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Prevention.

[FR Doc. 2018-05000 Filed 3-12-18; 8:45 am]

BILLING CODE 4163-18-P

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](https://www.cdc.gov/niosh/nora/sectors/twu/agenda.html)

FOR FURTHER INFORMATION CONTACT:
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(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.

[FR Doc. 2018-04988 Filed 3-12-18; 8:45 am]

BILLING CODE 4163-19-P

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
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and Drug Administration, Three White
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20852, 301-796-7726, [PRAStaff@
fda.hhs.gov](mailto:PRAStaff@
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