SUPPLEMENTARY INFORMATION: *Agenda:* The meeting presentations will be heard, viewed, captioned, and recorded through an online teleconferencing platform. On August 13, 2020, the committee will discuss biologics license application (BLA) 125706, for remestemcel-L (ex-vivo culture-expanded adult human mesenchymal stromal cells suspension for intravenous infusion), submitted by Mesoblast, Inc. The proposed indication (use) for this product is for the treatment of steroid-refractory acute graft-versus-host disease in pediatric patients. The morning session will discuss issues related to the characterization and critical quality attributes of remestemcel-L as they relate to clinical effectiveness. The afternoon session will discuss results from clinical trials included in BLA 125706.

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 on FDA's website at the time of the advisory committee meeting. Background material and the link to the online teleconference meeting room will be available at *https://www.fda.gov/AdvisoryCommittees/Calendar/default.htm*. Scroll down to the appropriate advisory committee meeting link. The meeting will include slide presentations with audio components to allow the presentation of materials in a manner that most closely resembles an in-person advisory committee meeting.

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 **ADDRESSES**) on or before August 6, 2020, will be provided to the committee. Written submissions may be made to the contact person on or before July 30, 2020. Oral presentations from the public will be scheduled between approximately 10 a.m. to 10:30 a.m. for the morning session and between approximately 3:30 p.m. to 4 p.m. for the afternoon session. 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 July 29, 2020. 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 July 30, 2020.

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 Joyce Yu (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: July 14, 2020.

Lowell J. Schiller,

Principal Associate Commissioner for Policy.

[FR Doc. 2020–15719 Filed 7–20–20; 8:45 am]

BILLING CODE 4164–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Health Resources and Services Administration

Agency Information Collection Activities: Proposed Collection: Public Comment Request; Information Collection Request Title: Application for Deemed Health Center Program Award Recipients To Sponsor Volunteer Health Professionals for Deemed Public Health Service Employment

AGENCY: Health Resources and Services Administration (HRSA), Department of Health and Human Services.

ACTION: Notice.

SUMMARY: In compliance with the requirement for opportunity for public comment on proposed data collection projects of the Paperwork Reduction Act of 1995, HRSA announces plans to submit an Information Collection Request (ICR), described below, to the Office of Management and Budget (OMB). Prior to submitting the ICR to OMB, HRSA seeks comments from the public regarding the burden estimate, below, or any other aspect of the ICR.

DATES: Comments on this ICR must be received no later than September 21, 2020.

ADDRESSES: Submit your comments to *paperwork@hrsa.gov* or mail the HRSA Information Collection Clearance Officer, Room 14N136B, 5600 Fishers Lane, Rockville, MD 20857.

FOR FURTHER INFORMATION CONTACT: To request more information on the proposed project or to obtain a copy of the data collection plans and draft instruments, email *paperwork@hrsa.gov* or call Lisa Wright-Solomon, the HRSA Information Collection Clearance Officer at (301) 443–1984.

SUPPLEMENTARY INFORMATION: When submitting comments or requesting information, please include the information request collection title for reference.

Information Collection Request Title: Application for Deemed Health Center Program Award Recipients to Sponsor Volunteer Health Professionals for Deemed Public Health Service Employment, OMB No. 0915–0032—Revision.

Abstract: Subsection 224(q) to the Public Health Service (PHS) Act (42 U.S.C. 233(q)), extended liability protections for the performance of medical, surgical, dental, and related functions to Volunteer Health Professionals (VHPs) of health centers that have also been deemed as employees of the PHS for this purpose. Through the process established by HRSA, VHPs of deemed health centers may be deemed as PHS employees for this purpose, with associated Federal Tort Claims Act (FTCA) coverage.

Deemed PHS employment provides the covered individual with immunity from lawsuits and related civil actions resulting from the performance of medical, surgical, dental, and related functions within the scope of deemed employment.

Health centers must submit to HRSA an annual deeming sponsorship application on behalf of their individually named volunteers. For deeming to apply, such annual applications for each individual volunteer must be approved by HRSA, and deeming status for liability protections to apply during the calendar year is documented by a Notice of Deeming Action.

HRSA is proposing several changes to the Application for Deemed Health Center Program Award Recipients to Sponsor VHPs for Deemed PHS Employment, to be used for deeming sponsorship applications for Calendar

Year 2022 and thereafter, to improve question clarity, clarify required documentation, and support HRSA's analysis and understanding of program impact. Specifically, the Application includes the proposed changes listed below.

- Updated application language: Specifically, throughout the application, alternate terminology was utilized to provide greater clarity and specificity. These changes were based on grantee feedback and various forms of information received from the HRSA Helpline. These changes are not substantive in nature.
- Updated language and requested documents in section III of the application: Specifically, section III was edited to clarify the qualifications for eligible individuals and clarify program expectations where individuals have a history of disciplinary action or malpractice.
- Deleted former section IV: It has been determined that the information requested in this section, which related to offsite events and particularized determinations, is not necessary to evaluate eligibility for deeming.

The FTCA Program has a web based application system, the Electronic Handbooks. These electronic application forms decrease the time and effort required to complete the older, paper-based OMB approved FTCA application forms. The application includes Acknowledgments of Deemed Status Requirements, Acknowledgment of Required Performance Conditions, and Information on the Volunteers Sponsored for Deeming.

Need and Proposed Use of the Information: Deeming sponsorship applications must address certain specified criteria required by law in order for deeming determinations to be issued. The application submissions provides HRSA with the information required to determine whether an individual meets the requirements for deemed PHS employment for purposes of providing liability protections under section 224(q) of the PHS Act.

Likely Respondents: Respondents include Health Center Program funds recipients seeking to sponsor their volunteer health professionals for deemed employment for purposes of FTCA coverage.

Burden Statement: Burden in this context means the time expended by persons to generate, maintain, retain, disclose or provide the information requested. This includes the time needed to review instructions; to develop, acquire, install, and utilize technology and systems for the purpose of collecting, validating, and verifying information, processing and maintaining information, and disclosing and providing information; to train personnel and to be able to respond to a collection of information; to search data sources; to complete and review the collection of information; and to transmit or otherwise disclose the information. The total annual burden hours estimated for this ICR are summarized in the table below.

TOTAL ESTIMATED ANNUALIZED BURDEN HOURS

Form name	Number of respondents	Number of responses per respondent	Total responses	Average burden per response (in hours)	Total burden hours
Application for Deemed Health Center Program Award Recipients to Sponsor VHPs for Deemed PHS Employment	1,156	3	3,468	2	6,936
Total	1,156		3,468		6,936

HRSA specifically requests comments on (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.

Maria G. Button,

Director, Executive Secretariat.

[FR Doc. 2020–15696 Filed 7–20–20; 8:45 am]

BILLING CODE 4165–15–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

National Institute of Allergy and Infectious Diseases; Notice of Closed Meeting

Pursuant to section 10(d) of the Federal Advisory Committee Act, as amended, notice is hereby given of the following meeting.

The meeting will be closed to the public in accordance with the provisions set forth in sections 552b(c)(4) and 552b(c)(6), Title 5 U.S.C., as amended. The grant applications and the discussions could disclose confidential trade secrets or commercial property such as patentable material, and personal information concerning individuals associated with the grant applications, the disclosure of which would constitute a clearly unwarranted invasion of personal privacy.

Name of Committee: Microbiology, Infectious Diseases and AIDS Initial Review Group; Acquired Immunodeficiency Syndrome Research Review Committee AIDSRRC Review Meeting.

Date: August 12–13, 2020.

Time: 10:00 a.m. to 4:00 p.m.

Agenda: To review and evaluate grant applications.

Place: National Institute of Allergy and Infectious Diseases, National Institutes of Health, 5601 Fishers Lane, Room 3F40A, Rockville, MD 20892 (Telephone Conference Call).

Contact Person: Robert C. Unfer, Ph.D., Scientific Review Officer, Scientific Review Program, Division of Extramural Activities, National Institute of Allergy and Infectious Diseases, National Institutes of Health, 5601 Fishers Lane, Room 3F40A Bethesda, MD 20892–9834, (240) 669–5035, *robert.unfer@nih.gov.*

(Catalogue of Federal Domestic Assistance Program Nos. 93.855, Allergy, Immunology, and Transplantation Research; 93.856, Microbiology and Infectious Diseases Research, National Institutes of Health, HHS)