DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration
Center for Tobacco Products
9200 Corporate Boulevard
Rockville MD 20850-3229

[Month] XX, 201X

[Address block]

Dear XX:

Under Section 907(f) of the Federal Food, Drug, and Cosmetic Act (the act), the FDA Tobacco Products Scientific Advisory Committee (TPSAC) is required to study "the issue of the nature and the impact of the use of dissolvable tobacco products on the public health, including such use among children," and to submit a report and recommendations to FDA. To ensure a comprehensive review of this issue, CTP is requesting tobacco industry data and information to support the work of TPSAC.

I. Submission Content

A. Submission of Documents Pursuant to a Section 904(b) Request

In accordance with section 904(b) of the act, FDA requests and you are therefore to submit documents and underlying scientific and financial information created prior to the date of this letter relating to research, and research findings, conducted, supported, or possessed by the manufacturer or its agents relating to a specified set of topics, as set forth below. For purposes of these requests, "research" may include, but is not limited to, focus groups, surveys, experimental clinical studies, post-marketing surveillance, toxicological and biochemical assays, taste panels, and assessments of the effectiveness of product marketing practices.

1. Topics

For the purposes of this section 904(b) request, you are to submit all documents and underlying scientific information relating to research and research findings on the following topics, subject to the limitations in I.A.2. below.

1. Marketing research involving the use of dissolvable tobacco products
2. Marketing practices used by tobacco manufacturers and distributors for dissolvable tobacco products
3. The effectiveness of marketing practices used by tobacco manufacturers and distributors.
4. The health effects of dissolvable tobacco products
5. The toxicological effects of dissolvable tobacco products
6. The behavioral effects of dissolvable tobacco products
7. The physiologic effects of dissolvable tobacco products

FDA also requests, and you are required to submit, all underlying financial information relating to topics (1)-(3), subject to the limitations in I.A.2 below.

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Note that these requests apply to all dissolvable tobacco products, including but not limited to products for research, investigational use, developmental studies, test marketing, and/or commercial marketing, and also to the components, parts, or accessories of such products.

In your production of documents, we ask that each document be identified as responsive to one or more of the seven numbered topics above. In your cover letter, please indicate how many documents you are submitting for each of the above categories.

2. Limitations - types of documents and information

With respect to the topics listed above, FDA requests only the following documents and information:

- Study proposals, protocols (including all amendments), analysis plans, agreements, data collection forms and tools, and assessment scales for planned, ongoing, or completed studies, surveys and other research, whether for external release or internal use;
- Interim or final data analyses and reports regarding studies, surveys, or other research, whether for external release or internal use;
- Posters and/or presentations exhibited or to be exhibited at external meetings or conferences;
- Manuscripts, articles, editorials, and letters that have been submitted for publication but not yet published (e.g., in review, accepted, rejected);
- Underlying scientific or financial data (e.g., in the form of spreadsheets, SAS datasets, charts, tables, and diagrams) analyzed to produce any of the data analyses, reports, posters, manuscripts, or articles requested above.

With respect to documents, **FDA requests only the final version, or in the absence of a final version, the most recent draft of each document.** As such, please do not submit a) past iterations of a completed or more recent document, b) document duplicates, or c) near duplicates that only vary in minor ways (e.g., differences in addressee or changes in letterhead). Also, published (publicly available) press releases, abstracts, editorials, letters, and manuscripts are not requested, although we would appreciate a list of such publications. Information responsive to this 904(b) request that has been previously provided to FDA under the act does not have to be re-submitted as long as the document is fully referenced. For documents provided pursuant to a 904(b) request or the 904(a)(4) requirement to submit certain tobacco health documents, please provide the file name and file extension, Bates number (begin Bates number to end Bates number), the date of submission, and relevant page numbers. For documents previously provided to FDA under the 904(a)(1), 904(c)(1), 904(c)(2), or 904(c)(3) requirement to submit listings of ingredients in tobacco products, please provide the date of submission, section under which the document was submitted, tobacco product brand/subbrand name, and product identification number.

With respect to underlying scientific and financial data, FDA asks that data (e.g., spreadsheets, SAS datasets) be submitted in a file type and structured format that allows for meaningful review and analysis of the data. Where relevant, data submissions should be accompanied by the name and version of software used to create the file, names and definitions of variables, and copies of programs and macros needed to generate your analyses. Any data analyses, e.g. that stratify scientific results by gender, race/ethnicity, or age, are to be included in your submission. With respect to underlying financial data, FDA is not requesting underlying financial data relating to your costs of conducting any research.

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3. Date for submission of documents

All information under section I.A. of this document is to be received by CTP no later than [six weeks from date of letter] XX, 201X. If you do not have any documents responsive to this request, you are to inform FDA of this in writing by [six weeks from date of letter] XX, 201X. If you anticipate difficulties with this document production, please contact CTP within 30 days of this letter so that we may assist you in resolving any technical difficulties you may have and facilitate compliance with the above timeline. .

The failure to provide information requested by FDA in accordance with section 904(b) of the act is a violation of the act and subject to regulatory and enforcement action by FDA.

B. Additional Requests

If you are providing documents in response to the 904(b) requests in section I.A., CTP also asks that you submit the following additional information, as applicable, to provide context and background for TPSAC.

8. A complete description of the composition and design of each dissolvable tobacco product.
9. A brief summary (e.g., one to five pages) of the process, criteria and considerations utilized in selecting the form (e.g. size, color, shape), flavoring, and sugar content of each dissolvable tobacco product.
10. A one to five page summary of marketing research on the use of dissolvable tobacco products, e.g. by age, type of prior tobacco use (if any), and by interest in quitting cigarette smoking or traditional smokeless tobacco use. Among other things, address consumer perceptions of taste, impact, nicotine strength, and product harm.
11. A one to five page summary of marketing practices (e.g. by age, type of prior tobacco use if any, and by interest in quitting cigarette smoking or traditional smokeless tobacco use) used for dissolvable tobacco products.
12. A one to five page summary of the effectiveness of marketing practices (e.g. by age, type of prior tobacco use if any, and by interest in quitting cigarette smoking or traditional smokeless tobacco use) used for dissolvable tobacco products.
13. A one to five page summary of research results on health effects of dissolvable tobacco products.
14. A one to five page summary of research results on toxicological effects of dissolvable tobacco products.
15. A one to five page summary of research results on behavioral effects of dissolvable tobacco products among users and non-users of other tobacco products regarding appeal, use, initiation, cessation, switching between cigarettes and dissolvable tobacco products, switching between traditional smokeless and dissolvable tobacco products, and dual use of cigarettes and dissolvable tobacco products. Summarize these results for users of different ages.
16. A one to five page summary of research results on physiological effects of dissolvable tobacco products on users and non-users of other tobacco products, including but not limited to chemosensory effects and abuse liability.

For topics 8 through 16, provide cross-references to relevant documents you have submitted to CTP under section 904(a)(4) or 904(b).

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We ask that you submit all information responsive to section I(B) of this document to be received by CTP no later than [six weeks from date of letter] XX, 201X.

II. Submission Instructions

Consistent with applicable statutes and regulations, the confidentiality of trade secret and confidential commercial information submitted to FDA pursuant to this request will be preserved.

We encourage you to submit your response in an electronic format on CD-ROM, DVD, or hard drive. Please see the enclosed document for guidance in preparing your submission to CTP.

Your submission should be prominently identified with the manufacturer's or importer's name, the label "FDA XX-201X Dissolvable Tobacco Request" and sent to the following address:

Center for Tobacco Products
Food and Drug Administration
Attn: Document Control Center
9200 Corporate Boulevard
Rockville, MD 20850

We look forward to your prompt response and appreciate your support of the TPSAC in the review and evaluation of this important topic. If you have questions regarding this document request, please contact Florence O. Moore, Lead Project Manager, at 301-796-9226 or TPSAC@fda.hhs.gov.

Sincerely,

Lawrence R. Deyton, M.S.P.H., M.D.
Director, Center for Tobacco Products

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Enclosure: Submission Instructions

A. General Instructions

We request that you submit documents in text-searchable PDF file(s) on a CD-ROM, DVD, or hard drive. The files should include a signed cover letter prominently identified as "FDA XX-201X Dissolvable Tobacco Product Request, and should also identify the software (name, version, and company) that you used to confirm the submission is free of viruses or other malware.

The electronic media should be labeled with your company name, a contact phone number, "FDA XX-201X Dissolvable Tobacco Product Request," submission date, and series number (e.g., "disc 1 of 2"). In order for FDA to accept, access, review, and archive the documents, all documents are to be submitted in their native color and **files, including compressed files and archives, cannot be password protected**. Ensure all documents are text-searchable and restriction settings under Document Properties are set to "allowed". If you submit PDF files, they should not contain any attached, embedded or bundled files. If any documents are scanned, you should verify the accuracy of optical character recognition and legibility of the document. In addition, multi-page documents should be properly unitized, instead of several single-page files.

B. Instructions for Information Submitted Under Section I(A)

In order to ensure accessibility of your documents and facilitate more fluent and efficient communication between you and FDA regarding your submissions, FDA recommends that you take the following steps:

- Uniquely number all pages of your submission, a process commonly referred to in the litigation context as Bates numbering; and
- Translate all foreign language documents into English.
- Create and submit a glossary or explanation of any abbreviations, jargon or internal names (e.g., code names).

In order to provide context and background for each document, FDA recommends that the following metadata accompany each document:

- Manufacturer filing the document;
- Document date;
- Document author(s);
- Document recipient(s);
- Document custodian;
- Document title or identification number;
- Beginning and ending Bates numbers;
- Bates number ranges for other documents physically or digitally attached to the document;
- OCR text (for scanned paper documents);
- Topic(s) (i.e., the topic or topics listed in Section I.A.1 of the attached letter to which the document relates); and
- Product name(s) (e.g., brand or sub-brand, or a unique, consistent identifying name for any tobacco product in research or development).

FDA requests that load files containing metadata be submitted in a comma delimited ASCII format and be organized so that data fields will appear in the same order as they appear here, i.e.,

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"Manufacturer filing the document" should be the first field, and "Product name(s)" should be the last field. Metadata load file delimiters should be as follows:

Metadata Load File Delimiters

Field separator:	**Vertical Pipe (ASCII 124)**
Field encapsulate:	**Carat (ASCII 094)**
Return value in data:	**Tilde (ASCII 126)**
Multi-value field:	**Semi Colon (ASCII 059)**
Dates format:	**MM/DD/YYYY**

Hard Returns should appear only at the end of each record.

If you scan paper documents or digital production, please use optical character recognition software (OCR) technology to extract searchable text data from the document image. Any extracted searchable text should be produced with the document as metadata.

The instructions in this enclosure are based on communications that CTP has received from industry and our evaluation of submissions received under the Act to date. If you have questions about how to prepare your submission, please contact us.

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