third party may not wish to be posted, such as medical information, your or anyone else’s Social Security number, or confidential business information, such as a manufacturing process. Please note that if you include your name, contact information, or other information that identifies you in the body of your comments, that information will be posted on [https://www.regulations.gov](https://www.regulations.gov).

- If you want to submit a comment with confidential information that you do not wish to be made available to the public, submit the comment as a written/paper submission and in the manner detailed (see “Written/Paper Submissions” and “InSTRUCTIONS”).

**Written/Paper Submissions**

Submit written/paper submissions as follows:

- Mail/Hand delivery/Courier (for written/paper submissions): Dockets Management Staff (HFA–405), Food and Drug Administration, 5630 Fishers Lane, Rm. 1061, Rockville, MD 20852.
- For written/paper comments submitted to the Dockets Management Staff, FDA will post your comment, as well as any attachments, except for information submitted, marked and identified, as confidential, if submitted as detailed in “InSTRUCTIONS.”

**Instructions:** All submissions received must include the Docket No. FDA–2017–N–4515 for “International Drug Scheduling; Convention on Psychotropic Substances; Single Convention on Narcotic Drugs; Ocfentanil, Carfentanil, Pregabalin, Tramadol, Cannabidiol, Ketamine, and Eleven Other Substances; Extension of Comment Period.” Received comments, those filed in a timely manner (see **ADDRESSES**), will be placed in the docket and, except for those submitted as “Confidential Submissions,” publicly viewable at [https://www.regulations.gov](https://www.regulations.gov) or at the Dockets Management Staff Office between 9 a.m. and 4 p.m., Monday through Friday.

- **Confidential Submissions**—To submit a comment with confidential information that you do not wish to be made publicly available, submit your comments only as a written/paper submission. You should submit two copies total. One copy will include the information you claim to be confidential with a heading or cover note that states “THIS DOCUMENT CONTAINS CONFIDENTIAL INFORMATION.” The Agency will review this copy, including the claimed confidential information, in its consideration of comments. The second copy, which will have the claimed confidential information redacted/blacked out, will be available for public viewing and posted on [https://www.regulations.gov](https://www.regulations.gov). Submit both copies to the Dockets Management Staff. If you do not wish your name and contact information to be made publicly available, you can provide this information on the cover sheet and not in the body of your comments and you must identify this information as “confidential.” Any information marked as “confidential” will not be disclosed except in accordance with 21 CFR 10.20 and other applicable disclosure law. For more information about FDA’s posting of comments to public dockets, see 80 FR 56469, September 18, 2015, or access the information at: [https://www.gpo.gov/fdsys/pkg/FR-2015-09-18/pdf/2015-23369.pdf](https://www.gpo.gov/fdsys/pkg/FR-2015-09-18/pdf/2015-23369.pdf).

**Docket:** For access to the docket to read background documents or the electronic and written/paper comments received, go to [https://www.regulations.gov](https://www.regulations.gov) and insert the docket number, found in brackets in the heading of this document, into the “Search” box and follow the prompts and/or go to the Dockets Management Staff, 5630 Fishers Lane, Rm. 1061, Rockville, MD 20852.

**FOR FURTHER INFORMATION CONTACT:** James R. Hunter, Center for Drug Evaluation and Research, Controlled Substance Staff, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 51, Rm. 5150, Silver Spring, MD 20993–0002, 301–796–3156, email: james.hunter@fda.hhs.gov.

**SUPPLEMENTARY INFORMATION:** In the **Federal Register** of August 14, 2017, FDA published a notice with a 30-day comment period to request comments on abuse potential, actual abuse, medical usefulness, trafficking, and impact of scheduling changes on availability for medical use of 17 drug substances.

The Agency has received requests for an extension of the comment period for the notice. Each request conveyed concern that the current 30-day comment period does not allow sufficient time to develop a meaningful or thoughtful response to the notice.

FDA has considered the requests and is extending the comment period for the notice until September 20, 2017. The Agency believes this extension allows adequate time for interested persons to submit comments.


Anna K. Abram,
Deputy Commissioner for Policy, Planning, Legislation, and Analysis.

**DEPARTMENT OF HEALTH AND HUMAN SERVICES**

**Food and Drug Administration**

[Docket No. FDA–2016–D–0734]

**Evaluation and Reporting of Age, Race, and Ethnicity Data in Medical Device Clinical Studies; Guidance for Industry and Food and Drug Administration Staff; Availability**

**AGENCY:** Food and Drug Administration, HHS.

**ACTION:** Notice of availability.

**SUMMARY:** The Food and Drug Administration (FDA or Agency) is announcing the availability of the guidance entitled “Evaluation and Reporting of Age, Race, and Ethnicity Data in Medical Device Clinical Studies.”

The purpose of this document is to outline FDA’s recommendations and expectations for the evaluation and reporting of age, race, and ethnicity data in medical device clinical studies. The primary intent of these recommendations is to improve the quality, consistency, and transparency of data regarding the performance of medical devices within specific age, race, and ethnic groups.

**DATES:** The announcement of the guidance is published in the **Federal Register** on September 12, 2017.

**ADDRESSES:** You may submit either electronic or written comments on Agency guidances at any time as follows:

**Electronic Submissions**

Submit electronic comments in the following way:

- **Federal eRulemaking Portal:** [https://www.regulations.gov](https://www.regulations.gov). Follow the instructions for submitting comments. Comments submitted electronically, including attachments, to [https://www.regulations.gov](https://www.regulations.gov) will be posted to the docket unchanged. Because your comment will be made public, you are solely responsible for ensuring that your comment does not include any confidential information that you or a third party may not wish to be posted, such as medical information, your or anyone else’s Social Security number, or confidential business information, such as a manufacturing process. Please note that if you include your name, contact information, or other information that identifies you in the body of your comments, that information will be posted on [https://www.regulations.gov](https://www.regulations.gov).

- If you want to submit a comment with confidential information that you do not wish to be made available to the public, submit the comment as a
written/paper submission and in the manner
detailed (see “Written/Paper Submissions” and “Instructions”).

Written/Paper Submissions

Submit written/paper submissions as follows:

- Mail/Hand delivery/Courier (for written/paper submissions): Dockets
  Management Staff (HFA–305), Food and Drug Administration, 5630 Fishers
  Lane, Rm. 1061, Rockville, MD 20852.

- For written/paper comments submitted to the Dockets Management
  Staff, FDA will post your comment, as well as any attachments, except for
  information submitted, marked and identified, as confidential, if submitted
  as detailed in “Instructions.”

Instructions: All submissions received must include the Docket No. FDA–
2016–D–0734 for “Evaluation and Reporting of Age, Race, and Ethnicity
Data in Medical Device Clinical Studies; Guidance for Industry and Food and
Drug Administration Staff; Availability.” Received comments will be
placed in the docket and, except for those submitted as “Confidential
Submissions,” publicly viewable at
https://www.regulations.gov or at the
Dockets Management Staff between 9
a.m. and 4 p.m., Monday through
Friday.

- Confidential Submissions—To submit a comment with confidential
information that you do not wish to be
made publicly available, submit your
comments only as a written/paper
submission. You should submit two
copies total. One copy will include the
information you claim to be confidential
with a heading or cover note that states
“THIS DOCUMENT CONTAINS
CONFIDENTIAL INFORMATION.” The
Agency will review this copy, including the
claimed confidential information, in its
consideration of comments. The
second copy, which will have the
claimed confidential information
redacted/blacked out, will be available
for public viewing and posted on
https://www.regulations.gov. Submit
both copies to the Dockets Management
Staff. If you do not wish your name and
contact information to be made publicly
available, you can provide this
information on the cover sheet and not
in the body of your comments and you
must identify this information as
“confidential.” Any information marked
as “confidential” will not be disclosed
except in accordance with 21 CFR 10.20
and other applicable disclosure law. For
more information about FDA’s posting
of comments to public dockets, see 80
FR 56469, September 18, 2015, or access
the information at: https://www.gpo.gov/

SUPPLEMENTARY INFORMATION
section for information on electronic access to the
guidance. Submit written requests for a
single hard copy of the guidance
document entitled “Evaluation and Reporting of Age, Race, and Ethnicity
Data in Medical Device Clinical Studies” to the Office of the Center
Director, Guidance and Policy
Development, Center for Devices and
Radiological Health, Food and Drug
Administration, 10903 New Hampshire
Ave., Bldg. 66, Rm. 5418, Silver Spring,
MD 20993–0002 or the Office of
Communication, Outreach, and
Development, Center for Biologics
Evaluation and Research, Food and
Drug Administration, 10903 New
Hampshire Ave., Bldg. 71, Rm.
3128, Silver Spring, MD 20993–0002.
If you have any questions about
this guidance, please contact

Katheryn O’Callaghan, Center for
Devices and Radiological Health, Food
and Drug Administration, 10903 New
Hampshire Ave., Bldg. 66, Rm.
5418, Silver Spring, MD 20993–0002.
301–796–6349; or Stephen Ripley, Center
for Biologics Evaluation and Research,
Food and Drug Administration, 10903 New
Hampshire Ave., Bldg. 71, Rm.
7301, Silver Spring, MD 20993–0002.

I. Background

Section 907 of the Food and Drug
Administration Safety and Innovation
Act (Pub. L. 112–144) (FDASIA)
directed the Agency to publish and
provide to Congress a report describing
the extent to which clinical trial
participation and safety and
effectiveness data by demographic
subgroups, including sex, age, race,
and ethnicity, is included in
applications submitted to FDA (Ref. 1).
Section 907 also directed FDA to publish
and provide to Congress an action plan
outlining recommendations to improve
the completeness and quality of
analyses of data on demographic
subgroups in summaries of product
safety and effectiveness data and in
labeling; on the inclusion of such data,
or the lack of availability of such data,
in labeling, and to improve the public
availability of such data to patients
health care providers and researchers,
and to indicate the applicability of these
recommendations to the types of
medical products addressed in
section 907. In the Action Plan, FDA
committed to developing this guidance as part of
the strategy to fulfill FDASIA
requirements (Ref. 2).

This guidance outlines FDA’s
recommendations and expectations for
patient enrollment, data analysis, and
reporting of age, race, and ethnicity
data in medical device clinical studies.
Specific objectives of this guidance are
(1) encourage the collection and
consideration of age, race, ethnicity,
and associated covariates (e.g., body size,
biomarkers, bone density) during the
study design stage; (2) outline
recommended analyses of study
subgroup data with a framework for
considering demographic data when
interpreting overall study outcomes; and
(3) specify FDA’s recommendations for
reporting age, race, and ethnicity-
specific information in summaries and
labeling for approved or cleared medical
devices. FDA believes these
recommendations will help improve the
quality, consistency, and transparency
of data regarding the performance of
medical devices within specific age,
race, and ethnic groups as well as
encourage appropriate enrollment of
diverse populations including relevant
age, race, and ethnic groups. Proper
evaluation and reporting of these data
can benefit patients, clinicians,
researchers, regulators, and other
stakeholders.

FDA considered comments received
on the draft guidance that appeared in the
Federal Register of June 20, 2016
(81 FR 39927). FDA revised the
guidance as appropriate in response to
the comments. This document extends
the policy established in FDA’s
previous guidance entitled “Evaluation of Sex-
Specific Data in Medical Device Clinical
Studies” to additional demographic
subgroups of age, race, and ethnicity
(Ref. 3).

II. Significance of Guidance

This guidance is being issued
consistent with FDA’s good guidance
practices regulation (21 CFR 10.115).
The guidance represents the current
thinking of FDA on “Evaluation and
Reporting of Age, Race, and Ethnicity
data in Medical Device Clinical
III. Electronic Access

Persons interested in obtaining a copy of the guidance may do so by downloading an electronic copy from the internet. A search capability for all Center for Devices and Radiological Health guidance documents is available at https://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/GuidanceDocuments/default.htm. Guidance documents are also available at https://www.fda.gov/BiologicsBloodVaccines/GuidanceComplianceRegulatoryInformation/default.htm or https://www.regulations.gov. Persons unable to download an electronic copy of “Evaluation and Reporting of Age, Race, and Ethnicity Data in Medical Device Clinical Studies” may send an email request to CDRH-Guidance@fda.hhs.gov to receive an electronic copy of the document. Please use the document number 1500626 to identify the guidance you are requesting.

IV. Paperwork Reduction Act of 1995

This guidance refers to previously approved collections of information found in FDA regulations. These collections of information are subject to review by the Office of Management and Budget (OMB) under the Paperwork Reduction Act of 1995 (44 U.S.C. 3501–3520). These collections of information in 21 CFR part 812 have been approved under OMB control number 0910–0078; the collections of information in 21 CFR part 807, subpart E, have been approved under OMB control number 0910–0120; the collections of information in 21 CFR part 814, subparts A through E, have been approved under OMB control number 0910–0231; the collections of information in 21 CFR part 814, subpart H, have been approved under OMB control number 0910–0332; the collections of information in 21 CFR part 822 have been approved under OMB control number 0910–0449; and the collections of information in 21 CFR part 801 have been approved under OMB control number 0910–0485.

V. References

The following references are on display in the Dockets Management Staff office (see ADDRESSES) and are available for viewing by interested persons between 9 a.m. and 4 p.m. Monday through Friday; they are also available electronically at https://www.regulations.gov. FDA has verified the Web site addresses, as of the date this document publishes in the Federal Register, but Web sites are subject to change over time.


Leslie Kux,
Associate Commissioner for Policy.

SUPPLEMENTARY INFORMATION: When submitting comments or requesting information, please include the information request collection title for reference, in compliance with Section 3506(c)(2)(A) of the Paperwork Reduction Act of 1995.

Information Collection Request Title: National Practitioner Data Bank for Adverse Information on Physicians and Other Health Care Practitioners—45 CFR part 60 Regulations and Forms, OMB No. 0915–0126—Revision.

Abstract: This is a request for a revision of OMB approval of the information collection contained in regulations found at 45 CFR part 60 governing the National Practitioner Data Bank (NPDB) and the forms to be used in registering with, reporting information to, and requesting information from the NPDB. Administrative forms are also included to aid in monitoring compliance with Federal reporting and querying requirements. Responsibility for NPDB implementation and operation resides in HRSA’s Bureau of Health Workforce.

The intent of the NPDB is to improve the quality of health care by encouraging hospitals, State licensing boards, professional societies, and other entities providing health care services to identify and discipline those who engage in unprofessional behavior, and to restrict the ability of incompetent health care practitioners, providers, or suppliers to move from State to State without disclosure of previous damaging or incompetent performance. It also serves as a fraud and abuse clearinghouse for the reporting and disclosing of certain final adverse actions (excluding settlements in which no findings of liability have been made) taken against health care practitioners, providers, or suppliers by health plans, Federal agencies, and State agencies.

The reporting forms, request for information forms (query forms), and administrative forms (used to monitor compliance) are accessed, completed, and submitted to the NPDB.