-up which would not permit a reliable assessment of these reading behaviors.

Another comment discussed sample size issues, limited resources, and tradeoffs. Comment 2 suggested that we have a minimum of 75 respondents per cell, rather than 30 per cell. Comment 1 described a plan that would have doubled our sample size from approximately 400 to approximately 800, but expressed understanding that resource limitations may prohibit this approach. Therefore, this comment suggested reducing the number of medical conditions studied from four to two, maintaining asthma and high cholesterol. Additionally, the comment suggested that disease severity within the condition may be an important variable that affects consumer use of the brief summary.

Our modifications have taken these related comments into account. Our original plan was a 4 x 2 design, with four medical conditions (asthma, high cholesterol, allergies, and obesity) and two levels of drug risk severity (high and low) included. We proposed this design for several reasons. First, to ensure generalizability, we suggested four medical conditions that would vary in symptom presentation, severity, and chronicity. Second, we manipulated drug risk severity to address the idea that information-search of the brief summary page might differ given the risk information included on the main page.

On the basis of all comments, we have revised this design. We now propose a 3 x 2 design, with three medical conditions (asthma, high cholesterol, and obesity) and two levels of disease severity (high and low). Dropping the allergy category, which already includes a number of OTC options, still leaves us with a range of conditions. We will maintain the obesity category due to its public health implications and current public interest. We were persuaded by the argument that severity within a disease may be an important driver of information-search and will include this variable as a covariate.

C. Comments Considered and Not Adopted

Comment 2 suggested that we conduct qualitative research before embarking on a quantitative project. Specifically, it was suggested that qualitative one-on-one interviews may better address the questions we plan to ask. We have already conducted focus groups on this question that have guided the development of the questions we plan to ask in the three quantitative studies and provided initial ideas about how people use the brief summary and what they prefer in terms of content and format.

Comment 2 also requested that we ask more qualitative questions at the beginning of the study before delving into quantitative questions. We are, however, limited to approximately 20 minutes with each respondent, and can therefore ask only a limited number of questions. Recognizing this, we have included as many open-ended questions as we can, but at this time we feel we cannot add substantially more questions to the interview.

Comment 2 also suggested that we use an existing, known prescription product in our stimulus materials instead of a new-to-market, novel one. Given the research goal, we feel it is essential to control for likely confounds that might arise from prior experience with existing, known product. Therefore, we will continue to use a new-to-market drug as a stimulus.

Comment 1 recommended that we avoid randomly selecting people face-to-face inside a mall, but instead use a random-digit dialing procedure to recruit participants. We discussed with the contractor using a prescreened panel. However, given resource constraints, the contractor felt that recruitment would be more effective if the traditional mall-intercept procedure was employed. As noted earlier, prior to the study these respondents will not be sensitized to the specific task or the purpose of the research; participants will be informed of these issues at the end of the study.

We will not be using a mock-up of a magazine, as suggested by comment 1, for reasons discussed earlier in this document. Our main interest is in participants' viewing of the brief summary when they have viewed it, rather than whether it is compelling enough to stop to look at. We instead plan to use computer technology to measure the amount of time spent reading the main page and the brief summary page. Based in part on comment 1's suggestions, we will include at least two other advertisements, to obtain comparative reading times, and to diffuse the pressure on the reading of the stimulus ad.

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

TABLE 1.—ESTIMATED ANNUAL REPORTING BURDEN[1]

No. of Respondents	Annual Frequency per Response	Total Annual Responses	Hours per Response	Total Hours
800 (screener)	1	800	.017	14
420 (survey)	1	420	.33	139
Total				153

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

Dated: December 8, 2005.

Jeffrey Shuren,

Assistant Commissioner for Policy.

[FR Doc. 05–24040 Filed 12–14–05; 8:45 am]

BILLING CODE 4160–01–S

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. 2005N–0389]

Agency Information Collection Activities; Submission for Office of Management and Budget Review; Comment Request; Reprocessed Single-Use Device Labeling

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 17, 2006..

ADDRESSES: OMB is still experiencing significant delays in the regular mail, including first class and express mail, and messenger deliveries are not being accepted. To ensure that comments on the information collection are received, OMB recommends that comments be faxed to the Office of Information and Regulatory Affairs, OMB, Attn: Fumie Yokota, Desk Officer for FDA, FAX: 202–395–6974.

FOR FURTHER INFORMATION CONTACT: Peggy Robbins, Office of Management Programs (HFA–250), Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857, 301–827–1223.

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.

Reprocessed Single-Use Device Labeling (21 U.S.C. 352(u))

Section 502 of the Federal Food, Drug, and Cosmetic Act (the act) (21 U.S.C. 352), among other things, establishes requirements that the label or labeling of a medical device must meet so that it is not misbranded and subject to regulatory action. The Medical Device User Fee and Modernization Act of 2002 (MDUFMA) (Public Law 107–250) amended section 502 of the act to add section 502(u) to require devices (both new and reprocessed) to bear prominently and conspicuously the name of the manufacturer, a generally recognized abbreviation of such name, or a unique and generally recognized symbol identifying the manufacturer. Section 2(c) of The Medical Device User Fee Stabilization Act of 2005 (MDUFSA) (Public Law 109–43) amends section 502(u) of the act by limiting the provision to reprocessed single-use devices (SUDs) and the manufacturers who reprocess them. Under the amended provision, if the original SUD or an attachment to it prominently and conspicuously bears the name of the manufacturer, then the reprocessor of the SUD is required to identify itself by name, abbreviation, or symbol, in a prominent and conspicuous manner on the device or attachment to the device. If the original SUD does not prominently and conspicuously bear the name of the manufacturer, the manufacturer who reprocesses the SUD for reuse may identify itself using a detachable label that is intended to be affixed to the patient record. MDUFSA was enacted on August 1, 2005, and becomes self-implementing on August 1, 2006.

The requirements of section 502(u) of the act impose a minimal burden on industry. This section of the act only requires the manufacturer, packer, or distributor of a device to include their name and address on the labeling of a device. This information is readily available to the establishment and easily supplied. From its registration and premarket submission database, FDA estimates that there are 3 establishments that distribute approximately 300 reprocessed SUDs. Each response is anticipated to take 0.1 hours resulting in a total burden to industry of 30 hours.

In the **Federal Register** of September 29, 2005 (70 FR 56910), FDA published a 60-day notice requesting public comment on the information collection provisions. No comments were received.

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

TABLE 1.—ESTIMATED ANNUAL REPORTING BURDEN[1]

Section of the Act	No. of Respondents	Annual Responses per Respondent	Total Annual Responses	Hours per Response	Total Hours
502(u)	3	100	300	0.1	30

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

Dated: December 8, 2005.

Jeffrey Shuren,

Assistant Commissioner for Policy.

[FR Doc. 05–24041 Filed 12–14–05; 8:45 am]

BILLING CODE 4160–01–S

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. 2004N–0442]

Agency Information Collection Activities; Announcement of Office of Management and Budget Approval; Food and Drug Administration Recall Regulations (Guidelines)

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is announcing that a collection of information entitled ''FDA Recall Regulations (Guidelines)'' has been approved by the Office of Management and Budget (OMB) under the Paperwork Reduction Act of 1995.

FOR FURTHER INFORMATION CONTACT: Karen Nelson, Office of Management Programs (HFA–250), Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857, 301–827–1482.

SUPPLEMENTARY INFORMATION: In the **Federal Register** of August 24, 2005 (70 FR 49654), the agency announced that the proposed information collection had been submitted to OMB for review and clearance under 44 U.S.C. 3507. An agency may not conduct or sponsor, and a person is not required to respond to,