led to a subsequent 2020 study conducted and published by Jones et al., which found that analysis of pooled samples was not equivalent to that of single samples. In environmental samples, the level of background microflora plays a role in the ability to detect SE, if present. When samples are pooled, the amount of background microflora is amplified, potentially causing the inability to detect SE by masking its presence. This is further exacerbated based on the number of pooled samples (*e.g.,* two vs. four samples per collection bag) and could result in false negative test results. After consideration of the science, FDA determined that at this time, there is not sufficient data to consider pooled samples equivalent to single samples, as required by the reference methods cited in § 118.8. While we understand cost considerations are important, the primary concern should always be the ability to detect SE if it is present.

The comment also suggested adjusting the egg testing protocol to two 1,000-egg samples instead of four 1,000-egg samples. Testing four 1,000-egg samples over an 8-week period results in approximately a 95 percent probability that a positive egg will be detected from a flock that is producing SE-contaminated eggs with a prevalence of 1 in 1,400. Testing fewer than 4,000 eggs over a period of 8 weeks, as required by § 118.7, would result in less than a 95 percent probability that a positive egg would be detected from a flock that is producing SE-contaminated eggs at that rate.

We find that the required testing established under 21 CFR 118.7 and 118.8 best protects the public health and that relaxing the current testing requirements, whether or not in an effort to reduce costs, would not provide the same level of protection necessary to ensure the public health.

FDA estimates the burden of this collection of information as follows:

TABLE 1—ESTIMATED ANNUAL RECORDKEEPING BURDEN [1]

Activity; 21 CFR section	Number of record-keepers [2]	Number of records per recordkeeper	Total annual records	Average burden per recordkeeping	Total hours
Refrigeration Records; § 118.10(a)(3)(iv)	2,600	52	135,200	0.5 (30 minutes)	67,600
Testing, Diversion, and Treatment Records; § 118.10(a)(3)(v) through (viii) (positive) [3].	343	52	17,836	0.5 (30 minutes)	8,918
Egg Testing; § 118.10(a)(3)(vii)	331	7	2,317	8.3	19,231
Environmental Testing; § 118.10(a)(3)(v) [3]	6,308	23	145,084	0.25 (15 minutes)	36,271
Testing, Diversion, and Treatment Records; § 118.10(a)(3)(v) through (viii) (negative) [3].	5,965	1	5,965	0.5 (30 minutes)	2,983
Prevention Plan Review and Modifications; § 118.10(a)(4).	331	1	331	10	3,310
Chick and Pullet Procurement Records; § 118.10(a)(2)	4,731	1	4,731	0.5 (30 minutes)	2,366
Rodent and Other Pest Control; § 118.10(a)(3)(ii), and Biosecurity Records, § 118.10(a)(3)(i).	9,462	52	492,024	0.5 (30 minutes)	246,012
Prevention Plan Design; § 118.10(a)(1)	350	1	350	20	7,000
Cleaning and Disinfection Records; § 118.10(a)(3)(iii)	331	1	331	0.5 (30 minutes)	166
Total					393,857

[1] There are no capital costs or operating and maintenance costs associated with this collection of information.
[2] Some records are kept on a by-farm basis and others are kept on a by-house basis.
[3] Calculations include requirements for pullet and layer houses.

TABLE 2—ESTIMATED ANNUAL REPORTING BURDEN [1]

Activity; 21 CFR section	Form	Number of respondents	Number of responses per respondent	Total annual responses	Average burden per response	Total hours
Registrations or Updates; § 118.11	FDA 3733 [2]	350	1	350	2.3	805
Cancellations; § 118.11	FDA 3733	30	1	30	1	30
Total						835

[1] There are no capital costs or operating and maintenance costs associated with this collection of information.
[2] The term "Form FDA 3733" refers to both the paper version of the form and the electronic system known as the Shell Egg Producer Registration Module, which is available at *http://www.access.fda.gov* per § 118.11(b)(1).

Based on a review of the information collection since our last request for OMB approval, we have made no adjustments to our burden estimate. Our estimates for the recordkeeping burden and the reporting burden are based on our experience with similar recordkeeping activities and the number of registrations and cancellations received in the past 3 years.

Dated: July 29, 2022.

Lauren K. Roth,

Associate Commissioner for Policy.

[FR Doc. 2022–16686 Filed 8–3–22; 8:45 am]

BILLING CODE 4164–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Health Resources and Services Administration

Meeting of the Advisory Committee on Heritable Disorders in Newborns and Children

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

ACTION: Notice.

SUMMARY: In accordance with the Federal Advisory Committee Act and the Public Health Service Act, this notice announces a public meeting of the Advisory Committee on Heritable Disorders in Newborns and Children (ACHDNC or Committee). Information about the ACHDNC and the agenda for this meeting can be found on the ACHDNC website at *https://www.hrsa.gov/advisory-committees/heritable-disorders/index.html.*

DATES: Tuesday, August 30, 2022, from 10:00 a.m. to 2:00 p.m. Eastern Time (ET) and Wednesday, August 31, 2022, from 10:00 a.m. to 1:00 p.m. ET.

ADDRESSES: This meeting will be held via webinar. While this meeting is open to the public, advance registration is required.

Please register online at *https://www.achdncmeetings.org/registration/* by the deadline of 12:00 p.m. ET on August 29, 2022. Instructions on how to access the meeting via webcast will be provided upon registration.

FOR FURTHER INFORMATION CONTACT: Alaina Harris, Maternal and Child Health Bureau, HRSA, 5600 Fishers Lane, Room 18W66, Rockville, Maryland 20857; 301–443–0721; or *ACHDNC@hrsa.gov.*

SUPPLEMENTARY INFORMATION: ACHDNC provides advice and recommendations to the Secretary of HHS (Secretary) on the development of newborn screening activities, technologies, policies, guidelines, and programs for effectively reducing morbidity and mortality in newborns and children having, or at risk for, heritable disorders. ACHDNC reviews and reports regularly on newborn and childhood screening practices, recommends improvements in the national newborn and childhood screening programs, and fulfills requirements stated in the authorizing legislation. In addition, ACHDNC's recommendations regarding inclusion of additional conditions for screening on the Recommended Uniform Screening Panel, following adoption by the Secretary, are evidence-informed preventive health services provided for in the comprehensive guidelines supported by HRSA, pursuant to section 2713 of the Public Health Service Act (42 U.S.C. 300gg–13). Under this provision, non-grandfathered group health plans and health insurance issuers offering non-grandfathered group or individual health insurance are required to provide insurance coverage without cost-sharing (a co-payment, co-insurance, or deductible) for preventive services for plan years (*i.e.,* policy years) beginning on or after the date that is one year from the Secretary's adoption of the condition for screening.

During the August 30–31, 2022, meeting, ACHDNC will hear from experts in the fields of public health, medicine, heritable disorders, rare disorders, and newborn screening. Agenda items include the following:

(1) A presentation on phase one of the Krabbe disease evidence review;

(2) A presentation and Committee discussion on the infant formula shortage;

(3) A presentation and Committee discussion on advancing the newborn screening system;

(4) A presentation on the Long-term Follow-up for Severe Combined Immunodeficiency and Other Newborn Screening Conditions Program; and

(5) Workgroup updates.

The agenda for this meeting does not include any vote or decision to recommend a condition for inclusion in the Recommended Uniform Screening Panel. As noted in the agenda items, the Committee will hear presentation on evidence review of Krabbe disease, which may lead to such a recommendation at a future time.

Agenda items are subject to change as priorities dictate. Information about ACHDNC, including a roster of members and past meeting summaries, is also available on the ACHDNC website.

Members of the public also will have the opportunity to provide comments. Public participants may request to provide general oral comments and may submit written statements in advance of the scheduled meeting. The Committee will honor oral comments in the order they are requested and may be limited as time allows. Participants who wish to provide a written statement or make oral comments to ACHDNC must submit their request via the registration website by 12:00 p.m. ET on Wednesday, August 24, 2022.

Individuals who need special assistance or another reasonable accommodation should notify Alaina Harris at the address and phone number listed above at least 10 business days prior to the meeting.

Maria G. Button,

Director, Executive Secretariat.

[FR Doc. 2022–16654 Filed 8–3–22; 8:45 am]

BILLING CODE 4165–15–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

National Institute on Aging; 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: National Institute on Aging Special Emphasis Panel Role of FSH—II.

Date: August 30, 2022.

Time: 12:30 p.m. to 5:00 p.m.

Agenda: To review and evaluate grant applications.

Place: National Institute on Aging, Gateway Building, 7201 Wisconsin Avenue, Bethesda, MD 20892 (Virtual Meeting).

Contact Person: NIJAGUNA PRASAD, Ph.D., Scientific Review Officer, Scientific Review Branch, National Institute on Aging, 7201 Wisconsin Avenue, Gateway Bldg, Suite 2W200, Bethesda, MD 20892, (301) 496–9667, *prasadnb@nia.nih.gov.*

Information is also available on the Institute's/Center's home page: *www.nia.nih.gov/,* where an agenda and any additional information for the meeting will be posted when available.

(Catalogue of Federal Domestic Assistance Program Nos. 93.866, Aging Research, National Institutes of Health, HHS)

Dated: August 1, 2022.

David W. Freeman,

Program Analyst, Office of Federal Advisory Committee Policy.

[FR Doc. 2022–16716 Filed 8–3–22; 8:45 am]

BILLING CODE 4140–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

National Institute of Diabetes and Digestive and Kidney 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