name of the technology for which they will be presenting.

Registration for attendees not presenting at the meeting is not required.

IV. Collection of Information

This document does not impose information collection requirements, that is, reporting, recordkeeping, or third-party disclosure requirements. Consequently, there is no need for review by the Office of Management and Budget under the authority of the Paperwork Reduction Act of 1995 (44 U.S.C. chapter 35).

The Administrator of the Centers for Medicare & Medicaid Services (CMS), Chiquita Brooks-LaSure, having reviewed and approved this document, authorizes Chyana Woodyard, who is the Federal Register Liaison, to electronically sign this document for purposes of publication in the **Federal Register**.

Chyana Woodyard,

Federal Register Liaison, Centers for Medicare & Medicaid Services.

[FR Doc. 2023–21186 Filed 9–27–23; 8:45 am]

BILLING CODE 4120–01–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, Agency, or we) 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 or generic drug.

DATES: Either electronic or written comments on the collection of information must be submitted by November 27, 2023.

ADDRESSES: You may submit comments as follows. Please note that late, untimely filed comments will not be considered. The *https://www.regulations.gov* electronic filing system will accept comments until 11:59 p.m. Eastern Time at the end of November 27, 2023. Comments received by mail/hand delivery/courier (for written/paper submissions) will be considered timely if they are received 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 ''Application for Food and Drug Administration 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.

Applications for FDA Approval To Market a New Drug—21 CFR Part 314

OMB Control Number 0910–0001—Revision

This information collection supports implementation of statutory and regulatory authorities that govern new drugs. Under section 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 section 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) that establish procedures and requirements for applications submitted in accordance with section 505 of the FD&C Act. 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 (PMRs). Respondents to the information collection are sponsors of these applications.

Regulations in subpart D (§§ 314.100 through 314.170) explain Agency actions on applications and set forth timeframes for FDA review. The information collection includes provisions established through our Agency user fee programs, most recently authorized under the FDA User Fee Reauthorization Act of 2022. These provisions pertain to performance goals, expedited programs, 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 ''User Fee Performance Goals for Fiscal Years 2023–2027'' Commitment Letters, which are available from our website at *https://www.fda.gov* along with more information about specific FDA user fee programs.

Included among the provisions in subpart G (§§ 314.410 through 314.445), § 314.420 covers information to include in drug master files (DMFs). To assist respondents to this information collection we have prepared templates, guidance, forms, and resources available from our website at *https://www.fda.gov/drugs/forms-submission-requirements/drug-master-files-dmfs*. We have developed Form FDA 3938 and accompanying instructions on submitting DMFs in accordance with the applicable regulations. We are revising Form FDA 3898 and the accompanying instructions to allow for multiple selections of submission types and to clarify the number of digits to be entered for the holder and establishment registration numbers.

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 21 CFR 10.115. To search available FDA guidance documents, visit our website at *https://www.fda.gov/regulatory-information/search-fda-guidance-documents*.

Applications submitted in accordance with subpart H (§§ 314.500 through 314.560) pertain to accelerated approval of new drugs for serious or life-threatening illnesses.

Information collection and associated burden for the submissions in subpart I (§§ 314.600 through 314.650) pertain to approval of certain new drugs when human efficacy studies are not ethical or feasible. The regulations provide for the submission of specific data elements, animal studies of safety and efficacy to establish likely clinical benefit in humans and upon approval of the drug product, additional requirements and/or restrictions to ensure safe use of the product. Additional PMRs, safety reporting, and promotional material as well as requirements for withdrawal of these human drug applications, and FDA termination of requirements for these human drug applications are included in §§ 314.620 through 314.650. The estimated burden for these human drug applications is included in the reported submissions and burden under general human drug applications, § 314.50, and other specific regulations in the table for human drug application requirements in general.

Finally, we are also revising the collection to include the submission of information pursuant to the CREATES Act (enacted as part of the Further Consolidated Appropriations Act of 2020 (21 U.S.C. 355–1(1) and 355–2)). Under the CREATES Act, developers of potential drug and biological products are enabled to use the CREATES pathway to obtain samples of brand products that are needed to support their applications. Relevant products include those submitted in generic drug applications under section 505(j) of the FD&C Act and NDAs submitted under section 505(b)(2) of the FD&C Act, and biosimilar products submitted under section 351(k) of the Public Health Service Act as amended by the Biologics Price Competition and Innovation Act of 2009. One of the requirements for using the CREATES pathway for products that are subject to a Risk Evaluation and Mitigation Strategy with elements to assure safe use is to obtain a Covered Product Authorization (CPA) from FDA (21 U.S.C. 355–2(b)(2)). New information collection burden for CPAs for new drug and biologic applications is included in the burden table below.

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

- *Form FDA 356h (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
- *Forms FDA 3331/3331a (and instructions):* Field Alert Reports
- *Form FDA 3542 (and instructions):* Patent Information Submitted Upon and After Approval of an NDA or Supplement
- *FDA 3542a (and instructions):* Patent Information Submitted with the Filing of an NDA, Amendment, or Supplement
- *Revised Form FDA 3938 (and revised instruction):* DMF submission
- *Form FDA 3988 (and instruction):* Transmittal of post marketing requirements (PMR)/postmarketing commitments (PMC) submissions for Drugs and Biologics
- *Form FDA 3989 (and instruction):* Transmittal of PMR/PMC Annual Status Report Information

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

Information collection pertaining to hearings and other administrative proceedings covered in 21 CFR subpart E are approved under OMB control number 0910–0191. Unless otherwise noted, information collection pertaining to postmarket safety reporting and associated recordkeeping is approved under OMB control numbers 0910–0230 and 0910–0291.

Respondents for this information collection include pharmaceutical industry entities who contribute to the preparation and marketing of pharmaceutical products to the U.S. public.

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

TABLE 1—ESTIMATED ANNUAL REPORTING BURDEN [1]

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 ..	85	1.42	121	1,921	232,441
314.50(i)(1)—Patent certifications: Form FDA 3542	170	6.55	1,113	10	11,130
314.50(i)(1)—Patent certifications: Form FDA 3542a	1	1	1	15	15
314.50(i)(6)—Amended patent certifications	73	4.33	316	2	632
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.	7	1.14	8	10	80
314.53(f)(2)—Correction of patent information errors by the NDA holder	8	1.13	9	1	9
314.60—Amendments to unapproved NDA, supplement or resubmission ...	269	7.22	1,942	80	155,360
314.60(f)—Patent certifications for unapproved applications	6	1	6	2	12
314.65—Withdrawal of unapproved applications	20	1.05	21	2	42
314.70 and 314.71—Supplements and other changes to approved application.	501	5.13	2,570	150	385,500
314.72—Changes of ownership of NDAs	73	1.67	122	2	244
314.81—Other PMR 314.81(b)(1) [3331 and 3331a field alert reports and follow-ups].	532	18.5	9,834	8	78,672
314.81(b)(2)—[Form FDA 2252]—Annual reports	692	4.46	3,090	40	123,600
314.81(b)(2)—[Form FDA 2253]—Promotional labeling	310	121	37,508	2	75,016
314.81(b)(2)(vii) Form FDA 3988—PMR/PMC	737	0.87	642	24	15,408
314.81(b)(2)(vii) Form FDA 3989—PMR/PMC Annual Status Report for Drugs and Biologics.	737	0.29	216	24	5,184
Subpart C					
314.93—Suitability Petitions	16	1.31	21	24	504
314.94(a) and (d)—ANDA content	213	4.02	857	480	411,360
314.94(a)(12)(viii)—Amended patent certifications before approval of ANDA.	153	1	153	2	306
314.95(c)—Noninfringement of patents (ANDAs)	209	3	627	16	10,032
314.96(a)(1)—Amendments to unapproved ANDAs	514	26.55	13,647	80	1,091,760
314.96(c)—Amendment for pharmaceutical equivalent to a listed drug other than reference listed drug.	1	1	1	300	300
314.96(d)—Patent certification requirements	100	1	100	2	200
314.97—Supplements and other changes to ANDAs	343	17.57	6,027	80	482,160
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	58	2.41	140	2	280
314.99(a)—ANDA Transfer of ownership	137	1.24	170	2	340
Subpart D					
314.101(a)—NDA or ANDA filing over protest	1	1	1	0.5 (30 minutes)	0.5
314.107(e)—notification of court actions or written consent to approval	54	1.98	107	0.5 (30 minutes)	53.5
Subparts G, H, and I					
314.420—Drug Master Files—original Form FDA 3938	491	2.05	1,005	61	61,305
DMF Amendments—Technical	1,335	18.71	24,979	8	199,832
DMF Amendments—REMS	2	1	2	8	16
DM Amendments—administrative	1,024	9.67	6,851	6	41,106
DMFs—Annual reports	1,836	6.04	11,097	4	44,388
314.550—Promotional material and subpart H applications [2]	69	5.84	403	120	48,360

TABLE 1—ESTIMATED ANNUAL REPORTING BURDEN [1]—Continued

21 CFR section	Number of respondents	Number of responses per respondent	Total annual responses	Average burden per response (in hours)	Total hours
CPA Requests for NDA/Biologics License Application Products	1	1	1	5	5
Total					3,476,650

[1] Total burden hours have been rounded.
[2] We have included burden attendant to subpart H applications activity in our estimate of burden associated with § 314.50.

Our estimated burden for the information collection reflects an overall decrease of 642,293.5 hours. The reporting period for this information collection renewal includes the 3 years of the COVID–19 pandemic. We attribute this adjustment to a decrease in the number of submissions received during the public health emergency. We anticipate that the numbers of submissions to FDA will return to pre-pandemic levels as economic activity recovers. We also attribute a portion of the burden adjustment to improved operational efficiencies with regard to Agency data systems and digital submission processes.

Dated: September 23, 2023.

Lauren K. Roth,

Associate Commissioner for Policy.

[FR Doc. 2023–21256 Filed 9–27–23; 8:45 am]

BILLING CODE 4164–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2023–N–3847]

Agency Information Collection Activities: Proposed Collection; Comment Request; Adverse Experience Reporting for Licensed Biological Products; and General Records

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 the proposed extension of the collection of information applicable to required adverse experience reporting for licensed biological products, and general records associated with the manufacture and distribution of biological products.

DATES: Submit either electronic or written comments on the collection of information by November 27, 2023.

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 27, 2023. The *https://www.regulations.gov* electronic filing system will accept comments until 11:59 p.m. Eastern Time at the end of November 27, 2023 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–2023–N–3847 for ''Adverse Experience Reporting for Licensed Biological Products; and General Records.'' 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