TABLE 1—ESTIMATED ANNUAL REPORTING BURDEN [1]—Continued

21 CFR section; activity	Number of respondents	Number of responses per respondent	Total annual responses	Average burden per response	Total hours
507.67, 507.69, and 507.71; submission of an appeal, including submission of a request for an informal hearing.	1	1	1	4	4
507.85(b); requests for reinstatement of exemption	1	1	1	2	2
Total					286

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

TABLE 2—ESTIMATED ANNUAL RECORDKEEPING BURDEN [1]

21 CFR section; activity	Number of record-keepers	Number of records per record-keeper	Total annual records	Average burden per recordkeeping	Total hours
Subpart A—General Provisions					
507.7(e); records attesting that the facility is a "qualified" facility	1,120	0.5	560	0.1 (6 minutes)	56
507.4(d); documentation of animal food safety and hygiene training	7,469	0.75	5,579	0.05 (3 minutes)	279
Subpart C—Hazard Analysis and Risk-Based Preventive Controls					
507.31 through 507.55; food safety plan—including hazard analysis, preventive controls, monitoring, corrective actions, verification, validation reanalysis, modifications, and implementation records.	7,469	519	3,876,411	0.1 (6 minutes)	387,641
Subpart E—Supply-Chain Program					
507.105 through 507.175; written supply-chain program—including records documenting program.	7,469	519	3,876,411	0.1 (6 minutes)	387,641
Subpart F—Requirements Applying to Records					
507.200 through 507.215; general requirements, additional requirements applying to food safety plan, requirements for record retention, use of existing records, and special requirements applicable to written assurance.	7,469	519	3,876,411	0.1 (6 minutes)	387,641
Totals			11,635,372		1,163,258

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

TABLE 3—ESTIMATED ANNUAL THIRD-PARTY DISCLOSURE BURDEN [1]

21 CFR section; activity	Number of respondents	Number of disclosures per respondent	Total annual disclosures	Average burden per disclosure	Total hours
507.27(b); labeling for the animal food product contains the specific information and instructions needed so the food can be safely used for the intended animal species.	330	10	3,300	0.25 (15 minutes)	825
507.7(e)(1); change labels on products with labels	1,526	4	6,104	1	6,104
507.7(e)(2); change address on labeling (sales documents) for qualified facilities.	1,329	1	1,329	1	1,329
507.25(a)(2); animal food, including raw materials, other ingredients, and rework, is accurately identified.	330	312	102,960	0.01 (36 seconds)	1,030
507.28(b); holding and distribution of human food byproducts for use as animal food.	40,798	2	81,596	0.25 (15 minutes)	20,399
Total					29,687

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

As previously stated, we retain the currently approved burden estimate for the information collection. These figures are based on our regulatory impact analysis in support of the final rule on Preventive Controls for Food for Animals, which published in the **Federal Register** of September 17, 2015 (80 FR 56170). Using Agency data, we estimated the number of animal food facilities that we believe are subject to the regulations. We base our estimate of the time necessary for the individual reporting, recordkeeping, and third-party disclosure activities on our experience with similar information collections.

Dated: September 7, 2018.

Leslie Kux,

Associate Commissioner for Policy.

[FR Doc. 2018–19909 Filed 9–12–18; 8:45 am]

BILLING CODE 4164–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2018–N–3381]

Science Board to the Food and Drug Administration Advisory Committee; Notice of Meeting

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) announces a forthcoming public advisory committee meeting of the Science Board to the Food and Drug Administration. The Science Board provides advice to the Commissioner of Food and Drugs and other appropriate officials on specific, complex scientific and technical issues important to FDA and its mission, including emerging issues within the scientific community. Additionally, the Science Board provides advice to the Agency on keeping pace with technical and scientific developments including in regulatory science, input into the Agency's research agenda, and on upgrading its scientific and research facilities and training opportunities. It will also provide, where requested, expert review of Agency sponsored intramural and extramural scientific research programs. The meeting will be open to the public.

DATES: The meeting will be held on October 22, 2018, from 8:30 a.m. to 4:30 p.m.

ADDRESSES: FDA White Oak Campus, 10903 New Hampshire Ave., Bldg. 31 Conference Center, the Great Room (Rm. 1503, section A), Silver Spring, MD 20993. For those unable to attend in person, the meeting will also be webcast. The link for the webcast is available at *https://collaboration.fda.gov/scienceboard2018/.* 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: Rakesh Raghuwanshi, Office of the Chief Scientist, Office of the Commissioner, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 1, Rm. 3309, Silver Spring, MD 20993, 301–796–4769, *rakesh.raghuwanshi@fda.hhs.gov,* 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 Science Board will hear a response from the Center for Veterinary Medicine (CVM) to the recommendations made by the Science Board's 2017 review of CVM's National Antibiotic Resistance Monitoring System program. The Science Board will also discuss potential hazards and nutritional considerations in the production of food derived from animal cell culture technologies.

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 at the location of the advisory committee meeting, and the background material will be posted on FDA's website after the meeting. Background material is available at *https://www.fda.gov/AdvisoryCommittees/Calendar/default.htm.* Scroll down to the appropriate advisory committee meeting link.

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 October 15, 2018. Oral presentations from the public will be scheduled between approximately 3:30 p.m. and 4:30 p.m. 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 October 5, 2018. 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 October 9, 2018.

Persons attending FDA's advisory committee meetings are advised that the Agency is not responsible for providing access to electrical outlets.

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 Rakesh Raghuwanshi 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: September 10, 2018.

Leslie Kux,

Associate Commissioner for Policy.

[FR Doc. 2018–19906 Filed 9–12–18; 8:45 am]

BILLING CODE 4164–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2016–N–1984]

Request for Nominations on the Tobacco Products Scientific Advisory Committee

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA or Agency) is requesting that any small business tobacco manufacturing industry organizations interested in participating in the selection of a nonvoting industry representative to serve on the Tobacco Products Scientific Advisory Committee for the Center for Tobacco Products notify FDA in writing. FDA is also requesting nominations for nonvoting industry representatives to be included in a pool of individuals to represent the interests of the small business tobacco manufacturing industry on the Tobacco Products Scientific Advisory Committee. A nominee may either be self-nominated or nominated by an organization to serve as a nonvoting industry representative. This position may be filled on a rotating, sequential basis by representatives of different small business tobacco manufacturers based on areas of expertise relevant to the topics being considered by the Advisory Committee. Nominations will be accepted for current vacancies effective with this notice.

DATES: Any small business tobacco manufacturing industry organization interested in participating in the selection of appropriate nonvoting members to represent industry interests