



Date

Company Name

ATTENTION: Insert Authorized Contact Name, Title

Address

Address

FDA Submission Tracking Number (STN): RD0000XXX

Dear [COMPANY OFFICIAL]:

Under Section 904(b) of the Federal Food, Drug, and Cosmetic Act (FD&C Act), FDA is requesting that [COMPANY] submit documents relating to its marketing practices for [BRAND] products. Specifically, FDA is requesting documents related to youth exposure to [COMPANY'S] social media marketing of [BRAND], as well as the [COMPANY'S] use of influencers in social media marketing. This request applies to all of [BRAND] electronic nicotine delivery system (ENDS) products and their components or parts.

FDA is requesting these documents based on the epidemic of youth ENDS use and based on your marketing of [BRAND] product on [SOCIAL MEDIA PLATFORMS]. Youth e-cigarette use has been consistently increasing, and in 2019, more than a quarter of high school students (27.5%) and one in ten (10.5%) middle school students were current e-cigarettes users.¹ These findings have led to a growing concern that a new generation may become addicted to nicotine and tobacco products. The percent of youth exposed to online ENDS marketing more than doubled between 2013-2014 and 2014-2015, from 8.6% to 20.9%, and continues to be concerning.² Further, youth engagement with online tobacco marketing, including social media marketing, is associated with increased likelihood of tobacco use.^{3,4} A recent FDA analysis of ENDS brand marketing on social media found that several companies including yours, have active brand pages on multiple popular social media platforms, a large number of followers, and did not use age restriction tools to prevent youth exposure.⁵ In sum, the Center for Tobacco Products (CTP) seeks this information to further understand the relationship between rising youth exposure to online ENDS marketing and youth ENDS use.

¹ Wang, T. W., Neff, L. J., Park-Lee, E., Ren, C., Cullen, K. A., King, B. A. (2020). E-cigarette Use Among Middle and High School Students — United States, 2020. *MMWR Morb Mortal Wkly Rep.* 69, 1310–1312.

² Soneji, S., Yang, J., Moran, M. B., Tan, A. S., Sargent, J., Knutzen, K. E., & Choi, K. (2018). Engagement With Online Tobacco Marketing Among Adolescents in the United States: 2013–2014 to 2014–2015. *Nicotine and Tobacco Research*, 21(7), 918-925.

³ Soneji, S., Pierce, J. P., Choi, K., Portnoy, D. B., Margolis, K. A., Stanton, C. A., ... & Sargent, J. (2017). Engagement with online tobacco marketing and associations with tobacco product use among US youth. *Journal of Adolescent Health*, 61(1), 61-69.

⁴ Soneji, S., Yang, J., Knutzen, K. E., Moran, M. B., Tan, A. S., Sargent, J., & Choi, K. (2018). Online tobacco marketing and subsequent tobacco use. *Pediatrics*, 141(2), e20172927.

⁵ O'Brien, E. K., Hoffman, L., Navarro, M. A., Ganz, O. (2020). Social media use by leading e-cigarette, cigarette, smokeless tobacco, cigar, and hookah brands. *Tobacco Control*. epub ahead of print. <http://dx.doi.org/10.1136/tobaccocontrol-2019-055406>

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 financial information and electronically stored information, as specified below) relating to marketing practices conducted, supported, or possessed by you or your agents (including contractors, sub-contractors, and anyone promoting the brand on your behalf, such as brand ambassadors and influencers) relating to a specified set of topics, as set forth below. The request includes, but is not limited to, documents relating to activities, if any, that you possess as the result of acquiring or merging with, or obtaining the services or products of, another company. The request applies to any and all [BRAND] ENDS products, including the components or parts of such products.

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 financial information and electronically stored information, as specified below) relating to marketing practices, developed for [BRANDS] subject to the limitations in I.A.2 of this letter, on *all* of the following topics. Documents and information may originate from [COMPANY] or from any agents (including contractors, sub-contractors, and anyone promoting the brand on your behalf, such as brand ambassadors and influencers).

- (1) All social media advertising and marketing plans, including planned content, cost of plans, plans to target specific audiences, and plans to restrict youth exposure and/or access to ads.
- (2) Use of partners, promoters, affiliates, influencers, bloggers, and/or brand ambassadors (collectively referred to as “influencers” in this document) recruited and/or contracted by you, on your behalf, or at your direction to advertise, market, and/or promote your products using social media channels; including, by channel and by product, the original date such plans were first used, the date they were discontinued, the age of the influencers, the age range of the influencers’ followers, how the influencers promoted products (e.g., posts, comments, group chats), how the influencers were recruited, if and how the influencers were compensated, if and how the influencers disclose the relationship to the brand in every promotional post, whether the influencer used any age restriction tools, and the age break-down of those who liked or otherwise interacted with the post for each post using an influencer.
- (3) Number of (a) followers and (b) viewers on each of official [BRAND’S] social media channel (e.g., Facebook, Instagram, YouTube) broken out by age group (i.e., adults ages 21+; young adults ages 18-20; and youth, both from ages 13-17 and those under 13). Also include how the ages of followers and viewers are tracked and managed, and any actions taken to restrict youth-access and/or limit youth-exposure to the products’ labeling, advertising, marketing, and/or promotion in social media channels, and a summary of the effectiveness of such actions.

- a. The scope of (3) above includes summary reports on exposure and engagement such as those that can be obtained, by [COMPANY], or any agents thereof (including contractors or sub-contractors), by visiting account owner pages (e.g., on Facebook, Instagram, and YouTube). FDA asks that this information be submitted as pdf, image, or video files, as appropriate (e.g., .jpeg, .tiff, mpg, mp4, mov).

Your submission should include information about exposure and engagement with your social media content broken out by one or more of the following: gender, race/ethnicity, geographic location, or other similar audience demographics.

To the extent you do not have any of the items listed above, then please expressly state as such in your response.

2. Limitations — types of documents and information

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, 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.

Information responsive to this 904(b) request that has been previously provided to FDA under section 904(b) of the FD&C Act does not have to be re-submitted, if the document is fully referenced in a metadata load file, as described in Appendix A below.

3. Date for submission of documents

All information for this request is to be received by FDA no later than 60 days from the date of this letter. **If you do not have any documents responsive to this request, inform FDA of this in writing no later than 60 days from the date of this letter.** 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.

Your submission should be prominently identified with the manufacturer's or importer's name and the label "FDA MM-2020 Social Media 904(b) Request for [RDXXXXXX]."

We encourage you to submit your response electronically via the CTP Portal^{6,7} using eSubmitter⁸ and to consult additional electronic document technical specifications that are published.⁹ When submitting to CTP, it's important to submit using file formats that CTP can receive, archive, and process, such as concatenated, searchable, .pdf documents with a table of contents. If you have questions about electronic submissions, please contact the eSub Helpdesk at CTPeSub@fda.hhs.gov.

The CTP Portal and FDA's Electronic Submission Gateway (ESG) are generally available 24 hours a day, seven days a week; submissions are considered received by the Document Control Center (DCC) on the day of successful upload. Submissions delivered to DCC by courier or physical mail will be considered timely if received during delivery hours on or before the due date¹⁰; 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.

Alternatively, CD-ROM, DVD, or hard drive submissions should clearly identify the manufacturer's or importer's name and address, include the label "FDA MM-2020 Social Media 904(b) Request for [RDXXXXXX]," and 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

⁶ For more information about CTP Portal, see

<https://www.fda.gov/tobacco-products/manufacturing/submit-documents-ctp-portal>

⁷ FDA's Electronic Submission Gateway (ESG) is still available as an alternative to the CTP Portal. For more information, please see, <https://www.fda.gov/industry/electronic-submissions-gateway>

⁸ For more information about eSubmitter, see <http://www.fda.gov/ForIndustry/FDAeSubmitter>

⁹ For more information about document technical specifications, see <https://www.fda.gov/media/122970/download>

¹⁰ <https://www.fda.gov/tobacco-products/about-center-tobacco-products-ctp/contact-ctp>

If you have questions regarding this document request, please contact XXXXXXX, Regulatory Health Project Manager, at XXX-XXX-XXXX.

Sincerely,

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

Enclosure: Appendix A – Submission Information

Appendix A

Submission Information

A. General Instructions

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 MM-2020 Social Media 904(b) Request for [RDXXXXXX],” 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 MM-2020 Social Media 904(b) Request for [RDXXXXXX],” submission date, and series number (e.g., “disc 1 of 2”).

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, and should not be password protected or encrypted. 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.

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;
- Provide English translation for all foreign language documents; and
- Create and submit a glossary or explanation of any abbreviations, acronyms, jargon, or internal names (e.g., code names).

To provide context and background for each document, FDA recommends inclusion of an index file (a metadata load file), using a spreadsheet format, containing the following metadata describing 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;

- Ensure that all documents have recognizable text, performing Optical Character Recognition (OCR) for scanned 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 Library¹¹ (formerly Legacy Tobacco Documents Library) as one of the following: present with the Bates number (beginning Bates number to end Bates number), not present, or unknown; and if applicable
- 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 (beginning Bates number to end Bates number);
 - Relevant page numbers.

FDA requests that the index file 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.

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.

¹¹ If a responsive document is present in the University of California San Francisco Truth Tobacco Industry Documents library, such document is not excluded from this request.