



## 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 [INSERT DATE 30 DAYS AFTER DATE OF PUBLICATION IN THE *FEDERAL REGISTER*].

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

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](http://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	No. of Respondents	No. of Responses per Respondent	Total Annual Responses	Average Burden per Response (in hours)	Total Hours
<b>Subpart B</b>					
314.50(a)-(1)--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	1	1	1	300	300

equivalent to a listed drug other than RLD					
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
314.107(e)--notification of court actions or written consent to approval	247	2	494	0.5 (30 minutes)	247
Subparts G, H, and 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: February 8, 2021.

Lauren K. Roth,

Acting Principal Associate Commissioner for Policy.

