of QSIT, and informed by the PMA CtQ information developed jointly by FDA and the PMA applicant.

7. Following completion of the inspection, participating FDA Offices and applicants provide the information/data needed to assess the voluntary PMA CtQ pilot program's impact on resource utilization and quality focus, utilizing the evaluation forms provided in Appendices A and B (Ref. 11).

During this voluntary PMA CtQ pilot program, CDRH staff intends to be available to answer questions or concerns that may arise. The voluntary PMA CtQ pilot program participants will be asked to comment on and discuss their experiences with the PMA CtQ pilot submission process. Comments and discussions may assist FDA in determining whether the goals of this voluntary PMA CtQ pilot program goal are clearly communicated and attainable.

II. Duration of the Premarket Approval Application Critical to Quality Pilot Program

FDA intends to accept requests for participation in the voluntary PMA CtQ pilot program from September 29, 2017, to December 31, 2018, or until such time as when a total of nine PMAs have been enrolled.

III. Paperwork Reduction Act of 1995

This notice 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). 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 820 have been approved under OMB control number 0910–0073; and the collections of information in ''Requests for Feedback on Medical Device Submissions: The Pre-Submission Program and Meetings with Food and Drug Administration Staff'' have been approved under OMB control number 0910–0756.

IV. References

The following references have been placed on display in the Division of Dockets Management (see **ADDRESSES**), and may be seen by interested persons between 9 a.m. and 4 p.m., Monday through Friday, and are available electronically at *https://www.regulations.gov.* (FDA has verified the Web site addresses, but we are not responsible for any subsequent changes to the Web sites after this document publishes in the **Federal Register**.)

1. Implantable Devices that Contain Batteries Critical to Quality Inspection Pilot. Available at *https://www.fda.gov/downloads/MedicalDevices/DeviceRegulationandGuidance/MedicalDeviceQualityandCompliance/UCM469128.pdf.*
2. FDA's Case for Quality, available at *http://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/MedicalDeviceQualityandCompliance/ucm378185.htm.*
3. FDA's Guide to Inspections of Quality Systems, Quality System Inspection Technique, available at *http://www.fda.gov/ICECI/Inspections/InspectionGuides/ucm074883.htm.*
4. FDA Guidance for Industry and FDA Staff ''Requests for Feedback on Medical Device Submissions: The Pre-Submission Program and Meetings with Food and Drug Administration Staff'' dated February 18, 2014. Available at *https://www.fda.gov/ucm/groups/fdagov-public/@fdagov-meddev-gen/documents/document/ucm311176.pdf.*
5. FDA's Guidance for Industry and FDA Staff: Acceptance and Filing Reviews for Premarket Approval Applications (PMAs) at *https://www.fda.gov/ucm/groups/fdagov-public/@fdagov-meddev-gen/documents/document/ucm313368.pdf.*
6. FDA's Guidance for Industry and FDA Staff: Quality System Information for Certain Premarket Application Reviews, available at *http://www.fda.gov/medicaldevices/deviceregulationandguidance/guidancedocuments/ucm070897.htm.*
7. FDA's Official Action Indicated, available at *http://www.fda.gov/downloads/AboutFDA/Transparency/PublicDisclosure/GlossaryofAcronymsandAbbreviations/UCM212061.pdf.*
8. 2017 FDA Investigations Operations Manual (IOM) Chapter 5 at *https://www.fda.gov/ucm/groups/fdagov-public/@fdagov-afda-ice/documents/document/ucm123522.pdf.*
9. FDA Compliance Program 7383.001 at *http://www.fda.gov/downloads/MedicalDevices/DeviceRegulationandGuidance/MedicalDeviceQualityandCompliance/UCM295570.pdf.*
10. FDA Compliance Program 7382.845 at *https://www.fda.gov/downloads/MedicalDevices/DeviceRegulationandGuidance/GuidanceDocuments/UCM244277.pdf.*
11. Appendices A and B.

Dated: September 5, 2017.

Leslie Kux,

Associate Commissioner for Policy.

[FR Doc. 2017–19258 Filed 9–11–17; 8:45 am]

BILLING CODE 4164–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2017–N–4515]

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

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice; extension of comment period.

SUMMARY: The Food and Drug Administration (FDA or the Agency) is extending the comment period for the notice that appeared in the **Federal Register** of August 14, 2017. In the notice, FDA requested comments concerning abuse potential, actual abuse, medical usefulness, trafficking, and impact of scheduling changes on availability for medical use of 17 drug substances. The Agency is taking this action in response to requests for an extension to allow interested persons additional time to submit comments.

DATES: FDA is extending the comment period on the notice published August 14, 2017 (82 FR 37866). Submit either electronic or written comments by September 20, 2017.

ADDRESSES: You may submit comments as follows. Please note that late, untimely filed comments will not be considered. Electronic comments must be submitted on or before September 20, 2017. The *https://www.regulations.gov* electronic filing system will accept comments until midnight Eastern Time at the end of September 20, 2017. Comments received by mail/hand delivery/courier (for written/paper submissions) will be considered timely if they are postmarked or the delivery service acceptance receipt is on or before that date.

Electronic Submissions

Submit electronic comments in the following way:

- *Federal eRulemaking Portal: https://www.regulations.gov.* Follow the instructions for submitting comments. Comments submitted electronically, including attachments, to *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.*

• 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–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* 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.* 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/2015-23389.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* 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.

Dated: September 7, 2017.

Anna K. Abram,

Deputy Commissioner for Policy, Planning, Legislation, and Analysis.

[FR Doc. 2017–19261 Filed 9–11–17; 8:45 am]

BILLING CODE 4164–01–P

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.* Follow the instructions for submitting comments. Comments submitted electronically, including attachments, to *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.*

• 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