Agenda: The committee will discuss new drug application (NDA) 204017 (levonorgestrel and ethinyl estradiol) transdermal system, submitted by Agile Therapeutics, Inc., for the prevention of pregnancy in women of reproductive potential.

FDA intends to make background material available to the public no later than 2 business days before the meeting. If FDA is unable to post the background material on its website prior to the meeting, the background material will be made publicly available at the location of the advisory committee meeting, and the background material will be posted on FDA's website after the meeting. Background material is available at *https://www.fda.gov/AdvisoryCommittees/Calendar/default.htm*. Scroll down to the appropriate advisory committee meeting link.

Procedure: Interested persons may present data, information, or views, orally or in writing, on issues pending before the committee. All electronic and written submissions submitted to the Docket (see the **ADDRESSES** section) on or before October 16, 2019, will be provided to the committee. Oral presentations from the public will be scheduled between approximately 1 p.m. and 2 p.m. Those individuals interested in making formal oral presentations should notify the contact person and submit a brief statement of the general nature of the evidence or arguments they wish to present, the names and addresses of proposed participants, and an indication of the approximate time requested to make their presentation on or before October 7, 2019. Time allotted for each presentation may be limited. If the number of registrants requesting to speak is greater than can be reasonably accommodated during the scheduled open public hearing session, FDA may conduct a lottery to determine the speakers for the scheduled open public hearing session. The contact person will notify interested persons regarding their request to speak by October 8, 2019.

Persons attending FDA's advisory committee meetings are advised that FDA is not responsible for providing access to electrical outlets.

For press inquiries, please contact the Office of Media Affairs at *fdaoma@fda.hhs.gov* or 301–796–4540.

FDA welcomes the attendance of the public at its advisory committee meetings and will make every effort to accommodate persons with disabilities. If you require accommodations due to a disability, please contact Kalyani Bhatt (see **FOR FURTHER INFORMATION CONTACT**) at least 7 days in advance of the meeting.

FDA is committed to the orderly conduct of its advisory committee meetings. Please visit our website at: *https://www.fda.gov/AdvisoryCommittees/AboutAdvisoryCommittees/ucm111462.htm* for procedures on public conduct during advisory committee meetings.

Notice of this meeting is given under the Federal Advisory Committee Act (5 U.S.C. app. 2).

Dated: August 14, 2019.

Lowell J. Schiller,

Principal Associate Commissioner for Policy.

[FR Doc. 2019–17932 Filed 8–19–19; 8:45 am]

BILLING CODE 4164–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

[Document Identifier: OS–0990–new]

Agency Information Collection Request; 30-Day Public Comment Request

AGENCY: Office of the Secretary, HHS

ACTION: Notice.

SUMMARY: In compliance with the requirement of the Paperwork Reduction Act of 1995, the Office of the Secretary (OS), Department of Health and Human Services, is publishing the following summary of a proposed collection for public comment.

DATES: Comments on the ICR must be received on or before September 19, 2019.

ADDRESSES: Submit your comments to *OIRA_submission@omb.eop.gov* or via facsimile to (202) 395–5806.

FOR FURTHER INFORMATION CONTACT: Sherrette Funn, *Sherrette.Funn@hhs.gov* or (202) 795–7714. When submitting comments or requesting information, please include the document identifier 0990–New–30D and project title for reference.

SUPPLEMENTARY INFORMATION: Interested persons are invited to send comments regarding this burden estimate or any other aspect of this collection of information, including any of the following subjects: (1) The necessity and utility of the proposed information collection for the proper performance of the agency's functions; (2) the accuracy of the estimated burden; (3) ways to enhance the quality, utility, and clarity of the information to be collected; and (4) the use of automated collection techniques or other forms of information technology to minimize the information collection burden.

Title of the Collection: Evaluation of the Kidney Innovation Accelerator (KidneyX).

Type of Collection: New.

OMB No. 0990–NEW—Office of the Chief Technology Officer

Abstract: The Office of the Chief Technology Officer (CTO) is initiating an independent evaluation under the Department of Health & Human Services (HHS) of the Kidney Innovation Accelerator—or KidneyX—a public-private partnership between HHS/CTO and the American Society of Nephrology (ASN).

The KidneyX evaluation involves a mixed-methods design for data collection and analysis. The evaluation integrates qualitative techniques, such as document analysis and stakeholder interviews, to capture the details and effects of processes and changes within the KidneyX initiative. We will apply quantitative methods, such as surveys and econometric analysis, in discrete situations in which we find sufficient certainty and coherence in environmental conditions to conduct rigorous analysis.

The evaluation will use a data-driven set of methodologies to address, to the extent possible, the central question of the effectiveness of KidneyX: The degree to which KidneyX contributed to any acceleration in the rate of innovation in the targeted area of kidney technology compared with how innovation would have progressed without KidneyX.

ESTIMATED ANNUALIZED BURDEN HOURS:

Type of respondent	Form name	Number of respondents	Number of responses per respondent	Average burden per response (in min)	Total burden (in hr)
Prize competition applicants	Applicant Interview Guide	12	1	50/60	10
Prize competition awardees	Awardee Interview Guide	6	1	50/60	5

ESTIMATED ANNUALIZED BURDEN HOURS:—Continued

Type of respondent	Form name	Number of respondents	Number of responses per respondent	Average burden per response (in min)	Total burden (in hr)
Prize competition non-awardees	Non-awardee Interview Guide	6	1	50/60	5
Other Stakeholders	Other Stakeholder Interview Guide	6	1	50/60	5
Prize competition applicants	Pre-award Survey Instrument	300	1	30/60	150
Prize competition awardees and non-awardees.	Post-award Survey Instrument	300	1	30/60	150
Total					325

Terry Clark,

Office of the Secretary, Paperwork Reduction Act Reports Clearance Officer.

[FR Doc. 2019–17887 Filed 8–19–19; 8:45 am]

BILLING CODE 4150–04–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

[Document Identifier: OS–0990–new]

Agency Information Collection Request; 30-Day Public Comment Request

AGENCY: Office of the Secretary, HHS.

ACTION: Notice.

SUMMARY: In compliance with the requirement of the Paperwork Reduction Act of 1995, the Office of the Secretary (OS), Department of Health and Human Services, is publishing the following summary of a proposed collection for public comment.

DATES: Comments on the ICR must be received on or before September 19, 2019.

ADDRESSES: Submit your comments to *OIRA_submission@omb.eop.gov* or via facsimile to (202) 395–5806.

FOR FURTHER INFORMATION CONTACT: Sherrette Funn, *Sherrette.Funn@hhs.gov* or (202) 795–7714. When submitting comments or requesting information, please include the document identifier 0990–New–30D and project title for reference.

SUPPLEMENTARY INFORMATION: Interested persons are invited to send comments regarding this burden estimate or any other aspect of this collection of information, including any of the following subjects: (1) The necessity and utility of the proposed information collection for the proper performance of the agency's functions; (2) the accuracy of the estimated burden; (3) ways to enhance the quality, utility, and clarity of the information to be collected; and (4) the use of automated collection techniques or other forms of information technology to minimize the information collection burden.

Title of the Collection: Youth Engagement in Sports (YES) Performance Measures.

Type of Collection: New.

OMB No. 0990–NEW—Youth Engagement in Sports (YES) Performance Measures

Abstract: The Office of Minority Health (OMH) and Office of Women's Health (OWH) are seeking an approval by OMB on a new information collection, Youth Engagement in Sports (YES Initiative) Performance Measures (hereafter YES Initiative Performance Measures). The purpose of this data collection is to gather quantitative data from YES grant recipients to monitor project performance in achieving process and outcome measures over the course of the three-year project. Grantees will collect a small set of process and outcome measures from program participants to assess the degree to which YES Initiative projects increase sports participation and physical activity and improve nutrition in adolescents.

Need and Proposed Use of the Information: The clearance is needed to collect performance data to enable OMH and OWH to comply with Federal reporting requirements, monitor, and evaluate performance by enabling the efficient collection of performance-oriented data tied to OMH- and OWH-wide performance reporting needs. The ability to monitor and evaluate performance in this manner, and to work towards continuous program improvement are basic functions that OMH and OWH must be able to accomplish in order to carry out their respective mandates with the most effective and appropriate use of resources.

Likely Respondents: Project Directors, Youth Participants, Data Entry Persons Affected public includes non-profit institutions, State, Local, or Tribal Governments.

ANNUALIZED BURDEN HOUR TABLE

Forms (if necessary)	Respondents (if necessary)	Number of respondents	Number of responses per respondents	Average burden per response	Total burden hours
Physical Activity & Nutrition Survey	Youth	2800	3	20/60	2800
Sports Inventory	Youth	2800	2	5/60	467
Sports Literacy Form	Youth (Staff observe youth)	2800	3	20/60	2800
Program Participation Record	Staff	14	2	4.17	117
Total					6184