

**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: This is Our Watch Retailer Feedback Study

1. PURPOSE:

The FDA Office of Health Communication and Education has created and maintains retailer education materials (e.g. pamphlets, posters, calendar) designed to educate retailers about their obligation to adhere to minimum legal purchase age requirements for the sale of tobacco products. Referred to as This is Our Watch (TIOW) the customer for these materials are adult, retailers and owners of retail establishments who sell tobacco products. On December 20, 2019, the president signed legislation raising the federal minimum age for purchasing tobacco products from 18 to 21 years. As a result, this legislation (known as “Tobacco 21” or “T21”) requires the U.S. Food and Drug Administration (FDA) Center for Tobacco Products (CTP) to update TIOW retailer education materials. The goal of this collection is to obtain feedback from retailers about their awareness, preferences and experiences related to the TIOW materials.

2. DESCRIPTION OF RESPONDENTS:

Respondents will include clerks, managers, and owners of tobacco retailers identified through the State Synar Program managed by Substance Abuse and Mental Health Services Administration. Respondents will include a mix of English and Spanish speaking participants. Respondents must be 18 years of age and older, must sell any type of tobacco in the United States, and must have worked a minimum of 3 months in tobacco retail.

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.)

- | | |
|---|--|
| <input type="checkbox"/> Customer Comment Card/Complaint Form | <input type="checkbox"/> Customer Satisfaction Survey |
| <input type="checkbox"/> Usability Testing (e.g., Website or Software | <input type="checkbox"/> Small Discussion Group |
| <input type="checkbox"/> Focus Group | <input checked="" type="checkbox"/> Other: <u>Interviews</u> |

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: Matt Walker
Office of Health Communication and Education
Center for Tobacco Products
240-402-3824
Matthew.Walker@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 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

As interviewees often have competing demands for their time, compensation for participation in this project is warranted. The compensation for participation in the interview will be a \$40 pre-paid gift card provided at the completion of the interview as a thank you for taking part in this study. The IQ Team will offer each interviewee the option of receiving an e-gift card or a mailed gift card. This incentive is warranted as we will be interviewing a mix of clerks, managers, and owners of tobacco retailers. The mean hourly wage for owners of tobacco retailers (General and Operations Managers) is \$59.15. (U.S. Department of Labor and Statistics - [May 2019 data](#)).

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)
Private Sector; Retailers that sell tobacco products - Interview	40	60 mins (1 hour)	40
Private Sector; Retailers that sell tobacco products - Screening	120	5 mins (0.0833 hours)	10
Totals	120		50

8. FEDERAL COST: The estimated annual cost to the Federal government is approximately \$5,000 (one-time cost)

B. STATISTICAL METHODS

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

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 Synar Program is responsible for implementing the requirements of the Synar Amendment which requires each state to enact and enforce laws prohibiting the sale and distribution of tobacco products to minors. CTP will reach out to State Synar Program managers to obtain a list of tobacco retailers in their state. The final sampling plan for selecting participants from this list will be determined after lists have been received and CTP determines the contact information that we will have access to. We will screen interviewees using an interviewee recruitment screener questionnaire to ensure interviewee eligibility. In order to ensure we capture a range of retailer types, we will strive to recruit a diverse range of participants with respect to business size (chain versus small business), role (clerk, manager, or owner), and geographic location (region/state; urban, rural, suburban).

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
- In-person
- Mail
- Other, Explain

2. Will interviewers or facilitators be used? Yes No

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

REQUESTED APPROVAL DATE: March 8, 2021

NAME OF PRA ANALYST & PROGRAM CONTACT:

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

Matt Walker
Office of Health Communication and Education
Center for Tobacco Products
240-402-3824
Matthew.Walker@fda.hhs.gov

FDA CENTER: Center to Tobacco Products