U.S. FOOD & DRUG ADMINISTRATION

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

May 17, 2018

FDA Submission Tracking Number (STN): [STN NUMBER]

Dear COMPANY:

Under section 904(b) of the Federal Food, Drug, and Cosmetic Act (FD&C Act), FDA is requesting that [COMPANY] submit documents relating to marketing practices and research on marketing, effects of product design, public health impact, and adverse experiences and complaints related to [PRODUCT] (including e-liquid pods, device, and charger). This request applies to research relating to [PRODUCT] and their components or parts, including those products for research, investigational use, developmental studies, test marketing, and/or commercial marketing.

FDA is requesting these documents based on concern about youth use of JUUL and other similar Electronic Nicotine Delivery System (ENDS) products. These products share similar characteristics, including e-liquids that contain nicotine salts with corresponding high nicotine concentration, small size which makes them easily concealable, and product design features that are intuitive, even for novice ENDS users. These attributes may relate to the appeal and addictiveness of the product, particularly for youth who may be experimenting with tobacco products. Youth use may be related to different aspects of the product, including the product design, promotion, or distribution, and CTP seeks information to further understand the appeal and use of these products in youth.

I. Submission Content

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

In accordance with section 904(b) of the FD&C Act, FDA requests that you submit all documents (including underlying scientific and financial information, as specified below) relating to marketing practices and research activities and research findings, conducted, supported, or possessed by you or your agents relating to a specified set of topics, as set forth below. The request includes but is not limited to documents relating to research findings and activities, if any, that you possess as the result of acquiring or merging with, or obtaining the services or products of another company. For purposes of this request, "research" may include, but is not limited to focus groups, surveys, experimental clinical studies, toxicological and biochemical assays, *in vivo* and *in vitro* assays including animal testing, laboratory formulation and processing testing, taste panels, and assessments of the effectiveness of product marketing practices. The request applies to research relating to the particular ENDS product(s) noted above including the components or parts of such products, including but not limited to products for research, investigational use, developmental studies, test marketing, and/or commercial marketing.

For products not manufactured in the United States, the request applies to the extent you have imported such products into the United States. An importer of a tobacco product not manufactured

in the United States is required to supply the information required of the manufacturer of that product.

1. Topics

Pursuant to section 904(b), FDA requests all documents (including underlying scientific and financial information, as specified below) relating to research activities and findings (including marketing research) and marketing practices for [PRODUCT], subject to the limitations in I.A.2 of this letter, on *all* of the following topics:

1. Product marketing— documents (including underlying scientific or financial information) related to marketing research or marketing practices and the effectiveness of such practices. Potential relevant areas of research or marketing practices include:
    - Target consumer groups, including direct (e.g., smokers, ENDS users) and indirect (e.g., youth)
    - Consumer perception studies/market testing
    - Marketing themes and content, including depictions of young people and how ENDS are characterized
    - Means of advertisement and promotion, such as:
        - General marketing strategies (e.g., social media)
        - Price promotions, promotional games and contests
        - Retailer agreements/incentives or partnerships with media and publishing organizations
        - Any other consumer or business-to-business advertising or promotion strategies not listed above
        - Educational materials or products for schools to limit youth use
    - Means of product distribution as it might relate to youth exposure to marketing or youth access
    - Information about how youth are accessing the product and information about how the company plans to prevent youth from gaining access to the product.

2. Product design— documents (including underlying scientific information) related to research on the health, toxicological, behavioral, and physiologic effects, including appeal or addictive potential for youth, as it relates to product design, including the following:
    - Product shape or form (e.g., similarity in appearance to USB stick)
    - Product size (e.g., easily concealed in palm of hand)
    - Nicotine formulation, (e.g., nicotine salt formula) and nicotine concentration/content
    - Flavors
    - Product features such as: ease of use (e.g., prefilled cartridges, draw activation, USB rechargeability) appearance, or lack thereof, of plume; safety features/prevention of misuse

3. Public health impacts involving youth—documents (including underlying scientific information, such as survey information) related to research on the health, toxicological, behavioral, or physiologic effects of the product(s) on youth, including, but not limited to:

- Awareness, susceptibility, intentions to use, and use patterns (e.g., frequency of use, dual use with other tobacco products; pharmacokinetics and topography)
- Perceptions of risk, harm, and addictiveness compared to other ENDS products, other tobacco products, and in general
- Appeal, liking, product satisfaction
- Health impacts of short-term and long-term use

4. Adverse experiences and complaints involving youth—documents (including underlying scientific information) related to research on health, toxicological, behavioral, or physiologic effects described in adverse experience reports or consumer complaints related to youth use associated with the products, including:
   - Reports of youth use and uptake
   - Reports of addiction or withdrawal
   - Reports of acute hazards or risk of injury

2. Limitations — types of documents and information

With respect to the topics listed above, FDA requests *all* of the following documents and information:

- Study proposals, original implemented protocols (including all amendments), analysis plans, agreements, notebooks, data collection tools, including, but not limited to, forms and assessment scales for planned, ongoing, or completed studies, surveys, and other research, whether for external release or internal use
- Final data analyses and reports regarding studies, surveys, data compilations, or other research, whether for external or internal use (if there were no final analyses, interim data analyses should be submitted)
- Posters and/or presentations exhibited or to be exhibited at external meetings or conferences if the underlying data has not been presented in other documents and information within this request
- Manuscripts, articles, editorials, and letters that have been submitted for publication but not yet published (e.g., in review, accepted, rejected)
- Underlying data (e.g., in the form of spreadsheets, 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. 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). FDA does not request published (publicly available) press releases, abstracts, editorials, letters, manuscripts, material safety data sheets (MSDS), and HHS correspondences; if you seek to voluntarily submit such information, we request a list of such publications be provided as a separate appendix only, in lieu of submitting such publications. Electronic mail should be in portable document format (.pdf) and responsive to the above topic areas. Transmittal email should not be included. Submitted documents should not be redacted.

Included within the request are supporting summary reports and the underlying data that support those reports. FDA asks that spreadsheets or datasets be submitted both in pdf and in a file type and structured format that allows for meaningful review and analysis of the data (e.g., Excel (.xls), comma separated values (.csv), or SAS transport (.xpt). 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. Your submission should include any data analyses that stratify scientific results by one or more of the following: gender, race/ethnicity, age, health condition, or other similar factors.

As an option, information responsive to this 904(b) request that has been previously provided to FDA under section 904 the FD&C Act does not have to be re-submitted as long as the document is fully referenced in the metadata load file.

3. Date for submission of documents

All information for this request is to be received by FDA no later than July 12, 2018. **If you do not have any documents responsive to this request, inform FDA of this in writing by July 12, 2018.** If you anticipate difficulties with this document production, please contact FDA 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 time line.

Failure to provide information requested by FDA in accordance with section 904(b) of the FD&C Act is a violation of the FD&C Act and subject to regulatory and enforcement action by FDA.

B. Submission of Additional Information

To provide context and background for the 904(b) requests in section I.A of this letter, FDA also asks that you voluntarily submit a summary (one to five pages in length) for each of the topics in section I.A that includes the number and type of documents included, and a high-level overview of the content

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.

Please see the enclosed document for guidance in preparing your submission to FDA.

Clearly identify the manufacturer's or importer's name and address, include the label "**FDA 05-2018 [PRODUCT] Request for [STN NUMBER]**", and submitted electronically via the CTP Portal[1] using eSubmitter[2].

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[1] http://www.fda.gov/TobaccoProducts/GuidanceComplianceRegulatoryInformation/Manufacturing/ucm515047.htm. FDA's Electronic Submission Gateway (ESG) is still available as an alternative to the CTP Portal.

[2] http://www.fda.gov/ForIndustry/FDAeSubmitter

Alternatively, CD-ROM, DVD, or hard drive 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 Electronic Submission Gateway (ESG) are both generally available 24 hours a day, seven days a week. Submissions delivered to DCC by couriers or physical mail will be considered timely if received during delivery hours on or before the due date[3]; if the due date falls on a weekend or holiday the delivery must be received on the prior business day. We are unable to accept regulatory submissions by e-mail.

If you have questions regarding this document request, please contact [REGULATORY HEALTH PROJECT MANAGER], at [PHONE NUMBER].

Sincerely,

Matthew R. Holman, Ph.D.
Director
Office of Science
Center for Tobacco Products

Enclosure

[3] http://www.fda.gov/TobaccoProducts/AboutCTP/ContactUs/default.htm

Enclosure: Submission Information

A. General Instructions

We request that you submit documents and related material on a CD-ROM, DVD, or hard drive. Documents should be in text-searchable PDF file(s) per FDA guidance on electronic submissions, the FDA eSubmitter User Manual, and the National Archives and Records Administration (NARA) Technical Guidelines for Digitizing Archival Materials for Electronic Access, for document preservation of content and format. The files should include a signed cover letter prominently identified as "**FDA 05-2018 [PRODUCT] Request for [STN NUMBER]**," 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 cover letter should include the number of documents you are submitting for each of the topics. The electronic media should be labeled with your company name, a contact phone number, "FDA 05-2018 [PRODUCT] Request for [STN NUMBER]," 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. File formats that should be avoided are proprietary, requiring specialized software to read, and active content that can contain macros or change the content upon opening the file. 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.

Each document (e.g., presentation, email exchange, report) can be multiple pages but should be saved as a separate PDF file. Each row of metadata within the load file (defined below section I.B) will then reference its associated pdf file.

B. Instructions for Information Submitted Under Section I.A

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
- 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)

To provide context and background for each document, FDA recommends inclusion of a load file, which serves as an index of files, containing the following metadata for each document:

- Manufacturer filing the document
- Filename
- 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)
- Identification of each document as one of the following document types: Email, Briefing Slides, Publication, Memo, Report, Meeting minutes, Proposal, Study design, Other;
- Topic(s) (i.e., the topic or topics listed in Section I.A.1 of the attached letter to which the document relates)
- Product name(s) (e.g., brand or sub-brand, or a unique, consistent identifying name for any tobacco product in research or development)
- Product identification number
- Identify the presence of each document in the University of California San Francisco Truth Tobacco Industry Documents Library[4] (formerly Legacy Tobacco Documents Library) as one of the following: present with the Bates number (begin Bates number to end Bates number), not present, or unknown
- For information previously provided to FDA:
    - Date of previous FDA submission
    - Regulatory section under which the document was submitted
    - File name
    - File extension
    - Bates number (begin Bates number to end Bates number)
    - Relevant page numbers

FDA requests that load files containing metadata be submitted in a comma delimited ASCII text or spreadsheet format and be organized so that data fields will appear in the same order as they appear here (i.e., "Manufacturer filing the document" should be the first field, and "Relevant page numbers" 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 for digital production, please use optical character recognition software (OCR) technology to render the images as functional text against the resulting PDF. Any extracted searchable text should be produced with the document as metadata.

[4] If a responsive document is present in the University of California San Francisco Truth Tobacco Industry Documents library, that does not preclude it from this request.

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