TABLE 1—ESTIMATED ANNUAL REPORTING BURDEN [1]

FDA center	Number of respondents	Annual frequency per response	Total annual responses	Hours per response	Total hours
CDRH	3,502	1	3,502	137	479,774
CBER	91	1	91	137	12,467
Total					492,241

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

Respondents are medical device manufacturers subject to FDA's laws and regulations. FDA's annual estimate of 3,593 submissions is based on experienced recent trends. FDA's administrative and technical staffs, who are familiar with Q-Submissions, estimate that an average of 137 hours is required to prepare a Q-Submission.

Our estimated burden for the information collection reflects an overall increase of 143,713 hours. We attribute this adjustment to an increase in the number of submissions we received based on FY18 data.

Dated: August 6, 2019.

Lowell J. Schiller,

Principal Associate Commissioner for Policy.

[FR Doc. 2019–17345 Filed 8–12–19; 8:45 am]

BILLING CODE 4164–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2019–N–2281]

Incorporating Alternative Approaches in Clinical Investigations for New Animal Drugs; Public Meeting; Extension of Comment Period

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice of public meeting; extension of comment period.

SUMMARY: The Food and Drug Administration (FDA, the Agency, or we) is extending the comment period for the notice of public meeting entitled ''Incorporating Alternative Approaches in Clinical Investigations for New Animal Drugs; Public Meeting; Request for Comments'' that appeared in the **Federal Register** of July 9, 2019. In the notice of public meeting, FDA requested comments on the use of complex adaptive and other novel investigation designs, data from foreign countries, real world evidence, and biomarkers and surrogate endpoints in animal drug development and regulatory decision making. The Agency is taking this action in response to a request for an extension to allow interested persons additional time to submit comments.

DATES: FDA is extending the comment period on the notice of public meeting published July 9, 2019 (84 FR 32749). Submit either electronic or written comments by September 16, 2019.

ADDRESSES: You may submit comments as follows. Please note that late, untimely filed comments will not be considered. Electronic comments must be submitted on or before September 16, 2019. The *https://www.regulations.gov* electronic filing system will accept comments until 11:59 p.m. Eastern Time at the end of September 16, 2019. Comments received by mail/hand delivery/courier (for written/paper submissions) will be considered timely if they are postmarked or the delivery service acceptance receipt is on or before that date.

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–2019–N–2281 for ''Incorporating Alternative Approaches in Clinical Investigations for New Animal Drugs; Public Meeting; Request for Comments.'' Received comments, those filed in a timely manner (see **ADDRESSES**), will be placed in the docket and, except for those submitted as ''Confidential Submissions,'' publicly viewable at *https://www.regulations.gov* or at the Dockets Management Staff between 9 a.m. and 4 p.m., Monday through Friday.

- Confidential Submissions—To submit a comment with confidential information that you do not wish to be made publicly available, submit your comments only as a written/paper submission. You should submit two copies total. One copy will include the information you claim to be confidential with a heading or cover note that states ''THIS DOCUMENT CONTAINS CONFIDENTIAL INFORMATION.'' The Agency will review this copy, including the claimed confidential information, in its consideration of comments. The second copy, which will have the claimed confidential information redacted/blacked out, will be available for public viewing and posted on *https://www.regulations.gov.* Submit both copies to the Dockets Management Staff. If you do not wish your name and contact information to be made publicly available, you can provide this information on the cover sheet and not in the body of your comments and you must identify this information as

''confidential.'' Any information marked as ''confidential'' will not be disclosed except in accordance with 21 CFR 10.20 and other applicable disclosure law. For more information about FDA's posting of comments to public dockets, see 80 FR 56469, September 18, 2015, or access the information at: *https://www.gpo.gov/fdsys/pkg/FR-2015-09-18/pdf/2015-23389.pdf.*

Docket: For access to the docket to read background documents or the electronic and written/paper comments received, go to *https://www.regulations.gov* and insert the docket number, found in brackets in the heading of this document, into the ''Search'' box and follow the prompts and/or go to the Dockets Management Staff, 5630 Fishers Lane, Rm. 1061, Rockville, MD 20852.

FOR FURTHER INFORMATION CONTACT: Susan Storey, Center for Veterinary Medicine, Food and Drug Administration, 7500 Standish Pl. (HFV–131), Rockville, MD, 20855, 240–402–0578, *susan.storey@fda.hhs.gov.*

SUPPLEMENTARY INFORMATION: In the **Federal Register** of July 9, 2019 (84 FR 32749), FDA published a notice of public meeting and request for comment with a 30-day comment period to request comments on the use of complex adaptive and other novel investigation designs, data from foreign countries, real world evidence, and biomarkers and surrogate endpoints in animal drug development and regulatory decision making. Comments are intended to support FDA guidance development as required under section 305 of the Animal Drug and Animal Generic Drug User Fee Amendments of 2018 (Pub. L. 115–234). Section 305 directs FDA to develop guidance to address several alternative approaches in clinical investigations for new animal drugs.

The Agency has received a request for a 30-day extension of the comment period for the notice of meeting. The request conveyed concern that the current 30-day comment period does not allow sufficient time to develop a meaningful or thoughtful response to alternative approaches in clinical investigations for new animal drugs.

FDA has considered the request and is extending the comment period for the notice of public meeting for 30 days, until September 16, 2019. The Agency believes that a 30-day extension allows adequate time for interested persons to submit comments without significantly delaying the development of guidance on these important issues.

Dated: August 7, 2019.

Lowell J. Schiller,

Principal Associate Commissioner for Policy.

[FR Doc. 2019–17258 Filed 8–12–19; 8:45 am]

BILLING CODE 4164–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

Office of the Director; Notice of Charter Renewal

In accordance with Title 41 of the U.S. Code of Federal Regulations, Section 102–3.65(a), notice is hereby given that the Charter for the Novel and Exceptional Technology and Research Advisory Committee was renewed for an additional two-year period on June 30, 2019. Prior to this renewal, the Charter was amended to reflect the Committee's name change from the Recombinant DNA Advisory Committee to the Novel and Exceptional Technology and Research Advisory Committee.

It is determined that the Novel and Exceptional Technology and Research Advisory Committee is in the public interest in connection with the performance of duties imposed on the National Institutes of Health by law, and that these duties can best be performed through the advice and counsel of this group.

Inquiries may be directed to Claire Harris, Director, Office of Federal Advisory Committee Policy, Office of the Director, National Institutes of Health, 6701 Democracy Boulevard, Suite 1000, Bethesda, Maryland 20892 (Mail code 4875), Telephone (301) 496–2123, or *harriscl@mail.nih.gov.*

Dated: August 7, 2019.

Ronald J. Livingston, Jr.,

Program Analyst, Office of Federal Advisory Committee Policy.

[FR Doc. 2019–17244 Filed 8–12–19; 8:45 am]

BILLING CODE 4140–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

Center for Scientific Review; 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: Center for Scientific Review Special Emphasis Panel; PAR17–097: Planning for Non-Communicable Diseases and Disorders Research Training Programs.

Date: August 20, 2019.

Time: 9:00 a.m. to 5:00 p.m.

Agenda: To review and evaluate grant applications.

Place: National Institutes of Health, Rockledge II, 6701 Rockledge Drive, Bethesda, MD 20892 (Telephone Conference Call).

Contact Person: Brian H. Scott, Ph.D., Scientific Review Officer, National Institutes of Health, Center for Scientific Review, 6701 Rockledge Drive, Bethesda, MD 20892, 301–827–7490, *brianscott@mail.nih.gov.*

(Catalogue of Federal Domestic Assistance Program Nos. 93.306, Comparative Medicine; 93.333, Clinical Research, 93.306, 93.333, 93.337, 93.393–93.396, 93.837–93.844, 93.846–93.878, 93.892, 93.893, National Institutes of Health, HHS)

Dated: August 7, 2019.

Sylvia L. Neal,

Program Analyst, Office of Federal Advisory Committee Policy.

[FR Doc. 2019–17246 Filed 8–12–19; 8:45 am]

BILLING CODE 4140–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

Scientific Advisory Committee on Alternative Toxicological Methods; Announcement of Meeting; Request for Comments

AGENCY: National Institutes of Health, HHS.

ACTION: Notice.

SUMMARY: This notice announces the next meeting of the Scientific Advisory Committee on Alternative Toxicological Methods (SACATM). SACATM, a federally chartered external advisory group of scientists from the public and private sectors, including representatives of regulated industry and national animal protection organizations, advises the Interagency Coordinating Committee on the Validation of Alternative Methods (ICCVAM), the National Toxicology Program (NTP) Interagency Center for the Evaluation of Alternative Toxicological Methods (NICEATM), and the Director of the National Institute of