causes of death and disability, as well as the ability to respond rapidly to emerging health issues, including outbreaks of food-borne infections and water-borne diseases. CSTLTS ensures that the CDC PHHS Block Grant Program Manager and recipients account for funds in accordance with legislative mandates. Each recipient is required to submit a work plan with its selected health outcome objectives, as well as descriptions of the health problems, identified target populations (including portions of those populations disproportionately affected by the health problems), and activities to be addressed in the planned work. CDC will use the Block Grant Information System to collect recipient data, monitor recipients' progress, identify activities and personnel supported with Block Grant funding, conduct compliance reviews of Block Grant recipients, and promote the use of evidence-based guidelines and interventions.

CDC requests OMB approval for revision of this existing information collection request to accommodate the needed updates to the system and templates used to collect the information. As specified in the authorizing legislation, CDC currently collects information from Block Grant recipients to monitor their objectives and activities. Recipients will submit information on the following:

- *Recipient information:* Unique identifying information about each recipient.
- *Work plan:* Information about objectives, activities, and the populations to be addressed each year.
- *Annual Progress Report:* Information about success and progress toward meeting health objectives.

Since 2008, CDC has collected this information using a web-based electronic system, the Block Grant Management Information System (BGMIS). Beginning with the FY2021 award, CDC will begin using a new information management system, the Block Grant Information System (BGIS) to collect this information. The new system will essentially collect the same information as the old system, but will offer a variety of updates and improvements. Examples of improvements include updated technological infrastructure, updated Healthy People Objectives (from 2020 to 2030) for recipients to use when planning programs, usability improvements, and redesigned instruments to capture data in more useful formats for both the recipients and reporting purposes.

The respondent universe will include PHHS Block Grant Coordinators(n=61). All modules will be accessed electronically through the BGIS system. CDC requests approval for an estimated 1,525 burden hours annually.

ESTIMATED ANNUALIZED BURDEN HOURS

Type of respondents	Form name	Number of respondents	Number of responses per respondent	Average burden per response (in hours)
PHHS Block Grant Coordinator	Recipient Information	61	1	2
PHHS Block Grant Coordinator	Work Plan	61	1	12
PHHS Block Grant Coordinator	Annual Progress Report	61	1	11

Jeffrey M. Zirger,
Lead, Information Collection Review Office, Office of Scientific Integrity, Office of Science, Centers for Disease Control and Prevention.

[FR Doc. 2020–20213 Filed 9–11–20; 8:45 am]
BILLING CODE 4163–18–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Centers for Disease Control and Prevention

Clinical Laboratory Improvement Advisory Committee (CLIAC)

AGENCY: Centers for Disease Control and Prevention (CDC), Department of Health and Human Services (HHS).

ACTION: Notice of meeting.

SUMMARY: In accordance with the Federal Advisory Committee Act, the CDC announces the following meeting for the Clinical Laboratory Improvement Advisory Committee (CLIAC). This meeting is open to the public, limited only by the webcast lines available. Check the CLIAC website on the day of the meeting for the web conference link *www.cdc.gov/cliac.*

DATES: The meeting will be held on October 28, 2020, from 11:00 a.m. to 6:30 p.m., EDT and October 29, 2020, from 11:00 a.m. to 3:00 p.m., EDT.

ADDRESSES: This is a virtual meeting. Meeting times are tentative and subject to change. The confirmed meeting times, agenda items, and meeting materials including instructions for accessing the live meeting broadcast will be available on the CLIAC website at *www.cdc.gov/cliac.*

FOR FURTHER INFORMATION CONTACT: Nancy Anderson, MMSc, MT(ASCP), Senior Advisor for Clinical Laboratories, Division of Laboratory Systems, Center for Surveillance, Epidemiology and Laboratory Services, Office of Public Health Scientific Services, Centers for Disease Control and Prevention, 1600 Clifton Road, NE, Mailstop V24–3, Atlanta, Georgia 30329–4018, Telephone: (404) 498–2741; Email: *NAnderson@cdc.gov.*

SUPPLEMENTARY INFORMATION:

Purpose: This Committee is charged with providing scientific and technical advice and guidance to the Secretary, HHS; the Assistant Secretary for Health; the Director, CDC; the Commissioner, Food and Drug Administration (FDA); and the Administrator, Centers for Medicare and Medicaid Services (CMS). The advice and guidance pertain to general issues related to improvement in clinical laboratory quality and laboratory medicine practice and specific questions related to possible revision of the Clinical Laboratory Improvement Amendments of 1988 (CLIA) standards. Examples include providing guidance on studies designed to improve safety, effectiveness, efficiency, timeliness, equity, and patient-centeredness of laboratory services; revisions to the standards under which clinical laboratories are regulated; the impact of proposed revisions to the standards on medical and laboratory practice; and the modification of the standards and provision of non-regulatory guidelines to accommodate technological advances, such as new test methods, the electronic transmission of laboratory information, and mechanisms to

improve the integration of public health and clinical laboratory practices.

Matters To Be Considered: The agenda will include agency updates from CDC, CMS, and FDA. The focus of the meeting is Clinical Laboratory Medicine in the Age of COVID–19 and will include presentations and discussions on preparedness and response: the partnership between clinical laboratories and public health; laboratory data exchanges during COVID–19; and the clinical laboratory's role in identifying health inequities during the COVID–19 response. Agenda items are subject to change as priorities dictate.

It is the policy of CLIAC to accept written public comments and provide a brief period for oral public comments pertinent to agenda items.

Procedure for Public Comment: Public comment periods for each agenda item are scheduled immediately prior to the Committee discussion period for that item. In general, each individual or group requesting to present an oral comment will be limited to a total time of five minutes (unless otherwise indicated). Speakers should email *CLIAC@cdc.gov* or notify the contact person at least 5 business days prior to the meeting date.

Procedure for Written Public Comment: For individuals or groups unable to attend the meeting, CLIAC accepts written comments until the date of the meeting (unless otherwise stated). However, it is requested that comments be submitted at least 5 business days prior to the meeting date so that the comments may be made available to the Committee for their consideration and public distribution. All written comments will be included in the meeting Summary Report posted on the CLIAC website.

The Director, Strategic Business Initiatives Unit, Office of the Chief Operating Officer, Centers for Disease Control and Prevention, has been delegated the authority to sign **Federal Register** notices pertaining to announcements of meetings and other committee management activities, for both the Centers for Disease Control and Prevention and the Agency for Toxic Substances and Disease Registry.

Kalwant Smagh,

Director, Strategic Business Initiatives Unit, Office of the Chief Operating Officer, Centers for Disease Control and Prevention.

[FR Doc. 2020–20182 Filed 9–11–20; 8:45 am]

BILLING CODE 4163–18–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2019–E–1943]

Determination of Regulatory Review Period for Purposes of Patent Extension; TAKHZYRO

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

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA or the Agency) has determined the regulatory review period for TAKHZYRO and is publishing this notice of that determination as required by law. FDA has made the determination because of the submission of an application to the Director of the U.S. Patent and Trademark Office (USPTO), Department of Commerce, for the extension of a patent which claims that human biological product.

DATES: Anyone with knowledge that any of the dates as published (see **SUPPLEMENTARY INFORMATION**) are incorrect may submit either electronic or written comments and ask for a redetermination by November 13, 2020. Furthermore, any interested person may petition FDA for a determination regarding whether the applicant for extension acted with due diligence during the regulatory review period by March 15, 2021. See ''Petitions'' in the **SUPPLEMENTARY INFORMATION** section for more information.

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 November 13, 2020. The *https://www.regulations.gov* electronic filing system will accept comments until 11:59 p.m. Eastern Time at the end of November 13, 2020. 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–E–1943 for ''Determination of Regulatory Review Period for Purposes of Patent Extension; TAKHZYRO.'' 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, 240–402–7500.

- 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