DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2025–N–0352]

Agency Information Collection Activities; Proposed Collection; Comment Request; Guidance for Industry on Establishing That a Tobacco Product Was Commercially Marketed in the United States as of February 15, 2007

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA or Agency) 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 Guidance for Industry on Establishing That a Tobacco Product Was Commercially Marketed in the United States as of February 15, 2007.

DATES: Either electronic or written comments on the collection of information must be submitted by August 26, 2025.

ADDRESSES: You may submit comments as follows. Please note that late, untimely filed comments will not be considered. The *https://www.regulations.gov* electronic filing system will accept comments until 11:59 p.m. Eastern Time at the end of August 26, 2025. Comments received by mail/hand delivery/courier (for written/paper submissions) will be considered timely if they are received 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–2025–N–0352 for ''Guidance for Industry on Establishing That a Tobacco Product Was Commercially Marketed in the United States as of February 15, 2007.'' 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.'' 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, 240–402–7500.

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.*

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.

Guidance for Industry on Establishing That a Tobacco Product Was Commercially Marketed in the United States as of February 15, 2007

OMB Control Number—0910–0775 Extension

This information collection supports Food and Drug Administration guidance. The Federal Food, Drug, and Cosmetic Act (FD&C Act) authorizes FDA to regulate the manufacture, marketing, and distribution of tobacco products to protect the public health generally and to reduce tobacco use by minors.

Tobacco products are governed by chapter IX of the FD&C Act (sections 900 through 920) (21 U.S.C. 387 through 387t). Section 201(rr) of the FD&C Act (21 U.S.C. 321(rr)), as amended, defines a tobacco product as any product made or derived from tobacco, or containing nicotine from any source, that is intended for human consumption, including any component, part, or accessory of a tobacco product (except for raw materials other than tobacco used in manufacturing a component, part, or accessory of a tobacco product). Section 910 of the FD&C Act sets out premarket requirements for new tobacco products. The term new tobacco product is defined as any tobacco product (including those products in test markets) that was not commercially marketed in the United States as of February 15, 2007, or any modification (including a change in design, any component, any part, or any constituent, including a smoke constituent, or in the content, delivery, or form of nicotine, or any other additive or ingredient) of a tobacco product where the modified product was commercially marketed in the United States after February 15, 2007 (section 910(a)(1) of the FD&C Act).

FDA refers to tobacco products that were commercially marketed (including those products in test markets) in the United States as of February 15, 2007, as Pre-Existing tobacco products. Pre-Existing tobacco products are not considered new tobacco products and are not subject to the premarket requirements of section 910 of the FD&C Act. The guidance document associated with this information collection provides information on how a manufacturer may establish that a tobacco product was commercially marketed in the United States as of February 15, 2007. A Pre-Existing tobacco product (except such products exclusively in test markets) may also serve as the predicate tobacco product in a section 905(j) report (intended to be used toward demonstrating substantial equivalence) for a new tobacco product (section 905(j)(1)A)(i)) of the FD&C Act.

The guidance document ''Establishing That a Tobacco Product Was Commercially Marketed in the United States as of February 15, 2007 (Revised)'' (2023) (*https://www.fda.gov/regulatory-information/search-fda-guidance-documents/establishing-tobacco-product-was-commercially-marketed-united-states-february-15-2007-revised*) recommends that the manufacturer submit information adequate to demonstrate that the tobacco product was commercially marketed in the United States as of February 15, 2007. Examples of such information may include, but are not limited to, the following: dated copies of advertisements, dated catalog pages, dated promotional material, and dated bills of lading.

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 (in hours)	Total hours
Submit evidence of commercial marketing in the United States as of February 15, 2007	500	1	500	5	2,500

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

FDA's estimate of the number of respondents is based on the fact that requesting an Agency determination of the Pre-Existing status of a tobacco product under the guidance is not required and also on the number of Pre-Existing tobacco product submissions received from 2011 to October 2024. All new tobacco products require a marketing authorization order from FDA before introducing such products in the U.S. market. If a deemed new tobacco product was on the market as of August 8, 2016, a marketing application was required to be submitted by September 9, 2020 as required by the Court, and as set forth in the Center for Tobacco Products compliance policy (see exception for premium cigars).[1] A marketing application must be submitted and receive authorization to market a new tobacco product that was not on the market as of August 8, 2016.[2] The number of hours to gather the evidence is FDA's estimate of how long it might take a manufacturer to review, gather, and submit dated information if making a request for Agency determination.

FDA further estimates it would take a manufacturer approximately 5 hours to put together this collection of evidence and to submit the package to FDA for review. FDA estimates that it would take approximately 2,500 hours annually to respond to this collection of information.

We have adjusted our burden estimate, which has resulted in a decrease to the currently approved burden. Our estimated burden for the information collection reflects an overall decrease of 2,500 hours and a corresponding decrease of 500 responses. The number of submissions FDA received to establish marketing as of February 15, 2007 has decreased and we have therefore revised the number of respondents to the information collection based on this data.

[1] Cigar Ass'n of Am. v. FDA, No. 16–cv–01460, Dkt. No. 277 (D.D.C. Aug. 9, 2023). FDA has appealed this decision. See *https://www.fda.gov/regulatory-information/search-fda-guidance-documents/enforcement-priorities-electronic-nicotine-delivery-system-ends-and-other-deemed-products-market.*

[2] See *https://www.fda.gov/tobacco-products/manufacturing/submit-tobacco-product-applications-deemed-tobacco-products#:~:text=On%20August%208%2C%202016%2C%20all,authorization%20requirements%20in%20the%20Federal.*

Dated: June 24, 2025.

Grace R. Graham,

Deputy Commissioner for Policy, Legislation, and International Affairs.

[FR Doc. 2025–11961 Filed 6–26–25; 8:45 am]

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2021–D–1158]

Cybersecurity in Medical Devices: Quality System Considerations and Content of Premarket Submissions; Guidance for Industry and Food and Drug Administration Staff; Availability

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice of availability.

SUMMARY: The Food and Drug Administration (FDA or Agency) is announcing the availability of a final guidance entitled ''Cybersecurity in Medical Devices: Quality System Considerations and Content of Premarket Submissions.'' This guidance updates the previous version of the guidance, of the same title, issued on September 27, 2023, and finalizes the draft guidance entitled ''Select Updates for the Premarket Cybersecurity Guidance: Section 524B of the FD&C Act'' issued on March 13, 2024. This guidance provides FDA's recommendations to industry regarding cybersecurity device design, labeling, and the documentation that FDA recommends be included in premarket submissions for devices with cybersecurity risk. Additionally, this guidance has been updated to identify the information FDA generally considers to be necessary for cyber devices to support obligations under the new amendments to the Federal Food, Drug, and Cosmetic Act (FD&C Act) for ensuring cybersecurity of devices.

DATES: The announcement of the guidance is published in the **Federal Register** on June 27, 2025.

ADDRESSES: You may submit either electronic or written comments on Agency guidances at any time 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–D–1158 for ''Cybersecurity in Medical Devices: Quality System Considerations and Content of Premarket Submissions.'' Received comments 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.'' 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, 240–402–7500.

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

An electronic copy of the guidance document is available for download from the internet. See the **SUPPLEMENTARY INFORMATION** section for information on electronic access to the guidance. Submit written requests for a single hard copy of the guidance document entitled ''Cybersecurity in Medical Devices: Quality System Considerations and Content of Premarket Submissions'' to the Office of Policy, Center for Devices and Radiological Health, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 66, Rm. 5441, Silver Spring, MD 20993–0002. Send one self-addressed adhesive label to assist that office in processing your request.

FOR FURTHER INFORMATION CONTACT: Suzanne Schwartz, Center for Devices and Radiological Health, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 66, Rm. 5410, Silver Spring, MD 20993–0002, 301–796–6937; or Phillip Kurs, Center for Biologics Evaluation and Research, Food and Drug Administration, 240–402–7911.

SUPPLEMENTARY INFORMATION:

I. Background

Section 3305 of the Food and Drug Omnibus Reform Act of 2022, enacted on December 29, 2022, added section 524B ''Ensuring Cybersecurity of Medical Devices'' to the FD&C Act. Under section 524B(a) of the FD&C Act