TABLE 1—ESTIMATED ANNUAL REPORTING BURDEN [1]

Guidance recommendations	Number of respondents	Number of responses per respondent	Total annual responses	Average burden per response	Total hours
New written requests to be placed on the lists	370	1	370	1	370
Third-party certification	370	1	370	21	7,770
Biennial update	555	1	555	1	555
Third-party certification biennial update	555	1	555	21	11,655
Occasional updates	100	1	100	0.5	50
Total					20,400

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

This is a newly established information collection. Based on our experience maintaining other export lists, we estimate that, annually, an average of 370 new manufacturers/processors will submit written requests to be placed on the China lists. The estimate of the number of hours that it will take a manufacturer/processor to gather the information needed to be placed on a list or update its information is based on FDA's experience with manufacturers/processors submitting similar requests. FDA believes that the information to be submitted will be readily available to manufacturers/processors. We estimate that a firm will require 1 hour to read the guidance, to gather the information needed, and to prepare a communication to FDA that contains the information needed to request that the manufacturer/processor be placed on a list.

To be placed on a list, manufacturers/processors should provide FDA with evidence that they have obtained third-party certification from a CNCA-acknowledged certifier that the manufacturer/processor complies with the standards, laws and regulations of China according to relevant requirements specified in AQSIQ Decree 145. Based on our experience with other certification programs, FDA estimates that it will take each new manufacturer/processor about 21 hours to complete the third-party certification process for a total of 7,770 burden hours (370 manufacturers/processors × 21 hours).

Under the guidance, every 2 years each manufacturer/processor on the lists must provide updated information to remain on the lists. FDA estimates that each year approximately half of the manufacturers/processors on the lists, or 555 manufacturers/processors (1110 manufacturers/processors × 0.5 = 555), will resubmit the information to remain on the lists. We estimate that a manufacturer/processor already on the lists will require 1 hour to biennially update and resubmit the information to FDA, including time reviewing the information and corresponding with FDA, for a total of 555 hours.

During the biennial update, manufacturers/processors also need to be recertified by a third-party certifier to remain on the lists. FDA estimates that each year approximately half of the manufacturers/processors on the lists, 555 manufacturers/processors (1110 manufacturers/processors × 0.5 = 555), will get recertified. We estimate that it will take each manufacturer/processor about 21 hours to complete the certification process for a total of 11,655 burden hours (555 manufacturers/processors × 21 hours).

FDA expects that, each year, approximately 100 manufacturers/processors will need to submit an occasional update and each manufacturer/processor will require 0.5 hours to prepare a communication to FDA reporting the change, for a total of 50 hours.

Dated: November 29, 2017.

Leslie Kux,

Associate Commissioner for Policy.

[FR Doc. 2017–26042 Filed 12–1–17; 8:45 am]

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

National Center for Advancing Translational Sciences; 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 Center for Advancing Translational Sciences Special Emphasis Panel; CTSA.

Date: February 21, 2018.

Time: 8:00 a.m. to 5:00 p.m.

Agenda: To review and evaluate grant applications.

Place: Bethesda Marriott Suites, Independence Ballrooms 1 & 2, 6711 Democracy Blvd., Bethesda, MD 20817.

Contact Person: Carol Lambert, Ph.D., Acting Director, Office of Scientific Review, National Center for Advancing Translational Sciences (NCATS), National Institutes of Health, 6701 Democracy Blvd., Democracy 1, Room 1076, Bethesda, MD 20892, 301–435–0814, *lambert@mail.nih.gov*.

(Catalogue of Federal Domestic Assistance Program Nos. 93.859, Pharmacology, Physiology, and Biological Chemistry Research; 93.350, B—Cooperative Agreements; 93.859, Biomedical Research and Research Training, National Institutes of Health, HHS)

Dated: November 28, 2017.

David Clary,

Program Analyst, Office of Federal Advisory Committee Policy.

[FR Doc. 2017–25982 Filed 12–1–17; 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 Meetings

Pursuant to section 10(d) of the Federal Advisory Committee Act, as amended, notice is hereby given of the following meetings.

The meetings 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