not licensed by the owner of the patent engaged in the manufacture, use, or sale of the drug product (§ 314.53(b)). Such patents claim the drug substance (active ingredient), drug product (formulation and composition), or method(s) of use. If a patent is issued after the application is filed with FDA, but before the application is approved, the applicant must submit the required patent information on Form FDA 3542a as an amendment to the application, within 30 days of the date of issuance of the patent.

Within 30 days after the date of approval of an application, the applicant must submit Form FDA 3542 for each patent that claims the drug substance (active ingredient), drug product (formulation and composition), or approved method(s) of use of the product for listing in the Orange Book. For patents issued after the date of approval of an application, Form FDA 3542 must be submitted within 30 days of the date of issuance of the patent. In addition, an NDA applicant's amendment to the description of the approved method(s) of use claimed by the patent must be submitted within the timeframes described in §§ 314.50(i)(4) and 314.94(a)(12)(vi) (21 CFR 314.94(a)(12)(vi)) to be considered timely filed.

Description of Respondents: The respondents to this collection of information are NDA applicants for original applications, amendments, or supplements to an NDA or NDA applicants submitting information on a patent after approval of the NDA or supplement.

The final rule ''Abbreviated New Drug Applications and 505(b)(2) Applications,'' implemented portions of Title XI of the Medicare Prescription Drug, Improvement and Modernization Act of 2003 (MMA) and also amended certain regulations regarding 505(b)(2) applications and abbreviated new drug applications (ANDAs) to facilitate compliance with and efficient enforcement of the FD&C Act (81 FR 69580; October 6, 2016) (MMA Final Rule). In the MMA Final Rule, we estimated that the burden for Form FDA 3542a would be reduced by 5 hours from 20 hours to 15 hours per response; we further estimated that the burden for Form FDA 3542 would increase by 5 hours from 5 to 10 hours per response. The burden hours were adjusted to shift a portion of the time spent preparing Form FDA 3542a to the estimated time spent preparing Form FDA 3542 to reflect the additional time spent by the NDA holder to develop the use code in accordance with FDA's revised regulations and identify the specific section(s) and subsection(s) of labeling that describe the specific approved method of use claimed by the patent. The burden hours of Forms FDA 3542 and 3542a in this notice reflect the reporting burden approved by OMB under OMB control number 0910–0786 in connection with the MMA Final Rule. The effective date of the MMA Final Rule was December 5, 2016. Consequently, the annual reporting burden estimated below is based on calendar year 2017 data only to reflect the post-MMA Final Rule regulatory requirements and reporting burden estimate.

FDA requests OMB approval for the following information collection:

TABLE 1—ESTIMATED ANNUAL REPORTING BURDEN

21 CFR 314.50 (citing § 314.53)	Number of respondents	Number of responses per respondent	Total annual responses CY 2017	Hours per response	Total hours
Form FDA 3542	281	2.875	808	10	8,080
Form FDA 3542a	310	2.084	646	15	9,690
Total					17,770

[1] There are no capital costs or operating and maintenance costs associated with this collection of information.

For purposes of this analysis, we consider the number of respondents to correspond to the number of NDAs and efficacy supplements submitted or approved, respectively, in calendar year (CY) 2017, even though one company may submit or hold multiple NDAs or may submit multiple efficacy supplements to one or more NDAs. FDA approved 127 NDAs and 154 efficacy supplements to NDAs during CY 2017, which corresponds to 281 respondents. Based on information provided by the Orange Book staff, approximately 623 patent records were created in CY 2017, which corresponds to an estimated 513 Forms FDA 3542 submitted to FDA for listing of patent information in the Orange Book for NDAs approved in CY 2017 and an estimated 110 Forms FDA 3542 submitted to FDA for listing of patent information in the Orange Book for efficacy supplements approved in CY 2017. In addition, based on information provided by the Orange Book staff and FDA's experience, we estimate that approximately 185 Forms FDA 3542 were submitted in CY 2017 to modify patent information, which results in an estimated total of 808 Forms FDA 3542 submitted in CY 2017.

During calendar year 2017, FDA received 141 original NDAs and 169 efficacy supplements to NDAs for FDA review and approval. We estimate that applicants submitted approximately 405 Forms FDA 3542a for the original NDAs submitted during CY 2017. In addition, based on a review of the submitted efficacy supplements, FDA received 241 Forms FDA 3542a with the efficacy supplements received during CY 2017, resulting in a total of 646 Forms FDA 3542a submitted in CY 2017.

Our estimated burden for the information collection reflects an overall decrease. We attribute this adjustment to a decrease in the number of duplicative submissions of Forms FDA 3542a and 3542 in connection with supplements submitted or approved after the effective date of the MMA final rule, and improved data collection from upgraded data software tools.

Dated: May 14, 2019.

Lowell J. Schiller,

Principal Associate Commissioner for Policy.

[FR Doc. 2019–10421 Filed 5–17–19; 8:45 am]

BILLING CODE 4164–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2013–N–0377]

Agency Information Collection Activities; Submission for Office of Management and Budget Review; Comment Request; Tobacco Health Document Submission

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA or Agency) 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: Fax written comments on the collection of information by June 19, 2019.

ADDRESSES: To ensure that comments on the information collection are received, OMB recommends that written comments be faxed to the Office of Information and Regulatory Affairs, OMB, Attn: FDA Desk Officer, Fax: 202–395–7285, or emailed to *oira_submission@omb.eop.gov.* All comments should be identified with the OMB control number 0910–0654. Also include the FDA docket number found in brackets in the heading of this document.

FOR FURTHER INFORMATION CONTACT: Amber Sanford, Office of Operations, Food and Drug Administration, Three White Flint North, 10A–12M, 11601 Landsdown St., North Bethesda, MD 20852, 301–796–8867, *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.

Tobacco Health Document Submission

OMB Control Number 0910–0654—Extension

On June 22, 2009, the President signed the Family Smoking Prevention and Tobacco Control Act (Tobacco Control Act) (Pub. L. 111–31) into law. The Tobacco Control Act amended the Federal Food, Drug, and Cosmetic Act (FD&C Act) by adding, among other things, a new chapter granting FDA important authority to regulate the manufacture, marketing, and distribution of tobacco products to protect the public health generally and to reduce tobacco use by minors. Additionally, section 101 of the Tobacco Control Act amended the FD&C Act by adding, among other things, new section 904(a)(4) (21 U.S.C. 387d(a)(4)).

Section 904(a)(4) of the FD&C Act requires each tobacco product manufacturer or importer, or agent thereof, to submit all documents developed after June 22, 2009, ''that relate to health, toxicological, behavioral, or physiologic effects of current or future tobacco products, their constituents (including smoke constituents), ingredients, components, and additives'' (herein referred to as ''tobacco health documents'').

FDA announced the availability of a guidance on this collection in the **Federal Register** of April 4, 2010, (75 FR 20606) (revised December 5, 2016, (81 FR 87565) and August 10, 2017, (82 FR 37459) (extending compliance dates)) and requested health documents that were created during the period of June 23, 2009, through December 31, 2009, based on the statutory requirements. The guidance stated that information required under section 904(a)(4) of the FD&C Act must be submitted to FDA beginning December 22, 2009. However, FDA also explained that it did not intend to enforce the December 22, 2009, deadline provided that the documents were submitted by April 30, 2010, for all health documents developed between June 23, 2009, and December 31, 2009. Further, FDA stated it would publish a revised guidance specifying the timing of subsequent reporting.

FDA has been collecting the information submitted pursuant to section 904(a)(4) of the FD&C Act through a facilitative electronic form and through a paper form (Form FDA 3743) for those individuals who choose not to use the electronic method. On both forms, FDA is requesting the following information from firms that have not already reported or still have documents to report:

- Submitter identification
- Submitter type, company name, address, country, company headquarter's Dun and Bradstreet D–U–N–S number, and FDA assigned Facility Establishment Identifier number
- Submitter point of contact
- Contact name, title, position title, email, telephone, and fax
- Submission format and contents (as applicable)
- *Electronic documents:* Media type, media quantity, size of submission, quantity of documents, file type, and file software
- *Paper documents:* Quantity of documents, quantity of volumes, and quantity of boxes
- Whether or not a submission is being provided
- Confirmation statement
- Identification and signature of submitter including name, company name, address, position title, email, telephone, and Fax
- *Document categorization (as applicable):* relationship of the document or set of documents to the following:
  - Health, behavioral, toxicological, or physiological effects
  - Uniquely identified current or future tobacco product(s)
  - Category of current or future tobacco product(s)
  - Specific ingredient(s), constituent(s), component(s), or additive(s)
  - Class of ingredient(s), constituent(s), component(s), or additive(s)
- *Document readability and accessibility:* Keywords; glossary or explanation of any abbreviations, jargon, or internal (*e.g.,* code) names; special instructions for loading or compiling submission.
- *Document metadata:* Date document was created, document author(s), document recipient(s), document custodian, document title or identification number, beginning and ending Bates numbers, Bates number ranges for documents attached to a submitted email, document type, and whether the document is present in the University of California San Francisco's Truth Tobacco Documents database.

In addition to the electronic and paper forms, FDA issued guidance documents intended to assist persons making tobacco health document submissions (draft guidance: December 28, 2009 (74 FR 68629); final guidance: April 20, 2010 (75 FR 20606); revised December 5, 2016 (81 FR 87565); and August 10, 2017 (82 FR 37459) (extending compliance dates)). For further assistance, FDA is providing a technical guide, embedded hints, and a web tutorial on the electronic portal.

FDA issued a final rule on May 10, 2016 (81 FR 28973), which became effective on August 8, 2016, to deem products meeting the statutory definition of ''tobacco product'' to be subject to the FD&C Act. The FD&C Act provides FDA authority to regulate cigarettes, cigarette tobacco, roll-your-own tobacco (RYO), smokeless tobacco, and any other tobacco products that the Agency by regulation deems to be subject to the law. This final rule extends the Agency's ''tobacco product'' authorities to all other categories of products that meet the statutory definition of ''tobacco product'' in the FD&C Act, except accessories of such deemed tobacco products.

For tobacco products subject to the deeming rule, FDA understands ''current or future tobacco products'' to refer to products commercially distributed on or after August 8, 2016, or products in any stage of research or development at any time after August 8,

2016, including experimental products and developmental products intended for introduction into the market for consumer use. For cigarettes, cigarette tobacco, RYO, and smokeless tobacco, FDA understands ''current or future tobacco products'' to refer to products commercially distributed on or after June 23, 2009, or products in any stage of research or development at any time after June 23, 2009, including experimental products and developmental products intended for introduction into the market for consumer use.

All manufacturers and importers of tobacco products are now subject to the FD&C Act and are required to comply with section 904(a)(4), which requires immediate and ongoing submission of health documents developed after June 22, 2009 (the date of enactment of the Tobacco Control Act). However, FDA generally does not intend to enforce the requirement at this time with respect to all such health documents relating to the deemed tobacco products, so long as a specified set of documents, those developed between June 23, 2009, and December 31, 2009, were submitted by February 8, 2017, or in the case of small-scale deemed tobacco product manufacturers (small-scale manufacturers), by November 8, 2017 (81 FR 28974 at 29008–09). Additionally, FDA extended the compliance deadlines by an additional 6 months to May 8, 2018, for small-scale manufacturers in the areas impacted by recent natural disasters. Thereafter, FDA's compliance plan requests deemed manufacturers provide tobacco health document submissions from the specified period at least 90 days prior to the delivery for introduction into interstate commerce of tobacco products to which the health documents relate. Manufacturers or importers of cigarettes, cigarette tobacco, RYO, or smokeless tobacco products must provide all health documents developed between June 23, 2009, and December 31, 2009, at least 90 days prior to the delivery for introduction of tobacco products into interstate commerce.

In the **Federal Register** of August 23, 2018 (83 FR 42664), FDA published a 60-day notice requesting public comment on the proposed collection of information. One comment was received that was PRA related.

(Comment) FDA received one comment requesting that FDA exercise enforcement discretion by suspending the collection and utilizing the Agency's other authorities to inform regulatory decisions due to the associated burden of manufacturers to retain documents for future submission to FDA. Additionally, the commenter requests FDA to narrow the scope of the collection by defining key terms.

(Response) At this time, FDA does not intend to suspend the collection as respondents have the option to submit documents directly to FDA independent of the compliance policy. Additionally, at this time, FDA believes narrowly defining health effects could potentially exclude relevant scientific information from being retained by industry and subsequently submitted as part of future health document submissions.

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

TABLE 1—ESTIMATED ANNUAL REPORTING BURDEN [1]

Activity	Number of respondents	Number of responses per respondent	Total annual responses	Average burden per response	Total hours
Tobacco Health Document Submissions and Form FDA 3743	10	3.2	32	50	1,600

[1] There are no capital costs or operating and maintenance costs associated with this collection of information.

The number of documents received each year since the original collection period has fallen to less than 5 percent of what was received in the original collection period. FDA expects this is because documents created within the specified period should have already been submitted. The Agency bases this estimate on the total number of tobacco firms it is aware of and its experience with document production and the number of additional documents that have been reported each year since the original estimate of the reporting burden.

FDA estimates that a tobacco health document submission for cigars, pipe and waterpipe tobacco, electronic nicotine delivery systems (ENDS), and other tobacco products as required by section 904(a)(4) of the FD&C Act, will take approximately 50 hours per submission based on the existing collection that applies to tobacco products currently subject to the FD&C Act and FDA experience. To derive the number of respondents for this provision, FDA assumes that very few manufacturers or importers of deemed tobacco products, or agents thereof, would have health documents to submit. In addition to the existing 4 respondents, the Agency estimates that approximately 6 submissions (2 for cigar manufacturers, 1 for pipe and waterpipe tobacco manufacturers, 1 for other tobacco product manufacturers, 1 for tobacco importers, and 1 for importers of ENDS that are considered manufacturers) will be submitted on an annual basis for a total of 10 respondents. FDA estimates the total annual reporting burden to be 1,600 hours.

Based on a review of the information collection of our current OMB approval, we have made no adjustments to our burden estimate.

Dated: May 14, 2019.

Lowell J. Schiller,

Principal Associate Commissioner for Policy.

[FR Doc. 2019–10402 Filed 5–17–19; 8:45 am]

BILLING CODE 4164–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2014–N–1533]

Agency Information Collection Activities; Submission for Office of Management and Budget Review; Comment Request; National Panel of Tobacco Consumer Studies

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA or we) 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: Fax written comments on the collection of information by June 19, 2019.

ADDRESSES: To ensure that comments on the information collection are received,