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

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2025–N–7022]

Roundtable on Premarket Tobacco Application Submissions for Electronic Nicotine Delivery Systems Products; Notice of Meeting; Establishment of a Public Docket; Request for Comments

AGENCY: Food and Drug Administration, HHS.

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

SUMMARY: The Food and Drug Administration (FDA, the Agency, or we) is announcing a roundtable discussion with small tobacco product manufacturers to solicit input on premarket tobacco product application (PMTA) submissions for electronic nicotine delivery systems (ENDS) products. The topics to be discussed will include certain components of PMTAs such as product characterization, manufacturing controls, pharmacological profile (*e.g.,* pharmacokinetic studies), studies of adult benefit (*e.g.,* longitudinal cohort/randomized controlled trial (RCT) studies), and toxicological profile (*e.g.,* estimated lifetime cancer risk). The purpose of the roundtable is to provide manufacturers an opportunity to share their experience with, and other opinions about, the premarket application process. This notice provides information on meeting participation and selection. FDA is establishing a docket for public comments related to the roundtable meeting.

DATES: The roundtable meeting will be held on February 10, 2026, 9:00 a.m. to 5 p.m., Eastern Time. Electronic or written comments on the roundtable may be submitted beginning December 29, 2025. See the **SUPPLEMENTARY INFORMATION** section for registration date and information.

ADDRESSES: The roundtable meeting will be held in the White Oak Great Room and virtually. Entrance for the roundtable panelists (non-FDA employees) is through Building 1 where routine security check procedures will be performed. For parking and security information, please refer to *https://www.fda.gov/about-fda/visitor-information.*

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 3, 2026, to be considered for the roundtable discussion. All other electronic comments must be submitted on or before March 12, 2026. The *https://www.regulations.gov* electronic filing system will accept comments until 11:59 p.m. Eastern Time at the end of March 12, 2026. Comments received by mail/hand delivery/courier (for written/paper submissions) will be considered timely if they are received on or before these dates.

The public can submit comments on the roundtable topics during the open comment period; the request for comments is not limited to small tobacco product manufacturers.

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–7022 for ''Roundtable on Premarket Tobacco Application Submissions for Electronic Nicotine Delivery Systems Products; Notice of Meeting; Establishment of a Public Docket; Request for Comments.'' Received, timely comments (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.gpo.gov/fdsys/pkg/FR-2015-09-18/pdf/2015-23389.pdf.*

Docket: For access to the docket to read 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: Daniel Gittleson, Office of Regulations, Center for Tobacco Products, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 71, Rm. G335, Silver Spring, MD 20993–0002, 1–877–287–1373, email: *CTPRegulations@fda.hhs.gov.*

SUPPLEMENTARY INFORMATION:

I. Background

Tobacco products that meet the definition of a ''new tobacco product,'' and that an applicant intends to market in the United States, including ENDS, are subject to the requirements for a PMTA set forth in section 910(b) of the Federal Food, Drug, and Cosmetic Act (FD&C Act). When reviewing PMTAs, the Agency evaluates, among other things, a tobacco product's components, ingredients, additives, constituents, design, harmful and potentially harmful constituents (HPHCs), and health risks, as well as how the product is manufactured, packaged, and labeled. After reviewing a company's PMTA, FDA determines if the application includes or lacks sufficient evidence to demonstrate that permitting the marketing of the products would be appropriate for the protection of the public health (APPH), which is the applicable legal standard required by the FD&C Act (see section 910(c) of the FD&C Act).

Through this notice, FDA announces a roundtable discussion to gather feedback from small tobacco product manufacturers (see 21 U.S.C. 387(16)) about their experience with, and other opinions about, the premarket application process. The topics to be discussed will include certain components of PMTAs such as product characterization, manufacturing controls, pharmacological profile (*e.g.,* pharmacokinetic studies), studies of adult benefit (*e.g.,* longitudinal cohort/randomized controlled trial (RCT) studies), and toxicological profile (*e.g.,* estimated lifetime cancer risk (ELCR)). FDA also is establishing a public docket to solicit comment on these topics.

II. Topics for Discussion at the Roundtable and for the Request for Comments

The purpose of the roundtable is to provide small ENDS manufacturers an opportunity to share their experience and other opinions about the premarket application process. Roundtable topics to be discussed include certain components of ENDS PMTAs, such as product characterization, manufacturing controls, pharmacological profile (*e.g.,* pharmacokinetic studies), studies of adult benefit (*e.g.,* longitudinal cohort/RCT studies), and toxicological profile (*e.g.,* ELCR).

A. Product Characterization

The foundational information necessary to evaluate the quality and consistency of a new tobacco product is based on an understanding of the product as delivered to the user. One of the critical pieces of information is a complete product listing and description, including details of the product design. Also included in ENDS product characterization is the measurement of constituents in the aerosol, including HPHCs, which provide details of a user's exposure to nicotine and other potentially harmful ingredients. This roundtable will discuss the types of information needed to fully characterize a product in an application and can cover topics including product formulation, validation of analytical measurements, and the assessment of leachables and extractables, where appropriate.

B. Manufacturing Controls

In addition to product characterization, a complete understanding of a manufacturer's internal controls and practices is important for FDA to ensure that products delivered to a user will be sufficiently similar to the products that were tested and that form the basis of our scientific assessment of nicotine and potential toxic constituent exposure from the new product. This information includes standard operating procedures (SOPs); work instructions; certificates of analysis; the linkage between label claim and actual measured nicotine delivery; and stability of new products during storage, transport, and shelf life, and these are all topics which may be covered and discussed in the roundtable.

C. Pharmacological Profile (e.g., Pharmacokinetic Studies)

One of the most important aspects of FDA's evaluation of APPH for a new tobacco product focuses on the abuse liability of the new tobacco product including the delivery and uptake of nicotine by a user of the product. Nicotine exposure typically is evaluated through clinical studies that evaluate nicotine pharmacokinetics after use of the new tobacco product. Occasionally, it is possible to bridge the findings of one ENDS product to another, thus allowing a reduction in the number of studies needed to support a product. However, the proper designs of these clinical studies for ENDS products can be complex and need to be highly developed before work is initiated. This roundtable will address criteria that could improve the quality of the clinical studies for ENDS products submitted by applicants and provide participants an opportunity to ask questions about design basics to inform their applications.

D. Studies of Adult Benefit (e.g., Longitudinal Cohort/RCT Studies)

The understanding of the potential benefits that a new ENDS tobacco product may offer to users of combusted tobacco products by switching to the new ENDS tobacco product is critical to FDA's APPH determination. Examples of population studies to assess switching include longitudinal cohort studies or randomized controlled trials of the new tobacco product with adult users. This roundtable will include a discussion of the critical considerations in the design and administration of these adult benefit studies.

E. Toxicological Profile (e.g., ELCR)

The toxicological assessment of a new tobacco product application for APPH includes a careful evaluation of critical elements of potential and actual risk posed by the use of the product. These critical elements typically include, among other topics, the hazard identification and associated risk assessment of HPHCs found in the aerosol of ENDS products and the risks associated with constituents in a new product. This roundtable will discuss approaches that an applicant could use to evaluate their products for potential risks from a genotoxicity approach (ELCR), inhalation toxicity, and HPHC exposure.

III. Participating in the Roundtable and Selection of Participants

Registration for the roundtable is open to small tobacco product manufacturers as defined in section 900(16) of the FD&C Act. The term ''small tobacco product manufacturer'' means a tobacco product manufacturer that employs fewer than 350 employees. For purposes of determining the number of employees of a manufacturer under the preceding sentence, the employees of a manufacturer are deemed to include the employees of each entity that controls, is controlled by, or is under common control with such manufacturer. For example, if a parent company owns two subsidiaries, the total number of employees would include the employees in the parent company plus the number of employees in the two subsidiaries. Additionally, registration for participation in the roundtable will be limited to 30 participants

representing manufacturers who have previously submitted an ENDS PMTA, including those with a PMTA currently pending with FDA. Final eligibility for attendance will be determined by FDA. Participants should be at a sufficiently senior level with significant scientific and/or regulatory responsibility to be knowledgeable about their company's PMTA.

Registration: Registration is free. For information on how to register for the roundtable as a panelist, please visit the following website: *https://www.fda.gov/tobacco-products/ctp-newsroom/february-10-2026-roundtable-premarket-tobacco-application-submissions-electronic-nicotine-delivery,* by January 27, 2026, 11:59 p.m. Eastern Time. Registrants should include the following information for the attendee in their request to participate in the roundtable:

- Name of proposed attendee, job title, address, email, and telephone number
- Name of company and brief company description
- How many people the company employs (including subsidiaries)
- Indicate which of the 5 topics you wish to discuss as a panel member (you may select multiple topics):

A. Product Characterization
B. Manufacturing Controls
C. Pharmacological Profile
D. Studies of Adult Benefit
E. Toxicological Profile

Registration for panelists is on a rolling basis determined by space availability, with priority given to early registrants. FDA will evaluate registrations based on the submitted information until a maximum of 30 participants have been selected for the roundtable and will then inform applicants of selection decisions. Due to time and space constraints, there is a limit of one person to represent and speak on behalf of each company. Panel registrants will receive confirmation as to whether they have been accepted. If panelist registration closes prior to the submission deadline, we will update the website to reflect that change. For persons interested in viewing the roundtable virtually, information will be provided on our website: *https://www.fda.gov/tobacco-products/ctp-newsroom/february-10-2026-roundtable-premarket-tobacco-application-submissions-electronic-nicotine-delivery.*

If you need special accommodations due to a disability, please email: *CTP-OS-ACS@fda.hhs.gov* no later than February 3, 2026.

Virtual Participation and Live Streaming of the Roundtable: This roundtable will also be available for virtual attendance. If you have been accepted to participate in the roundtable meeting as a panelist but will attend virtually, you will receive details prior to the roundtable. For non-panelist attendees interested in viewing the roundtable virtually, information will be provided on our website: *https://www.fda.gov/tobacco-products/ctp-newsroom/february-10-2026-roundtable-premarket-tobacco-application-submissions-electronic-nicotine-delivery.*

Transcripts: Please be advised that as soon as a transcript of the roundtable 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/tobacco-products/ctp-newsroom/february-10-2026-roundtable-premarket-tobacco-application-submissions-electronic-nicotine-delivery.*

Notice of this meeting is given pursuant to 21 CFR 10.65.

Lowell M. Zeta,

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

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2023–E–3236]

Determination of Regulatory Review Period for Purposes of Patent Extension; LEQEMBI

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA or the Agency) has determined the regulatory review period for LEQEMBI and is publishing this notice of that determination as required by law. FDA has made the determination because of the submission of an application to the Director of the U.S. Patent and Trademark Office (USPTO), Department of Commerce, for the extension of a patent which claims that human biological product.

DATES: Anyone with knowledge that any of the dates as published (see **SUPPLEMENTARY INFORMATION**) are incorrect must submit either electronic or written comments and ask for a redetermination by February 27, 2026. Furthermore, any interested person may petition FDA for a determination regarding whether the applicant for extension acted with due diligence during the regulatory review period by June 29, 2026. See ''Petitions'' in the **SUPPLEMENTARY INFORMATION** section for more information.

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 February 27, 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.

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'').

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- 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–