

# DEPARTMENT OF HEALTH AND HUMAN SERVICES

## Food and Drug Administration

[Docket No. FDA-2020-N-2030]

### Agency Information Collection Activities; Submission for Office of Management and Budget Review; 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) 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 18, 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 0910-0001. Also include the FDA docket number found in brackets in the heading of this document.

**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, [PRASStaff@fda.hhs.gov](mailto:PRASStaff@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.

### Application for FDA Approval To Market a New Drug; OMB Control No. 0910-0001—Revision

This information collection supports FDA regulations. 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) 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](mailto: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 to 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](https://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 <https://www.fda.gov/drugs/drug-approvals-and-databases/approved-drug-products-therapeutic-equivalence-evaluations-orange-book>.

In the **Federal Register** of November 16, 2020 (85 FR 73057), we published a 60-day notice requesting public

comment on the proposed collection of information. No comments were received and we have therefore made no adjustments to our estimate, which is 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
<b>Subpart B</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
<b>Subpart C</b>					
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
<b>Subpart D</b>					
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 .....	247	2	494	0.5 (30 minutes)	247
<b>Subparts G, H, and I</b>					
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: February 8, 2021.

**Lauren K. Roth,**

*Acting Principal Associate Commissioner for Policy.*

[FR Doc. 2021-03023 Filed 2-12-21; 8:45 am]

**BILLING CODE 4164-01-P**

## DEPARTMENT OF HEALTH AND HUMAN SERVICES

### Food and Drug Administration

[Docket No. FDA-2021-N-0134]

#### Joint Meeting of the Arthritis Advisory Committee and the Drug Safety and Risk Management Advisory Committee; Notice of Meeting; Establishment of a Public Docket; Request for Comments

**AGENCY:** Food and Drug Administration, HHS.

**ACTION:** Notice; establishment of a public docket; request for comments.

**SUMMARY:** The Food and Drug Administration (FDA) announces a forthcoming public advisory committee meeting of the Arthritis Advisory Committee and the Drug Safety and Risk Management Advisory Committee. The general function of the committees is to provide advice and recommendations to FDA on regulatory issues. The meeting will be open to the public. FDA is establishing a docket for public comment on this document.

**DATES:** The meeting will be held on March 24, 2021, from 9 a.m. to 4:30 p.m. Eastern Time and March 25, 2021, from 10 a.m. to 1 p.m. Eastern Time.

**ADDRESSES:** Please note that due to the impact of this COVID-19 pandemic, all meeting participants will be joining this advisory committee meeting via an online teleconferencing platform. Answers to commonly asked questions about FDA advisory committee meetings may be accessed at: <https://www.fda.gov/AdvisoryCommittees/AboutAdvisoryCommittees/ucm408555.htm>.

FDA is establishing a docket for public comment on this meeting. The docket number is FDA-2021-N-0134. The docket will close on March 23, 2021. Submit either electronic or written comments on this public meeting by March 23, 2021. Please note that late, untimely filed comments will not be considered. Electronic comments

must be submitted on or before March 23, 2021. The <https://www.regulations.gov> electronic filing system will accept comments until 11:59 p.m. Eastern Time at the end of March 23, 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.

Comments received on or before March 10, 2021, will be provided to the committees. Comments received after that date will be taken into consideration by FDA. In the event that the meeting is cancelled, FDA will continue to evaluate any relevant applications or information, and consider any comments submitted to the docket, as appropriate.

You may submit comments as follows:

#### 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-2021-N-0134 for "Joint Meeting of the Arthritis Advisory Committee and the Drug Safety and Risk Management Advisory Committee; Notice of Meeting; Establishment of a Public Docket; Request for Comments." 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." FDA 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 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 the 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:** Moon Hee V. Choi, Center for Drug