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. 2021–03234 Filed 2–17–21; 8:45 am]

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2011–N–0275]

Agency Information Collection Activities; Submission for Office of Management and Budget Review; Comment Request; Certification To Accompany Drug, Biological Product, and Device Applications or Submissions

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is announcing that a proposed collection of information has been submitted to the Office of Management and Budget (OMB) for review and clearance under the Paperwork Reduction Act of 1995.

DATES: Submit written comments (including recommendations) on the collection of information by March 22, 2021.

ADDRESSES: To ensure that comments on the information collection are received, OMB recommends that written comments be submitted to *https://www.reginfo.gov/public/do/PRAMain.* Find this particular information collection by selecting ''Currently under Review—Open for Public Comments'' or by using the search function. The OMB control number for this information collection is 0910–0616. Also include the FDA docket number found in brackets in the heading of this document.

FOR FURTHER INFORMATION CONTACT: JonnaLynn Capezzuto, Office of Operations, Food and Drug Administration, Three White Flint North, 10A–12M, 11601 Landsdown St., North Bethesda, MD 20852, 301–796–3794, *PRAStaff@fda.hhs.gov.*

SUPPLEMENTARY INFORMATION: In compliance with 44 U.S.C. 3507, FDA has submitted the following proposed collection of information to OMB for review and clearance.

Certification To Accompany Drug, Biological Product, and Device Applications or Submissions (Form FDA 3674)

OMB Control Number 0910–0616—Extension

The information required under section 402(j)(5)(B) of the Public Health Service Act (PHS Act) (42 U.S.C. 282(j)(5)(B)) is submitted in the form of a certification, Form FDA 3674, which accompanies applications and submissions currently submitted to FDA and already approved by OMB. The OMB control numbers and expiration dates for those applications and submissions are: 21 CFR parts 312 and 314 (human drugs), OMB control number 0910–0014, expiring March 31, 2022, and OMB control number 0910–0001, expiring March 31, 2021; 21 CFR parts 312 and 601 (biological products), OMB control number 0910–0014, expiring March 31, 2022, and OMB control number 0910–0338, expiring February 28, 2023; 21 CFR parts 807 and 814 (devices), OMB control number 0910–0120, expiring June 30, 2020, and OMB control number 0910–0231, expiring March 31, 2023.

Title VIII of the Food and Drug Administration Amendments Act of 2007 (FDAAA) (Pub. L. 110–85) amended the PHS Act by adding section 402(j). The provisions broadened the scope of clinical trials subject to submitting information and required additional information to be submitted to the clinical trials databank (*https://clinicaltrials.gov/*) (FDA has verified the website address, but FDA is not responsible for any subsequent changes to the website after this document publishes in the **Federal Register**) previously established by the National Institutes of Health (NIH)/National Library of Medicine. This includes expanded information on applicable clinical trials and summary information on the results of certain clinical trials. The provisions include responsibilities for FDA as well as several amendments to the Federal Food, Drug, and Cosmetic Act (FD&C Act).

One provision, section 402(j)(5)(B) of the PHS Act, requires that a certification accompany human drug, biological, and device product submissions made to FDA. Specifically, at the time of submission of an application under sections 505, 515, or 520(m) of the FD&C Act (21 U.S.C. 355, 360e, or 360j(m)), or under section 351 of the PHS Act (42 U.S.C. 262), or submission of a report under section 510(k) of the FD&C Act (21 U.S.C. 360(k)), such application or submission must be accompanied by a certification, Form FDA 3674, that all applicable requirements of section 402(j) of the PHS Act have been met. Where available, such certification must include the appropriate National Clinical Trial (NCT) numbers that are assigned upon submission of required information to the NIH databank at *https://clinicaltrials.gov/.*

The proposed extension of the collection of information is necessary to satisfy the previously mentioned statutory requirement. The importance of obtaining these data relates to adherence to the legal requirements for submissions to the clinical trials registry and results data bank and ensuring that individuals and organizations submitting applications or reports to FDA under the listed provisions of the FD&C Act or the PHS Act adhere to the appropriate legal and regulatory requirements for certifying to having complied with those requirements. The failure to submit the certification required by section 402(j)(5)(B) of the PHS Act, and the knowing submission of a false certification, are both prohibited acts under section 301 of the FD&C Act (21 U.S.C. 331). Violations are subject to civil money penalties. Form FDA 3674 provides a convenient mechanism for sponsors/applicants/submitters to satisfy the certification requirements of the statutory provision.

To assist sponsors/applicants/submitters in understanding the statutory requirements associated with Form FDA 3674, we have provided a guidance available at: *https://www.fda.gov/RegulatoryInformation/Guidances/ucm125335.htm.* This guidance recommends the applications and submissions FDA considers should be accompanied by the certification form, Form FDA 3674. The applications and submissions identified in the guidance are reflected in the burden analysis. FDA last updated this guidance in 2017.

Investigational New Drug Applications. FDA's Center for Drug Evaluation and Research (CDER) received 1,661 investigational new drug applications (INDs) and 11,328 clinical protocol IND amendments in calendar year (CY) 2019. CDER anticipates that IND and clinical protocol amendment submission rates will remain at or near this level in the near future.

FDA's Center for Biologics Evaluation and Research (CBER) received 639 new INDs and 581 clinical protocol IND amendments in CY 2019. CBER anticipates that IND and clinical protocol amendment submission rates will remain at or near this level in the near future. The estimated total number of submissions (new INDs and new

protocol submissions) subject to mandatory certification requirements under section 402(j)(5)(B) of the PHS Act, is 12,989 for CDER plus 1,220 for CBER, or 14,209 submissions per year. The minutes per response is the estimated number of minutes that a respondent would spend preparing the information to be submitted to FDA under section 402(j)(5)(B) of the PHS Act, including the time it takes to enter the necessary information on the form.

Based on its experience with current submissions, FDA estimates that approximately 15 minutes on average would be needed per response for certifications that accompany IND applications and clinical protocol amendment submissions. It is assumed that most submissions to investigational applications will reference only a few protocols for which the sponsor/applicant/submitter has obtained a NCT number from *https://clinicaltrials.gov/* prior to making the submission to FDA. It is also assumed that the sponsor/applicant/submitter has electronic capabilities allowing them to retrieve the information necessary to complete the form in an efficient manner.

Marketing Applications/Submissions. In CY 2019, CDER and CBER received 252 new drug applications (NDA)/biologics license applications (BLA)/premarket approvals (PMA)/resubmissions and 701 NDA/BLA amendments for which certifications are needed. CDER and CBER received 295 efficacy supplements/resubmissions to previously approved NDAs/BLAs in CY 2019. CDER and CBER received 893 abbreviated new drug applications (ANDAs) in CY 2019. CDER received 765 bioequivalence amendments/supplements in CY 2019. CDER and CBER anticipate that new drug/biologic applications/resubmissions and efficacy supplement submission rates will remain at or near this level in the near future.

FDA's Center for Devices and Radiological Health (CDRH) received a total of 324 new applications for PMA, 510(k) submissions containing clinical information, PMA supplements, applications for humanitarian device exemptions (HDE) and amendments in CY 2019. CDRH anticipates that application, amendment, supplement, and annual report submission rates will remain at or near this level in the near future.

Based on its experience reviewing NDAs, BLAs, PMAs, HDEs, 510(k)s, and ANDAs and experience with current submissions of Form FDA 3674, FDA estimates that approximately 45 minutes on average would be needed per response for certifications which accompany NDA, BLA, PMA, HDE, 510(k), and ANDA marketing applications and submissions. It is assumed that the sponsor/applicant/submitter has electronic capabilities allowing them to retrieve the information necessary to complete the form in an efficient manner.

In the **Federal Register** of May 14, 2020 (85 FR 28955), FDA published a 60-day notice requesting public comment on the proposed collection of information. No comments were received.

FDA estimates the burden of this collection of information as follows:

TABLE 1—ESTIMATED ANNUAL REPORTING BURDEN [1]

FDA; center activity	Number of respondents (investigational applications)	Number of respondents (marketing applications)	Number of responses per respondent	Total annual responses	Average burden per response	Total hours
CDER						
New Applications (IND)	1,661		1	1,661	0.25 (15 minutes)	415
Clinical Protocol Amendments (IND)	11,328		1	11,328	0.25 (15 minutes)	2,832
New Marketing Applications/Resubmissions (NDA/BLA).		220	1	220	0.75 (45 minutes)	165
Clinical Amendments to Marketing Applications.		701	1	701	0.75 (45 minutes)	526
Efficacy Supplements/Resubmissions		257	1	257	0.75 (45 minutes)	193
Abbreviated New Drug Applications (ANDA)—Original Applications.		892	1	892	0.75 (45 minutes)	669
ANDA Bioequivalence Supplements/Amendments.		765	1	765	0.75 (45 minutes)	573
CBER						
New Applications (IND)	639		1	639	0.25 (15 minutes)	160
Clinical Protocol Amendments (IND)	581		1	581	0.25 (15 minutes)	145
New Marketing Applications/Resubmissions (NDA/BLA/PMA).		32	1	32	0.75 (45 minutes)	24
Clinical Amendments to Marketing Applications.		0	1	0	0.75 (45 minutes)	0
Efficacy Supplements/Resubmissions (BLA only).		38	1	38	0.75 (45 minutes)	28
Abbreviated New Drug Applications (ANDA)—Original Applications.		1	1	1	0.75 (45 minutes)	1
ANDA Bioequivalence Supplements/Amendments.		0	1	0	0.75 (45 minutes)	0
CDRH						
New Marketing Applications (includes PMAs, HDEs, Supplements and 510(k)s expected to contain clinical data).		324	1	324	0.75 (45 minutes)	243
Total						5,974

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

Dated: February 11, 2021.

Lauren K. Roth,

Acting Principal Associate Commissioner for Policy.

[FR Doc. 2021–03243 Filed 2–17–21; 8:45 am]

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Centers for Disease Control and Prevention

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, and the Determination of the Director, Strategic Business Initiatives Unit, Office of the Chief Operating Officer, CDC, pursuant to Public Law 92–463. 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: Disease, Disability, and Injury Prevention and Control Special Emphasis Panel (SEP)—SIP21–007, Epilepsy Incidence and Etiology: Important Information for Public Health Prevention and Health Promotion in the US Community.

Date: May 11, 2021.

Time: 11:00 a.m.–6:00 p.m., EDT.

Place: Teleconference.

Agenda: To review and evaluate grant applications.

For Further Information Contact: Jaya Raman, Ph.D., Scientific Review Officer, National Center for Chronic Disease Prevention and Health Promotion, CDC, 4770 Buford Highway, Mailstop S107–8, Atlanta, Georgia 30341, Telephone (770) 488–6511, *JRaman@cdc.gov*.

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. 2021–03232 Filed 2–17–21; 8:45 am]

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Centers for Medicare & Medicaid Services

[Document Identifier: CMS–10733]

Agency Information Collection Activities: Submission for OMB Review; Comment Request

AGENCY: Centers for Medicare & Medicaid Services, Health and Human Services (HHS).

ACTION: Notice.

SUMMARY: The Centers for Medicare & Medicaid Services (CMS) is announcing an opportunity for the public to comment on CMS' intention to collect information from the public. Under the Paperwork Reduction Act of 1995 (PRA), federal agencies are required to publish notice in the **Federal Register** concerning each proposed collection of information, including each proposed extension or reinstatement of an existing collection of information, and to allow a second opportunity for public comment on the notice. Interested persons are invited to send comments regarding the burden estimate or any other aspect of this collection of information, including the necessity and utility of the proposed information collection for the proper performance of the agency's functions, the accuracy of the estimated burden, ways to enhance the quality, utility, and clarity of the information to be collected, and the use of automated collection techniques or other forms of information technology to minimize the information collection burden.

DATES: Comments on the collection(s) of information must be received by the OMB desk officer by *March 22, 2021.*

ADDRESSES: Written comments and recommendations for the proposed information collection should be sent within 30 days of publication of this notice to *www.reginfo.gov/public/do/PRAMain.* Find this particular information collection by selecting ''Currently under 30-day Review—Open for Public Comments'' or by using the search function.

To obtain copies of a supporting statement and any related forms for the proposed collection(s) summarized in this notice, you may make your request using one of following:

1. Access CMS' website address at website address at: *https://www.cms.gov/Regulations-and-Guidance/Legislation/PaperworkReductionActof1995/PRA-Listing.html*

FOR FURTHER INFORMATION CONTACT: William Parham at (410) 786–4669.

SUPPLEMENTARY INFORMATION: Under the Paperwork Reduction Act of 1995 (PRA) (44 U.S.C. 3501–3520), federal agencies must obtain approval from the Office of Management and Budget (OMB) for each collection of information they conduct or sponsor. The term ''collection of information'' is defined in 44 U.S.C. 3502(3) and 5 CFR 1320.3(c) and includes agency requests or requirements that members of the public submit reports, keep records, or provide information to a third party. Section 3506(c)(2)(A) of the PRA (44 U.S.C. 3506(c)(2)(A)) requires federal agencies to publish a 30-day notice in the **Federal Register** concerning each proposed collection of information, including each proposed extension or reinstatement of an existing collection of information, before submitting the collection to OMB for approval. To comply with this requirement, CMS is publishing this notice that summarizes the following proposed collection(s) of information for public comment:

1. *Type of Information Collection Request:* New collection (Request for a new OMB control number); *Title of Information Collection:* Data Management Plan Self-Attestation Questionnaire (DMP SAQ); *Use:* The Privacy Act of 1974 allows for discretionary releases of data maintained in Privacy Act protected systems of records under § 552a(b) (Conditions of Disclosure). The mandate to account for disclosures of data under the Privacy Act is found at § 552a(c)(Accounting of Certain Disclosures). This section states that certain information must be maintained regarding disclosures made by each agency. This information is: Date, Nature, Purpose, and Name/Address of Recipient. Section 552a(e) sets the overall Agency Requirements that each agency must meet in order to maintain records under the Privacy Act. The Data Use Agreement (DUA) form is needed as part of the review of each CMS data request to ensure compliance with the requirements of the Privacy Act for disclosures that contain PII.