TABLE 1—ESTIMATED ANNUAL THIRD-PARTY DISCLOSURE BURDEN [1]—Continued

Activity	Number of respondents	Number of disclosures per respondent	Total annual disclosures	Average burden per disclosure	Total hours
Notifying immediate previous source of the article of food under section 417(d)(7)(C)(i) of the FD&C Act (mandatory reporters only).	1,200	1	1,200	0.6 (36 minutes)	720
Notifying immediate subsequent recipient of the article of food under section 417(d)(7)(C)(ii) of the FD&C Act (mandatory reporters only).	1,200	1	1,200	0.6 (36 minutes)	720
Total	.....	.....	.....	.....	2,880

[1] There are no capital costs or operating and maintenance costs associated with this collection of information.

Based on a review of the information collection since our last request for OMB approval, we have made no adjustments to our burden estimate.

Third Party Disclosure: We estimate that approximately 1,200 reportable food events with mandatory reporters occur annually. Based on past FDA experiences, we estimate that we could receive 200 to 1,200 ''reportable'' food reports annually from 200 to 1,200 mandatory and voluntary users of the electronic reporting system. We utilized the upper-bound estimate of 1,200 for these calculations.

We estimate that notifying the immediate previous source(s) takes 0.6 hours per reportable food and notifying the immediate subsequent recipient(s) takes 0.6 hours per reportable food. We also estimate that it takes 0.6 hours for the immediate previous source and/or the immediate subsequent recipient to also notify their immediate previous source(s) and/or immediate subsequent recipient(s). The Agency bases its estimate on its experience with mandatory and voluntary reports submitted to FDA.

Although it is not mandatory under section 1005 of FDAAA that responsible persons notify the sources and recipients of instances of reportable food, for purposes of the burden estimate we are assuming FDA would exercise its authority and require such notifications in all such instances for mandatory reporters. This notification burden does not affect voluntary reporters of reportable food events. Therefore, we estimate that the total burden of notifying the immediate previous source(s) and immediate subsequent recipient(s) under section 417(d)(6)(B)(i) and (ii), (d)(7)(C)(i) and (ii) of the FD&C Act for 1,200 reportable foods is 2,880 hours annually (1,200 × 0.6 hours) + (1,200 × 0.6 hours) + (1,200 × 0.6 hours) + (1,200 × 0.6 hours). This annual burden is shown in table 1.

TABLE 2—ESTIMATED ANNUAL RECORDKEEPING BURDEN [1]

Activity	Number of recordkeepers	Number of records per recordkeeper	Total annual records	Average burden per recordkeeping	Total hours
Maintenance of reportable food records under section 417(g) of the FD&C Act—mandatory reports.	1,200	1	1,200	0.25 (15 minutes)	300
Maintenance of reportable food records under section 417(g) of the FD&C Act—voluntary reports.	4	1	4	0.25 (15 minutes)	1
Total	.....	.....	.....	.....	301

[1] There are no capital costs or operating and maintenance costs associated with this collection of information.

Recordkeeping: As noted previously, section 417(g) of the FD&C Act requires that responsible persons maintain records related to reportable foods reports and notifications for a period of 2 years. Based on past FDA experiences, we estimate that each mandatory report and its associated notifications requires 30 minutes of recordkeeping for the 2-year period, or 15 minutes per record per year. The annual recordkeeping burden for mandatory reportable food reports and their associated notifications is thus estimated to be 300 hours (1,200 × 0.25 hours).

We do not expect that records will always be kept in relation to voluntary reportable food reports. Therefore, we estimate that records will be kept for 4 voluntary reports we expect to receive annually. The recordkeeping burden associated with voluntary reports is thus estimated to be 1 hour annually (4 × 0.25 hours). The estimated total annual recordkeeping burden is 301 hours annually (1,200 × 0.25 hours) + (4 × 0.25 hours). This annual burden is shown in table 2.

Dated: July 30, 2020.

Lauren K. Roth,

Associate Commissioner for Policy.

[FR Doc. 2020–17506 Filed 8–10–20; 8:45 am]

BILLING CODE 4164–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2020–N–0001]

Vaccines and Related Biological Products Advisory Committee; Notice of Meeting

AGENCY: Food and Drug Administration, Health and Human Services (HHS).

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA or Agency) announces a forthcoming public advisory committee meeting of the Vaccines and Related Biological Products Advisory Committee (VRBPAC). The general function of the

committee is to provide advice and recommendations to the Agency on FDA's regulatory issues. Members will participate via teleconference.

DATES: The meeting will be held on October 2, 2020, from 11 a.m. Eastern Time to 3:30 p.m. Eastern Time.

ADDRESSES: Please note that due to the impact of this COVID–19 pandemic, all meeting participants will be joining this advisory committee meeting via an online teleconferencing platform. Answers to commonly asked questions including information regarding special accommodations due to a disability, visitor parking, and transportation may be accessed at: *https://www.fda.gov/AdvisoryCommittees/AboutAdvisoryCommittees/ucm408555.htm.*

FOR FURTHER INFORMATION CONTACT: Kathleen Hayes or Monique Hill, Center for Biologics Evaluation and Research, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 71, Rm. 6307C, Silver Spring, MD 20993–0002, 301–796–7864, *Kathleen.Hayes@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.

SUPPLEMENTARY INFORMATION:

Agenda: The meeting presentations will be heard, viewed, captioned, and recorded through an online teleconferencing platform. In open session, the committee will discuss and make recommendations on the selection of strains to be included in an influenza virus vaccine for the 2021 southern hemisphere influenza season.

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. Written submissions may be made to the contact person on or before September 25, 2020. Oral presentations from the public will be scheduled between approximately 1:30 p.m. Eastern Time and 2:30 p.m. Eastern Time. 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 September 17, 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 September 18, 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 Kathleen Hayes (*Kathleen.Hayes@fda.hhs.gov*) 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 30, 2020.

Lauren K. Roth,

Associate Commissioner for Policy.

[FR Doc. 2020–17495 Filed 8–10–20; 8:45 am]

BILLING CODE 4164–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

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

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

ACTION: Notice.

SUMMARY: As required by the Federal Advisory Committee Act, the U.S. Department of Health and Human Services is hereby giving notice that the Advisory Committee on Blood and Tissue Safety and Availability (ACBTSA) will hold a meeting. The meeting will be open to the public. The committee will discuss recommendations to improve the blood community's response to future public health emergencies. In order to facilitate this discussion, key stakeholders from across the nation will present on their lessons learned during the latest pandemic. The committee will analyze strengths and weaknesses from the COVID–19 response on the blood community and blood supply.

DATES: The meeting will take place virtually on Wednesday, August 26, 2020 from approximately 12:30 p.m.–5:15 p.m. and Thursday, August 27, 2020 from approximately 8:00 a.m.–5:00 p.m. Meeting times are tentative and subject to change. The confirmed times and agenda items for the meeting will be posted on the ACBTSA web page at *https://www.hhs.gov/oidp/advisory-committee/blood-tissue-safety-availability/meetings/2020-08-26/index.html* when this information becomes available.

FOR FURTHER INFORMATION CONTACT: James Berger, Designated Federal Officer for the ACBTSA; Office of Infectious Disease and HIV/AIDS Policy, Office of the Assistant Secretary for Health, Department of Health and Human Services, Mary E. Switzer Building, 330 C Street SW, Suite L600, Washington, DC 20024. Email: *ACBTSA@hhs.gov;* Phone: 202–795–7608.

SUPPLEMENTARY INFORMATION: The registration link for the meeting will be posted at *https://www.hhs.gov/oidp/advisory-committee/blood-tissue-safety-availability/meetings/2020-08-26/index.html* when it becomes available. After registering, you will receive an email confirmation with a personalized link to access the webcast on August 26–27.

The public will have an opportunity to present their views to the ACBTSA orally during the meeting's public