

comments, that information will be posted on <http://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):* Division of Dockets Management (HFA-305), Food and Drug Administration, 5630 Fishers Lane, rm. 1061, Rockville, MD 20852.

- For written/paper comments submitted to the Division of Dockets Management, 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-2015-N-4602 for “Streamlining Regulations for Good Manufacturing Practices for Hearing Aids; Public Workshop; Request for Comments.” Received comments will be placed in the docket and, except for those submitted as “Confidential Submissions,” publicly viewable at <http://www.regulations.gov> or at the Division of Dockets Management 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 <http://www.regulations.gov>. Submit both copies to the Division of Dockets Management. 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: <http://www.fda.gov/regulatoryinformation/dockets/default.htm>.

Docket: For access to the docket to read background documents or the electronic and written/paper comments received, go to <http://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 Division of Dockets Management, 5630 Fishers Lane, Rm. 1061, Rockville, MD 20852.

FOR FURTHER INFORMATION CONTACT:

Srinivas Nandkumar, Food and Drug Administration, Center for Devices and Radiological Health, Bldg. 66, Rm. 2436, 10903 New Hampshire Ave., Silver Spring, MD 20993, 301-796-6480, FAX: 301-847-8126, Srinivas.nandkumar@fda.hhs.gov.

SUPPLEMENTARY INFORMATION: In the **Federal Register** of January 7, 2016 (81 FR 784), FDA published a document with a 30-day comment period to request comments on the appropriate level of GMPs regulation to ensure the safety and effectiveness of air-conduction hearing aid devices; the current regulations for air-conduction hearing aids that may hinder innovation, reduce competition, and lead to increased cost and reduced use of these devices by Americans with age-related hearing loss; and the potential exemption of hearing aids from the Quality System Regulation (QSR) through use of alternative standards developed in collaboration with key stakeholders and standards development organizations, and recognized by FDA and recordkeeping to ensure product quality. Comments on the “Streamlining Regulations for Good Manufacturing Practices for Hearing Aids” will inform the Agency on an alternative model for quality verification.

The Agency has received requests for a 30-day extension of the comment period for the document. 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 document on “Streamlining Regulations for Good Manufacturing Practices for Hearing Aids.”

FDA has considered the requests and is extending the comment period for the document on “Streamlining Regulations for Good Manufacturing Practices for

Hearing Aids” for 30 days, until June 30, 2016. The Agency believes that a 30-day extension allows adequate time for interested persons to submit comments without significantly delaying regulation on these important issues.

Dated: May 3, 2016.

Leslie Kux,

Associate Commissioner for Policy.

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA-2016-N-0001]

Advisory Committee; Anesthetic and Analgesic Drug Products Advisory Committee, Renewal

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice; renewal of advisory committee.

SUMMARY: The Food and Drug Administration (FDA) is announcing the renewal of the Anesthetic and Analgesic Drug Products Advisory Committee by the Commissioner of Food and Drugs (the Commissioner). The Commissioner has determined that it is in the public interest to renew the Anesthetic and Analgesic Drug Products Advisory Committee for an additional 2 years beyond the charter expiration date. The new charter will be in effect until May 1, 2018.

DATES: Authority for the Anesthetic and Analgesic Drug Products Advisory Committee will expire on May 1, 2016, unless the Commissioner formally determines that renewal is in the public interest.

FOR FURTHER INFORMATION CONTACT:

Stephanie L. Begansky, Center for Drug Evaluation and Research, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 31, Rm. 2417, Silver Spring, MD 20993-0002, (301) 796-9001, AADPAC@fda.hhs.gov.

SUPPLEMENTARY INFORMATION: Issued in 41 CFR 102-3.65 and approval by the Department of Health and Human Services issued in 45 CFR part 11 and by the General Services Administration, FDA is announcing the renewal of the Anesthetic and Analgesic Drug Products Advisory Committee. The committee is a discretionary Federal advisory committee established to provide advice to the Commissioner. The Anesthetic and Analgesic Drug Products Advisory Committee advises the Commissioner or designee in discharging responsibilities

as they relate to helping to ensure safe and effective drugs for human use and, as required, any other product for which the Food and Drug Administration has regulatory responsibility. The Committee reviews and evaluates available data concerning the safety and effectiveness of marketed and investigational human drug products including analgesics, *e.g.*, abuse-deterrent opioids, novel analgesics, and issues related to opioid abuse, and those for use in anesthesiology and makes appropriate recommendations to the Commissioner of Food and Drugs.

The Committee shall consist of a core of 11 voting members including the Chair. Members and the Chair are selected by the Commissioner or designee from among authorities knowledgeable in the fields of anesthesiology, analgesics (such as: abuse deterrent opioids, novel analgesics, and issues related to opioid abuse) epidemiology or statistics, and related specialties. Members will be invited to serve for overlapping terms of up to four years. Almost all non-Federal members of this committee serve as Special Government Employees. The core of voting members may include one technically qualified member, selected by the Commissioner or designee, who is identified with consumer interests and is recommended by either a consortium of consumer-oriented organizations or other interested persons. In addition to the voting members, the Committee may include one non-voting member who is identified with industry interests.

Further information regarding the most recent charter and other information can be found at <http://www.fda.gov/AdvisoryCommittees/CommitteesMeetingMaterials/Drugs/AnestheticAndAnalgesicDrugProductsAdvisoryCommittee/ucm094127.htm> or by contacting the Designated Federal Officer (see **FOR FURTHER INFORMATION CONTACT**). Since no change has been made to the committee name or description of duties, no amendment will be made to 21 CFR 14.100.

This document is issued under the Federal Advisory Committee Act (5

U.S.C. app.). For general information related to FDA advisory committees, please visit us at <http://www.fda.gov/AdvisoryCommittees/default.htm>.

Dated: May 3, 2016.

Jill Hartzler Warner,

Associate Commissioner for Special Medical Programs.

[FR Doc. 2016-10766 Filed 5-6-16; 8:45 am]

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Office of the Secretary

[Document Identifier: OMB # 0990-0424-60D]

Agency Information Collection Activities; Proposed Collection; Public Comment Request

AGENCY: Office of the Assistant Secretary for Health, Office of Adolescent Health, HHS.

ACTION: Notice.

SUMMARY: In compliance with section 3506(c)(2)(A) of the Paperwork Reduction Act of 1995, the Office of the Secretary (OS), Department of Health and Human Services, announces plans to submit an Information Collection Request (ICR), described below, to the Office of Management and Budget (OMB). Prior to submitting that ICR to OMB, OS seeks comments from the public regarding the burden estimate, below, or any other aspect of the ICR.

DATES: Comments on the ICR must be received on or before July 8, 2016.

ADDRESSES: Submit your comments to Information.CollectionClearance@hhs.gov or by calling (202) 690-6162.

FOR FURTHER INFORMATION CONTACT: Information Collection Clearance staff, Information.CollectionClearance@hhs.gov or (202) 690-6162.

SUPPLEMENTARY INFORMATION: When submitting comments or requesting information, please include the document identifier OMB # 0990-0424-60D for reference.

Information Collection Request Title: Positive Adolescent Futures (PAF)

Study Abstract: The Office of Adolescent Health (OAH), U.S. Department of Health and Human Services (HHS) is requesting approval by OMB on a revised data collection. The Positive Adolescent Futures (PAF) Study will provide information about program design, implementation, and impacts through a rigorous assessment of program impacts and implementation of two programs designed to support expectant and parenting teens. These programs are located in Houston, Texas and throughout the state of California. This revised information collection request includes the 24-month follow-up survey instrument related to the impact study. The data collected from this instrument in the two study sites will provide a detailed understanding of program impacts about two years after youth are enrolled in the study and first have access to the programming offered by each site.

Need and Proposed Use of the Information: The data will serve two main purposes. First, the data will be used to determine program effectiveness by comparing outcomes on repeat pregnancies, sexual risk behaviors, health and well-being, and parenting behaviors between treatment (program) and control youth. Second, the data will be used to understand whether the programs are more effective for some youth than others. The findings from these analyses of program impacts will be of interest to the general public, to policymakers, and to organizations interested in supporting expectant and parenting teens.

Likely Respondents: The 24-month follow-up survey data will be collected through a web-based survey or through telephone interviews with study participants; *i.e.* adolescents randomly assigned to a program for expectant and parenting teens being tested for program effectiveness, or to a control group. The mode of survey administration will primarily be based on the preference of the study participants. The survey will be completed by 1,515 respondents across the two study sites. Clearance is requested for three years.

TOTAL ESTIMATED ANNUALIZED BURDEN—HOURS

Form name	Number of respondents	Number of responses per respondent	Average burden per response (in hours)	Total burden hours
24-month follow-up survey of impact study participants	505	1	30/60	252.5
Total				252.5