Completed Exposure Pathway Site Count Report. A completed exposure pathway (CEP) links a contaminant source to a receptor population. The CEP ranking is similar to a subcomponent of the substance priority list algorithm's potential-for-human-exposure component. The CEP ranking is based on a site frequency count and thus lists the number of sites at which a substance has been found in a CEP. This information is derived from ATSDR public health assessments and from ATSDR health consultations. The CEP report therefore focuses on documented exposure, and lists hazardous substances according to exposure frequency.

The substances in the CEP report are similar to those in the Priority List of Hazardous Substances. However, some substances in the CEP report have a very low toxicity and as a result are not included in the substance priority list. Since the substance priority list uses toxicity, frequency of occurrence, and potential for human exposure to determine its priority substances, other low-toxicity substances will not appear on the list and, consequently, will not become subjects of toxicological profiles. In addition, because CERCLA mandates the preparation of the Priority List of Hazardous Substances, that list only incorporates data from CERCLA NPL sites. The CEP report, on the other hand, uses data from all ATSDR-activity sites at which a CEP has been detected.

Dated: May 21, 2014.

Sascha Chaney,

Acting Director, Office of Policy Planning and Evaluation, National Center for Environmental Health/Agency for Toxic Substances and Disease Registry.

[FR Doc. 2014–12262 Filed 5–27–14; 8:45 am]

BILLING CODE 4163–70–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2013–N–1422]

Agency Information Collection Activities; Submission for Office of Management and Budget Review; 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 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 June 27, 2014.

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—New and title, ''Eye Tracking Study of Direct-to-Consumer Prescription Drug Advertisement Viewing.'' 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.

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 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 product's major risks be included in at least the audio of direct-to-consumer (DTC) prescription drug television ads; this disclosure of major risks is sometimes referred to as the major statement. FDA has proposed including such risk information 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 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''). However, these two new communications 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 previously 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. The effects 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 superimposed risk information and the MedWatch statement are perceived in DTC ads and also 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 further in this notice, 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 then 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 to watch television. 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 two test conditions (low and high distraction in a DTC television ad). The ad will be for a fictitious weight loss prescription drug. The ads have been 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 increases. Pretesting led us to using two rather than three ads, as we proposed in the 60-day **Federal Register** notice.

When participants start the study, we will explain the study procedure 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 23 inches and a minimum display resolution of 1,920 x 1,080. To simulate normal television ad viewing, participants will watch an approximately 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 non-study 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.

In the **Federal Register** of November 29, 2013 (78 FR 71621), FDA published a 60-day notice requesting public comment on the proposed collection of information. Two comments were received.

(Comment 1)

The first suggestion in this comment was to avoid biasing participants by ensuring that at the beginning of the study participants are not aware that (1) the study is being conducted by or for FDA and (2) the advertisements are the subject of interest in the study. We are aware of these issues and have designed the wording of the study materials accordingly.

The second suggestion was to increase the minimum display resolution from 1,280 x 1,024 to 1,920 x 1,080 and the minimum computer monitor size from 20 inches to 24 inches. We agree that a bigger screen is better and have changed the minimum conditions to the following specifications: A display resolution of 1,920 x 1,080 pixels on a monitor of at least 23 inches measured diagonally.

The third suggestion was to exclude individuals who wear progressive or other multifocal lenses and individuals with any form of strabismus or nystagmus from participating in the study. We will exclude individuals who wear bifocals or hard contact lenses while watching television. In response to the next comment, we explain why these individuals need to be excluded. We do not believe we need to exclude participants who wear progressive or other multifocal lenses to collect usable data with the eye trackers in this study. Because we will use binocular tracking (where we track both eyes) we do not need to exclude individuals with strabismus or nystagmus; if we encounter these conditions in one eye, we will track the other eye. In addition, we cannot test for or diagnose these conditions and individuals may not know they have these conditions, making excluding these individuals difficult.

(Comment 2)

The first request in this comment was to specify the study timeline, comment on whether the results of this study will be incorporated into the draft guidance, ''Presenting Risk Information in Prescription Drug and Medical Device Promotion,'' and state whether the draft guidance will be re-issued for public comment. Regarding the study timeline, data collection on the study cannot begin until OMB approval is received. We estimate that data collection will be completed within a year after OMB approval. If the results of the study suggest that changes are needed to the draft guidance we will consider that at the time. The draft guidance will be reissued for public comment if changes are necessary as a result of the study.

The second request in this comment was to explain why individuals who wear bifocals or hard contact lenses would be excluded and to consider including such individuals in the study to avoid biasing the sample. First, only individuals who can only wear bifocals or hard contacts to watch television will be excluded from the study. If individuals can wear regular glasses or soft contacts during the study, they may participate. There are two reasons to exclude participants who wear only bifocals or contact lenses to watch television. The first is that the glasses themselves may have ''lines'' on them which impact the data being recorded by the eye tracker's camera. To record properly, the eye trackers must make accurate estimates of the pupil, and the ''lines'' on the glasses distort these estimates. A similar problem exists with hard contact lenses, which are smaller than soft lenses and project sharp lines around their circumference. The second reason to exclude individuals who wear bifocals to watch television is that many people who wear bifocals move their heads up and down to get their best vision of a particular target. This head bobbing also impacts eye tracking because the cameras must constantly adjust to head movement. If we do not screen for these conditions and have several individuals who cannot be tracked well, we will have to discard their data, which will impact both the study design (which is based on the assumption of having equal sample sizes across conditions) and the power of our statistical tests. In an effort to measure any sampling bias, we will move this question to the end of the pilot study screener so we can compare the demographic information of those who are excluded with those who are not.

This comment suggested that we create a more ''real world'' environment in the study by using a 30-minute video clip instead of a 2 to 5 minute video clip as proposed. We understand the concern, but there are tradeoffs inherent in any study. Although a 30-minute video clip may be a stronger proxy for ''typical'' TV viewing, it would require more resources and a greater burden on participants. We have taken steps to try to increase the ecological validity of the experiment. First, we have created ads that are very realistic. Second, we will

use a real TV show clip that is closer to 5 minutes long, which is the length of a typical news story segment. Third, we will include two additional, ''real'' advertisements, rather than just showing the experimental ad.

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: May 21, 2014.

Leslie Kux,

Assistant Commissioner for Policy.

[FR Doc. 2014–12281 Filed 5–27–14; 8:45 am]

BILLING CODE 4160–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2013–N–1619]

Agency Information Collection Activities; Announcement of Office of Management and Budget Approval; Current Good Manufacturing Practice in Manufacturing, Packaging, Labeling, or Holding Operations for Dietary Supplements

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is announcing that a collection of information entitled ''Current Good Manufacturing Practice in Manufacturing, Packaging, Labeling, or Holding Operations for Dietary Supplements'' has been approved by the Office of Management and Budget (OMB) under the Paperwork Reduction Act of 1995.

FOR FURTHER INFORMATION CONTACT: FDA PRA Staff, Office of Operations, Food and Drug Administration, 8455 Colesville Rd., COLE–14526, Silver Spring, MD 20993–0002, *PRAStaff@fda.hhs.gov*.

SUPPLEMENTARY INFORMATION: On February 27, 2014, the Agency submitted a proposed collection of information entitled ''Current Good Manufacturing Practice in Manufacturing, Packaging, Labeling, or Holding Operations for Dietary Supplements'' 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, a collection of information unless it displays a currently valid OMB control number. OMB has now approved the information collection and has assigned OMB control number 0910–0606. The approval expires on May 31, 2017. A copy of the supporting statement for this information collection is available on the Internet at *http://www.reginfo.gov/public/do/PRAMain*.

Dated: May 21, 2014.

Leslie Kux,

Assistant Commissioner for Policy.

[FR Doc. 2014–12293 Filed 5–27–14; 8:45 am]

BILLING CODE 4164–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2011–N–0017]

Agency Information Collection Activities; Submission for Office of Management and Budget Review; Comment Request; Voluntary National Retail Food Regulatory Program Standards

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 June 27, 2014.

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 0910–0621. 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, 8455 Colesville Rd., COLE–14526, Silver Spring, MD 20993–0002, *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.

Voluntary National Retail Food Regulatory Program Standards—(OMB Control Number 0910–0621)—Extension

The Voluntary National Retail Food Regulatory Program Standards (Program Standards) define nine essential elements of an effective regulatory program for retail food establishments; establish basic quality control criteria for each element; and provide a means of recognition for those State, local, territorial, tribal, and Federal regulatory programs that meet the Program Standards. The program elements addressed by the Program Standards are as follows: (1) Regulatory foundation, (2) trained regulatory staff, (3) inspection program based on Hazard Analysis and Critical Control Point (HACCP) principles, (4) uniform inspection program, (5) foodborne illness and food defense preparedness and response, (6) compliance and enforcement, (7) industry and community relations, (8) program support and resources, and (9) program assessment. Each standard includes a list of records needed to document conformance with the standard (referred to in the Program Standards document