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.

Adverse Event Program for Medical Devices (Medical Product Safety Network)—(OMB Control Number 0910–0471)—Extension

Among other things, section 519 of the Federal Food, Drug, and Cosmetic Act (the FD&C Act) (21 U.S.C. 360i) authorizes FDA to require: (1) manufacturers to report medical device-related deaths, serious injuries, and malfunctions and (2) user facilities to report device-related deaths directly to manufacturers and FDA and serious injuries to the manufacturer. Section 213 of the Food and Drug Administration Modernization Act of 1997 (Pub. L. 105–115) amended section 519(b) of the FD&C Act relating to mandatory reporting by user facilities of deaths, serious injuries, and serious illnesses associated with the use of medical devices. This amendment legislated the replacement of universal user facility reporting by a system that is limited to a ''. . . subset of user facilities that constitutes a representative profile of user reports'' for device-related deaths and serious injuries. This amendment is reflected in section 519(b)(5)(A) of the FD&C Act. This legislation provides FDA with the opportunity to design and implement a national surveillance network, composed of well-trained clinical facilities, to provide high-quality data on medical devices in clinical use. This system is called the Medical Product Safety Network (MedSun).

FDA is seeking OMB clearance to continue to use electronic data collection to obtain the information on Form FDA 3500A (approved under OMB control number 0910–0291) related to medical devices and tissue products from the user facilities participating in MedSun, to obtain a demographic profile of the facilities, and for additional questions which will permit FDA to better understand the cause of reported adverse events. Participation in the program is voluntary and currently includes 250 facilities.

In addition to collecting data on the electronic adverse event report form, MedSun collects additional information from participating sites about reported problems emerging from the MedSun hospitals. This data collection is also voluntary and is collected on the same Web site as the report information.

The burden estimate is based on the number of facilities currently participating in MedSun (250). FDA estimates an average of 15 reports per site annually. This estimate is based on MedSun working to promote reporting in general from the sites, as well as promoting reporting from specific parts of the hospitals, such as the pediatric intensive care units, the electrophysiology laboratories, and the hospital laboratories.

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

TABLE 1—ESTIMATED ANNUAL REPORTING BURDEN [1]

Activity	No. of respondents	No. of responses per respondent	Total annual responses	Average burden per response	Total hours
MedSun facilities participating in the electronic reporting of adverse events program (Form FDA 3670)	250	15	3,750	0.75	2,813

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

Dated: November 22, 2013.

Leslie Kux,

Assistant Commissioner for Policy.

[FR Doc. 2013–28600 Filed 11–27–13; 8:45 am]

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2013–N–1422]

Agency Information Collection Activities; Proposed Collection; Comment Request; Eye Tracking Study of Direct-to-Consumer Prescription Drug Advertisement Viewing

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 research entitled, ''Eye Tracking Study of Direct-to-Consumer Prescription Drug Advertisement Viewing.'' This study is designed to use eye tracking technology to explore how consumers view direct-to-consumer (DTC) prescription drug advertisements (ads) that include text regarding risk information and reporting side effects and that vary in the amount of distracting audio and visual content during the presentation of the risk information.

DATES: Submit either electronic or written comments on the collection of information by January 28, 2014.

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: FDA PRA Staff, Office of Operations, Food and Drug Administration, 1350 Piccard Dr., PI50–400B, Rockville, MD 20850, *PRAStaff@fda.hhs.gov.*

SUPPLEMENTARY INFORMATION: Under the PRA (44 U.S.C. 3501–3520), Federal Agencies must obtain approval from the Office of Management and Budget (OMB) for each collection of information they conduct or sponsor. ''Collection of information'' is defined in 44 U.S.C. 3502(3) and 5 CFR 1320.3(c) and includes Agency requests or requirements that members of the public submit reports, keep records, or provide information to a third party. Section 3506(c)(2)(A) of the PRA (44 U.S.C. 3506(c)(2)(A)) requires Federal

Agencies to provide a 60-day notice in the **Federal Register** concerning each proposed collection of information before submitting the collection to OMB for approval. To comply with this requirement, FDA is publishing notice of the proposed collection of information set forth in this document.

With respect to the following collection of information, FDA invites comments on these topics: (1) Whether the proposed collection of information is necessary for the proper performance of FDA's functions, including whether the information will have practical utility; (2) the accuracy of FDA's estimate of the burden of the proposed collection of information, including the validity of the methodology and assumptions used; (3) ways to enhance the quality, utility, and clarity of the information to be collected; and (4) ways to minimize the burden of the collection of information on respondents, including through the use of automated collection techniques, when appropriate, and other forms of information technology.

Eye Tracking Study of Direct-to-Consumer Prescription Drug Advertisement Viewing—(OMB Control Number 0910–NEW)

Section 1701(a)(4) of the Public Health Service Act (42 U.S.C. 300u(a)(4)) authorizes the FDA to conduct research relating to health information. Section 1003(d)(2)(C) of the Federal Food, Drug, and Cosmetic Act (the FD&C Act) (21 U.S.C. 393(b)(2)(c)) authorizes FDA to conduct research relating to drugs and other FDA regulated products in carrying out the provisions of the FD&C Act.

Current regulations require that a major statement of the risks of prescription drugs be included in at least the audio of DTC television ads. FDA has proposed including the risk information in DTC television ads in superimposed text as well as in the audio (75 FR 15376, ''Direct-to-Consumer Prescription Drug Advertisements; Presentation of the Major Statement in Television and Radio Advertisements in a Clear, Conspicuous, and Neutral Manner''). In addition, Title IX of the Food and Drug Administration Amendments Act (Pub. L. 110–85) required a study to determine if the statement ''You are encouraged to report negative side effects of prescription drugs to the FDA. Visit *www.fda.gov/medwatch,* or call 1–800–FDA–1088'' (the MedWatch statement) is appropriate for inclusion in DTC television ads. These communications have been tested separately by FDA. The first study found that participants were better able to recall the drug risks when they were presented in superimposed text as well as in audio (OMB Control Number 0910–0634, ''Experimental Evaluation of the Impact of Distraction''). The second study found that the inclusion of the MedWatch statement does not interfere with participants' understanding of the risk information (OMB Control Number 0910–0652,''Experimental Study: Toll-Free Number for Consumer Reporting of Drug Product Side Effects in Direct-to-Consumer Television Advertisements for Prescription Drugs''). Thus, these two new communications may appear in future DTC television ads. However, they have not been examined together.

In addition, questions continue to arise about the use of potentially distracting images and sounds during the major statement of risks in DTC television ads. The first study referenced above found no differences among ads that differed in the affective tone of static, non-moving visuals presented during the major statement of risks. Previous research has shown that factors such as multiple scene changes and music in advertising can be distracting. However, the effects of this kind of distraction during the major statement of risks on consumers' perceptions and risk recall has not been tested in the presence of risk reinforcing superimposed text.

This project is designed to use eye tracking technology to determine how these communications in DTC ads are perceived and the impact of distraction. Eye tracking technology is an effective method to determine the extent to which consumers attend to risk information presented in DTC television ads. This technology allows researchers to unobtrusively detect and measure where a participant looks while viewing a television ad and for how long, and the pattern of their eye movements may indicate attention to and processing of information in the ad.

We plan to collect descriptive eye tracking data on participants' attention to (1) the superimposed text during the major statement of risk information and (2) the MedWatch statement. Further, we plan to examine experimentally the effect of distraction. We hypothesize that distracting audio and visuals during the major statement will decrease risk recall, risk perceptions, and attention to superimposed text risk information. To test these hypotheses, we will conduct inferential statistical tests such as analysis of variance. With the sample size described below, we will have sufficient power to detect small- to medium-sized effects in the main study.

We plan to conduct one 60-minute pilot study with 30 participants and one 30-minute main study with 300 participants. All participants will be 18 years of age or older who self-identify as needing to lose more than 30 pounds. We will exclude individuals who work in healthcare or marketing or who wear bifocals or hard contact lenses. The studies will be conducted in person in at least five different cities across the United States.

The pilot study and main study will have the same design and will follow the same procedure. Participants will be randomly assigned to one of three test conditions (low, medium, and high distraction in a DTC television ad). The ad will be for a fictitious weight loss prescription drug. The ads are currently being created and pretested to ensure that consumers perceive different levels of distraction across the ads (OMB Control Number 0910–0695, ''Stimuli Development and Pretests for an Attentional Effects Study''). For instance, as the distraction level increases, the number of scene changes and on-screen activity during the major statement will increase.

We will explain the study procedure to participants and calibrate the eye tracking device. To collect eye tracking data, we will use an unobtrusive computer-interfaced eye tracker with a minimum speed of 60 Hertz. The test images will be shown on a computer monitor with a minimum size of 20 inches and a minimum display resolution of $1,280 \times 1,024$. To simulate normal television ad viewing, participants will watch a 2 to 5 minute video clip followed by a series of three ads. One of the ads will be the study ad. The video clip and non-study ads will be unrelated to health. The order of the ads will be counterbalanced, and only eye tracking data from the study ad will be analyzed. Next, participants will complete a questionnaire that assesses risk perceptions, risk recall, recall of the MedWatch statement, and covariates such as demographics and health literacy. In the pilot study, participants will also answer questions as part of a debriefing interview to assess the study design and questionnaire. The questionnaire is available upon request.

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

TABLE 1—ESTIMATED ANNUAL REPORTING BURDEN [1]

Eye tracking study of DTC prescription drug advertisement viewing	Number of respondents	Number of responses per respondent	Total annual responses	Average burden per response	Total hours
Pilot study screener	200	1	200	0.03 (2 minutes)	6
Main study screener	2,000	1	2,000	0.03 (2 minutes)	60
Pilot study	30	1	30	1	30
Main study	300	1	300	0.50 (30 minutes)	150
Total					246

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

Dated: November 22, 2013.

Leslie Kux,

Assistant Commissioner for Policy.

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2013–N–0716]

Agency Information Collection Activities; Submission for Office of Management and Budget Review; Comment Request; Designated New Animal Drugs for Minor Use and Minor Species

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 December 30, 2013.

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 emailed to *oira_submission@omb.eop.gov.* All comments should be identified with the OMB control number 0910–0605. Also include the FDA docket number found in brackets in the heading of this document.

FOR FURTHER INFORMATION CONTACT: FDA PRA Staff, Office of Operations, Food and Drug Administration, 1350 Piccard Dr., PI50–400B, Rockville, MD 20850, *PRAStaff@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.

Designated New Animal Drugs for Minor Use and Minor Species; 21 CFR Part 516—(OMB Control Number 0910–0605)—Extension

Description: The Minor Use and Minor Species Animal Health Act of 2004 (MUMS) (Pub. L. 108–282) 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 as well as uncommon diseases in major animal species. This legislation provides incentives designed to help pharmaceutical companies overcome the financial burdens they face in providing limited-demand animal drugs. These incentives are only available to sponsors whose drugs are ''MUMS-designated'' by FDA. Minor use drugs are drugs for use in major species (cattle, horses, swine, chickens, turkeys, dogs, and cats) that are needed for diseases that occur in only a small number of animals either because they occur infrequently or in limited geographic areas. Minor species are all animals other than the major species; for example, zoo animals, ornamental fish, parrots, ferrets, and guinea pigs. Some animals of agricultural importance are also minor species. These include animals such as sheep, goats, catfish, and honeybees. Participation in the MUMS program is completely optional for drug sponsors so the associated paperwork only applies to those sponsors who request and are subsequently granted ''MUMS designation.'' The rule specifies the criteria and procedures for requesting MUMS designation as well as the annual reporting requirements for MUMS designees.

Section 516.20 (21 CFR 516.20) provides requirements on the content and format of a request for MUMS-drug designation; § 516.26 (21 CFR 516.26) provides requirements for amending MUMS-drug designation; provisions for change in sponsorship of MUMS-drug designation can be found under § 516.27 (21 CFR 516.27); under § 516.29 (21 CFR 516.29) are provisions for termination of MUMS-drug designation; under § 516.30 (21 CFR 516.30) are requirements for annual reports from sponsor(s) of MUMS-designated drugs; and under § 516.36 (21 CFR 516.36) are provisions for insufficient quantities of MUMS-designated drugs.

Description of Respondents: Pharmaceutical companies that sponsor new animal drugs.

In the **Federal Register** of July 2, 2013 (78 FR 39734), FDA published a 60-day notice requesting public comment on the proposed collection of information. No comments were received.

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

TABLE 1—ESTIMATED ANNUAL REPORTING BURDEN [1]

21 CFR Section	Number of respondents	Number of responses per respondent	Total annual responses	Average burden per response	Total hours
516.20; Content and format of MUMS request	15	5	75	16	1,200
516.26; Requirements for amending MUMS designation	3	1	3	2	6
516.27; Change in sponsorship	1	1	1	1	1