sensitive information is being collected or used in furtherance of the research. Historically, a CoC generally protected a researcher from being compelled in a legal proceeding (such as by subpoena or court order) to disclose identifiable and sensitive information about the research participant, created or compiled for purposes of the human subject research. The Cures Act broadened the protections of the statutory provision by affirmatively prohibiting holders of CoCs from disclosing such information unless a specific exception applies.

The Cures Act simplified certain aspects of the issuance of CoCs by requiring that CoCs be issued for federally funded human subject research that collects or uses identifiable, sensitive information (referred to in the guidance as mandatory CoCs). For non-federally funded research, issuance of CoCs is not required but may be issued at the discretion of FDA (referred to in the guidance as discretionary CoCs) when the study involves a product subject to FDA's jurisdiction and regulatory authority. FDA intends to continue receiving such requests and will issue discretionary CoCs as appropriate. This guidance is intended to provide information on how to request a discretionary CoC, the statutory requirements for requesting such a CoC, and the statutory responsibilities associated with possessing a CoC. Although the mandatory CoC and the discretionary CoC are issued under different processes, the protections afforded by the issuance of either CoC are identical and the statutory responsibilities are applicable to both.

This guidance finalizes the draft guidance entitled ''Certificates of Confidentiality; Guidance for Sponsors, Sponsor-Investigators, Researchers, Industry, and Food and Drug Administration Staff'' issued on November 25, 2019 (84 FR 64906). FDA considered comments received on the draft guidance as the guidance was finalized. Changes from the draft to the final guidance were made to address requests for definitional and process clarity.

This guidance is being issued consistent with FDA's good guidance practices regulation (21 CFR 10.115). The guidance represents the current thinking of FDA on ''Certificates of Confidentiality; Guidance for Sponsors, Sponsor-Investigators, Researchers, Industry, and Food and Drug Administration Staff.'' 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.

II. Paperwork Reduction Act of 1995

While this guidance contains no collection of information, it does refer to a previously approved FDA collection of information. Therefore, clearance by the Office of Management and Budget (OMB) under the Paperwork Reduction Act of 1995 (PRA) (44 U.S.C. 3501–3521) is not required. The previously approved collections of information are subject to review by OMB under the PRA. The collections of information have been approved under OMB control number 0910–0130.

III. Electronic Access

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

Dated: November 9, 2020.

Lauren K. Roth,

Acting Principal Associate Commissioner for Policy.

[FR Doc. 2020–25238 Filed 11–13–20; 8:45 am]

BILLING CODE 4164–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2020–N–2030]

Agency Information Collection Activities; Proposed Collection; Comment Request; Application for Food and Drug Administration Approval To Market a New Drug

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA or Agency) is announcing an opportunity for public comment on the proposed collection of certain information by the Agency. 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 of an existing collection of information, and to allow 60 days for public comment in response to the notice. This notice solicits comments on information collection associated with applications for FDA approval to market a new drug.

DATES: Submit either electronic or written comments on the collection of information by January 15, 2021.

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 January 15, 2021. The *https://www.regulations.gov* electronic filing system will accept comments until 11:59 p.m. Eastern Time at the end of January 15, 2021. 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–2020–N–2030 for ''Agency Information Collection Activities; Proposed Collection; Comment Request; Application for FDA Approval To

Market a New Drug.'' 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 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.govinfo.gov/content/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, 240–402–7500.

FOR FURTHER INFORMATION CONTACT: Domini Bean, Office of Operations, Food and Drug Administration, Three White Flint North, 10A–12M, 11601 Landsdown St., North Bethesda, MD 20852, 301–796–5733, *PRAStaff@fda.hhs.gov.*

SUPPLEMENTARY INFORMATION: Under the PRA (44 U.S.C. 3501–3521), Federal Agencies must obtain approval from the Office of Management and Budget (OMB) for each collection of information they conduct or sponsor. ''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 provide a 60-day notice in the **Federal Register** concerning each proposed collection of information, including each proposed extension of an existing collection of information, before submitting the collection to OMB for approval. To comply with this requirement, FDA is publishing notice of the proposed collection of information set forth in this document.

With respect to the following collection of information, FDA invites comments on these topics: (1) Whether the proposed collection of information is necessary for the proper performance of FDA's functions, including whether the information will have practical utility; (2) the accuracy of FDA's estimate of the burden of the proposed collection of information, including the validity of the methodology and assumptions used; (3) ways to enhance the quality, utility, and clarity of the information to be collected; and (4) ways to minimize the burden of the collection of information on respondents, including through the use of automated collection techniques, when appropriate, and other forms of information technology.

Application for FDA Approval To Market a New Drug;

OMB Control No. 0910–0001—Revision

This information collection supports FDA regulations. Under § 505(a) of the Federal Food, Drug, and Cosmetic Act (FD&C Act) (21 U.S.C. 355(a)), a new drug may not be commercially marketed in the United States unless an approval of an application filed with FDA under § 505(b) or (j) of the FD&C Act is effective with respect to such drug. We have issued regulations in part 314 (21 CFR part 314) to govern procedures and requirements for applications submitted in accordance with section 505. The regulations in subpart A (§§ 314.1 through 314.3) set forth general provisions, while regulations in subparts B and C (§§ 314.50 through 314.99) set forth content and format requirements for new drug applications (NDAs) and abbreviated new drug applications (ANDAs) respectively. The regulations include requirements for the submission of specific data elements along with patent information, pediatric use information, supplements and amendments, proposed labeling, and specific postmarketing reports. Respondents to the information collection are sponsors of these applications.

To assist respondents to the information collection we have developed the following forms:

- Form FDA 0356h (and instructions): Application to Market a New or Abbreviated New Drug or Biologic for Human Use;
- Form FDA 2252 (and instructions): Transmittal of Annual Reports for Drugs and Biologics For Human Use (§ 314.81);
- Form FDA 2253 (and instructions): Transmittal of Advertisements and Promotional Labeling For Drugs and Biologics For Human Use; and
- Forms FDA 3331/3331a: Field Alert Report and Instruction;
- Forms FDA 3542 and 3542a and Instructions: Patent Information Submitted *Upon and After Approval* of an NDA Supplement; Patent Information Submitted *With the Filing* of an NDA, Amendment, or Supplement;
- New Draft Form FDA 3898 and Instruction: Drug Master File.

Individuals requesting printed forms are instructed to contact the FDA Forms Manager by email at *formsmanager@OC.FDA.GOV.* Certain fees may be applicable.

Regulations in subpart D (§§ 314.100 through 314.170) explain Agency actions on applications and set forth timeframes for FDA review. We are revising the information collection to include provisions established through our Agency user fee programs, most recently authorized under the FDA Reauthorization Act of 2017. These provisions pertain to review transparency, communications with FDA, dispute resolution, drug safety enhancements, and the allocation of Agency resources to align with these program objectives as agreed to with our stakeholders and set forth in our ''Performance Goals for Fiscal Years 2018–2022'' Commitment Letters, which are available from our website at *https://www.fda.gov* along with more information about FDA user fee programs.

Information collection pertaining to hearing and other administrative proceedings covered in 21 CFR subpart E are approved under OMB control no. 0910–0191. Unless otherwise noted, information collection pertaining to postmarket safety reporting and associated recordkeeping is approved under OMB control nos. 0910–0230, 0910–0291, and 0910–0645.

Included among the miscellaneous provisions in subpart G (§§ 314.410–314.445), § 314.420 covers information to include in drug master files (DMFs). To assist respondents to this information collection we have prepared templates and resources available from our website at *www.fda.gov/drugs/forms-submission-requirements/drug-master-files-dmfs.* As noted above, we have developed new Form FDA 3898 and accompanying instructions on submitting DMFs in accordance with the applicable regulations. In accordance with § 314.445, we also develop Agency guidance documents to assist respondents in complying with provisions in part 314. These guidance documents are issued consistent with our good guidance practice regulations at § 10.115. To search available FDA guidance documents, visit our website at *https://www.fda.gov/regulatory-information/search-fda-guidance-documents.* Finally, applications submitted in accordance with subpart H (§§ 314.500 through 314.560) pertain to accelerated approval of new drugs for serious or life-threatening illness, and submissions in subpart I (§§ 314.600 through 314.650) pertain to approval of new drugs when human efficacy studies are not ethical or feasible. The regulations provide for the submission of specific data elements along with promotional material.

We use the information collection to approve drugs shown to be safe and effective and to implement effective public health monitoring systems. We also use product approval and related patent and exclusivity information to publish the ''Approved Drug Products with Therapeutic Equivalence Evaluations'' list (the Orange Book). More information regarding the Orange book is available from our website at *www.fda.gov/drugs/drug-approvals-and-databases/approved-drug-products-therapeutic-equivalence-evaluations-orange-book.*

We estimate the burden for this collection of information as follows:

TABLE 1—ESTIMATED ANNUAL REPORTING BURDEN

21 CFR section	Number of respondents	Number of responses per respondent	Total annual responses	Average burden per response (in hours)	Total hours
SUBPART B					
314.50(a)–(l)—Content and format of a 505(b)(1) or 505(b)(2) application.	121	1.15	139	1,921	267,019
314.50(i)(1)—patent certifications Form FDA 3542	281	2.875	808	10	8,080
Form FDA 3542a	310	2.084	646	15	9,690
314.50(i)(6) amended patent certifications	17	1	17	2	34
314.52(a), (b), and (e)—NDAs—notice of noninfringement of patent certification.	15	3	45	15	675
314.52(c)—Noninfringement of patent certification notice content.	22	3	66	0.33 (20 minutes)	22
314.53(f)(1)—Correction of patent information errors by persons other than the NDA holder.	24	1	24	10	240
314.53(f)(2)—Correction of patent information errors by the NDA holder.	28	1.4	39	1	39
314.60—Amendments to unapproved NDA, supplement or resubmission.	256	8.23	2,106	80	168,480
314.60(f)—patent certifications for unapproved applications.	6	1	6	2	12
314.65—Withdrawal of unapproved applications	14	1.21	17	2	34
314.70 and 314.71—Supplements and other changes to approved application.	492	6.57	3,232	150	484,800
314.72—Changes of ownership of NDAs	67	1.45	97	2	194
314.81—Other postmarketing reports 314.81(b)(1) [3331 and 3331a field alert reports and followups].	484	20.3	9,834	8	78,672
314.81(b)(2)[2252]—Annual reports	626	4.9	3,066	40	122,640
314.81(b)(2)[2253]—Promotional labeling	331	141.3	46,782	2	93,564
SUBPART C					
314.94(a)and(d)—ANDA content	229	4.3	987	480	473,760
314.94(a)(12)(viii) amended patent certifications before approval of ANDA.	153	1	153	2	306
314.95(c)—Non-infringement of patents (ANDAs)	400	3	1,200	0.33 (20 minutes)	400
314.96(a)(1)—Amendments to unapproved ANDAs	451	36.2	16,311	80	1,304,880
314.96(c) amendment for pharmaceutical equivalent to a listed drug other than RLD.	1	1	1	300	300
314.96(d)—patent certification requirements	100	1	100	2	200
314.97—Supplements and other changes to ANDAs	361	22.8	8,237	80	658,960
314.97(b) Supplements to ANDA for pharmaceutical equivalent to a listed drug other than RLD.	1	1	1	300	300
314.99(a)—ANDA Applicants: Withdrawal of unapproved ANDAs.	77	2.3	177	2	354
314.99(a)—ANDA Transfer of ownership	135	1.24	167	2	334
SUBPART D					
314.101(a)—NDA or ANDA filing over protest	1	1	1	0.5 (30 minutes)	0.5

TABLE 1—ESTIMATED ANNUAL REPORTING BURDEN—Continued

21 CFR section	Number of respondents	Number of responses per respondent	Total annual responses	Average burden per response (in hours)	Total hours
314.107(e)—notification of court actions or written consent to approval.	247	2	494	0.5 (30 minutes) ..	247
SUBPART G, H, I					
314.420—drug master files [FDA 3938]—original amendments.	36	27.2	981	61	59,841
DMFs—technical, administrative, REMS)	2,946	11.4	33,590	8	268,720
DMFs—annual reports	2,946	3.33	9,834	4	39,336
314.550—Promotional material and subpart H applications.	55	11.6	640	120	76,800
Total	.....	.....	.....	.....	4,118,933.5

Our estimated burden for the information collection reflects a decrease. We attribute this adjustment to improved operational efficiencies with regard to Agency data systems and digital submission processes.

Dated: November 10, 2020.

Lauren K. Roth,

Acting Principal Associate Commissioner for Policy.

[FR Doc. 2020–25239 Filed 11–13–20; 8:45 am]

BILLING CODE 4164–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Health Resources and Services Administration

Agency Information Collection Activities: Submission to OMB for Review and Approval; Public Comment Request; Information Collection Request Title: Coronavirus 2019 (COVID–19) Data Report OMB No. 0906–0053—Extension

AGENCY: Health Resources and Services Administration (HRSA), Department of Health and Human Services.

ACTION: Notice.

SUMMARY: In compliance with of the Paperwork Reduction Act of 1995, HRSA has submitted an Information Collection Request (ICR) to the Office of Management and Budget (OMB) for review and approval. Comments submitted during the first public review of this ICR will be provided to OMB. OMB will accept further comments from the public during the review and approval period. OMB may act on HRSA's ICR only after the 30 day comment period for this notice has closed.

DATES: Comments on this ICR should be received no later than December 16, 2020.

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 Review—Open for Public Comments'' or by using the search function.

FOR FURTHER INFORMATION CONTACT: To request a copy of the clearance requests submitted to OMB for review, email Lisa Wright-Solomon, the HRSA Information Collection Clearance Officer at *paperwork@hrsa.gov* or call (301) 443–1984.

SUPPLEMENTARY INFORMATION:

Information Collection Request Title: Coronavirus 2019 Data Report OMB No. 0906–0053—Extension.

Abstract: HRSA's Ryan White HIV/AIDS Program (RWHAP) funds and coordinates with cities, states, and local clinics/community-based organizations to deliver efficient and effective HIV care, treatment, and support to low income people with HIV. Nearly two-thirds of clients (patients) live at or below 100 percent of the federal poverty level and approximately three-quarters of RWHAP clients are racial/ethnic minorities. Since 1990, the RWHAP has developed a comprehensive system of safety net providers who deliver high quality direct health care and support services to over half a million people with HIV—more than 50 percent of all people with diagnosed HIV in the United States.

FY 2020 Coronavirus Aid, Relief, and Economic Security (CARES) Act

On March 27, 2020, the President signed into law the ''Coronavirus Aid, Relief, and Economic Security Act'' (CARES Act). The CARES Act appropriated $90 million to HRSA's RWHAP to prevent, prepare for, and respond to coronavirus disease 2019 (COVID–19). This funding supports 581 RWHAP Parts A, B, C, D and F recipients across the country, including city/county health departments, state health departments, health clinics, community-based organizations, and AIDS Education and Training Centers in their efforts to help prevent or minimize the impact of COVID–19 on RWHAP clients. The award provides RWHAP recipients the flexibility to meet evolving COVID–19 needs in their respective communities, including extending operational hours, increasing staffing hours, purchasing additional equipment, enhancing workforce training and capacity development, and providing critical services to people with HIV during this pandemic, such as home-delivered meals, emergency housing, and transportation.

HRSA's HIV/AIDS Bureau identified a new data collection need to support HRSA's requirement to monitor and report quarterly to the Secretary of HHS the COVID–19 activities conducted with the CARES Act funding. The COVID–19 Data Report (CDR) module will collect information on the types of services provided and number of people served for the treatment or prevention of COVID–19 among RWHAP clients (and immediate household members in limited circumstances). This module will be required for all providers (*e.g.,* recipients or subrecipients) who receive CARES Act RWHAP funding.

A 60-day notice published in the **Federal Register** on September 1, 2020, vol. 85, No. 170; pp. 54390–54391. There were no public comments.

Need and Proposed Use of the Information: HRSA proposes that service providers who receive CARES Act RWHAP funding report aggregate