5. How can AHRQ have the greatest impact and success at achieving the vision and mission of the strategic framework?

a. What is the most effective way to ensure the *sustainability* of initiatives that seek to enhance the integration of patient-centered outcomes research findings into practice?

b. What complementary partnerships and collaborations (both public and private) would increase the impact of AHRQ's PCORTF investments?

c. What will be the best way of measuring progress and the overall impact of AHRQ's PCORTF investments?

6. Is there anything else you would like to share regarding the strategic framework?

AHRQ is interested in all of the questions listed above, but respondents are welcome to address as many or as few as they choose and to address additional areas of interest not listed. It is helpful to identify which question a particular answer is a response to.

This RFI is for planning purposes only and should not be construed as a policy, solicitation for applications, or as an obligation on the part of the Government to provide support for any ideas identified in response to it. AHRQ will use the information submitted in response to this RFI at its discretion and will not provide comments to any responder's submission. However, responses to the RFI may be reflected in future solicitation(s) or policies. The information provided will be analyzed and may appear in reports. Respondents will not be identified in any published reports. Respondents are advised that the Government is under no obligation to acknowledge receipt of the information received or provide feedback to respondents with respect to any information submitted. No proprietary, classified, confidential, or sensitive information should be included in your response. The contents of all submissions will be made available to the public upon request. Materials submitted must be publicly available or able to be made public.

Dated: April 11, 2022.

Marquita Cullom,

Associate Director.

[FR Doc. 2022–08038 Filed 4–14–22; 8:45 am]

BILLING CODE 4160–90–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Centers for Disease Control and Prevention

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, and the Determination of the Director, Strategic Business Initiatives Unit, Office of the Chief Operating Officer, CDC, pursuant to Public Law 92–463. 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: Disease, Disability, and Injury Prevention and Control Special Emphasis Panel (SEP)—RFA–OH–20–002, Commercial Fishing Occupational Safety Research Cooperative Agreement; and RFA–OH–20–003, Commercial Fishing Occupational Safety Training Project Grants.

Date: May 18, 2022.

Time: 12:00 p.m.–3:00 p.m., EDT.

Place: Video-Assisted Meeting.

Agenda: To review and evaluate grant applications.

FOR FURTHER INFORMATION CONTACT: Michael Goldcamp, Ph.D., Scientific Review Officer, Office of Extramural Programs, National Institute for Occupational Safety and Health, CDC, 1095 Willowdale Road, Morgantown, West Virginia 26505, Telephone: (304) 285–5951; Email: *MGoldcamp@cdc.gov.*

The Director, Strategic Business Initiatives Unit, Office of the Chief Operating Officer, Centers for Disease Control and Prevention, has been delegated the authority to sign **Federal Register** notices pertaining to announcements of meetings and other committee management activities, for both the Centers for Disease Control and Prevention and the Agency for Toxic Substances and Disease Registry.

Kalwant Smagh,

Director, Strategic Business Initiatives Unit, Office of the Chief Operating Officer, Centers for Disease Control and Prevention.

[FR Doc. 2022–08051 Filed 4–14–22; 8:45 am]

BILLING CODE 4163–18–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Centers for Medicare & Medicaid Services

[CMS–3423–N]

Announcement of the Re-Approval of the American Society of Histocompatibility and Immunogenetics (ASHI) as an Accreditation Organization Under the Clinical Laboratory Improvement Amendments of 1988

AGENCY: Centers for Medicare & Medicaid Services (CMS), HHS.

ACTION: Notice.

SUMMARY: This notice announces the application of the American Society for Histocompatibility and Immunogenetics (ASHI) for approval as an accreditation organization for clinical laboratories under the Clinical Laboratory Improvement Amendments of 1988 (CLIA) program for the following specialty and subspecialty areas: General Immunology; Histocompatibility; and ABO/Rh typing. We have determined that the ASHI meets or exceeds the applicable CLIA requirements. In this notice, we announce the approval and grant the ASHI deeming authority for a period of 6 years.

DATES: This notice is effective from April 15, 2022 to April 15, 2028.

FOR FURTHER INFORMATION CONTACT: Penny Keller, (410) 786–2035.

SUPPLEMENTARY INFORMATION:

I. Background and Legislative Authority

On October 31, 1988, the Congress enacted the Clinical Laboratory Improvement Amendments of 1988 (CLIA) (Pub. L. 100–578). CLIA amended section 353 of the Public Health Service Act. We issued a final rule implementing the accreditation provisions of CLIA on July 31, 1992 (57 FR 33992). Under those provisions, CMS may grant deeming authority to an accreditation organization if its requirements for laboratories accredited under its program are equal to or more stringent than the applicable CLIA program requirements in 42 CFR part 493 (Laboratory Requirements). Subpart E of part 493 (Accreditation by a Private, Nonprofit Accreditation Organization or Exemption Under an Approved State Laboratory Program) specifies the requirements an accreditation organization must meet to be approved by CMS as an accreditation organization under CLIA.

II. Notice of Approval of ASHI as an Accreditation Organization

In this notice, we approve the American Society for Histocompatibility and Immunogenetics (ASHI) as an organization that may accredit laboratories for purposes of establishing their compliance with CLIA requirements for the subspecialty of General Immunology, the specialty of Histocompatibility, and the subspecialty of ABO/Rh typing. We have examined the initial ASHI application and all subsequent submissions to determine its accreditation program's equivalency with the requirements for approval of an accreditation organization under subpart E of part 493. We have determined that the ASHI meets or exceeds the applicable CLIA requirements. We have also determined that the ASHI will ensure that its accredited laboratories will meet or exceed the applicable requirements in subparts H, I, J, K, M, Q, and the applicable sections of R. Therefore, we grant the ASHI approval as an accreditation organization under subpart E of part 493, for the period stated in the **DATES** section of this notice for the subspecialty of General Immunology, the specialty of Histocompatibility, and the subspecialty of ABO/Rh typing. As a result of this determination, any laboratory that is accredited by the ASHI during the time period stated in the **DATES** section of this notice will be deemed to meet the CLIA requirements for the listed subspecialties and specialties, and therefore, will generally not be subject to routine inspections by a State survey agency to determine its compliance with CLIA requirements. The accredited laboratory, however, is subject to validation and complaint investigation surveys performed by CMS, or its agent(s).

III. Evaluation of the ASHI Request for Approval as an Accreditation Organization Under CLIA

The following describes the process used to determine that the ASHI accreditation program meets the necessary requirements to be approved by CMS and that, as such, CMS may approve ASHI as an accreditation program with deeming authority under the CLIA program. The ASHI formally applied to CMS for approval as an accreditation organization under CLIA for the subspecialty of General Immunology, the specialty of Histocompatibility, and the subspecialty of ABO/Rh typing. In reviewing these materials, we reached the following determinations for each applicable part of the CLIA regulations:

A. Subpart E—Accreditation by a Private, Nonprofit Accreditation Organization or Exemption Under an Approved State Laboratory Program

The ASHI submitted a description of its mechanism for monitoring compliance with all requirements equivalent to condition-level requirements; a list of all its current laboratories and the expiration date of their accreditation; and a detailed comparison of the individual accreditation requirements with the comparable condition-level requirements. We have determined that the ASHI policies and procedures for oversight of laboratories performing laboratory testing for the subspecialty of General Immunology, the specialty of Histocompatibility, and the subspecialty of ABO/Rh typing are equivalent to those of CLIA in the matters of inspection, monitoring proficiency testing (PT) performance, investigating complaints, and making PT information available. ASHI's requirements for monitoring and inspecting laboratories are the same as those previously approved by CMS for laboratories in the areas of accreditation organization, data management, the inspection process, procedures for removal or withdrawal of accreditation, notification requirements, and accreditation organization resources. We have determined that the requirements of the accreditation program submitted for approval are equal to or more stringent than the requirements of the CLIA regulations.

B. Subpart H—Participation in Proficiency Testing for Laboratories Performing Nonwaived Testing

We have determined that the ASHI's requirements are equal to or more stringent than the CLIA requirements at §§ 493.801 through 493.865.

For the specialty of Histocompatibility, ASHI requires participation in at least one external PT program, if available, in histocompatibility testing with an 80 percent score required for successful participation and enhanced PT for laboratories that fail an event. The CLIA regulations do not contain a requirement for external PT for the specialty of Histocompatibility. For the subspecialty of General Immunology, and the subspecialty of ABO/Rh typing, ASHI's requirements are equal to the CLIA requirements.

C. Subpart J—Facility Administration for Nonwaived Testing

The ASHI's requirements for the submitted subspecialties and specialties are equal to or more stringent than the CLIA requirements at §§ 493.1100 through 493.1105.

D. Subpart K—Quality System for Nonwaived Testing

We have determined that the ASHI requirements for the submitted subspecialties and specialties are equal to or more stringent than the CLIA requirements at §§ 493.1200 through 493.1299. For instance, ASHI's control procedure requirements for the test procedures Nucleic Acid Testing and Flow Cytometry are more specific and detailed than the CLIA language for requirements for control procedures. Sections 493.1256(c)(1) and (c)(2) require control procedures that will detect immediate errors that occur due to test system failure, adverse environmental conditions and operator performance, and monitor accuracy and precision of test performance that may be influenced by changes in test system performance and environmental conditions and variance in operator performance, respectively. ASHI standards provide detailed, specific requirements for the control materials to be used to meet these CLIA requirements.

E. Subpart M—Personnel for Nonwaived Testing

We have determined that the ASHI requirements for the submitted subspecialties and specialties are equal to or more stringent than the CLIA requirements at §§ 493.1403 through 493.1495 for laboratories that perform moderate and high complexity testing. Experience requirements for Director, Technical Supervisor, and General Supervisor exceed CLIA's personnel experience requirements in the specialty of Histocompatibility.

F. Subpart Q—Inspections

We have determined that the ASHI requirements for the submitted subspecialties and specialties are equal to or more stringent than the CLIA requirements at §§ 493.1771 through 493.1780. The ASHI inspections are more frequent than CLIA requires. ASHI performs an onsite inspection every 2 years and requires submission of a self-evaluation inspection in the intervening years. If the self-evaluation inspection indicates that an onsite inspection is warranted, ASHI conducts an additional onsite review.

G. Subpart R—Enforcement Procedures

We have determined that the ASHI meets the requirements of subpart R to the extent that it applies to accreditation organizations. The ASHI policy sets forth the actions the organization takes when laboratories it accredits do not comply with its requirements and standards for accreditation. When appropriate, the ASHI will deny, suspend, or revoke accreditation in a laboratory accredited by the ASHI and report that action to us within 30 days. The ASHI also provides an appeals process for laboratories that have had accreditation denied, suspended, or revoked.

We have determined that the ASHI's laboratory enforcement and appeal policies are equal to or more stringent than the requirements of part 493 subpart R as they apply to accreditation organizations.

IV. Federal Validation Inspections and Continuing Oversight

The Federal validation inspections of laboratories accredited by the ASHI may be conducted on a representative sample basis or in response to substantial allegations of noncompliance (that is, complaint inspections). The outcome of those validation inspections, performed by CMS or our agents, or the State survey agencies, will be our principal means for verifying that the laboratories accredited by the ASHI remain in compliance with CLIA requirements. This Federal monitoring is an ongoing process.

V. Removal of Approval as an Accrediting Organization

CLIA regulations at § 493.575 provide that we may rescind the approval of an accreditation organization, such as that of the ASHI, before the end of the effective date of approval in certain circumstances. For example, If we determine that the ASHI has failed to adopt, maintain and enforce requirements that are equal to, or more stringent than, the CLIA requirements, or that systemic problems exist in its monitoring, inspection or enforcement processes, we may impose a probationary period, not to exceed 1 year, in which the ASHI would be allowed to address any identified issues. Should the ASHI be unable to address the identified issues within that timeframe, CMS may, in accordance with the applicable regulations, revoke the ASHI's deeming authority under CLIA.

Should circumstances result in our withdrawal of the ASHI's approval, we will publish a notice in the **Federal Register** explaining the basis for removing its approval.

VI. Collection of Information Requirements

This document does not impose information collection requirements, that is, reporting, recordkeeping or third-party disclosure requirements. Consequently, there is no need for review by the Office of Management and Budget (OMB) under the authority of the Paperwork Reduction Act (PRA) of 1995 (44 U.S.C. Chapter 35). The requirements associated with the accreditation process for clinical laboratories under the CLIA program, codified in 42 CFR part 493 subpart E, are currently approved by OMB under OMB approval number 0938–0686.

VII. Executive Order 12866 Statement

In accordance with the provisions of Executive Order 12866, this notice was not reviewed by the Office of Management and Budget.

The Administrator of the Centers for Medicare & Medicaid Services (CMS), Chiquita Brooks-LaSure, having reviewed and approved this document, authorizes Lynette Wilson, who is the Federal Register Liaison, to electronically sign this document for purposes of publication in the **Federal Register**.

Dated: April 12, 2022.

Lynette Wilson,

Federal Register Liaison, Centers for Medicare & Medicaid Services.

[FR Doc. 2022–08153 Filed 4–14–22; 8:45 am]

BILLING CODE 4120–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2021–D–1238]

Celiac Disease: Developing Drugs for Adjunctive Treatment to a Gluten-Free Diet; Draft Guidance for Industry; Availability

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice of availability.

SUMMARY: The Food and Drug Administration (FDA or Agency) is announcing the availability of a draft guidance for industry entitled ''Celiac Disease: Developing Drugs for Adjunctive Treatment to a Gluten-Free Diet.'' This draft guidance addresses FDA's recommendations regarding clinical trials for drugs being developed for the treatment of celiac disease as an adjunct to a gluten-free diet in adults.

DATES: Submit either electronic or written comments on the draft guidance by June 14, 2022 to ensure that the Agency considers your comment on this draft guidance before it begins work on the final version of the guidance.

ADDRESSES: You may submit comments on any guidance at any time as follows:

Electronic Submissions

Submit electronic comments in the following way:

- *Federal eRulemaking Portal: https://www.regulations.gov.* Follow the instructions for submitting comments. Comments submitted electronically, including attachments, to *https://www.regulations.gov* will be posted to the docket unchanged. Because your comment will be made public, you are solely responsible for ensuring that your comment does not include any confidential information that you or a third party may not wish to be posted, such as medical information, your or anyone else's Social Security number, or confidential business information, such as a manufacturing process. Please note that if you include your name, contact information, or other information that identifies you in the body of your comments, that information will be posted on *https://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):* Dockets Management Staff (HFA–305), Food and Drug Administration, 5630 Fishers Lane, Rm. 1061, Rockville, MD 20852.
- For written/paper comments submitted to the Dockets Management Staff, 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–2021–D–1238 for ''Celiac Disease: Developing Drugs for Adjunctive Treatment to a Gluten-Free Diet.'' Received comments will be placed in the docket and, except for those submitted as ''Confidential Submissions,'' publicly viewable at *https://www.regulations.gov* or at the