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## DEPARTMENT OF HEALTH AND HUMAN SERVICES

### Centers for Disease Control and Prevention

[CDC-2017-0114; Docket Number NIOSH-305]

#### Final National Occupational Research Agenda for Transportation, Warehousing and Utilities

**AGENCY:** National Institute for Occupational Safety and Health (NIOSH) of the Centers for Disease Control and Prevention (CDC), Department of Health and Human Services (HHS).

**ACTION:** Notice of availability.

**SUMMARY:** NIOSH announces the availability of the final National Occupational Research Agenda for Transportation, Warehousing and Utilities

**DATES:** The final document was published on March 7, 2018.

**ADDRESSES:** The document may be obtained at the following link: <https://www.cdc.gov/niosh/nora/sectors/twu/agenda.html>

**FOR FURTHER INFORMATION CONTACT:** Emily Novicki, M.A., M.P.H., (NORACoordinator@cdc.gov), National Institute for Occupational Safety and Health, Centers for Disease Control and Prevention, Mailstop E-20, 1600 Clifton Road NE, Atlanta, GA 30329, phone (404) 498-2581 (not a toll free number).

**SUPPLEMENTARY INFORMATION:** On December 1, 2017, NIOSH published a request for public review in the **Federal Register** [82 FR 56973] of the draft version of the National Occupational Research Agenda for Transportation, Warehousing and Utilities. No comments were received.

Dated: March 8, 2018.

**Frank Hearl,**  
Chief of Staff, National Institute for Occupational Safety and Health, Centers for Disease Control and Prevention.

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## DEPARTMENT OF HEALTH AND HUMAN SERVICES

### Food and Drug Administration

[Docket No. FDA-2017-N-0493]

#### Agency Information Collection Activities; Submission for Office of Management and Budget Review; Comment Request; Utilization of Adequate Provision Among Low to Non-Internet Users

**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:** Submit either electronic or written comments on the collection of information by April 12, 2018.

**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 [aira\\_submission@omb.eop.gov](mailto:aira_submission@omb.eop.gov). All comments should be identified with the OMB control number 0910-New and title "Utilization of Adequate Provision Among Low to Non-internet Users." Also include the FDA docket number found in brackets in the heading of this document.

**FOR FURTHER INFORMATION CONTACT:** Ila S. Mizrahi, Office of Operations, Food and Drug Administration, Three White Flint North, 10A-12M, 11601 Landsdown St., North Bethesda, MD 20852, 301-796-7726, [PRStaff@fda.hhs.gov](mailto:PRStaff@fda.hhs.gov).

#### SUPPLEMENTARY INFORMATION:

##### I. Background

In compliance with 44 U.S.C. 3507, FDA has submitted the following proposed collection of information to OMB for review and clearance.

##### Utilization of Adequate Provision Among Low to Non-Internet Users

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 (FD&C Act) (21 U.S.C. 393(d)(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.

Prescription drug advertising regulations require that broadcast advertisements containing product claims present the product's major side effects and contraindications in either audio or audio and visual parts of the advertisement (21 CFR 202.1(e)(1)); this is often called the major statement. The regulations also require that broadcast advertisements contain a brief summary of all necessary information related to side effects and contraindications or that "adequate provision" be made for dissemination of the approved package labeling in connection with the broadcast (§ 202.1(e)(1)). The requirement for adequate provision is generally fulfilled when a firm gives consumers the option of obtaining FDA-required labeling or other information via a toll-free telephone number, through print advertisements or product brochures, through information disseminated at health care provider offices or pharmacies, and through the internet (Ref. 1). The purpose of including all four elements is to ensure that most of a potentially diverse audience can access the information.

Internet accessibility is increasing, but many members of certain demographic groups (e.g., older adults, low socioeconomic status individuals) nonetheless report that the internet is inaccessible to them either as a resource or due to limited knowledge, and so a website alone may not adequately serve all potential audiences (Refs. 2 and 3). Similarly, some consumers may prefer to consult sources other than a health care provider to conduct initial research, for privacy reasons or otherwise (Refs. 1, 4, and 5). In light of these considerations, the toll-free number and print ad may provide special value to consumers who are low to non-internet users and/or those who value privacy when conducting initial research on a medication, though not necessarily unique value relative to one another. As such, a primary purpose of this research is to examine the value of including both the toll-free number and print ad as part of adequate provision in direct-to-consumer (DTC) prescription drug broadcast ads. We will also investigate the ability and willingness of low to non-internet users to make use of internet resources if other options were unavailable. These questions will be assessed using a survey methodology administered via telephone.

In addition, building on concurrent FDA research regarding drug risk