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Dated: May 15, 2014.

Christopher Grundler,

Director, Office of Transportation and Air Quality, Office of Air and Radiation.

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Agency for Toxic Substances and Disease Registry

Notice of the Revised Priority List of Hazardous Substances That Will Be Candidates for Toxicological Profiles

AGENCY: Agency for Toxic Substances and Disease Registry (ATSDR), Department of Health and Human Services (HHS).

ACTION: Notice.

SUMMARY: The Comprehensive Environmental Response, Compensation, and Liability Act of 1980 (CERCLA or Superfund), as amended by the Superfund Amendments and Reauthorization Act of 1986 (SARA), requires that ATSDR and the Environmental Protection Agency (EPA) prepare a Priority List of Hazardous Substances commonly found at facilities on the CERCLA National Priorities List (NPL). The Priority List of Hazardous Substances includes substances that have been determined to be of greatest public health concern to persons at or near NPL sites. CERCLA, as amended, also requires that the Priority List of

Hazardous Substances be revised periodically.

This announcement provides notice that a revised Priority List of 275 Hazardous Substances has been developed and is now available. CERCLA, as amended, also requires ATSDR to prepare and to periodically revise toxicological profiles on hazardous substances included in the priority list. Thus, each priority list substance is a potential toxicological profile subject, as well as a candidate for identification of priority data needs.

In addition to the Priority List of Hazardous Substances, ATSDR has developed a Completed Exposure Pathway Site Count Report. This report lists the number of sites or events at which ATSDR is involved and wherein a substance has been found in a completed exposure pathway (CEP).

Address for Printed Copy: Requests for a printed copy of the 2013 Priority List of Hazardous Substances and Support Document, including the CEP report, should be submitted to Ms. Nickolette Roney, Division of Toxicology and Human Health Sciences, ATSDR, Mail Stop F-57, 1600 Clifton Road, NE., Atlanta, GA 30333.

Electronic Availability: The 2013 Priority List of Hazardous Substances and Support Document are posted on ATSDR's Web site located at www.atsdr.cdc.gov/SPL. The CEP Report is posted at www.atsdr.cdc.gov/CEP.

FOR FURTHER INFORMATION CONTACT: Ms. Nickolette Roney, Division of Toxicology and Human Health Sciences, ATSDR, 1600 Clifton Road NE., Mail Stop F-57, Atlanta, GA 30333, telephone 800-232-4636.

This is an informational notice only; comments are not being solicited at this time.

SUPPLEMENTARY INFORMATION: CERCLA establishes certain requirements for ATSDR and EPA with regard to hazardous substances most commonly found at facilities on the CERCLA NPL. Section 104(i)(2)(A) of CERCLA, as amended,¹ requires that ATSDR and EPA prepare a list, in order of priority, of at least 100 hazardous substances most commonly found at facilities on the NPL and which, in the agencies' sole discretion, pose the most significant potential threats to human health (see also 52 FR 12866, April 17, 1987). CERCLA section 104(i)(2)(B)² also requires the agencies to revise the priority list to include 100 or more additional hazardous substances (see also 53 FR 41280, October 20, 1988),

and to include at least 25 additional hazardous substances in each of the three successive years following the 1988 revision (see 54 FR 43615, October 26, 1989; 55 FR 42067, October 17, 1990; and 56 FR 52166, October 17, 1991). CERCLA section 104(i)(2)(B) further requires ATSDR and EPA at least annually to revise the list to include any additional hazardous substances that have been determined to pose the most significant potential threat to human health.

In 1995, the agencies, recognizing the stability of this listing activity, altered the priority list publication schedule (60 FR 16478, March 30, 1995). As a result, the substance priority list is now on a 2-year publication schedule, with annual informal review and revision. Each substance on the Priority List of Hazardous Substances is a potential subject of a toxicological profile prepared by ATSDR and, subsequently, a candidate for the identification of priority data needs.

The ranking of substances on the priority list is based on an algorithm that consists of three criteria, weighted equally and combined to result in the total score. The three criteria are: (1) Frequency of occurrence at NPL sites; (2) toxicity; and (3) potential for human exposure. The site-specific information used to develop the priority list has been collected from ATSDR public health assessments and from site-file data packages used to develop the public health assessments. Since the development of the 2011 substance priority list, additional site specific information has been collected. The new information may include more recent NPL frequency-of-occurrence data, additional environmental media concentration data, and more information on exposure to substances at NPL sites. Using these additional data, one substance has been replaced on the list of 275 substances since the 2011 publication. Changes in the order of substances appearing on the Priority List of Hazardous Substances will be reflected in program activities that rely on the list for guiding future activities. Using the current algorithm, a total of 848 candidate substances have been analyzed and ranked. Of these candidates, the 275 substances on the priority list may in the future become the subject of toxicological profiles.

Additional information on the existing methodology used in the development of the Priority List of Hazardous Substances can be found in the Support Document and in the above-referenced **Federal Register** notices.

In addition to the revised priority list, ATSDR is also releasing a revised

¹ 42 U.S.C. 9604(i)(2)(A).

² 42 U.S.C. 9604(i)(2)(B).

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.

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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., P150-400B, 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