

§ 118.10(a)(2) is kept roughly once annually per layer house basis. We estimate that 4,731 layer houses maintain 1 record each and that it takes approximately 0.5 hour per recordkeeping. Thus, the total annual burden for chick and pullet procurement recordkeeping is calculated to be 2,366 hours (4,731 records × 0.5 hour).

We estimate that rodent and other pest control records under § 118.10(a)(3)(ii) and biosecurity records under § 118.10(a)(3)(i) are kept weekly on a per layer house basis. We assume that 4,731 layer houses maintain a weekly record under each provision.

Thus, we estimate 9,462 recordkeepers maintain 52 records each for a total of 492,024 records. We estimate a recordkeeping burden of 0.5 hours per record for a total of 246,012 burden hours (492,024 records × 0.5 hour).

New prevention plan design required by § 118.10(a)(1) is only undertaken by new farms and records are kept on a per farm basis. We estimate that there are 350 new farm registrations annually, and we assume that this reflects 350 new farms requiring prevention plan design. This is an increase from our previous estimate based on new registrations received. We estimate that it takes 20 hours to complete this work.

Thus, the total annual burden for prevention plan design is calculated to be 7,000 hours (350 records × 20 hours).

Cleaning and disinfection recordkeeping under § 118.10(a)(3)(iii) needs to be performed every time a house tests positive. We estimate that 331 layer houses test positive requiring 1 record each and that it takes approximately 0.5 hour per recordkeeping. Thus, the total annual burden for cleaning and disinfection recordkeeping in the event of a positive test result is calculated to be 166 hours (331 records × 0.5 hour).

TABLE 2—ESTIMATED ANNUAL REPORTING BURDEN¹

| Description and 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 | ² FDA 3733 | 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).

This estimate is based on the average number of new shell egg producer registrations and cancellations received in the past 3 years under § 118.11. We estimate that we will receive an average of 350 registrations or updates per year over the next 3 years and that it takes the average farm 2.3 hours to register, taking into account that some respondents completing the registration may not have readily available internet access. Thus, the total annual burden for new shell egg producer registrations or updates is calculated to be 805 hours (350 respondents × 2.3 hours).

We estimate that we will receive 30 cancellations per year over the next 3 years and that cancelling a registration, on average, requires a burden of 1 hour, taking into account that some respondents may not have readily available internet access. Thus, the total annual burden for cancelling shell egg producer registrations is calculated to be 30 hours (30 cancellations × 1 hour).

We have increased our burden estimate for the information collection based on an increase in annual new farm registrations.

Dated: March 20, 2019.

Lowell J. Schiller,

Acting Associate Commissioner for Policy.

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Solicitation of Nominations for Appointment to the Presidential Advisory Council on Combating Antibiotic-Resistant Bacteria

AGENCY: Office of the Assistant Secretary for Health, Office of the Secretary, Department of Health and Human Services.

ACTION: Notice.

SUMMARY: The U.S. Department of Health and Human Services (HHS) is soliciting nominations of individuals who are interested in being considered for appointment to the Presidential Advisory Council on Combating Antibiotic-Resistant Bacteria (Advisory Council) as a voting member or as a non-voting liaison representative member from an organization and/or interest group. Nominations from qualified individuals who wish to be considered for appointment to either member category of the Advisory Council are currently being accepted.

DATES: Nominations must be received no later than 5:00 p.m. ET on May 10, 2019.

ADDRESSES: Information on how to submit a nomination is on the Advisory Council website, <http://www.hhs.gov/ash/carb/>.

FOR FURTHER INFORMATION CONTACT:

Jomana Musmar, Designated Federal Officer, Presidential Advisory Council on Combating Antibiotic-Resistant Bacteria, Office of the Assistant Secretary for Health, U.S. Department of Health and Human Services, Room L133, Switzer Building, 330 C. St. SW, Washington, DC 20201. Phone: (202) 690-5566; email: CARB@hhs.gov. The Advisory Council charter may be accessed online at <http://www.hhs.gov/ash/carb/>. The charter includes detailed information about the Advisory Council’s purpose, function, and structure.

SUPPLEMENTARY INFORMATION: Under Executive Order 13676, dated September 18, 2014, authority was given to the Secretary of HHS to establish the Advisory Council, in consultation with the Secretaries of Defense and Agriculture. Activities of the Advisory Council are governed by the provisions of Public Law 92-463, as amended (5 U.S.C. App.), which sets forth standards for the formation and use of federal advisory committees. The Advisory Council will provide advice, information, and recommendations to the Secretary of HHS regarding programs and policies intended to: Preserve the effectiveness of antibiotics by optimizing their use; advance research to develop improved methods for combating antibiotic resistance and

conducting antibiotic stewardship; strengthen surveillance of antibiotic-resistant bacterial infections; prevent the transmission of antibiotic-resistant bacterial infections; advance the development of rapid point-of-care and agricultural diagnostics; further research on new treatments for bacterial infections; develop alternatives to antibiotics for agricultural purposes; maximize the dissemination of up-to-date information on the appropriate and proper use of antibiotics to the general public and human and animal healthcare providers; and improve international coordination of efforts to combat antibiotic resistance.

The Advisory Council is authorized to consist of not more than 30 members, including the voting and non-voting members and the Chair and Vice Chair. The current composition of the Advisory Council consists of 15 voting members, including the Chair and Vice Chair, five non-voting liaison representative members, and 10 non-voting *ex-officio* members.

This announcement is to solicit nominations to fill eight positions in the voting member category that are scheduled to be vacated during the 2019 calendar year, and the terms of five positions in the liaison representative category that are scheduled to be vacated during the 2020 calendar year. Voting members are appointed to serve three or four-year terms, and liaison representative members are appointed to serve a two-year term.

The eight public voting members sought for this solicitation will be selected from individuals who are engaged in: Research on, or implementation of, interventions regarding efforts to preserve the effectiveness of antibiotics by optimizing their use; advancing research to develop improved methods for combating antibiotic resistance and conducting antibiotic stewardship; strengthening surveillance of antibiotic-resistant bacterial infections; preventing the transmission of antibiotic-resistant bacterial infections; advancing the development of rapid point-of-care and agricultural diagnostics; furthering research on new treatments for bacterial infections; developing alternatives to antibiotics for agricultural purposes; maximizing the dissemination of up-to-date information on the appropriate and proper use of antibiotics to the general public and human and animal health care providers; and improving international coordination of efforts to combat antibiotic resistance.

The public voting members will represent balanced points of view from human biomedical, public health, and

agricultural fields to include surveillance of antibiotic-resistant infections, prevention and/or interruption of the spread of antibiotic-resistant threats, or development of rapid diagnostics and novel treatments. The public voting members may be physicians, veterinarians, epidemiologists, microbiologists, or other health care professionals (*e.g.*, nurses, pharmacists, others); individuals who have expertise and experience as consumer or patient advocates concerned with antibiotic resistance, or in the fields of agriculture and pharmaceuticals; and they also may be from state or local health agencies or public health organizations. The voting public members will be appointed by the Secretary, in consultation with the Secretaries of Defense and Agriculture. All public voting members will be classified as special government employees (SGEs).

Individuals who are appointed to serve as voting members may be allowed to receive per diem and reimbursement for any applicable expenses for travel that is performed to attend meetings of the Advisory Council as authorized by 5 U.S.C. 5703, for persons employed intermittently in the Government service. The Advisory Council meets, at a minimum, two times per fiscal year depending on the availability of funds. Meetings are open to the public, except as determined otherwise by the Secretary, or other official to whom the authority has been delegated, in accordance with guidelines under the Government in the Sunshine Act, 5 U.S.C. 552b(c).

The non-voting liaison representative members are selected from organizations and/or interest groups that have involvement in the development, testing, licensing, production, procurement, distribution, and/or use of antibiotics and/or antibiotic research. Organizations are invited to participate as non-voting liaison representatives as it is deemed necessary by the Secretary or designee to accomplish the established mission of the Advisory Council. Non-voting liaison representative members are appointed to serve two-year terms. Individuals from the following sectors are being sought to serve as non-voting liaison representatives:

- Professional organizations or associations representing providers or professionals for human and/or animal health involved in infection control and prevention; this can include physicians, nurses, pharmacists, microbiologists, veterinarians.
- Public health, environmental health, and/or animal health

organizations or associations (state/territorial, county, or local) representing laboratories, health officials, epidemiologists, agricultural state departments, or environmental associations.

- Other organizations representing patients and consumer advocates, hospitals, pharmaceutical industry, food producers and retailers, or other commodity groups.

Individuals who are appointed to serve as non-voting liaison representative members may be allowed to receive per diem and reimbursement for any applicable expenses for travel that is performed to attend meetings of the Advisory Council in accordance with federal travel regulations. The Advisory Council meets, at a minimum, two times per fiscal year depending on the availability of funds. Meetings are open to the public, except as determined otherwise by the Secretary or other official to whom the authority has been delegated in accordance with guidelines under the Government in the Sunshine Act, 5 U.S.C. 552b(c).

Nominations, including self-nominations, of individuals who represent organizations that have the specified expertise and knowledge sought will be considered for appointment as non-voting liaison representative members of the Advisory Council.

Every effort will be made to ensure that the membership of federal advisory committees is fairly balanced in terms of points of view represented. Detailed information on what is required in a nomination package and how to submit one is on the Advisory Council website, <http://www.hhs.gov/ash/carb/>.

Dated: March 12, 2019.

Jomana F. Musmar,
Designated Federal Officer, Presidential Advisory Council on Combating Antibiotic-Resistant Bacteria, Committee Manager.

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Meeting of the Advisory Committee on Blood and Tissue Safety and Availability; Amendment

AGENCY: Department of Health and Human Services, Office of the Secretary, Office of the Assistant Secretary for Health.

ACTION: Notice; amendment.

SUMMARY: A notice was published in the *Federal Register* on Monday, March 11, 2019 (Vol. 84, No. 47, pages 8731-8732),