

Our estimated burden for the information collection reflects an overall decrease of 113 hours despite a corresponding increase of 1,650 responses. We attribute this adjustment to an increase in the number of submissions we received over the last few years but a decrease in the amount of time spent entering data due to IT efficiencies that have been built into the MedSun reporting system to reduce data entry by user facilities.

Dated: May 6, 2020.

Lowell J. Schiller,

Principal Associate Commissioner for Policy.

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA-2011-N-0275]

Agency Information Collection Activities; Proposed Collection; 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 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 requirements for certain FDA applications or submissions to be accompanied by a certification, Form FDA 3674, to ensure all applicable statutory requirements have been met.

DATES: Submit either electronic or written comments on the collection of information by July 13, 2020.

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 July 13, 2020. The <https://www.regulations.gov> electronic filing system will accept comments until midnight Eastern Time at the end of July 13, 2020. 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-2011-N-0275 for "Agency Information Collection Activities; Proposed Collection; Comment Request; Certification to Accompany Drug, Biological Product, and Device Applications or Submissions." 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.

- **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.

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, PRASStaff@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.

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 (the 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.

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

TABLE 1—ESTIMATED ANNUAL REPORTING BURDEN¹

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: May 6, 2020.

Lowell J. Schiller,

Principal Associate Commissioner for Policy.

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2013–N–0618]

Agency Information Collection Activities; Submission for Office of Management and Budget Review; Comment Request; Electronic Products

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 June 15, 2020.

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 0910–0025. 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, 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.

Electronic Products

OMB Control Number 0910–0025—Extension

Under sections 532 through 542 of the Federal Food, Drug, and Cosmetic Act (FD&C Act) (21 U.S.C. 360ii through

360ss), FDA has the responsibility to protect the public from unnecessary exposure of radiation from electronic products. The regulations issued under these authorities are listed in Title 21 of the Code of Federal Regulations, chapter I, subchapter J, parts 1000 through 1050 (21 CFR parts 1000 through 1050).

Section 532 of the FD&C Act directs the Secretary of Health and Human Services (the Secretary), to establish and carry out an electronic product radiation control program, including the development, issuance, and administration of performance standards to control the emission of electronic product radiation from electronic products. The program is designed to protect the public health and safety from electronic radiation, and the FD&C Act authorizes the Secretary to procure (by negotiation or otherwise) electronic products for research and testing purposes and to sell or otherwise dispose of such products. Section 534(g) of the FD&C Act directs the Secretary to review and evaluate industry testing programs on a continuing basis; and section 535(e) and (f) of the FD&C Act directs the Secretary to immediately notify manufacturers of, and ensure correction of, radiation defects or noncompliance with performance standards. Section 537(b) of the FD&C Act contains the authority to require manufacturers of electronic products to establish and maintain records (including testing records), make reports, and provide information to determine whether the manufacturer has acted in compliance.

The regulations under parts 1002 through 1010 specify reports to be provided by manufacturers and distributors to FDA and records to be maintained in the event of an investigation of a safety concern or a product recall. FDA conducts laboratory compliance testing of products covered by regulations for product standards in parts 1020, 1030, 1040, and 1050.

FDA details product-specific performance standards that specify information to be supplied with the product or require specific reports. The information collections are either specifically called for in the FD&C Act or were developed to aid the Agency in performing its obligations under the FD&C Act. The data reported to FDA and the records maintained are used by FDA and the industry to make decisions and take actions that protect the public from radiation hazards presented by electronic products. This information refers to the identification of, location of, operational characteristics of, quality assurance programs for, and problem identification and correction of

electronic products. The data provided to users and others are intended to encourage actions to reduce or eliminate radiation exposures.

FDA uses the following forms to aid respondents in the submission of information for this information collection:

- Form FDA 2579 “Report of Assembly of a Diagnostic X-Ray System”
- Form FDA 2767 “Notice of Availability of Sample Electronic Product”
- Form FDA 2877 “Declaration for Imported Electronic Products Subject to Radiation Control Standards”
- Form FDA 3649 “Accidental Radiation Occurrence (ARO)”
- Form FDA 3626 “A Guide for the Submission of Initial Reports on Diagnostic X-Ray Systems and Their Major Components”
- Form FDA 3627 “Diagnostic X-Ray CT [Computed Tomography] Products Radiation Safety Report”
- Form FDA 3628 “General Annual Report (Includes Medical, Analytical, and Industrial X-Ray Products Annual Report)”
- Form FDA 3629 “Abbreviated Report”
- Form FDA 3630 “Guide for Preparing Product Reports on Sunlamps and Sunlamp Products”
- Form FDA 3631 “Guide for Preparing Annual Reports on Radiation Safety Testing of Sunlamp Products”
- Form FDA 3632 “Guide for Preparing Product Reports on Lasers and Products Containing Lasers”
- Form FDA 3633 “General Variance Request”
- Form FDA 3634 “Television Products Annual Report”
- Form FDA 3635 “Laser Light Show Notification”
- Form FDA 3636 “Guide for Preparing Annual Reports on Radiation Safety Testing of Laser and Laser Light Show Products”
- Form FDA 3637 “Laser Original Equipment Manufacturer (OEM) Report”
- Form FDA 3638 “Guide for Filing Annual Reports for X-Ray Components and Systems”
- Form FDA 3639 “Guidance for the Submission of Cabinet X-Ray System Reports Pursuant to 21 CFR 1020.40”
- Form FDA 3640 “Reporting Guide for Laser Light Shows and Displays”
- Form FDA 3147 “Application for a Variance From 21 CFR 1040.11(c) for a Laser Light Show, Display, or Device”
- Form FDA 3641 “Cabinet X-Ray Annual Report”