Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 71, Rm. 1232, Silver Spring, MD 20993–0002, 301–796–9025, email: *CBERVRBPAC@fda.hhs.gov,* or FDA Advisory Committee Information Line, 1–800–741–8138 (301–443–0572 in the Washington, DC area). A notice in the **Federal Register** about last-minute modifications that impact a previously announced advisory committee meeting cannot always be published quickly enough to provide timely notice. Therefore, you should always check FDA's website at *https://www.fda.gov/AdvisoryCommittees/default.htm* and scroll down to the appropriate advisory committee meeting link or call the advisory committee information line to learn about possible modifications before the meeting.

SUPPLEMENTARY INFORMATION:

Agenda: The meeting presentations will be heard, viewed, captioned, and recorded through an online teleconferencing and/or video conferencing platform. On October 9, 2025, the Committee will meet in open session to discuss and make recommendations on the following separate topics. Under Topic I, the Committee will discuss and make recommendations on the strain selection for the influenza virus vaccines for the 2026 Southern Hemisphere influenza season. Under Topic II, the Committee will discuss and make recommendations on advancing CBER's allergen standardization program.

FDA intends to make background material available to the public no later than two (2) business days before the meeting. If FDA is unable to post the background material on its website prior to the meeting, the background material will be made publicly available on FDA's website at the time of the advisory committee meeting. Background material and the link to the online teleconference and/or video conference meeting will be available at *https://www.fda.gov/AdvisoryCommittees/Calendar/default.htm.* Scroll down to the appropriate advisory committee meeting link.

The meeting will include slide presentations with audio and video components to allow the presentation of materials in a manner that most closely resembles an in-person advisory committee meeting.

Procedure: Interested persons may present data, information, or views, orally or in writing, on issues pending before the Committee. All electronic and written submissions to the Docket (see **ADDRESSES**) on or before September 30, 2025, will be provided to the Committee. Oral presentations from the public will be scheduled between approximately 8:50 a.m. and 9:20 a.m. Eastern Time for Topic I, and between approximately 12:35 p.m. and 1:05 p.m. Eastern Time for Topic II on October 9, 2025. Those individuals interested in making formal oral presentations should notify the contact person and submit a brief statement of the general nature of the evidence or arguments they wish to present, along with the names, email addresses, and direct contact phone numbers of proposed participants, and an indication of the approximate time requested to make their presentation on or before 12:00 p.m. Eastern Time on September 29, 2025. Time allotted for each presentation may be limited. If the number of registrants requesting to speak is greater than can be reasonably accommodated during the scheduled open public hearing session, FDA may conduct a lottery to determine the speakers for the scheduled open public hearing session. The contact person will notify interested persons regarding their request to speak by 6:00 p.m. Eastern Time on October 1, 2025.

For press inquiries, please contact the FDA Newsroom at *www.fda.gov/news-events/fda-newsroom.*

FDA welcomes the attendance of the public at its advisory committee meetings and will make every effort to accommodate persons with disabilities. If you require accommodations due to a disability, please contact Cicely Reese or Valerie Marshall at *CBERVRBPAC@fda.hhs.gov* (see **FOR FURTHER INFORMATION CONTACT**) at least 7 days in advance of the meeting.

FDA is committed to the orderly conduct of its advisory committee meetings. Please visit our website at *https://www.fda.gov/AdvisoryCommittees/AboutAdvisoryCommittees/ucm111462.htm* for procedures on public conduct during advisory committee meetings.

Notice of this meeting is given under the Federal Advisory Committee Act (5 U.S.C. 1001 *et seq.*). This meeting notice also serves as notice that, pursuant to 21 CFR 10.19, the requirements in 21 CFR 14.22(b), (f), and (g) relating to the location of advisory committee meetings are hereby waived to allow for this meeting to take place using an online meeting platform. This waiver is in the interest of allowing greater transparency and opportunities for public participation, in addition to convenience for advisory committee members, speakers, and guest speakers. The conditions for issuance of a waiver under 21 CFR 10.19 are met.

Grace R. Graham,

Deputy Commissioner for Policy, Legislation, and International Affairs.

[FR Doc. 2025–18185 Filed 9–18–25; 8:45 am]

BILLING CODE 4164–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2025–N–0351]

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) 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 October 20, 2025.

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 0910–0654. 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—Revision

This information collection supports FDA 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.

Section 904(a)(4) of the FD&C Act ((21 U.S.C. 387d(a)(4)) 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'' or ''health documents'').

The guidance document ''Health Document Submission Requirements for Tobacco Products (Revised)'' (2023) (*www.fda.gov/regulatory-information/search-fda-guidance-documents/tobacco-health-document-submission*) requests tobacco health document submissions from manufacturers and importers of tobacco products based on statutory requirements and compliance dates.[1] We updated the guidance to reflect revised references to current FDA websites, which we will publish upon OMB approval. As indicated in the guidance, 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 Family Smoking Prevention and Tobacco Control Act (Pub. L. 111–31)). However, FDA generally does not intend to enforce the requirement at this time with respect to all such health documents, so long as a specified set of documents, those developed between June 23, 2009, and December 31, 2009, are provided at least 90 days prior to the delivery for introduction of tobacco products into interstate commerce. Thereafter, manufacturers should preserve all health documents, including those that relate to products for further manufacturing and those developed after December 31, 2009, for future submission to FDA. All Agency guidance documents are issued in accordance with our good guidance practice regulations in 21 CFR 10.115, which provide for public comment at any time.

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. You may access the electronic and paper forms on our website, at *www.fda.gov/tobacco-products/manufacturing/submit-documents-ctp-portal* and *www.fda.gov/media/78652/download,* respectively. In addition to the electronic and paper forms, FDA issued the guidance on this collection to assist persons making tobacco health document submissions. For further assistance, FDA has provided a technical guide, embedded hints, and a web tutorial on the electronic portal via *www.fda.gov/media/78631/download?attachment, www.fda.gov/tobacco-products/manufacturing/submit-documents-ctp-portal#what%20can,* and *www.fda.gov/industry/fda-esubmitter/using-esubmitter-prepare-tobacco-product-submissions.*

In this information collection, FDA is proposing to continue its compliance plan and request all manufacturers and importers of tobacco products, if not previously submitted, at least 90 days prior to the delivery for introduction into interstate commerce. Thereafter, manufacturers should preserve all health documents, including those that relate to products for further manufacturing and those developed after December 31, 2009, for future submission to FDA.

In the **Federal Register** of June 27, 2025 (90 FR 27640), FDA published a 60-day notice requesting public comment on the proposed collection of information. Although one comment was received, it was not responsive to the four collection of information topics solicited.

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

TABLE 1—ESTIMATED ANNUAL REPORTING BURDEN

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.

Since the publication of the 60-day **Federal Register** notice, FDA discovered that we erroneously omitted the discussion of the removal of a line item from the burden chart. As such, FDA estimates that a tobacco health document submission as required by section 904(a)(4) of the FD&C Act, will take approximately 50 hours per submission based on FDA experience. To derive the number of respondents for this provision, FDA assumes that very few manufacturers or importers, or agents thereof, would have health documents to submit. We anticipate 32 document submissions will be submitted on an annual basis by 10 respondents for an average of 3.2 submissions per respondent. We anticipate that manufacturers without additional documents have already completed their notification through a single FDA Form 3743 submission. Conversely, our experience shows that manufacturers with additional documents generally make multiple submissions. FDA estimates the annual reporting burden for these manufacturers to be 1,600 hours.

FDA has adjusted its burden estimate by removing estimates of burden associated with tobacco health document submissions for NTN products because the compliance period for initial submission from NTN manufacturers has passed. This has resulted in a decrease of 200 hours and 100 respondents. With this revision, all tobacco product manufacturers are now accounted for under the single tobacco health document submissions

[1] FDA announced the availability of a guidance on this collection in the **Federal Register** on April 20, 2010 (75 FR 20606) [revised December 5, 2016 (81 FR 87565), August 10, 2017 (82 FR 37459), and March 20, 2023 (88 FR 16636)].

information collection activity listed in Table 1.

Grace R. Graham,

Deputy Commissioner for Policy, Legislation, and International Affairs.

[FR Doc. 2025–18186 Filed 9–18–25; 8:45 am]

BILLING CODE 4164–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2011–D–0164]

Safety Labeling Changes—Implementation of Section 505(o)(4) of the Federal Food, Drug, and Cosmetic Act; Draft Guidance for Industry; 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 draft guidance for industry entitled ''Safety Labeling Changes—Implementation of Section 505(o)(4) of the Federal Food, Drug, and Cosmetic Act.'' This draft guidance provides information on the implementation of the statutory provision that authorizes FDA to require application holders for certain drug and biological products to make labeling changes based on new safety information that becomes available after approval of the drug that FDA determines should be included in the labeling of the drug. This guidance is being updated and reissued in draft to, among other things, include the addition of information related to Congress' 2018 changes to the definition of *adverse drug experience* regarding reduced effectiveness and make other changes to reflect current Agency processes and procedures regarding safety labeling changes. This draft guidance revises and, when finalized, will replace the guidance for industry entitled ''Safety Labeling Changes—Implementation of Section 505(o)(4) of the FD&C Act'' issued in July 2013.

DATES: Submit either electronic or written comments on the draft guidance by November 18, 2025 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:

- *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–D–0164 for ''Safety Labeling Changes—Implementation of Section 505(o)(4) of the Federal Food, Drug, and Cosmetic Act.'' 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)).

Submit written requests for single copies of the draft guidance to the Division of Drug Information, Center for Drug Evaluation and Research, Food and Drug Administration, 10001 New Hampshire Ave., Hillandale Building, 4th Floor, Silver Spring, MD 20993–0002; or the Office of Communication, Outreach and Development, Center for Biologics Evaluation and Research, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 71, Rm. 3103 Silver Spring, MD 20993–0002. Send one self-addressed adhesive label to assist that office in processing your requests. See the **SUPPLEMENTARY INFORMATION** section for electronic access to the draft guidance document.

FOR FURTHER INFORMATION CONTACT: Kimberly Lehrfeld, Center for Drug Evaluation and Research, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 51, Rm. 6250, Silver Spring, MD 20993–0002, 301–796–3137, *Kimberly.Lehrfeld@fda.hhs.gov* or Phillip Kurs, Center for Biologics Evaluation and Research, Food and Drug Administration, 240–402–7911.

SUPPLEMENTARY INFORMATION: