* * * (d) if the applicant is not a Tribe or Alaska Native Village government, the applicant must submit proof that a majority of the governing board of directors is representative of the community to be served.'' The reference to Native non-profit organizations was inadvertently placed in the text. This correction will be reflected in all three FY 05 ANA program announcements.

Technical Correction: Upon general review of the Notice, Section II. Evaluation Criteria (a) additional text is needed to clarify the use of the ANA Project Abstract form in relation to Criteria One: Introduction and Project Summary/Application Format. Instructional text will be inserted in the ANA evaluation Criterion One to state ''In addition to using the ANA Project Abstract form, applicants will submit a brief narrative summary of the project that provides more information on the applicant and proposed project.'' The additional text will provide clarity to the applicant as they respond to the program announcement.

Dated: January 31, 2005.

Quanah Crossland Stamps,

Commissioner, Administration for Native Americans.

[FR Doc. 05–2325 Filed 2–7–05; 8:45 am]

BILLING CODE 4184–01–M

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. 2005N–0016]

Agency Information Collection Activities; Proposed Collection; 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 an opportunity for public comment on a 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 a study of consumer evaluations of various consumer-friendly formats for the brief summary in direct-to-consumer (DTC) prescription drug print advertisements.

DATES: Submit written or electronic comments on the collection of information by April 11, 2005.

ADDRESSES: Submit electric comments on the collection of information to: *http://www.fda.gov/dockets/ecomments*. 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: Karen Nelson, Office of Management Programs (HFA–250), Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857, 301–827–1482.

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 each of 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.

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 its 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 *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 was 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 other prescription brands or over-the-counter (OTC) medications, to form a benefit-risk judgment, 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 careful 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, the current research will investigate the nature of consumers' goals when they read prescription drug print advertisements, and the relative usefulness of the information topics presented.

The current study will be the first in a series of studies examining the format and content of the brief summary in DTC print advertisements. Format and other content issues will be examined in following studies. 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. It is estimated that 46 percent of adults help provide healthcare for someone else.[2] Caregivers provide a range of activities, from reminding another person to follow a diet to deciding whether the person in their care will use a prescription drug at all. About 58 percent of caregivers report seeking additional information about the condition they are helping to manage.

Design Overview: This study will employ a between-subjects crossed factorial design using a mall-intercept protocol. Eight print advertisements will be created using two levels of drug risk severity and four medical conditions. Thus, the factors will be severity of risk (high versus low) and medical condition (high cholesterol versus obesity versus asthma versus allergies). Other side effect and risk information will be constant across conditions. Participants, those diagnosed with the condition and those who are caregivers for a person with the condition, will be asked to read a single print advertisement for a new prescription drug. After reading the advertisement, they will be asked questions about their use and evaluation of information topics presented in the advertisement.

Factors:

• Participants. Consumers will be screened and recruited by the contractor to be either currently diagnosed with one of the above conditions, at risk of developing one of the conditions, or currently giving care to someone who has been diagnosed. A caregiver will be defined as an adult male or female who has a concern for the well-being of another person (parent, child, spouse, close friend, or relative) who is currently receiving medication for one of the four medical conditions, and who provides a (near daily) support activity for that person. The support may range from simply reminding them to take their medication to providing direct guidance and physical assistance with their treatment regimen. Thus, participants will be nested within medical condition and randomly assigned to either high or low level of risk. Each condition will be balanced with respect to gender.

Multiple disease conditions will be incorporated to provide generality. The medical conditions chosen represent a variety of conditions varying in severity and for which treatments range from multiple over-the-counter possibilities (allergies) to those where the medications are potentially quite complex and serious (weight loss). These conditions are likely to occur in both males and females, may involve a caregiver, and have fairly high prevalence rates in the general population.

Participants will be screened to represent a range of education levels (some college or less vs. completed college or more). Because the task presumes basic reading abilities, all participants will have English as their primary language and, as appropriate, be required to bring reading glasses with them to the site.

• Severity of Risk. The severity of drug side effects is an important attribute in consumers' evaluation of new prescription products. For example, it may be an important reference point for evaluating benefit claims and for directing further information search. Variation in aspects of consumer mental processing of a prescription drug advertisement, such as confirmation or clarification of promotional claims, may be expected depending on the risk information presented in the display (first) page portion of the advertisement for a new brand.

By incorporating variation in brand risk as a design factor in this study, we can further our confidence in observing a more representative spectrum in how consumers use the brief summary. Risk will be varied to create ''high'' and ''low'' levels of perceived product risk as follows:

HIGH: In rare cases, Oncor may cause heart damage. You should contact your doctor right away if you get a severe cough or chest pain.

LOW: In rare cases, Oncor may cause dry mouth. You should contact your doctor if your dry mouth lasts for more than 4 days.

Procedure: Participants will be shown one ad, e.g., 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. Interviews are expected to last approximately 20 minutes and participants will be offered a $5

[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.

[2] Slaughter, E., *Seventh Annual Survey on Consumer Reaction to DTC Advertising of Prescription Medicines. Rodale, Inc., 2004.*

incentive for their time. A total of 432 participants will be involved. This will be a one time (rather than annual) collection of information.

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
432 (survey)	1	432	.33	143
Total				157

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

Dated: February 1, 2005.

Jeffrey Shuren,

Assistant Commissioner for Policy.

[FR Doc. 05–2419 Filed 2–7–05; 8:45 am]

BILLING CODE 4160–01–S

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. 2005N–0038]

Reporting of Adverse Events to Institutional Review Boards; Public Hearing

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice of public hearing; request for comment.

SUMMARY: The Food and Drug Administration (FDA) is announcing a public hearing to consider the process by which institutional review boards (IRBs) obtain and review information on adverse events that occur during the conduct of clinical investigations. FDA is increasingly aware of concerns within the IRB community that the process is burdensome, inefficient, and not as effective as it should be in providing IRBs the information they need to ensure that the rights and welfare of human subjects are protected during the course of a clinical study. The purpose of the hearing is to solicit information and views from interested persons on issues and concerns regarding the submission of adverse events to and their review by IRBs. FDA is seeking general information about the nature of the problem and possible solutions, responses to specific questions (see section III of this document), and any other pertinent information stakeholders would like to share.

Date and Time: The public hearing will be held on March 21, 2005, from 9 a.m. to 5 p.m. Submit written or electronic notices of participation by 4:30 p.m. on March 4, 2005. Submit written and electronic comments by April 21, 2005.

Location: The public hearing will be held at the Advisors and Consultants Staff Conference Room, 5630 Fishers Lane, Rockville, MD 20857.

Addresses: Written or electronic notices of participation should be submitted to the Division of Dockets Management (HFA–305), Food and Drug Administration, 5630 Fishers Lane, rm. 1061, Rockville, MD 20852, e-mail: *FDADockets@oc.fda.gov*; or on the Internet at *http://www.accessdata.fda.gov/scripts/oc/dockets/meetings/meetingdocket.cfm*. Written or electronic comments should be submitted to *http://www.accessdata.fda.gov/scripts/oc/dockets/commentdocket.cfm* or to the Division of Dockets Management (see *Addresses* above).

Contacts: Nancy L. Stanisic, Center for Drug Evaluation and Research (HFD–1), Food and Drug Administration, 5600 Fishers Lane, rm. 9–64, Rockville, MD 20857, 301–827–1660, FAX: 301–443–9718, e-mail: *stanisicn@cder.fda.gov*.

For Registration and/or to participate in the meeting: Because of limited seating, we recommend that persons interested in attending the meeting register at *http://www.accessdata.fda.gov/scripts/oc/dockets/meetings/meetingdocket.cfm*. Registration will be accepted on a first-come, first-served basis.

The procedures governing the hearing are found in part 15 (21 CFR part 15). If you wish to make an oral presentation during the open public comment period of the hearing, you must state your intention on your registration form (see *Addresses*). To participate, submit your name, title, business affiliation, address, telephone, fax number, and e-mail address. You should also submit a written statement at the time of registration for each discussion question you wish to address, the names and addresses of all individuals that plan to participate, and the approximate time requested to make your presentation. Individuals who have registered to make an oral presentation will be notified of the scheduled time for their presentation prior to the hearing. Depending on the number of presentations, FDA may need to limit the time allotted for each presentation. Presentations will be limited to the questions and subject matter identified in section III of this document. Presenters should submit two copies of each presentation given. All participants are encouraged to attend the entire day.

If you need special accommodations due to a disability, please inform the registration contact person when you register.

SUPPLEMENTARY INFORMATION:

I. Background

Clinical investigations regulated by FDA under sections 505(i) (drugs and biologics) and 520(g) (medical devices) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 355(i) and 360j(g)) must be reviewed and approved by an IRB in a manner consistent with the requirements of 21 CFR part 50 and part 56 (21 CFR part 56). To approve a proposed clinical investigation, IRBs must determine, among other things, that the risks to subjects are minimized; the risks are reasonable in relation to anticipated benefits (if any); the selection of subjects is equitable; and the informed consent process is adequate for the anticipated study population and appropriately documented (see § 56.111).

After their initial review and approval of a clinical study, IRBs are required to conduct continuing review of the study at intervals appropriate to the degree of risk presented by a study (at least annually) (§ 56.109(f)). IRBs are required to follow written procedures for continuing review of research and for determining which studies require review more often than annually (§ 56.108(a)), and must maintain records of continuing review activities (§ 56.115(a)(3)).