U.S. Food & Drug Administration
10903 New Hampshire Avenue
Silver Spring, MD 20993
www.fda.gov

April 17, 2026

MODIFIED RISK GRANTED ORDERS–
EXPOSURE MODIFICATION

Philip Morris Products S.A.
Attention: Sarah Amyot, Manager, US Regulatory Management
PMI US Corporate Services, Inc.
1399 New York Avenue Northwest, Suite 400
Washington, DC 20005

FDA Submission Tracking Numbers (STNs): MR0000254.PD1, MR0000254.PD3, MR0000254.PD5-MR0000254.PD7**,** see Appendix A

Dear Sarah Amyot:

We completed review of your MRTPAs[1] and are issuing modified risk granted orders for the modified risk tobacco products identified in Appendix A. Refer to Appendix B for a list of amendments and additional submissions received.[2]

Based on our review of your MRTPAs, we determined that the proposed modified risk tobacco products, as described in your applications and specified in Appendix A, as actually used by consumers, have satisfied the requirements of section 911(g)(2)(A) and (B), including that they are appropriate to promote the public health and are expected to benefit the health of the population as a whole, taking into account both users of tobacco products and persons who do not currently use tobacco products. Therefore, we authorize marketing of the tobacco products as modified risk tobacco products with the following reduced exposure information:

AVAILABLE EVIDENCE TO DATE:

- The IQOS system heats tobacco but does not burn it.
- This significantly reduces the production of harmful and potentially harmful chemicals.
- Scientific studies have shown that switching completely from conventional cigarettes to the IQOS system significantly reduces your body's exposure to harmful or potentially harmful chemicals

Under the provisions of section 911, you may introduce or deliver for introduction into interstate commerce the modified risk tobacco products, in accordance with these exposure modification orders. Under section 911(g)(2)(C)(ii), this order is conditioned on your agreement to conduct postmarket surveillance and studies (PMSS) in accordance with a protocol approved by FDA and to submit the results of such PMSS annually. See Appendix C for information on required PMSS. This order also includes requests related to other record retention and reporting, as outlined in this order,

[1] Modified Risk Tobacco Product Applications (MRTPAs) submitted under section 911(d) of the Federal Food, Drug, and Cosmetic Act (FD&C Act).
[2] Your amendment of August 4, 2025, requested removal of the Surgeon General's warnings. To provide additional information on the process of removing the Surgeon General's warnings, FDA intends to send a separate General Correspondence Letter to PMP S.A.

including appendices.

These modified risk orders are effective for five years from the issue date of this letter. We recommend you submit a renewal at least 365 days prior to the end of your effective timeframe. Your renewal may cross-reference your MRTPAs that are subject to these orders.

The requirements in these exposure modification orders are intended to help ensure that your modified risk tobacco products will continue to satisfy the requirements of section 911(g)(2)(A) and (B), e.g. that "the scientific evidence that is available without conducting long-term epidemiological studies demonstrates that a measurable and substantial reduction in morbidity or mortality among individual tobacco users is reasonably likely in subsequent studies" 911(g)(2)(A)(iv). However, compliance with these requirements alone is not a guarantee that the marketing of the tobacco products will continue to comply with the requirements of section 911, particularly if, despite these measures, there is a significant increase in youth initiation or initiation by non-users, for example. FDA will continue to monitor the marketing of your modified risk tobacco products and their impact on the population.

This order authorizing the marketing of these modified risk products does not mean we "approved" the modified risk tobacco products specified in Appendix A; therefore, you may not make any express or implied statement or representation directed to consumers that conveys, or misleads, or would mislead consumers into believing, among other things, that the modified risk tobacco products specified in Appendix A are "approved" by FDA (see Section 301(tt) of the FD&C Act).

These modified risk tobacco product's exposure modification orders under 911(g)(2) are subject to withdrawal as described in section 911(j) of the FD&C Act.

The modified risk tobacco products specified in Appendix A are subject to the requirements of the associated April 30, 2019, and December 7, 2020, PMTA orders and appendices.

We remind you that the modified risk tobacco products specified in Appendix A are subject to the requirements of the FD&C Act and its implementing regulations. It is your responsibility to ensure the tobacco products specified in Appendix A comply with all applicable statutory and regulatory requirements. FDA will monitor your compliance with all applicable statutes and regulations.

In accordance with 40 CFR 1506.6, we will make your Environmental Assessment (EA) publicly available.

We encourage you to submit all regulatory correspondence electronically via the CTP Portal[3,4] using eSubmitter.[5] Alternatively, submissions may be mailed to:

Food and Drug Administration
Center for Tobacco Products
Document Control Center (DCC)
Building 71, Room G335
10903 New Hampshire Avenue
Silver Spring, MD 20993-0002

The CTP Portal and FDA's Electronic Submission Gateway (ESG) are generally available 24 hours a day, seven days a week; if the upload is successful, submissions are considered received by DCC on the day of upload. Submissions delivered to DCC by courier or physical mail will be considered timely if received during delivery hours on or before the due date;[6] if the due date falls on a weekend or holiday, the delivery must be received on or before the preceding business day. We are unable to accept regulatory submissions by e-mail.

If you have any questions, please contact Anab Kemal, M.S., Regulatory Health Project Manager, at (301) 796-1260 or Anab.Kemal@fda.hhs.gov.

If you have any questions regarding postmarket activities for the tobacco products subject of these orders, please contact Chad Burger, Director, Division of Product Compliance, at CTP-OCE-Postmarket@fda.hhs.gov.

Sincerely,

Digitally signed by Benjamin Apelberg -S
Date: 2026.04.17 10:42:06 -04'00'

Benjamin Apelberg, Ph.D.
Deputy Director
Office of Science
Center for Tobacco Products

Enclosures:

Appendix A – Tobacco Products Subject of This Letter
Appendix B – Amendments and Additional Submissions
Appendix C – Required Postmarket Surveillance and Studies (PMSS)
Appendix D – Recordkeeping and Retention

[3] https://www.fda.gov/tobacco-products/manufacturing/submit-documents-ctp-portal
[4] FDA's Electronic Submission Gateway (ESG) is still available as an alternative to the CTP Portal.
[5] https://www.fda.gov/industry/fda-esubmitter
[6] https://www.fda.gov/tobacco-products/about-center-tobacco-products-ctp/contact-ctp

Appendix A

Tobacco Products Subject of This Letter

Common Attributes[7,8,9,10,11]	
Submit date	July 5, 2023
Receipt date	July 5, 2023
Applicant	Philip Morris Products S.A.
Product manufacturer	Philip Morris Products S.A.
Product category	Heated Tobacco Products (HTPs)
Product order under 911(g)	911(g)(2) Exposure Modification Order
Modified Risk Claim[12]	AVAILABLE EVIDENCE TO DATE: • The IQOS system heats tobacco but does not burn it. • This significantly reduces the production of harmful and potentially harmful chemicals. • Scientific studies have shown that switching completely from conventional cigarettes to the IQOS system significantly reduces your body's exposure to harmful or potentially harmful chemicals.
Attributes	**Tobacco Product**
STN	**MR0000254.PD1**
Previously authorized STN	MR0000133
Product name[13]	IQOS 2.4 System Holder and Charger
Product subcategory	Open HTP
Package type	Box
Product quantity	1 Holder, 1 Charger
Characterizing flavor (CF)	Unflavored
Nicotine source	None
Length	93.60 millimeters (mm) (Holder) 112.50 mm (Charger)
Diameter	15.04 mm (Holder)
Wattage	6 Watt (W) (Charger)
Battery capacity	120-130 milliampere-hour (mAh) (Holder) 2900-3200 mAh (Charger)
Additional property	Source of Energy: Electric (rechargeable battery) Depth: 21.86 mm (Charger) Width: 51.20 mm (Charger)

[7] We interpret package type to mean container closure system and product quantity to mean quantity within the container closure system, unless otherwise identified.

[8] Product name is brand/sub-brand or other commercial name used in commercial distribution. May also be identified by alternative names.

[9] Effective April 14, 2022, FDA's authority to regulate tobacco products was extended to include tobacco products containing nicotine from any source. Therefore, nicotine source should be included in future submissions.

[10] Attributes in Appendix A may display converted values.

[11] Attributes of certain products intentionally left blank, as these were not provided by the applicant.

[12] Provided by the applicant and not confirmed by FDA.

[13] The product is originally known as IQOS System Holder and Charger.

Attributes	Tobacco Product
STN	**MR0000254.PD3**
Previously authorized STN	MR0000192
Product name[14]	IQOS 3.0 System Holder and Charger
Product subcategory	Open HTP
Package type	Box
Product quantity	1 Holder, 1 Charger
Characterizing flavor (CF)	Unflavored
Nicotine source	None
Length	92.25 mm (Holder) 114.80 mm (Charger)
Diameter	14.40 mm (Holder) (smallest) 14.90 mm (Holder) (largest area with protruding button)
Wattage	
Battery capacity	>110 mAh (Holder) >2600 mAh (Charger)
Additional property	Source of Energy: Electric (rechargeable battery) Thickness: 23.00 mm (Charger) Width: 46.35 mm (Charger)
STN	**MR0000254.PD5**
Previously authorized STN	MR0000059
Product name[15]	Marlboro Amber HeatSticks
Product subcategory	HTP Consumable
Package type	Box
Product quantity	20 HeatSticks
Characterizing flavor (CF)	Tobacco
Nicotine source	Tobacco
Length	45 mm
Diameter	7.42 mm
Ventilation[16]	
Additional property	Source of Energy: Electric (rechargeable battery)
STN	**MR0000254.PD6**
Previously authorized STN	MR0000060
Product name[17]	Marlboro Green Menthol HeatSticks
Product subcategory	HTP Consumable
Package type	Box
Product quantity	20 HeatSticks
Characterizing flavor (CF)	Menthol
Nicotine source	Tobacco
Length	45 mm
Diameter	7.42 mm
Ventilation[16]	
Additional property	Source of Energy: Electric (rechargeable battery)

Attributes	Tobacco Product
STN	**MR0000254.PD7**
Previously authorized STN	MR0000061
Product name[18]	Marlboro Blue Menthol HeatSticks
Product subcategory	HTP Consumable
Package type	Box
Product quantity	20 HeatSticks
Characterizing flavor (CF)	Menthol
Nicotine source	Tobacco
Length	45 mm
Diameter	7.42 mm
Ventilation[16]	
Additional property	Source of Energy: Electric (rechargeable battery)

[14] The product is originally known as IQOS Originals.
[15] The product is also known as HEETS Amber and originally known as Marlboro HeatSticks.
[16] Filter efficiency or ventilation are not used to control aerosol deliveries.
[17] The product is also known as HEETS Green and originally known as Marlboro Smooth Menthol HeatSticks.
[18] The product is also known as HEETS Blue and originally known as Marlboro Fresh Menthol HeatSticks.

Appendix B

Amendments and Additional Submissions

Amendments Received for These Applications

Submit Date	Receipt Date	Applications being amended	Reviewed	Brief Description
April 24, 2024	April 24, 2024	All	Yes	Additional information for study report documents, data, and analysis
June 6, 2024	June 6, 2024	All	Yes	Additional information for study report documents, data, and analysis
October 3, 2024	October 3, 2024	All	Yes	Additional information for study report documents, data, and analysis
November 25, 2024	November 25, 2024	All	Yes	Extension request to respond to A/I letter dated November 22, 2024
December 5, 2024	December 5, 2024	All	Yes	Response to General Correspondence letter dated October 30, 2024
December 20, 2024	December 20, 2024	All	Yes	Response to A/I Letter dated November 22, 2024
July 11, 2025	July 11, 2025	All	No	Amendment withdrawn by applicant
August 4, 2025	August 4, 2025	All	Yes	Request to withdraw amendment received on July 11, 2025
August 4, 2025	August 4, 2025	All	Yes	Information on statutory definition and request to remove required warnings

Additional Submissions Received for These Applications

Submit Date	Receipt Date	Reviewed	Brief Description
March 18, 2024	March 18, 2024	Yes	Prioritization information
February 24, 2025	February 24, 2025	Yes	Update US Agent and Point of Contacts

Appendix C

Required Postmarket Surveillance and Studies (PMSS)

Under section 911(g)(2)(C)(ii) of the FD&C Act, an order under 911(g)(2) is conditioned on the applicant's agreement to conduct postmarket surveillance and studies in order to "determine the impact of the order on consumer perception, behavior, and health and to enable the [FDA] to review the accuracy of the determinations upon which the order was based in accordance with a protocol approved by the [FDA]."

MRTP Consumer Understanding and Perception

After receiving authorization, the determination of whether the tobacco products that are the subject of this order continue to satisfy the requirements of section 911(g)(2)(A) and (B), is driven, in part, by consumers' understanding of the claim and perceptions of the MRTPs. In particular, your PMSS must assess the extent to which users of these products understand that reducing their exposure to HPHCs is relative to smoking combustible cigarettes (CC) as described in the modified exposure information, and that adults who currently smoke CC must use the MRTPs exclusively and stop smoking CC. Thus, adults who currently smoke CC who start using the MRTPs must understand that they should switch completely to the MRTPs and stop smoking CC, and that cutting down on CC per day while using the MRTPs is not sufficient to reduce their exposure to HPHCs. People who use tobacco products other than CC must understand that the reduction in HPHCs from use of the MRTPs is relative to smoking CC and not to other types of tobacco use. In addition, your PMSS must include an assessment of exposure to, and awareness of, the reduced exposure claim to help elucidate the impact of real-world and repeated claim exposure on consumer understanding and perceptions.

MRTP Use Behavior

Your PMSS must monitor the use of the MRTPs at multiple time points among adults who smoke CC in terms of initiation, dual use with other tobacco products, and complete switching. Specifically, your PMSS must assess the current tobacco use behavior among people who use the MRTPs, including whether people exclusively use or dual use the MRTPs with CC or other tobacco products. Your PMSS must also assess the tobacco use history of people who use the MRTPs (e.g., never, formerly, or currently smoke CC; use of other tobacco products at time of initiating the MRTPs).

Your PMSS must include assessments of behavior and consumer understanding among people who use the MRTPs at multiple time points. Conducting a longitudinal cohort study, like the one planned for the original modified risk orders (but not conducted due to the Cease-and-Desist Order (CDO) that prohibited the importation, marketing, sale, and distribution of IQOS products in the U.S.), may produce robust and reliable evidence to demonstrate the impact of the MRTPs in terms of uptake, dual use with other tobacco products, and complete switching over time. If you are unable to conduct such a longitudinal study, a repeated cross-sectional study that collects valid information on recalled history of tobacco use may also provide evidence across multiple time points to determine whether people who use the MRTPs used them to switch completely from CC smoking.

Your PMSS must have clear research objectives, including assessing whether the MRTPs are leading to changes in product use behaviors that are expected to benefit population health. Your PMSS protocols must include a statistical analysis plan describing, among other things, how you plan to conduct inferential statistical analyses to address these objectives and table shells reflecting how you plan to report your results. In addition, for each study involving human subjects, submit Institutional Review Board (IRB)-related information (e.g., consent forms) and recruitment strategy details (e.g.,

inclusion/exclusion criteria, recruitment materials, and power calculations).

In addition, FDA has determined that assessing the impact of your MRTP orders on use of the MRTPs requires surveillance of sales and distribution of the MRTPs authorized under this order, which provide information to assess tobacco consumption at the population level. Your PMSS protocols must describe procedures for monitoring and reporting sales and distribution of the MRTPs authorized under this order in the United States by product, major metropolitan areas, and channels where the products are sold (e.g., stores and kiosks, convenience stores, food and drug stores, internet and digital retailers, tobacco specialty shops). Your annual PMSS reports must include:

1. A summary of sales and distribution of the MRTPs for the reporting period, to the extent that you collect or receive such data, including:
    - Total U.S. sales and distribution reported in dollars, units, and volume with breakdowns by U.S. census region, major retail markets, and channels in which the products are sold and distributed;
    - All Universal Product Codes that correspond to the products covered in the MRTPAs by product name and STN.PD; and
    - Demographic characteristics of product purchasers, such as age, sex, race/ethnicity, geographic region, and tobacco use status.
2. A brief synthesis and summary of the sales and distribution data for the initial reporting period or the previous reporting period (for all reports that follow), including annual and quarterly growth rate (percent change) in total U.S. sales and distribution of the MRTPs since this order was issued.

MRTP Use and Health Risks – Ongoing Surveillance of All Adverse Experiences

In order for FDA to determine whether the MRTPs authorized under this order, as actually used by consumers, continue to be appropriate to promote the public health and continue to benefit the health of the population as a whole (section 911(g)(2)(A) and (B)), your PMSS must include ongoing surveillance of all adverse experiences associated with the use of the MRTPs authorized under these orders. These experiences may become known to you through any source, including a customer complaint, request, or suggestion made as a result of an adverse experience; or tobacco product defect, or failure, reported to you, or identified in the literature or media. Your PMSS protocols must include procedures for monitoring and analyzing adverse experiences and your annual PMSS report must include:

- A summary of reported serious and unexpected adverse experiences for the MRTPs, which includes a listing of all serious and unexpected adverse experiences during the reporting period and a cumulative list, including all serious and unexpected adverse experiences previously reported. The summary must be accompanied by an analysis of the reports and a statement of any changes to risk information related to the MRTPs including nature, frequency, and potential aggravating factors.

Serious and Unexpected Adverse Experience Reporting

In addition, the PMTA marketing granted orders (MGOs) for your tobacco products issued on April 30, 2019, and December 7, 2020, require you to report to the FDA all adverse experiences that are serious, whether expected or unexpected, and your analysis of the association between the adverse experience and the tobacco product within 15 calendar days after the report is received by you. These experiences may become known to you through any source, including a customer complaint, request, or suggestion

made as a result of an adverse experience, tobacco product defect, or failure, reported to you, or identified in the literature or media. We request that when submitting such reports, you reference both your PMTAs and your MRTPAs for these products. Your information should be submitted with a cover letter that includes the following text in the subject line: **SERIOUS UNEXPECTED ADVERSE EXPERIENCE REPORT FOR PM0000424-PM0000426, PM0000479, PM0000634, MR0000059-MR0000061, MR0000133, MR0000192, MR0000254.PD1, MR0000254.PD3, MR0000254.PD5-MR0000254.PD7.** In addition, submit the information through our Safety Reporting Portal: https://www.safetyreporting.hhs.gov

For purposes of this reporting, *serious adverse experience* means an adverse experience that results in any of the following outcomes:

1. Death;
2. A life-threatening condition or illness;
3. Inpatient hospitalization or prolongation of existing hospitalization;
4. A persistent or significant incapacity or substantial disruption of the ability to conduct normal life functions;
5. A congenital anomaly/birth defect; or
6. Any other adverse experience that, based upon appropriate medical judgment, may jeopardize the health of a person and may require medical or surgical intervention to prevent one of the other outcomes listed in this definition.

For purposes of this reporting, *unexpected adverse experience* means an adverse experience occurring in one or more persons in which the nature, severity, or frequency of the experience is not consistent with:

1. The known or foreseeable risks associated with the use or exposure to the tobacco product as described in the MRTPA (including the results of human subject investigations) and other relevant sources of information, such as postmarket reports and studies;
2. The expected natural progression of any underlying disease, disorder, or condition of the person(s) experiencing the adverse experience and the person's predisposing risk factor profile for the adverse experience; or
3. The results of nonclinical laboratory studies.

Surveillance of Research Study Findings on the MRTPs

In order for FDA to determine whether the MRTPs authorized under this order, as actually used by the consumer, continue to be appropriate to promote the public health and expected to benefit the health of the population as a whole, your PMSS must report any previously unreported findings from any internal and unpublished research studies conducted by you or on your behalf, regardless of whether such studies were specifically required as part of PMSS.

Your PMSS must report any unpublished data about individuals under the age of 18 related to: (a) youth awareness of the MRTPs in order to evaluate how effectively any marketing is limiting unintended exposure to youth, and (b) youth use of the MRTPs, to help ensure that marketing of the MRTPs does not have unintended consequences for youth use. This unpublished data may also monitor young adults below the legal age to purchase tobacco products (i.e., ages 18-20).

Your PMSS must also include a literature review of all nonclinical studies published after the issuance of these orders that evaluate the toxicity of IQOS, with discussion of study results as they relate to IQOS

aerosol toxicity relative to CC.

A literature search and published scientific articles are not required for other topics.

Submitting PMSS Protocols and Reports

As required under section 911(g)(2)(C)(ii) of the FD&C Act, your modified risk order is conditioned on your agreement to conduct PMSS under an approved protocol, and to submit the results for FDA to determine the impact of the order and review the accuracy of determinations on which the order is based. Within 30 days of receiving this notice, you must submit your agreement to conduct PMSS and complete protocols for your PMSS.

Label your submission clearly as a "PMSS Protocol," and reference your MRTPA Submission Tracking Numbers (STNs). If applicable, each protocol should include the name(s) of the principal investigator(s) and materials that demonstrate the relevant professional credentials and training that qualify them to lead the study.

Within 60 days of receipt of the protocol(s), FDA intends to review the protocol(s) and evaluate if the principal investigator proposed to be used in the surveillance has sufficient qualifications and experience to conduct the surveillance and if the protocol(s) will result in collection of the data or other information that has the potential to enable FDA to accurately determine the impact of the order on consumer perception, behavior and health and to review of accuracy of the determinations upon which the order was based, pursuant to section 911(g)(2)(C)(iii) of the FD&C Act.

FDA will notify you of any deficiencies in the submission and provide an opportunity to address them. If the PMSS protocol is amended after FDA approval, the amended protocol must be submitted to the FDA promptly. For protocol amendments that are administrative in nature (e.g., corrections in punctuation or titles), the amended protocol must be received by FDA within 30 days of the update. For protocol amendments that seek to modify the study design (including endpoints, sites, questionnaires, methodology, etc.) or other scientific parameters, you may not initiate the change until you receive FDA approval.

As part of the requirement to conduct PMSS, you must initiate and conduct your PMSS per the timeframes established in your protocols and approved by FDA. Note that for PMSS that involve human subjects, the anticipated start date for each study must account for the time required for securing IRB approval, as needed. In addition to specifying the start date, your protocols must contain timelines for completion of major study milestones including, as applicable, the start and completion of participant recruitment, initiation of data collection (per wave, if applicable), completion of data collection, analysis, and report writing. If you deviate from these timelines, we request that you report the deviation within 30 days to FDA.

Section 911(g)(2)(C)(iii) of the FD&C Act requires that the results of the PMSS be submitted on an annual basis. These reports must be identified as "PMSS Report" and reference the MRTPA STNs for each report. The PMSS Report must indicate the beginning and ending date of the period covered by the report and must include accomplishments since the last reporting period. For quantitative updates on studies in progress (e.g., participant accrual), reports should describe both interim (since the last reporting period) as well as cumulative (since study initiation) accomplishments. The PMSS Report describing studies in progress must describe the status of PMSS, including, as applicable, the status of

recruitment, data collection, and analysis; a summary of the study milestones achieved and any deviations from the approved timelines in the protocol; a summary of protocol amendments; and a summary of any preliminary analyses conducted. Once a study is completed, the PMSS Report should include the complete final study report.

Appendix D

Recordkeeping and Retention

The exposure modification orders for your modified risk tobacco products are effective for five years from the issue date. We recommend you submit a request for renewal 365 days prior to the end of your effective timeframe, if applicable. In order to help ensure that your exposure modification order meets the standard for renewal and to expedite the review of any renewal applications, we request that you create and maintain the records listed below. The records should be retained for a period of not less than four years from the date of distribution of the last batch of the tobacco products listed in your orders under section 911(g)(2). The records should be legible, written in English, and available for inspection and copying by officers or employees duly designated by the Secretary upon request. Note that Appendix C requires you to periodically submit some of these records to FDA (e.g., in PMSS reports). Additionally, we remind you that the PMTA marketing granted orders (MGOs) for your tobacco products issued on April 30, 2019, and December 7, 2020, also require you to establish and maintain records, some of which overlap with the records listed below:

1. The MRTPAs submitted prior to the orders
2. Postmarket reports, as described in Appendix C, and adverse experience reports, including all relevant documentation associated with the experience
3. Records of all nonclinical or clinical studies, including:
    a. Source data;
    b. Study protocols (including statistical analysis plan);
    c. Amendments showing the dates and reasons for any protocol revisions;
    d. Institutional Review Board (IRB) or Independent Ethics Committee (IEC) approvals or non-approvals;
    e. Informed consent forms;
    f. Correspondence with study monitors/investigators/contract research organizations/sponsors/IRB/IEC;
    g. Investigator financial disclosure statements;
    h. Progress reports;
    i. Monitoring reports;
    j. Adverse experience reports;
    k. Case report forms/subject diaries/medical records/laboratory reports;
    l. Subject data line listings/observation records;
    m. Test article accountability records;
    n. Study results/protocol summaries/study reports; and
    o. Certifications and amendments to certifications
4. Records pertaining to the manufacture, in process and release testing, production process (including any changes to the process, facility, or controls), packaging, storage, and stability monitoring and testing (including protocol and results) of the products
5. Records pertaining to the sale, distribution, or other disposition of the products, specifically:
    a. A list of distributors and retailers of the products, including brick-and-mortar and digital. For the purposes of this order, here and throughout the document, “digital” includes internet/online and mobile.;
    b. Any available information (not to include personally identifiable information) about product purchases, such as purchasers’ demographics (e.g., age, sex, race/ethnicity, geographic region) and previous or current use of other tobacco products (i.e., dual use);

c. Policies and procedures regarding verification of the age and identity of purchasers of the products; and
d. Policies and procedures regarding restrictions on youth access to the products

6. Records pertaining to the products' labeling, advertising, marketing, and/or promotion – whether conducted by you, on your behalf, or at your direction – including:
    a. Specimens of all labeling, labels, inserts/onserts, instructions, and other accompanying information;
    b. Copies of all advertising, marketing, and/or promotional materials published, disseminated to consumers, or for use in engaging or communicating with consumers;
    c. Copies of any formative research studies conducted among any audiences in the formation of the labeling, advertising, marketing, and/or promotional materials, including qualitative and quantitative research studies used to determine message effectiveness, consumer knowledge, attitudes, beliefs, intentions, and behaviors toward using the products, and including copies of the stimuli used in testing;
    d. Copies of any consumer evaluation research studies conducted among any audiences to determine the effectiveness of labeling, advertising, marketing, and/or promotional materials and any shifts in consumer knowledge, attitudes, beliefs, intentions, and behaviors toward using the products, and including copies of the stimuli used in testing;
    e. Copies of any contractual agreements regarding the creation and/or dissemination of the products' labeling, advertising, marketing, and/or promotional materials;
    f. Copies of all advertising and marketing plans, including strategic creative briefs and paid media plans, by channel and by product, and the dollar amount(s) and flighting of such plans, by channel and by product, including any:
        i. Use of competent and reliable data sources, methodologies, and technologies to establish, maintain, and monitor highly targeted advertising and marketing plans and media buys;
        ii. Targeting of specific adult audiences by age-range(s), including young adult audiences, ages 18-24, and other demographic and/or psychographic characteristics that reflect your intended target audience;
        iii. Actions taken to restrict youth-access and limit youth-exposure to the products' labeling, advertising, marketing, and/or promotion;
        iv. Use of owned, earned, shared, and/or paid social media to create labeling for, advertise, market, and/or promote the products;
        v. Use of partners, influencers, bloggers, and/or brand ambassadors to create labeling for, advertise, market, and/or promote the products;
        vi. Consumer engagements – whether conducted by you, on your behalf, or at your direction – including events at which the products were demonstrated; and/or
        vii. Use of earned media and/or public-relations outreach to create labeling for, advertise, market, and/or promote the products
    g. Copies of all records pertaining to media tracking and optimization, by channel, by product, and by audience demographics (e.g., age, sex, race/ethnicity, geographic region), and all post-launch delivery-verification reports submitted to you from an accredited source, by channel, by product, and by audience demographics; and
    h. Policies and procedures for real-time digital media monitoring to identify, correct, and prevent any delivery of advertising impressions to individuals under the federal minimum age of sale of tobacco products including documentation of such monitoring activities and implementation of corrective and preventive measures
7. Health hazard analyses, if performed voluntarily or directed by FDA

8. Records pertaining to any and all complaints associated with any of the products that you receive or of which you are aware