guidances, BsUFA user fee rates, performance reports, and financial reports: *https://www.fda.gov/industry/fda-user-fee-programs/biosimilar-user-fee-amendments.*

The current authorization of BsUFA (BsUFA III) introduces new supplement categories, timelines, and performance goals to expedite the review of supplemental biosimilar biological product applications. It establishes new procedures and performance goals for the review of use-related risk analysis and human factors protocol submissions, aimed at advancing the development of biosimilar biological product-device combination products. To improve overall meeting management, BsUFA III modifies two meeting types (Biosimilar Initial Advisory and Type 4), creates a new meeting type (Type 2a), and provides a new follow up opportunity after meetings or written-response-only communication. The agreement introduces a regulatory science pilot program focused on advancing the development of interchangeable biosimilar biological products and improving the efficiency of biosimilar biological product development. It includes additional commitments to advance interchangeable biosimilar biological product development through publishing foundational guidances and stakeholder engagement. BsUFA III includes commitments to promote best practices in communication between FDA and sponsors during application reviews, enhance inspection communication, and provide guidance on alternative tools to assess manufacturing facilities.

BsUFA III builds on the financial enhancements included in BsUFA II to ensure optimal use of user fee resources, transparency around the use of financial resources, and management of the carryover balance. The agreement commits FDA to leveraging cloud technology to modernize the Electronic Submissions Gateway and to establish and progress a data and technology modernization strategy. A comprehensive list of the deliverables developed to meet BsUFA III commitments is available on the FDA website at *https://www.fda.gov/industry/biosimilar-user-fee-amendments/completed-bsufa-iii-deliverables.*

III. Public Meeting Information

A. Purpose and Scope of the Meeting

The public meeting's format will include presentations by FDA and other interested parties, which may include scientific and academic experts, healthcare professionals, representatives of patient and consumer advocacy groups, the biosimilar biological product industry, and the general public. FDA policy issues outside of the BsUFA program are beyond the scope of these reauthorization discussions. Accordingly, comments should focus on process enhancements and funding issues, and not on policy issues outside of the BsUFA program scope. A draft agenda and other background information for the public meeting will be posted at: *https://www.fda.gov/industry/public-meeting-reauthorization-biosimilar-user-fee-act-bsufa-12032025.*

B. Participating in the Public Meeting

Registration: To register for the public meeting, please visit the following web page: *https://bsufareauthorization.eventbrite.com/.* Please provide complete contact information for each attendee, including attendance format (in-person or virtual), name, title, affiliation, and email.

Registration is free for both in-person and virtual attendance. In-person attendance is based on space availability, with priority given to early registrants. Early registration is recommended because seating is limited; therefore, FDA may limit the number of participants from each organization. Registrants will receive confirmation when they have been accepted. If you need special accommodations due to a disability, please email *BsUFAReauthorization@fda.hhs.gov* no later than November 21, 2025, 11:59 p.m. Eastern Time.

Opportunity for Public Comment: During online registration, you may indicate if you wish to make a public comment. We will do our best to accommodate requests to make public comments. Individuals and organizations with common interests are urged to consolidate or coordinate their presentations and request time jointly. Following the close of registration, we will determine the amount of time allotted to each commenter and the approximate time each comment is to begin, and will notify participants by November 26, 2025. All requests to make a public comment during the meeting must be received via registration by November 21, 2025, 11:59 p.m. Eastern Time. No commercial or promotional material will be permitted to be presented or distributed at the public meeting.

Streaming Webcast of the Public Meeting: This public meeting will also be webcast. The webcast link for this public meeting can be found here: *https://teams.microsoft.com/l/meetup-join/19%3ameeting_MTVlZjIxZWEtZWU4YS00M2U1LWJjZjYtMjMwMjYzOTNhMTFh%40thread.v2/0?context=%7b%22Tid%22%3a%227d2fdb41-339c-4257-87f2-a665730b31fc%22%2c%22Oid%22%3a%228bdc93ee-b39c-48de-bb43-4e71da4f3d52%22%7d.*

Transcripts: Please be advised that as soon as a transcript of the public meeting is available, it will be accessible at *https://www.regulations.gov.* It may be viewed at the Dockets Management Staff (see **ADDRESSES**). A link to the transcript will also be available on the internet at *https://www.fda.gov/industry/public-meeting-reauthorization-biosimilar-user-fee-act-bsufa-12032025.*

Notice of this meeting is given pursuant to 21 U.S.C 379j–53.

Lowell M. Zeta,

Acting, Deputy Commissioner for Policy, Legislation, and International Affairs.

[FR Doc. 2025–20654 Filed 11–21–25; 8:45 am]

BILLING CODE 4164–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2025–N–0835]

Tobacco Products Scientific Advisory Committee; Notice of Meeting; Establishment of a Public Docket; Request for Comments

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice; establishment of a public docket; request for comments.

SUMMARY: The Food and Drug Administration (FDA) announces a forthcoming public advisory committee meeting of the Tobacco Products Scientific Advisory Committee (TPSAC or the Committee). The general function of the Committee is to provide advice and recommendations to FDA on regulatory issues related to tobacco products. The meeting will be open to the public. FDA is establishing a docket for public comments related to the TPSAC meeting.

DATES: The meeting will be held on January 22, 2026, from 9:00 a.m. to 4:30 p.m. Eastern Time (ET).

ADDRESSES: All meeting participants will be heard, viewed, captioned, and recorded for this advisory committee meeting via an online video conferencing platform. Answers to commonly asked questions about FDA advisory committee meetings may be

accessed at: *https://www.fda.gov/AdvisoryCommittees/default.htm.*

The online video conference meeting will be available at the following link on the day of the meeting at: *https://youtube.com/live/yrYtTTjlv8A?feature=share.*

FDA has established a docket for public comment on this meeting. The docket number is FDA–2025–N–0835. The docket will close on January 21, 2026. The *https://www.regulations.gov* electronic filing system will accept comments on this advisory committee meeting until 11:59 p.m. ET at the end of January 21, 2026. Comments received by mail/hand delivery/courier (for written/paper submissions) will be considered timely if they are received on or before that date.

Comments received on or before January 7, 2026, will be provided to the Committee. Comments received after that date will be taken into consideration by FDA but will not be considered by the Committee. FDA also reminds the public that comments directed to the application may be submitted to Docket No. FDA–2025–N–0835,[1] established on June 18, 2025.

You may submit comments 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–2025–N–0835 for ''Tobacco Products Scientific Advisory Committee; Notice of Meeting; Establishment of a Public Docket; Request for Comments.'' Received comments on the advisory committee meeting, those filed in a timely manner, 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 written/paper submissions. 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.'' FDA 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 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 the 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: Rachel Jang, PharmD, DFO, Center for Tobacco Products, Food and Drug Administration, Document Control Center, 10903 New Hampshire Ave., Bldg. 71, Silver Spring, MD 20993–0002, 1–877–287–1373, *TPSAC@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: On January 22, 2026, the Center for Tobacco Products' TPSAC will convene for one open session, during which the Committee will discuss modified risk tobacco product applications submitted by Swedish Match USA, Inc. for the following products:

- MR0000268.PD1: ZYN Cool Mint 3 mg
- MR0000268.PD2: ZYN Cool Mint 6 mg
- MR0000268.PD3: ZYN Peppermint 3 mg
- MR0000268.PD4: ZYN Peppermint 6 mg
- MR0000268.PD5: ZYN Spearmint 3 mg
- MR0000268.PD6: ZYN Spearmint 6 mg
- MR0000268.PD7: ZYN Wintergreen 3 mg
- MR0000268.PD8: ZYN Wintergreen 6 mg
- MR0000268.PD9: ZYN Citrus 3 mg
- MR0000268.PD10: ZYN Citrus 6 mg
- MR0000268.PD11: ZYN Coffee 3 mg
- MR0000268.PD12: ZYN Coffee 6 mg
- MR0000268.PD13: ZYN Cinnamon 3 mg

[1] On June 18, 2025, FDA established a docket, Docket No. FDA–2025–N–0835, for comments related to the same applications subject to this TPSAC meeting. *See* **Federal Register**:: Modified Risk Tobacco Product Application: Applications for ZYN Products Submitted by Swedish Match U.S.A., Inc. The closing date for the comment period for Docket No. FDA–2025–N–0835 will be no earlier than 180 days from the date of the **Federal Register** notice and at least 30 days from the date FDA posts the last group of application materials.

- MR0000268.PD14: ZYN Cinnamon 6 mg
- MR0000268.PD15: ZYN Smooth 3 mg [2]
- MR0000268.PD16: ZYN Smooth 6 mg [3]
- MR0000268.PD17: ZYN Chill 3 mg [4]
- MR0000268.PD18: ZYN Chill 6 mg [5]
- MR0000268.PD19: ZYN Menthol 3 mg [6]
- MR0000268.PD20: ZYN Menthol 6 mg [7]

Discussion generally will focus on evidence related to the relative health risks of the products, consumer understanding and perceptions of the applicant's proposed modified risk claim, and the potential public health impact of a modified risk marketing order.

FDA intends to make background material available to the public no later than 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 at the time of the advisory committee meeting and be posted on FDA's website after the meeting. Background material and the link to the online 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. Oral presentations from the public will be scheduled between approximately 1 p.m. and 2 p.m. ET on January 22, 2026. Those individuals interested in making formal oral presentations should notify the contact person (see **FOR FURTHER INFORMATION CONTACT**) and submit a brief statement of the general nature of the evidence or arguments they wish to present, along with their names, phone numbers, and email addresses of proposed participants, on or before 12 p.m. ET on December 31, 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 January 5, 2026.

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 Rachel Jang, PharmD, DFO (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 in conjunction with the physical meeting room (see location). 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.

Lowell M. Zeta,

Acting, Deputy Commissioner for Policy, Legislation, and International Affairs.

[FR Doc. 2025–20768 Filed 11–21–25; 8:45 am]

BILLING CODE 4164–01–P

[2] Swedish Match might also market this product as ZYN Original 3 mg.

[3] Swedish Match might also market this product as ZYN Original 6 mg.

[4] Swedish Match might also market this product as ZYN Classic 3 mg.

[5] Swedish Match might also market this product as ZYN Classic 6 mg.

[6] Swedish Match might also market this product as ZYN Fresh 3 mg.

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2025–N–1108]

Agency Information Collection Activities; Submission for Office of Management and Budget Review; Comment Request; 510(k) Third-Party Review Program

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 December 24, 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 0910–0375. Also include the FDA docket number found in brackets in the heading of this document.

FOR FURTHER INFORMATION CONTACT: Amber Barrett, 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.

Third-Party Review Program

OMB Control Number 0910–0375—Extension

Section 523 of the Federal Food, Drug, and Cosmetic Act (FD&C Act) (21 U.S.C. 360m), directs FDA to accredit persons in the private sector to review certain premarket notifications (510(k)s; see 21 U.S.C. 360(k)). Participation in the 510(k) third party (3P510k) review program by accredited persons is entirely voluntary. A third party wishing to participate will submit a