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: 2021 FDA CTP Email Survey Audience Analysis Study

1. PURPOSE:

   The FDA Center for Tobacco Products (CTP) uses email marketing as one of its primary tactics for conveying important tobacco education and regulatory information to stakeholders and the general public. On average, CTP sends email communications six times per month to its subscribers. The purpose of the proposed information collection is to expand and refine knowledge of the CTP email subscriber base to improve the following CTP email communications:

   CTP Connect – Provides regular updates on the health effects of tobacco, public health educational resources, and highlights on current tobacco issues and regulations.

   CTP News – Provides tobacco product news as it happens, including information about regulations, guidances, enforcement actions, and other announcements.

   Spotlight on Science – Provides updates on CTP's tobacco regulatory science and research program, scientific publications and study findings, and CTP grants.

2. DESCRIPTION OF RESPONDENTS:

   Respondents are those that actively opted in to subscribe to at least one of FDA CTP's three email communications: CTP Connect, CTP News, and/or Spotlight on Science. All respondents are 18 years of age or older.

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

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: Debra Mekos, PhD
Office of Health Communication and Education
Center for Tobacco Products
240-994-3243
Debra.Mekos@fda.hhs.gov

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? [ ] Yes [X] No
b) If Yes, will any information that is collected be included in records that are subject to the Privacy Act of 1974? [ ] Yes [ ] 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;
(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	**No. of Respondents**	**Participation Time**	**Burden (Rounded)**
Individuals; Email Subscribers – Receive Email Invitation	44,300	0.5 minute	369
Individuals; Email Subscribers – Screener & Informed Consent	1,329	1 minute	23
Individuals; Email Subscribers – Short Version Survey	665	5 minutes	56
Individuals; Email Subscribers – Long Version Survey	664	8 minutes	89
Total			**537**

8. FEDERAL COST: The estimated annual cost to the Federal government is approximately $7,646 (one-time cost).

B. <u>STATISTICAL METHODS</u>

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

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?

[X] Yes [ ] 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 entire CTP email subscriber list will make up the potential group of respondents for this survey. Any individuals who have voluntarily registered for the CTP email listserv may

participate. As such, there is no sampling plan; the whole population of email subscribers will be invited to participate.

Potential respondents will be randomly assigned to receive an email invitation to complete either the 5-minute survey (short version) or the 8-minute survey (long version) using GovDelivery, FDA CTP's email marketing platform.

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

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

Please make sure that all instruments, instructions, and scripts are submitted with the request.

REQUESTED APPROVAL DATE: November 29, 2021

NAME OF PRA ANALYST:

Ila S. Mizrachi
301-796-7726
Ila.Mizrachi@fda.hhs.gov

FDA CENTER: Center for Tobacco Products