ATTACHMENT C

60- and 30-Day *Federal Register* Notices

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Service Act (42 U.S.C. 262(k), referred to in this document as a 351(k) application).

This draft guidance describes how the Agency determines if: (1) The provisions of section 505(q) of the FD&C Act addressing the treatment of citizen petitions and petitions for stay of Agency action (collectively, petitions) apply to a particular petition and (2) a petition would delay approval of a pending ANDA, 505(b)(2) application, or 351(k) application. This draft guidance also describes how FDA implements the provisions of section 505(q) requiring that: (1) A petition include a certification and (2) supplemental information or comments to a petition include a verification. It also addresses the relationship between the review of petitions and pending ANDAs, 505(b)(2) applications, and 351(k) applications for which the Agency has not yet made a decision on approvability.

This draft guidance revises the guidance for industry entitled ''Citizen Petitions and Petitions for Stay of Action Subject to Section 505(q) of the Federal Food, Drug, and Cosmetic Act'' issued in November 2014. This draft guidance updates the November 2014 guidance to account for recent regulatory changes to add § 10.31 (21 CFR 10.31) to FDA's regulations and modify 21 CFR 10.30 and 10.35. The revision also describes a change in FDA's current thinking on what constitutes a 505(q) petition. In addition, FDA is revising this guidance to describe some of the considerations FDA will take into account in determining whether a petition is submitted with the primary purpose of delaying the approval of an application under section 505(q)(1)(E) of the FD&C Act.

This draft guidance is being issued consistent with FDA's good guidance practices regulation (21 CFR 10.115). The draft guidance, when finalized, will represent the current thinking of FDA on citizen petitions and petitions for stay of action subject to section 505(q) of the FD&C Act. It does not establish any rights for any person and is not binding on FDA or the public. You can use an alternative approach if it satisfies the requirements of the applicable statutes and regulations. This guidance is not subject to Executive Order 12866.

II. Paperwork Reduction Act of 1995

This draft guidance refers to previously approved collections of information found in FDA regulations. These collections of information are subject to review by the Office of Management and Budget (OMB) under the Paperwork Reduction Act of 1995 (PRA) (44 U.S.C. 3501–3520). The collections of information in 21 CFR 10.20, 10.30, and 10.35 have been approved under OMB control number 0910–0191; the collections of information in § 10.31 have been approved under OMB control number 0910–0679; and the collections of information in 21 CFR 314.54, 314.94, and 314.102 have been approved under OMB control number 0910–0001. The certification and verification statements required under § 10.31(c) and (d) are ''public disclosure[s] of information originally supplied by the Federal government to the recipient for the purpose of disclosure to the public . . .'' (5 CFR 1320.3(c)(2)) and therefore not subject to OMB review under the PRA.

III. Electronic Access

Persons with access to the internet may obtain the draft guidance at either *http://www.fda.gov/Drugs/GuidanceComplianceRegulatoryInformation/Guidances/default.htm* or *https://www.regulations.gov.*

Dated: September 28, 2018.

Leslie Kux,

Associate Commissioner for Policy.

[FR Doc. 2018–21532 Filed 10–2–18; 8:45 am]

BILLING CODE 4164–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

[Document Identifier OS–0990–New]

Agency Information Collection Request. 60-Day Public Comment Request

AGENCY: Office of the Secretary, HHS.

ACTION: Notice.

SUMMARY: In compliance with the requirement of the Paperwork Reduction Act of 1995, the Office of the Secretary (OS), Department of Health and Human Services, is publishing the following summary of a proposed collection for public comment.

DATES: Comments on the ICR must be received on or before December 3, 2018.

ADDRESSES: Submit your comments to *Sherrette.Funn@hhs.gov* or by calling (202) 795–7714.

FOR FURTHER INFORMATION CONTACT: When submitting comments or requesting information, please include the document identifier 0990–New–60D and project title for reference, to *Sherrette.funn@hhs.gov,* or call 202–795–7714, the Reports Clearance Officer.

SUPPLEMENTARY INFORMATION: Interested persons are invited to send comments regarding this burden estimate or any other aspect of this collection of information, including any of the following subjects: (1) The necessity and utility of the proposed information collection for the proper performance of the agency's functions; (2) the accuracy of the estimated burden; (3) ways to enhance the quality, utility, and clarity of the information to be collected; and (4) the use of automated collection techniques or other forms of information technology to minimize the information collection burden.

Title of the Collection: Fertility Knowledge Survey.

Type of Collection: OMB No. 0990–NEW—Office of the Assistant Secretary for Health (OASH).

Abstract: The Office of the Assistant Secretary for Health/Office of Population Affairs (OPA) is seeking an approval by the Office of Management and Budget on a new information collection. We seek to collect information to increase understanding of (1) adolescent and young adult knowledge of human (female and male) fertility and (2) how this knowledge is related to behaviors and intentions involving childbearing. We propose to collect this information through a 20-minute web survey (Fertility Knowledge Survey) of 2,100 females and 1,900 males, aged 15 to 29 years, using an online panel that is based on a probability-based sample of the U.S. population. The survey will produce evidence and findings that are expected to be generalizable to the population of English-speaking females and males aged 15 to 29 years in the United States.

Possessing accurate knowledge about human fertility is important information that enables reproductive-aged women and men to make informed decisions and plans about reproduction and empowers them to seek appropriate and timely health services (e.g., family planning, related preventive healthcare, or infertility assessment) to achieve those plans. OPA requires high-quality information on the fertility knowledge and related behaviors of U.S. adolescents and young adults to inform Title X policies and strategies that aim to close knowledge gaps, enhance reproductive life planning, and increase access to appropriate and evidence-informed care.

The Fertility Knowledge Survey will be administered once to each respondent. Respondents will include English-speaking females and males, aged 15 to 29 years, who are able to get pregnant or father a child, respectively. This study will rely on a web survey to

be self-administered at home on personal computers, tablets, or phones. A web survey has numerous methodological advantages, including increased accuracy in measurement of key variables of interest, and reduced burden on study participants. Respondents in this study will be members of the general public. This collection will not involve small business or small entities.

The estimated annualized hour burden of responding to this information collection is 1,333 hours, or a weighted average of 20 minutes (.33 hours) per respondent. The hour-burden estimate includes the time spent by a respondent to read the email invitation, review the online consent or assent (minor), and complete the survey. Participation is voluntary and there are no costs to respondents other than their time. OMB approval is requested for three years.

ANNUALIZED BURDEN HOUR TABLE

Forms (if necessary)	Respondents (if necessary)	Number of respondents	Number of responses per respondents	Average burden per response	Total burden hours
Fertility Knowledge Survey	General Public, aged 15 to 29 years	4,000	1	20/60	1,333
Total			4,000		1,333

Dated: September 27, 2018.

Terry Clark,

Paperwork Reduction Act Reports Clearance Officer, Office of the Secretary.

[FR Doc. 2018–21520 Filed 10–2–18; 8:45 am]

BILLING CODE 4150–34–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

National Heart, Lung, and Blood Institute; Notice of Closed Meetings

Pursuant to section 10(d) of the Federal Advisory Committee Act, as amended (5 U.S.C. App.), 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: Heart, Lung, and Blood Initial Review Group; Clinical Trials Review Committee.

Date: October 25–26, 2018.

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

Agenda: To review and evaluate grant applications.

Place: Residence Inn Bethesda, 7335 Wisconsin Avenue, Bethesda, MD 20814.

Contact Person: Keary A. Cope, Ph.D., Scientific Review Officer, Office of Scientific Review/DERA, National Heart, Lung, and Blood Institute, 6701 Rockledge Drive, Room 7190, Bethesda, MD 20892–7924, 301–827–7912, *copeka@mail.nih.gov*.

(Catalogue of Federal Domestic Assistance Program Nos. 93.233, National Center for Sleep Disorders Research; 93.837, Heart and Vascular Diseases Research; 93.838, Lung Diseases Research; 93.839, Blood Diseases and Resources Research, National Institutes of Health, HHS)

Dated: September 27, 2018.

Ronald J. Livingston, Jr.,

Program Analyst, Office of Federal Advisory Committee Policy.

[FR Doc. 2018–21501 Filed 10–2–18; 8:45 am]

BILLING CODE 4140–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

National Institute of Mental Health; 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 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 Institute of Mental Health Special Emphasis Panel; Jointly Sponsored Predoctoral Training Program in the Neurosciences (T32).

Date: October 23, 2018.

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

Agenda: To review and evaluate grant applications.

Place: The Westin Georgetown, 2350 M Street NW, Washington, DC 20037.

Contact Person: Erin E. Gray, Ph.D., Scientific Review Officer, Division of Extramural Activities, National Institute of Mental Health, National Institutes of Health, 6001 Executive Boulevard, NSC 6152B, Bethesda, MD 20892, 301–402–8152, *erin.gray@nih.gov*.

Name of Committee: National Institute of Mental Health Special Emphasis Panel; NIMH Pathway to Independence Awards (K99/R00).

Date: October 24, 2018.

Time: 12:00 p.m. to 5:00 p.m.

Agenda: To review and evaluate grant applications.

Place: National Institutes of Health, Neuroscience Center, 6001 Executive Boulevard, Rockville, MD 20852 (Virtual Meeting).

Contact Person: David W. Miller, Ph.D., Scientific Review Officer, Division of Extramural Activities, National Institute of Mental Health, NIH, Neuroscience Center, 6001 Executive Blvd., Room 6140, MSC 9608, Bethesda, MD 20892–9608, 301–443–9734, *millerda@mail.nih.gov*.

(Catalogue of Federal Domestic Assistance Program No. 93.242, Mental Health Research Grants, National Institutes of Health, HHS)

Dated: September 27, 2018.

Melanie J. Pantoja,

Program Analyst, Office of Federal Advisory Committee Policy.

[FR Doc. 2018–21504 Filed 10–2–18; 8:45 am]

BILLING CODE 4140–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

National Heart, Lung, and Blood Institute; Notice of Closed Meetings

Pursuant to section 10(d) of the Federal Advisory Committee Act, as amended (5 U.S.C. App.), 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

development for rare diseases, this draft guidance expands on the topic of natural history studies specifically.

There are approximately 7,000 recognized rare diseases. Individually, rare diseases affect a small number of people, but collectively rare diseases affect about 1 in 10 people in the United States. Most rare diseases have no approved therapies and thus present a significant unmet public health need. Although knowledge of a disease's natural history can benefit drug development for many disorders and conditions, natural history information is usually not available or is incomplete for most rare diseases; therefore, natural history information is particularly needed for these diseases.

This draft guidance describes the potential uses of a natural history study in all phases of drug development and in the postmarketing period, the strengths and weaknesses of various types of natural history studies that might be conducted to support drug development, data elements and research plans, and a practical framework for the conduct of a natural history study. The draft guidance also discusses patient confidentiality and data protection issues in natural history studies and the potential nature of interactions with FDA related to these studies.

This draft guidance is being issued consistent with FDA's good guidance practices regulation (21 CFR 10.115). The draft guidance, when finalized, will represent the current thinking of FDA on ''Rare Diseases: Natural History Studies for Drug Development.'' It does not establish any rights for any person and is not binding on FDA or the public. You can use an alternative approach if it satisfies the requirements of the applicable statutes and regulations. This guidance is not subject to Executive Order 12866.

II. Paperwork Reduction Act of 1995

This guidance refers to previously approved collections of information that are subject to review by the Office of Management and Budget (OMB) under the Paperwork Reduction Act of 1995 (44 U.S.C. 3501–3520). The collections of information in 21 CFR parts 312 and 314 have been approved under OMB control numbers 0910–0014 and 0910–0001, respectively. The collections of information in 21 CFR parts 50 and 56 (Protection of Human Subjects: Informed Consent; Institutional Review Boards) have been approved under OMB control number 0910–0755.

III. Electronic Access

Persons with access to the internet may obtain the draft guidance at *https://www.fda.gov/Drugs/GuidanceComplianceRegulatoryInformation/Guidances/default.htm, https://www.fda.gov/BiologicsBloodVaccines/GuidanceComplianceRegulatoryInformation/Guidances/default.htm, https://www.fda.gov/ForIndustry/DevelopingProductsforRareDiseasesConditions/default.htm,* or *https://www.regulations.gov.*

Dated: March 20, 2019.

Lowell J. Schiller,

Acting Associate Commissioner for Policy.

[FR Doc. 2019–05655 Filed 3–22–19; 8:45 am]

BILLING CODE 4164–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

[Document Identifier: OS–0937–New]

Agency Information Collection Request; 30-Day Public Comment Request

AGENCY: Office of the Secretary, HHS.

ACTION: Notice.

SUMMARY: In compliance with the requirement of the Paperwork Reduction Act of 1995, the Office of the Secretary (OS), Department of Health and Human Services, is publishing the following summary of a proposed collection for public comment.

DATES: Comments on the ICR must be received on or before April 24, 2019.

ADDRESSES: Submit your comments to *OIRA_submission@omb.eop.gov* or via facsimile to (202) 395–5806.

FOR FURTHER INFORMATION CONTACT: Sherrette Funn, *Sherrette.Funn@hhs.gov* or (202) 795–7714. When submitting comments or requesting information, please include the document identifier 0937-Fertility Knowledge Survey-30D and project title for reference.

SUPPLEMENTARY INFORMATION: Interested persons are invited to send comments regarding this burden estimate or any other aspect of this collection of information, including any of the following subjects: (1) The necessity and utility of the proposed information collection for the proper performance of the agency's functions; (2) the accuracy of the estimated burden; (3) ways to enhance the quality, utility, and clarity of the information to be collected; and (4) the use of automated collection techniques or other forms of information technology to minimize the information collection burden.

Title of the Collection: Fertility Knowledge Survey.

Type of Collection: New.

Abstract: The Office of the Assistant Secretary for Health/Office of Population Affairs (OPA) is requesting a three-year approval by the Office of Management and Budget of a new information collection. We are seeking to collect information to increase understanding of (1) adolescent and young adult knowledge of human (female and male) fertility and (2) how this knowledge is related to behaviors and intentions involving childbearing. We propose to collect this information through a 20-minute web survey (Fertility Knowledge Survey) of 2,100 females and 1,900 males, aged 15 to 29 years, using an online panel that is based on a probability-based sample of the U.S. population. Respondents will be members of the general public, and consist of English-speaking females and males, aged 15 to 29 years, who are able to get pregnant or to biologically father a child, respectively. The survey will produce evidence and findings that are expected to be generalizable to the population of individuals in the United States with these characteristics.

Possessing accurate knowledge about human fertility is important information that enables reproductive-aged women and men to make informed decisions and plans about reproduction and empowers them to seek appropriate and timely health services (*e.g.,* family planning, related preventive healthcare, or infertility assessment) to achieve those plans. OPA requires high-quality information on the fertility knowledge and related behaviors of U.S. adolescents and young adults to inform Title X policies and strategies that aim to close knowledge gaps, enhance reproductive life planning, and increase access to appropriate and evidence-informed care.

The web survey (Fertility Knowledge Survey) will be self-administered once by each respondent using a personal computer, tablet, or smart phone. A web survey has numerous methodological advantages, including increased accuracy in measurement of key variables of interest, and reduced burden on study participants. This collection will not involve small business or small entities.

The estimated annualized hour burden of responding to this information collection is 1,333 hours, or a weighted average of 20 minutes (.33 hours) per respondent. The hour-burden estimate includes the time spent by a respondent to read the email invitation, review the online consent or assent (minor), and complete the survey. Participation is voluntary and there are

no costs to respondents other than their time.

ANNUALIZED BURDEN HOUR TABLE

Forms (if necessary)	Respondents (if necessary)	Number of respondents	Number of responses per respondents	Average burden per response	Total burden hours
Fertility Knowledge Survey	General Public, aged 15 to 29 years	4,000	1	20/60	1,333
Total			4,000		1,333

Terry Clark,

Office of the Secretary, Paperwork Reduction Act Reports Clearance Officer.

[FR Doc. 2019–05595 Filed 3–22–19; 8:45 am]

BILLING CODE 4150–48–P

DEPARTMENT OF HOMELAND SECURITY

U.S. Customs and Border Protection

[1651–0010]

Agency Information Collection Activities: Certificate of Registration

AGENCY: U.S. Customs and Border Protection (CBP), Department of Homeland Security.

ACTION: 60-day notice and request for comments; Extension of an existing collection of information.

SUMMARY: The Department of Homeland Security, U.S. Customs and Border Protection will be submitting the following information collection request to the Office of Management and Budget (OMB) for review and approval in accordance with the Paperwork Reduction Act of 1995 (PRA). The information collection is published in the **Federal Register** to obtain comments from the public and affected agencies.

DATES: Comments are encouraged and must be submitted (no later than May 24, 2019) to be assured of consideration.

ADDRESSES: Written comments and/or suggestions regarding the item(s) contained in this notice must include the OMB Control Number 1651–0010 in the subject line and the agency name. To avoid duplicate submissions, please use only *one* of the following methods to submit comments:

(1) *Email.* Submit comments to: *CBP_PRA@cbp.dhs.gov.*

(2) *Mail.* Submit written comments to CBP Paperwork Reduction Act Officer, U.S. Customs and Border Protection, Office of Trade, Regulations and Rulings, Economic Impact Analysis Branch, 90 K Street NE, 10th Floor, Washington, DC 20229–1177.

FOR FURTHER INFORMATION CONTACT: Requests for additional PRA information should be directed to Seth Renkema, Chief, Economic Impact Analysis Branch, U.S. Customs and Border Protection, Office of Trade, Regulations and Rulings, 90 K Street NE, 10th Floor, Washington, DC 20229–1177, Telephone number 202–325–0056 or via email *CBP_PRA@cbp.dhs.gov.* Please note that the contact information provided here is solely for questions regarding this notice. Individuals seeking information about other CBP programs should contact the CBP National Customer Service Center at 877–227–5511, (TTY) 1–800–877–8339, or CBP website at *https://www.cbp.gov/.*

SUPPLEMENTARY INFORMATION: CBP invites the general public and other Federal agencies to comment on the proposed and/or continuing information collections pursuant to the Paperwork Reduction Act of 1995 (44 U.S.C. 3501 *et seq.*). This process is conducted in accordance with 5 CFR 1320.8. Written comments and suggestions from the public and affected agencies should address one or more of the following four points: (1) Whether the proposed collection of information is necessary for the proper performance of the functions of the agency, including whether the information will have practical utility; (2) the accuracy of the agency's estimate of the burden of the proposed collection of information, including the validity of the methodology and assumptions used; (3) suggestions to enhance the quality, utility, and clarity of the information to be collected; and (4) suggestions to minimize the burden of the collection of information on those who are to respond, including through the use of appropriate automated, electronic, mechanical, or other technological collection techniques or other forms of information technology, *e.g.,* permitting electronic submission of responses. The comments that are submitted will be summarized and included in the request for approval. All comments will become a matter of public record.

Overview of This Information Collection

Title: Certificate of Registration.

OMB Number: 1651–0010.

Form Number: CBP Forms 4455 and 4457.

Abstract: Travelers who do not have proof of prior possession in the United States of foreign made articles and who do not want to be assessed duty on these items can register them prior to departing on travel. In order to register these articles, the traveler completes CBP Form 4457, *Certificate of Registration for Personal Effects Taken Abroad,* and presents it at the port at the time of export. This form must be signed in the presence of a CBP official after verification of the description of the articles is completed. CBP Form 4457 is accessible at: *http://www.cbp.gov/newsroom/publications/forms?title=4457&=Apply.*

CBP Form 4455, *Certificate of Registration,* is used primarily for the registration, examination, and supervised lading of commercial shipments of articles exported for repair, alteration, or processing, which will subsequently be returned to the United States either duty free or at a reduced duty rate. CBP Form 4455 is accessible at: *http://www.cbp.gov/newsroom/publications/forms?title=4455&=Apply.*

CBP Forms 4455 and 4457 are provided for by 19 CFR 10.8, 10.9, 10.68, 148.1, 148.8, 148.32 and 148.37.

Action: CBP proposes to extend the expiration date of this information collection with no change to the burden hours or to the information collected on CBP Forms 4455 and 4457.

Type of Review: Extension (without change).

Affected Public: Businesses.

CBP Form 4455

Estimated Number of Respondents: 60,000.

Estimated Number of Annual Responses per Respondent: 1.

Estimated Number of Total Annual Responses: 60,000.

Estimated Time per Response: 10 minutes.