Request for Approval under the "Generic Clearance for the Collection of Qualitative Feedback on FDA Service Delivery" (OMB Control Number: 0910-0697)

A. TITLE OF INFORMATION COLLECTION: FDA CTP Exchange Lab Syndication Study — Potential Users

1. PURPOSE: This proposed study will request information to improve the FDA.gov Center for Tobacco Products (CTP) content syndication services provided through the CTP Exchange Lab website (https://digitalmedia.hhs.gov/tobacco/). Content syndication is a method by which digital content (e.g., text, infographics) is made available to other websites, blogs, and other digital channels. The goal of this study is to learn more about potential CTP Exchange Lab syndication users and their interest in using digital content through the Exchange Lab website. Information obtained through this study will establish a CTP Exchange Lab audience baseline for measuring progress and optimizing outreach tactics. An analysis of potential Exchange Lab syndication users will deepen the Center's understanding of ways to attract new subscribers. With this understanding, CTP will develop resources of greatest value to its Exchange Lab target audiences and, as such, sustain and increase engagement in the Exchange Lab among new target audience members.

2. DESCRIPTION OF RESPONDENTS: The study will invite 42,564 individuals—this includes approximately 40,000 CTP email communications subscribers, 1,264 unique Exchange Lab users who have either registered on the site or signed up to receive Exchange Lab updates but who have not created a content syndication feed, and approximately 1,300 other stakeholder contacts (e.g., public health professionals, educators, etc.,) that CTP obtained via its booth at conferences—to complete the survey.

   These users have opted in, voluntarily, to receive communication from CTP. We are aiming for up to 425 individuals to complete this survey. To be eligible to participate in the online survey for the FDA CTP Exchange Lab Syndication: Potential Users Study, each respondent must:

   - Be 18 years of age or older (as determined by a screener question on the survey).
   - Have access to the internet.
   - Not be an employee or a contractor working for CTP.

3. TYPE OF COLLECTION: (Check one box. If you are requesting approval of other instruments under the generic, you must complete a form for each instrument.)

   [ ] Customer Comment Card/Complaint Form
   [ ] Usability Testing (e.g., Website or Software
   [ ] Focus Group
   [X] Customer Satisfaction Survey
   [ ] Small Discussion Group
   [ ] Other:_____

Request for Approval under the "Generic Clearance for the Collection of Qualitative Feedback on FDA Service Delivery"
(OMB Control Number: 0910-0697)

4. CERTIFICATION: Please read the certification carefully. If you incorrectly certify, OMB will return the generic as improperly submitted or it will be disapproved.

   I certify the following to be true:

   a) The collection is voluntary.
   b) The collection is low-burden for respondents and low-cost for the Federal Government.
   c) The collection is non-controversial and does not raise issues of concern to other Federal Agencies.
   d) The results are not intended to be disseminated to the public.
   e) Information gathered will not be used for the purpose of substantially informing influential policy decisions.
   f) The collection is targeted to the solicitation of opinions from respondents who have experience with the program or may have experience with the program in the future.

   Contact Name: Atanaska (Nasi) Dineva, MS

To assist review, please provide answers to the following question:

5. PERSONALLY IDENTIFIABLE INFORMATION (PII): Provide answers to the questions. Note: Agencies should only collect PII to the extent necessary, and they should only retain PII for the period of time that is necessary to achieve a specific objective.

   a) Is personally identifiable information (PII) collected?

      [X] Yes [ ] No

The CTP research team will not collect any personally identifiable information (PII) from survey respondents (such as respondents' mailing addresses or social security numbers). However, for those respondents who are interested in being considered to participate in a future online usability test session of the CTP Exchange Lab, they will be asked to provide their name and email so that CTP team researchers can contact them in the future, accordingly. The contact information for those who express interest in participating in future usability testing will be stored separately from the rest of the survey data.

The CTP research team will keep all aggregated, anonymous electronic data for the study in a password-protected computer. Only study team members who are directly involved with the research study will have access to the aggregated data and the separate file that has the names and email addresses of participants who agreed to future contact.

b) If Yes, will any information that is collected be included in records that are subject to the Privacy Act of 1974?

[ ] Yes [X] No

c) If Yes, has an up-to-date System of Records Notice (SORN) been published?

[ ] Yes [ ] No

6. GIFTS OR PAYMENT: If you answer yes to the question, please describe the incentive and provide a justification for the amount.

Is an incentive (e.g., money or reimbursement of expenses, token of appreciation) provided to participants?

[] Yes [X] No

BURDEN HOURS: Identify who you expect the respondents to be in terms of the following categories:

(1) Individuals or Households;
(2) Private Sector;
(3) State, local, or tribal governments; or
(4) Federal Government.

Only one type of respondent can be selected per row.

No. of Respondents: Provide an estimate of the Number of respondents.
Participation Time: Provide an estimate of the amount of time required for a respondent to participate (e.g. fill out a survey or participate in a focus group)

7. BURDEN**:** Provide the Annual burden hours: Multiply the Number of responses and the participation time and divide by 60.

Category of Respondent		**Number of Respondents**	**Participation Time**	**Burden (rounded)**
Potential CTP Exchange Lab subscriber	Review email invitation to take survey, and click on survey link/Review email reminder (if necessary)	425	2 minutes	14

	Review informed consent form and agree to take the anonymous survey voluntarily	425	5 minutes	35
	Take survey	425	8 minutes	57
Total Annualized Hours				**106**

8. FEDERAL COST: The estimated annual cost to the Federal government is $ 0

B. STATISTICAL METHODS

<u>If you are conducting a focus group, survey, or plan to employ statistical methods, please provide answers to the following questions:</u>

The FDA is not conducting a focus group, survey, or is not planning to employ statistical methods.

The selection of your targeted respondents: Please provide a description of how you plan to identify your potential group of respondents and how you will select them. If the answer is yes, to the first question, you may provide the sampling plan in an attachment.

1. Do you have a customer list or something similar that defines the universe of potential respondents and do you have a sampling plan for selecting from this universe?

[ ] Yes [X] No

If the answer is yes, please provide a description of both below (or attach the sampling plan)? If the answer is no, please provide a description of how you plan to identify your potential group of respondents and how you will select them?

The CTP research team will send an email invitation to 42,564 individuals to take the survey—this includes CTP email communications subscribers, Exchange Lab users who have either registered on the site or signed up to receive Exchange Lab updates but who have not created a content syndication feed, and other CTP stakeholder contacts. These 42,564 individuals represent potentially new users of the Exchange Lab. Any of those individuals may participate in the survey. As such, there is no sampling plan but rather the whole population available for surveying will be invited to participate. We anticipate up to 1 percent of all the invitees will

complete the survey (for a sample size of up to 425 completed surveys). For two previous FDA CTP Email Communications Surveys (2017 and 2018) that did not offer a financial incentive and used some of the same mailing lists, the response rate of 0.83% to 0.88%. We anticipate a slightly higher response rate (up to 1 percent) since the contact lists used to disseminate this survey also include registered users of Exchange Lab and other stakeholders who may be already be familiar with Exchange Lab and, therefore, may have greater interest in participating in the survey.

Administration of the Instrument: Identify how the information will be collected. More than one box may be checked. Indicate whether there will be interviewers (e.g. for surveys) or facilitators (e.g., for focus groups) used.

1. How will you collect the information? (Check all that apply)

   [X] Web-based or other forms of Social Media
   [ ] Telephone
   [ ] In-person
   [ ] Mail
   [ ] Other, Explain

   The information will be collected through a one-time, self-administered online survey. The survey includes 15 questions, including four multipart questions. All of the survey questions include closed-ended response categories where the respondent must select one of various options. For the multipart questions, respondents who answer a specific way on one question will receive other specific questions afterwards.

2. Will interviewers or facilitators be used? [ ] Yes [X] No

REQUESTED APPROVAL DATE: June 21, 2019

NAME OF PRA ANALYST & PROGRAM CONTACT:

PRA Analyst: **Amber Sanford**
301-796-8867
Amber.Sanford@fda.hhs.gov

Program Contact: **Janine Delahanty**
240-402-9705
Janine Delahanty@fda.hhs.gov

FDA CENTER: **Center for Tobacco Products (FDA/CTP)**