

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:

Agenda: On September 13, 2019, the Center for Biologics Evaluation and Research's (CBER) Vaccines and Related Biological Products Advisory Committee (VRBPAC) will meet in open session to discuss and make recommendations on the safety and efficacy of Peanut [*Arachis hypogaea*] Allergen Powder manufactured by Aimmune Therapeutics, Inc, indicated for treatment to reduce the risk of anaphylaxis after accidental exposure to peanut in patients aged 4 to 17 years with a confirmed diagnosis of peanut allergy.

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: On September 13, 2019, from 8:30 a.m. to 4:30 p.m., the meeting is open to the public. Interested persons may present data, information, or views, orally or in writing, on issues pending

before the committee. Written submissions may be made to the contact person on or before September 6, 2019. On September 13, 2019, oral presentations from the public will be scheduled between approximately 1 p.m. to 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 August 29, 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 August 30, 2019.

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

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 Serina Hunter-Thomas 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: June 18, 2019.

Lowell J. Schiller,

Principal Associate Commissioner for Policy.

[FR Doc. 2019-13354 Filed 6-21-19; 8:45 am]

BILLING CODE 4164-01-P

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.

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. 0945-0002.

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.

ESTIMATED ANNUALIZED BURDEN TABLE

Written forms/ electronic forms	Type of respondent	Number of respondents	Number of responses per respondent	Average burden hours per response	Total burden hours
Civil Rights/Conscience Religious Free- dom Discrimination Complaint.	Individuals or households, Not- for-profit institutions.	8433	1	45/60	6325
Health Information Privacy Complaint	Individuals or households, Not- for-profit institutions.	25,299	1	45/60	18,974
Total	25,299

Terry Clark,

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

[FR Doc. 2019-13323 Filed 6-21-19; 8:45 am]

BILLING CODE 4153-01-P

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, 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); information confirming whether the submitter's age is 13 years or older (to ensure compliance with the Children's Online Privacy Protection Act of 1998 (15 U.S.C. 6501-6505) (COPPA) or 18 years or older (to ensure necessary consents are obtained); and a narrative

description of the solution. HHS may also request information indicating the submitter's technical background, educational level, ethnicity, age range, gender, and race (to evaluate entrants' diversity and backgrounds), how the submitter learned about the challenge or prize competition and what the submitter currently understands about the HHS agency hosting the challenge or prize competition (to gauge the effect of the challenge or prize competition on increasing public awareness of HHS programs and priorities, and generally to enable HHS to improve its outreach strategies to ensure a diverse and broad innovator constituency is fostered through the use of challenges and prize competitions). Finally, HHS may ask for additional information tailored to the particular challenge or prize competition through structured questions. This information will enable HHS to more effectively create and administer challenges and prize competitions.

Upon entry or during the judging process, solvers under the age of 18 may 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 in 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