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.gpo.gov/fdsys/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.

You may submit comments on any guidance at any time (see 21 CFR 10.115(g)(5)).

Submit written requests for single copies of this draft guidance to the Center for Tobacco Products, Food and Drug Administration, Document Control Center, Bldg. 71, Rm. G335, 10903 New Hampshire Ave., Silver Spring, MD 20993–0002. Send one self-addressed adhesive label to assist that office in processing your request or include a fax number to which the draft guidance may be sent. See the **SUPPLEMENTARY INFORMATION** section for information on electronic access to the draft guidance.

FOR FURTHER INFORMATION CONTACT: Lauren Belcher or Annette Marthaler, Center for Tobacco Products, Food and Drug Administration, 10903 New Hampshire Ave., Document Control Center, Bldg. 71, Rm. G335, 10903 New Hampshire Ave., Silver Spring, MD 20993–0002, 1–877–287–1373, email: *AskCTPRegulations@fda.hhs.gov.*

SUPPLEMENTARY INFORMATION:

I. Background

FDA is announcing the availability of a draft guidance for industry entitled ''Submission of Plans for Cigarette Packages and Cigarette Advertisements.'' The Family Smoking Prevention and Tobacco Control Act (Tobacco Control Act) (Pub. L. 111–31) was enacted on June 22, 2009, and granted FDA important new authority to regulate the manufacture, marketing, and distribution of tobacco products. The Tobacco Control Act also amended section 4 of the Federal Cigarette Labeling and Advertising Act (FCLAA) to direct FDA to issue regulations requiring each cigarette package and advertisement to bear a new textual warning label statement accompanied by color graphics depicting the negative health consequences of smoking (section 201 of the Tobacco Control Act). In enacting this legislation, Congress also provided that FDA may adjust the required warnings if FDA found that such a change would promote greater public understanding of the risks associated with the use of tobacco products (section 202 of the Tobacco Control Act). The Tobacco Control Act also modified the requirements of the FCLAA regarding the submission of cigarette plans for the random and equal display and distribution of required warnings on cigarette packaging and quarterly rotation of required warnings in cigarette advertising. It also requires that such cigarette plans be submitted to FDA for review and approval, rather than to the Federal Trade Commission.

FDA issued a proposed rule entitled ''Tobacco Products; Required Warnings for Cigarette Packages and Advertisements'' on August 16, 2019 (84 FR 42754). The proposed rule, once finalized, would specify the color graphics that must accompany the new textual warning statements and establish marketing requirements for cigarette packages and advertisements. The marketing requirements would require, among other things, submission of a cigarette plan that provides for the random and equal display and distribution of the required warnings on cigarette packaging and quarterly rotation of the required warnings in cigarette advertising, as described under section 4 of FCLAA. This draft guidance provides recommendations related to preparing and submitting those cigarette plans.

II. Significance of Draft Guidance

FDA is issuing this draft guidance consistent with FDA's good guidance practices regulation (21 CFR 10.115). The draft guidance, when finalized, will represent the current thinking of FDA regarding the submission of cigarette plans for cigarette packages and advertisements. It does not establish any rights for any person and is not binding on FDA or the public. You can use an alternative approach if it satisfies the requirements of the applicable statutes and regulations.

III. Paperwork Reduction Act of 1995

This draft guidance refers to proposed collections of information described in FDA's August 16, 2019, proposed rule on ''Tobacco Products; Required Warnings for Cigarette Packages and Advertisements'', which this draft guidance is intended to interpret. The proposed collections of information in the proposed rule are subject to review by the Office of Management and Budget (OMB) under the Paperwork Reduction Act of 1995 (PRA) (44 U.S.C. 3501–3521). As required by the PRA, FDA has published an analysis of the information collection provisions of the proposed rule (84 FR 42754 at 42787) and has submitted them for OMB approval.

IV. Electronic Access

Persons with access to the internet may obtain an electronic version of the draft guidance at either *https://www.regulations.gov* or *https://www.fda.gov/TobaccoProducts/GuidanceComplianceRegulatoryInformation/default.htm.*

Dated: December 20, 2019.

Lowell J. Schiller,

Principal Associate Commissioner for Policy.

[FR Doc. 2019–27991 Filed 12–27–19; 8:45 am]

BILLING CODE 4164–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2013–N–0804]

Agency Information Collection Activities; Proposed Collection; Comment Request; Premarket Notification

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 medical device premarket notification (510(k)).

DATES: Submit either electronic or written comments on the collection of information by February 28, 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 February 28, 2020. The *https://www.regulations.gov* electronic filing system will accept comments until 11:59 p.m. Eastern Time at the end of February 28, 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–2013–N–0804 for ''Agency Information Collection Activities; Proposed Collection; Comment Request; Premarket Notification.'' 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: 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: 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.

Premarket Notification—21 CFR Part 807, Subpart E OMB Control Number 0910–0120—Extension

Section 510(k) of the Federal Food, Drug, and Cosmetic Act (FD&C Act) (21 U.S.C. 360(k)) and the implementing regulation under part 807 (21 CFR part 807, subpart E) require a person who intends to market a medical device to submit a 510(k) submission to FDA at least 90 days before proposing to begin the introduction, or delivery for introduction into interstate commerce, for commercial distribution of a device intended for human use. Based on the information provided in the

notification, FDA must determine whether the new device is substantially equivalent to a legally marketed device, as defined in § 807.92(a)(3) (21 CFR 807.92(a)(3)). If the device is determined to be not substantially equivalent to a legally marketed device, it must have an approved premarket approval application (PMA), product development protocol, humanitarian device exemption (HDE), request for an evaluation of automatic class III designation (De Novo request), or be reclassified into class I or class II before being marketed (see OMB control numbers 0910–0231, 0910–0332, 0910–0844, and 0910–0138). FDA makes the final decision of whether a device is substantially equivalent or not substantially equivalent.

Section 807.81 states when a 510(k) is required. A 510(k) is required to be submitted by a person who is: (1) Introducing a device to the market for the first time; (2) introducing a device into commercial distribution for the first time by a person who is required to register; or (3) introducing or reintroducing a device that is significantly changed or modified in design, components, method of manufacturer, or the intended use that could affect the safety and effectiveness of the device. Section 807.87 lists the information required in each 510(k).

Form FDA 3514, a summary cover sheet form, assists respondents in categorizing administrative 510(k) information for submission to FDA. This form also assists respondents in categorizing information for other FDA medical device programs such as PMAs, investigational device exemptions, De Novo requests, HDEs, etc.

Section 204 of the Food and Drug Administration Modernization Act of 1997 (FDAMA) (Pub. L. 105–115) amended section 514 of the FD&C Act (21 U.S.C. 360d). Amended section 514 of the FD&C Act allows FDA to recognize consensus standards developed by international and national organizations for use in satisfying portions of device premarket review submissions including 510(k) or other requirements. FDA has published and updated regularly the list of recognized standards since enactment of FDAMA and has allowed 510(k) submitters to certify conformance to recognized standards to meet the requirements of § 807.87.

Under § 807.90(a)(3), inquiries regarding a 510(k) submission should be in writing and sent to one of the addresses in § 807.90(a).

Under § 807.87(h), each 510(k) submitter must include in the 510(k) either a summary of the information in the 510(k) as required by § 807.92 (510(k) summary) or a statement certifying that the submitter will make available upon request the information in the 510(k) with certain exceptions as per § 807.93 (510(k) statement).

Section 745A(b) of the FD&C Act, amended by section 207 of the FDA Reauthorization Act of 2017 (FDARA) (Pub. L. 115–52), requires that submissions for devices under section 510(k), among other submission types, be submitted in electronic format specified by FDA. In addition, in the Medical Device User Fee Amendments of 2017 (MDUFA IV) Commitment Letter from the Secretary of Health and Human Services to Congress,[1] FDA committed to developing ''electronic submission templates that will serve as guided submission preparation tools for industry to improve submission consistency and enhance efficiency in the review process.'' The Electronic Submission Template and Resource (eSTAR) is such an electronic submission template for 510(k) submissions to facilitate the preparation of submissions in electronic format.

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

TABLE 1—ESTIMATED ANNUAL REPORTING BURDEN [1]

Activity and 21 CFR part/ section	Form number	Number of respondents	Number of responses per respondent	Total annual responses	Average burden per response [2]	Total hours [2]
510(k) submission (807 subpart E).	FDA 3881	3,800	1	3,800	79.25	301,150
Summary cover sheet (807.87).	FDA 3514	1,906	1	1,906	0.5	953
Status request (807.90(a)(3)).		1	1	1	0.25	1
510(k) summary (807.92)		2,725	1	2,725	4	10,900
510(k) statement (807.93)		215	1	215	10	2,150
510(k) submission (807 subpart E)—via eSTAR.	FDA 4062	100	1	100	40	4,000
eSTAR setup—(one-time burden).		80	1	80	0.08 (5 minutes)	6
Total						319,160

[1] There are no capital costs or operating and maintenance costs associated with this collection of information.
[2] Numbers have been rounded.

Upon review of this information collection, we have made the following changes:

- We have updated the burden estimate consistent with new provisions in § 807.87(j) regarding ''Human Subject Protection; Acceptance of Data from Clinical Investigations for Medical Devices'' (83 FR 7366; February 21, 2018) (approved under OMB control number 0910–0741). Section 807.87 was amended to address requirements for 510(k) submissions supported by clinical data. For clinical investigations conducted in the United States, submitters are required to submit a statement as described in § 807.87(j)(1). For clinical investigations conducted outside the United States, submitters are required to submit the information as described in § 807.87(j)(2). Consistent with our estimate in OMB control number 0910–0741, this revision increases our burden estimate for a

[1] See 163 CONG. REC. S4729–S4736 (daily ed. August 2, 2017) (Food and Drug Administration User Fee Reauthorization), also available at *https://www.fda.gov/media/102699/download.*

510(k) submission by 15 minutes per submission.

- We corrected the burden table to include a line for the ''510(k) Summary'' under § 807.92. This section was inadvertently removed from the previous version of the information collection request (ICR).
- We are making available Form FDA 3881 ''Indications for Use'' that respondents include as part of a medical device 510(k). The information provided via the form is already approved under this ICR. The form does not ask for new information and does not bear on the underlying program or on the hour or cost burden associated with the information collection, rather it provides a fillable, 508-compliant format for respondents to use for the ''Indications for Use'' portion of their 510(k) submission.
- We updated the guidance ''Refuse to Accept Policy for 510(k)s'' to explicitly recommend providing an Acceptance Checklist in the 510(k) submission. The guidance previously provided the checklist as an example of a tool that FDA staff use when reviewing a 510(k) submission. While it was not explicitly recommended, respondents had used the example and had included it with their 510(k) submission. We believe the checklist can be a helpful tool for both reviewers and 510(k) submitters and have therefore updated the guidance to explicitly recommend inclusion of the checklist in the 510(k) submission. Because most submitters included the checklist on their own initiative and because it may simplify preparation of the 510(k), we do not believe adding the checklist to this ICR affects the overall burden for a 510(k) submission. Additionally, we have updated the checklist to include combination products, as appropriate. The estimated number of responses as updated with current data in this submission, reflects the inclusion of combination products.
- We revised and reformatted Form FDA 3514, ''CDRH Premarket Review Submission Cover Sheet,'' to improve usability and to be inclusive of most medical device product submission types. Form FDA 3514, a summary cover sheet form, assists respondents in categorizing 510(k) information for submission to FDA. This form also assists respondents in categorizing information for other FDA medical device programs. The total burden for Form FDA 3514 and for the 510(k) program is estimated in this ICR. The burden for the other medical device programs listed on Form FDA 3514 are approved under the corresponding product submission ICRs as follows: premarket approval applications (OMB control number 0910–0231), investigational device exemptions (OMB control number 0910–0078), humanitarian device exemptions (control number 0910–0332), CLIA waivers (OMB control number 0910–0598), Q-Submissions (OMB control number 0910–0756), De Novo requests (OMB control number 0910–0844), Emergency Use Authorizations (OMB control number 0910–0595), 513(g) requests (OMB control number 0910–0705); and Appeals (OMB control number 0910–0738).
- Certain revisions to Form FDA 3514, as previously described, eliminate the need for Form FDA 3654, ''Standards Data Report for 510(k)s.'' Additionally, the ability for Form FDA 3514 to be expandable for the number of standards cited will increase awareness of actual standards in a submission and how they were used on a single form (compared to including several Form FDA 3654 documents). In the rare occasions where the sponsor elects to not use Form FDA 3514 for standards, this would not have any effect on the review outcome, with regard to standards, as the form serves as a means to identify what standards are cited, how they are used, and where in the submission they are located.
- We have removed Form FDA 3541, ''Status Request.'' In practice, Form FDA 3541 is rarely used. We have adjusted the burden estimate to reflect this removal. Under § 807.90(a)(3), all inquiries regarding a premarket notification submission should be in writing and sent to one of the addresses listed in § 807.90(a).
- We have added burden estimates for the eSTAR and eSTAR setup (one-time burden). Under section 745A(b) of FD&C Act, amended by section 207 of FDARA (Pub. L. 115–52), and consistent with the MDUFA IV Commitment Letter, FDA has developed the eSTAR (eSTAR, Form FDA 4062) for 510(k) submissions to facilitate the preparation of submissions in electronic format. We expect to receive approximately 100 510(k) submissions via eSTAR per year. We estimate that eSTAR submissions will take approximately 40 hours per submission. Additionally, we've estimated a one-time setup burden of 5 minutes for approximately 80 new eSTAR users annually.

The adjustments and revisions previously mentioned have resulted in a 39,473-hour decrease in the total hour burden estimate since the last OMB approval.

Dated: December 13, 2019.

Lowell J. Schiller,

Principal Associate Commissioner for Policy.

[FR Doc. 2019–28098 Filed 12–27–19; 8:45 am]

BILLING CODE 4164–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2019–D–5743]

Importation of Certain Food and Drug Administration-Approved Human Prescription Drugs, Including Biological Products, Under Section 801(d)(1)(B) of the Federal Food, Drug, and Cosmetic Act; Draft Guidance for Industry; Availability; Correction

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice of availability; correction.

SUMMARY: This document corrects the Notice of Availability from the Food and Drug Administration (FDA, Agency, or we) announcing the availability of a draft guidance for industry entitled ''Importation of Certain FDA-Approved Human Prescription Drugs, Including Biological Products, under Section 801(d)(1)(B) of the Federal Food, Drug, and Cosmetic Act,'' which published in the **Federal Register** on Monday, December 23, 2019. This draft guidance describes procedures to obtain a National Drug Code (NDC) for an FDA-approved prescription drug that is imported into the United States in compliance with the Federal Food, Drug, and Cosmetic Act (FD&C Act), which would provide an additional avenue through which drugs could be sold at a lower cost in the U.S. market. This draft guidance is intended to address certain challenges in the private market faced by manufacturers seeking to sell their drugs at lower costs. The Notice was published with two omissions. This document corrects those omissions by republishing the Notice in its entirety to include the omitted language.

DATES: Submit either electronic or written comments on the draft guidance by February 21, 2020, to ensure that the Agency considers your comment on this draft guidance before it begins work on the final version of the guidance.

ADDRESSES: You may submit comments on any guidance at any time as follows:

Electronic Submissions

Submit electronic comments in the following way: