Monique Hill, Center for Biologics Evaluation and Research, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 71, Rm. 6338, Silver Spring, MD 20993–0002, 240–402–5771, serina.hunter-thomas@fda.hhs.gov or 301–796–4620, monique.hill@fda.hhs.gov respectively, or FDA Advisory Committee Information Line, 1–800–741–8138 (301–443–0572 in the Washington, DC area). A notice in the Federal Register about last minute modifications that impact a previously announced advisory committee meeting cannot always be published quickly enough to provide timely notice. Therefore, you should always check the Agency’s website at https://www.fda.gov/AdvisoryCommittees/default.htm and scroll down to the appropriate advisory committee meeting link, or call the advisory committee information line to learn about possible modifications before coming to the meeting. For those unable to attend in person, the meeting will also be available via Webcast. The Webcast will be available at the following link: https://collaboration.fda.gov/apac091319/.

SUPPLEMENTARY INFORMATION:

Chair: Lowell J. Schiller,

Dated: June 18, 2019.

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 July 24, 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: Health Information Privacy and Civil Rights/Conscience and Religious Freedom Discrimination Complaint.

Type of Collection: Revision.

OMB No. 0990–0002.

Abstract: The Office for Civil Rights is seeking a revision on an approval for a 3-year clearance on a previous collection. Individuals may file written or electronic complaints with the Office for Civil Rights when they believe they have been discriminated against by programs or entities that receive Federal financial assistance from the Health and Human Service or if they believe that their right to the privacy of protected health information freedom has been violated. Annual Number of Respondents frequency of submission is record keeping and reporting on occasion.

DEPARTMENT OF HEALTH AND HUMAN SERVICES

[Document Identifier: OS–0945–0002]

Agency Information Collection Request. 30-Day Public Comment Request

AGENCY: Office of the Secretary, HHS.
DEPARTMENT OF HEALTH AND HUMAN SERVICES

[- Document Identifier: OS–0990–0390]

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 (HHS), is publishing the following summary of a proposed collection for public comment.

DATES: Comments on the ICR must be received on or before July 24, 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: Challenge and Prize Competition Solicitations.

Type of Collection: Reinstatement w/chg.

OMB No. 0990–0390—Office of the Chief Technology Officer (CTO)

Abstract: The Office of the Secretary (OS), Department of Health & Human Services (HHS) requests that the Office of Management and Budget (OMB) approve a request for a generic clearance approval of the information collected for challenge and prize competition solicitations.

Challenges and prize competitions enable HHS to tap into the expertise and creativity of the public in new ways as well as extend awareness of HHS programs and priorities. Within HHS, the Office of the Chief Technology Officer (CTO) has taken lead responsibility in coordinating challenges and prize competitions and implementing policies regarding the use of these tools. HHS’s goal is to engage a broader number of stakeholders who are inspired to work on some of our most pressing health issues, thus supporting a new ecosystem of scientists, developers, and entrepreneurs who can continue to innovate for public health.

The generic clearance is necessary for HHS to launch several challenges or prize competitions annually in a short turnaround. The information collected for these challenges and prize competitions will generally include the submitter’s or other contact person’s first and last name, organizational affiliation and role in the organization (for identification purposes); email address or other contact information (to follow up if the submitted solution is selected as finalist or winner); street address (to confirm that the submitter or affiliated organization is located in the United States, for eligibility purposes); birthdate (to ensure solvers under 18 to be asked to confirm parental consent, thereby requiring solvers under 18 to have a parent or guardian signature in a format outlined in the specific criteria of each challenge or prize competition). In order to qualify for the contest. To protect online privacy of minors, birthdate may be required by the website host to ensure the challenge platform meets the requirements of COPPA. Eligibility to win a cash prize will be outlined in the specific criteria of each contest and will only apply to U.S. citizens, permanent residents, or private entities incorporated and maintaining a primary place of business in the U.S. To administer the cash prize, HHS will need to collect additional relevant payment information—such as Social Security Number and/or Taxpayer ID and information regarding the winners’ financial institutions—in order to comply with financial accounting processes.

Likely Respondents: Likely respondents include individuals, businesses, and state and local agencies

ESTIMATED ANNUALIZED BURDEN TABLE

<table>
<thead>
<tr>
<th>Written forms/ electronic forms</th>
<th>Type of respondent</th>
<th>Number of respondents</th>
<th>Number of responses per respondent</th>
<th>Average burden hours per response</th>
<th>Total burden hours</th>
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<tbody>
<tr>
<td>Civil Rights/Conscience Religious Freedom Discrimination Complaint</td>
<td>Individuals or households, Not-for-profit institutions.</td>
<td>8433</td>
<td>1</td>
<td>45/60</td>
<td>6325</td>
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<td>Health Information Privacy Complaint</td>
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<td>Total</td>
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