

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: 2020 FDA CTP Emails Survey Audience Analysis Study

1. **PURPOSE:** FDA sends email communications to subscribers with a desire to have the highest potential to be received, understood, and accepted by those for whom they are intended. The proposed study is seeking to conduct research on these communications. The study proposed in this document will request information to improve the following CTP email communications:

CTP Connect - This newsletter serves as a digest on the latest announcements and stories out of CTP as they happen, including information about regulations, guidance, enforcement actions, and other compliance-related announcements.

CTP News - This newsletter offers messages from CTP leadership, a regulatory news roundup, feature articles on current tobacco issues, and educational resources.

Spotlight on Science - This newsletter offers updates on CTP’s tobacco regulatory science and research efforts, tobacco scientific publications and study findings, and CTP grants.

Modified Risk Tobacco Product Application Updates - This newsletter provides updates when materials from any MRTP applications under scientific review have been posted.

2. **DESCRIPTION OF RESPONDENTS:** Respondents are those that actively opted in to subscribe to at least one of FDA CTP’s four email communications: CTP Connect, CTP News, Spotlight on Science, and/or Modified Risk Tobacco Product Application Updates.

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 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.

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- 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

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 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 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.

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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)
Email Subscribers	1240	5 mins (.0833 hours)	103

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

B. STATISTICAL METHODS

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

This study involves a one-time voluntary, online survey of subscribers to CTP’s email communications. FDA is not planning to employ statistical methods to analyze the results apart from a simple summary of survey responses.

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 No

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 in the survey. As such, there is no sampling plan; the whole population available for the survey will be invited to participate.

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)

Web-based or other forms of Social Media
 Telephone

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- In-person
- Mail
- Other, Explain

2. Will interviewers or facilitators be used? Yes No

REQUESTED APPROVAL DATE: October, 2020

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