U.S. Food and Drug Administration
Center for Tobacco Products
Copy Testing of Tobacco Prevention and Cessation Advertisements Research Study
OMB Control Number 0910-0810

SUPPORTING STATEMENT A

A. Justification

1. Circumstances Making the Collection of Information Necessary

On June 22, 2009, the President signed the Family Smoking Prevention and Tobacco Control Act (FSPTCA) (Public Law 111-31) into law. The FSPTCA granted FDA important new authority to regulate the manufacture, marketing, and distribution of tobacco products to protect the public health generally, and to reduce tobacco use by minors. FDA's Center for Tobacco Products (CTP) uses advertising campaigns to inform the public about the harms of tobacco use and prevent youth from using tobacco. In support of this effort, CTP conducts research to assess the extent to which pre-produced (i.e., preliminary versions of ads created prior to production, such as storyboards, boardomatics and animatics) or fully-produced advertisements communicate an understandable and engaging message about the harms of tobacco use without potential unintended consequences related to beliefs around the harms of tobacco use. This type of assessment of ads is known as "copy testing." The current study will assess the performance of pre-produced and fully-produced ads developed to reduce tobacco initiation and use among youth. Information obtained through this study will be used to refine the formative research testing process and optimize copy testing strategies.

2. Purpose and Use of the Information Collection

This research is designed to assess the performance of pre- and post-production ads developed to reduce tobacco initiation and use among youth, and to inform process improvements to CTP's formative ad development process. CTP's current formative approach includes the following steps: 1) Development of pre-production ads with script, storyboards or animatics with voiceover; 2) Qualitative testing of pre-production ads via focus groups; 3) Development of final (post-production) ads incorporating feedback from qualitative research; 4) Quantitative copy testing of post-production ads to ensure adequate performance on measures of ad reactions.

While the current process ensures that post-production ads meet minimum thresholds for ad performance, CTP is considering incorporating quantitative copy testing measures earlier in the formative ad development process to examine the relative performance of pre-production ads being considered for full production. This updated protocol would enable CTP to apply findings from the quantitative copy testing measures towards ad selection, development of the final post-production ads and allow for course corrections to ads or ad components that are underperforming at the pre-production stage.

To inform its formative approach to ad development, CTP is conducting an online survey of up to 900 youth aged 13-17 who have used[1] or are susceptible to using[2] electronic nicotine delivery systems (ENDS) or cigarettes to understand the extent to which reactions to tobacco prevention messaging and patterns of ad reaction scores vary between pre- and post-production ad versions. Specifically, the survey will be designed to answer the following research questions:

> **RQ1:** To what extent do ad reactions vary between pre- and post-production ad versions? Compared with pre-production ads, are post-production versions perceived as less, more, or equally effective?
>
> **RQ2:** To what extent are ad reactions for pre-production ads associated with ad reactions for post-production ads?

Findings from this research will provide scientific evidence to test the proposed updates to CTP's formative ad development process. Specifically, a finding that pre- and post-production scores and patterns of results are substantively equivalent would suggest that pre-production ad reactions are a good indicator of reactions for post-production ads.

3. **Use of Improved Information Technology and Burden Reduction**

In an effort to minimize burden on respondents, this is a web-based study to which 100% of the respondents will submit the information in an electronic format. Because there is no interviewer present, participant responses to a web-based survey are less prone to social desirability bias.

4. **Efforts to Identify Duplication and Use of Similar Information**

There is no duplicative collection of this information. No comparable data have been collected by any other entities. We carefully reviewed the literature and existing data sets to determine whether any of them are sufficiently similar or could be modified to address CTP's needs. We concluded that the existing literature and existing data sources do not include the measures needed by CTP.

5. **Impact on Small Businesses or Other Small Entities**

No small businesses will be involved in this collection of information.

6. **Consequences of Collecting the Information Less Frequently**

This is a one-time data collection. The collection of information will provide important data needed for FDA to determine the optimal approach for formative ad development and copy testing. Failure to collect these data could reduce effectiveness of CTP's messaging, and therefore reduce the benefit of the messages for youth in the United States.

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[1] Vaped or used cigarettes on 1 or more of the past 30 days.

[2] [2]Never vaped or used cigarettes and respond anything but "Definitely not" to at least 1 of the survey 3 items about susceptibility (whether will vape/smoke in the next year, try vaping/smoking soon, and try vaping/smoking if offered by a friend).

7. **Special Circumstances Relating to the Guidelines of 5 CFR 1320.5**

This information collection fully complies with 5 CFR 1320.5(d)(2). No special circumstances are associated with this information collection that would be inconsistent with the regulation.

8. **Comments in Response to the Federal Register Notice and Efforts to Consult Outside the Agency**

The following individuals inside the agency have been consulted on the design of the study, instrument development, or intra-agency coordination of information collection efforts:

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FDA collaborates with other federal government agencies that sponsor or endorse health communication projects, such as the Centers for Disease Control and Prevention, Office on Smoking and Health (CDC/OSH), the Substance Abuse and Mental Health Services Administration (SAMHSA) and the National Institutes of Health National Cancer Institute (NIH/NCI). These affiliations serve as information channels, help prevent redundancy, and promote use of consistent measures of effectiveness. Coordination activities include:

- Review of proposed messages for advertisements;
- Review of questionnaires for testing purposes;
- Sharing data; and
- Standardizing survey tools where at all possible.

The following individuals outside of the agency have been consulted on questionnaire development:

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9. **Explanation of Any Payment or Gift to Respondents**

The study will include recruitment of youth ages 13-17 through their parents using an online survey panel and/or recruitment of youth ages 15-17 directly using social media advertising. For parents recruited from the online panel, the panel will provide nonmonetary "points" valued at or equivalent to $10 to parents of youth who complete each survey. "Points" are a routine part of panel maintenance strategy and can be accrued and traded for material items with partner vendors (e.g., Amazon.com, Starbucks) or for cash. The panel will provide the unique, alphanumeric survey IDs of individuals who should be compensated to the partner company. Participants recruited through social media who complete and submit the full survey will receive a $10 gift card.

The token of appreciation allows us to treat participants justly and with respect by acknowledging competing demands for their time and the effort they spend participating. A reasonable token of appreciation is standard practice for research and is suggested by

organizations that set the standards for conducting ethical industry-led research among human subjects (Code of Ethics and Standards for Market Research and Data Analytics, 2021).[3]

Tokens of appreciation are important to recruit at-risk and multicultural populations. Such populations are important to the current study because of the risk factors for tobacco use; those populations are also historically difficult to recruit and retain in health research (Hooven et al., 2011; Murthy et al., 2004; Post et al., 2012; Siddiqui et al., 1996; Zand et al., 2006). The use of tokens of appreciation is associated with more diverse sample populations (Booker et al., 2011; Caldwell et al., 2010; Martinson et al., 2000; Walter et al., 2013). Tokens of appreciation are also associated with a more balanced and unbiased sample. Evidence suggests that participants who are offered a token of appreciation have significantly lower non-response rates and less missing data, potentially providing reduction in bias resulting from these factors (Singer, 2002).

CTP has previously used this $10 token approach in a study with similar participants (youth ages 13-17 who had experimented with ENDS use or at-risk of ENDS use) and study design; that study had a diverse sample and timely data collection (OMB control number 0910-0810). In that study, the response rate was about 19% (1,660 completed out of 8,837 screened). This past data show that this is a difficult population to recruit and enroll, and an incentive rate lower than $10 would severely negatively impact the response rate, costing the government additional time and money. Other CTP studies have used similar tokens of appreciation for surveys of similar length and with similar target populations (e.g., Monthly Monitoring Study, OMB control number 0910-0810).

10. **Assurance of Confidentiality Provided to Respondents**

Concern for privacy and protection of respondents' rights will play a central role in the study implementation, storage and handling of data, and data analysis and reporting. The Institutional Review Board (IRB) of RTI International, the research organization contracted to manage data collection has reviewed and approved the protocols for the survey. FDA's Research Involving Human Subjects Committee (RIHSC) conducted a courtesy review before submission to RTI IRB; RIHSC determined that FDA is not engaged in the research. The primary concern of IRB is protecting respondents' rights, one of which is maintaining the privacy of respondent information.

Privacy for survey respondents will be ensured in a number of ways. Prior to beginning the survey, all respondents are urged to find a private setting to take the survey. Participation in this study is voluntary, and respondents can choose not to answer any of the study questions and drop out of the survey at any time. Additional protections are specific to recruitment method and described below.

Panel Via Parent
For this recruitment method, both the screener and survey are hosted by the primary panel vendor. All of the provisions below apply.

(1) Panel providers maintain databases of panelist information with personally identifying information (PII). However, this information is kept separate from study data. Panel

[3] Insights Association. (2021). Code of Standards and Ethics for Market Research and Data Analytics. https://www.insightsassociation.org/sites/default/files/misc_files/ia_code_revised_november_2021_finalv2.pdf

vendor partners will not provide this PII to RTI or FDA. Neither RTI nor FDA will request the PII.

(2) The screener and survey are programmed such that one cannot back up to view previous responses. For example, if the respondent were to set down their electronic device, a family member or friend could not back up to see how the respondent answered prior survey items about tobacco use.

(3) Respondents' information will not be tied to their individual responses and all analyses will be conducted in the aggregate (i.e., any data used in reporting will not be attributed to individual participants). No respondent identifiers will be contained in reports to FDA.

(4) After receiving the data from the panel provider RTI will store it on the restricted-access study shared drive and the FIPS 199 moderate network. When the study is complete, RTI archives this shared drive and indicates its date of expiration, 5 years from the time that the project concludes. At the date of expiry, the shared drive and its contents are destroyed by RTI's information technology services. The panel provider will store survey data for up to 5 years.

Social Media Direct to Youth
For this recruitment method, the screener is hosted by Qualtrics and the survey is hosted by the primary panel vendor. Protections for the survey data match what is described above for *Direct to Youth* recruiting.

The following procedures will be applied to the screener data in Qualtrics used to ensure participant privacy before, during, and after fielding:

(1) Datasets of screener responses stored in Qualtrics will not contain any PII. All PII (e-mail address and birthdate) will be collected by Qualtrics, downloaded by RTI, and stored by Qualtrics as one file that contains only PII and a RTI-assigned unique study ID. We are using the study ID to connect PII with screener data and to determine if a participant has completed the survey and perform fraud detection procedures. IP address will be collected by Qualtrics, downloaded by RTI, and stored by Qualtrics and RTI as a second file that only contains IP address, the unique ID, and the participant responses to the screener (excluding PII). IP address and PII (e-mail address, birthdate, zip code) will not be collected in the same file.

(2) All of the data files (PII and screener data (with IP address) will be downloaded together from Qualtrics (which requires a password) daily (Monday through Friday) to run fraud detection.

a. The screener data (with IP address) and PII, when downloaded from Qualtrics, will be stored on the RTI share for up to 48 hours, and then placed in the Federal Information Processing Standards (FIPS) 199 moderate network. This is because the FIPS 199 moderate network does not permit access to the internet (and downloading the data from Qualtrics requires an internet connection). Additionally, fraud detection

measures involve combining IP address, PII, and screener responses, which is much easier to do on the study shared drive than on the FIPS 199 moderate network.

b. If the FIPS 199 moderate network is unavailable because of an RTI outage, we will move files with PII to the FIPS 199 moderate network as soon as availability is restored. As an additional quality control, a second study team member will confirm that PII has been moved to the FIPS 199 moderate network after fraud protection procedures have been completed.

c. The file containing only study ID and the screener responses will remain on the study shared drive. At the completion of data collection, all data will be deleted from our Qualtrics account and remain only on RTI's secure shared drive and the FIPS 199 moderate network. Data files will be stored on the restricted-access study shared drive and the FIPS 199 moderate network. When the study is complete, RTI archives this shared drive and indicates its date of expiration, 5 years from the time that the project concludes. At the date of expiry, the share drive and its contents are destroyed by RTI's information technology services.

(3) The password to access all survey data files in Qualtrics will not be shared with FDA. Only the necessary study staff at RTI will have access to PII for the purpose of fraud detection and incentive delivery.

(4) Respondents cannot back up in the survey to view previous responses. Additionally, if there is a 60-minute lapse in data entry suggesting that the respondent has stepped away from the survey, the respondent will be automatically logged out to protect both data and respondent. Respondents will not be allowed re-enter the survey.

(5) Respondents' information will not be tied to their individual responses and all analyses will be conducted in the aggregate (i.e., any data used in reporting will not be attributed to individual participants). No respondent identifiers will be contained in reports to FDA.

Reason for collection e-mail address (PII): E-mail address is necessary for all participants, even those who screen out as ineligible, for fraud detection purposes (we have to be able to detect and eliminate duplicates across both eligible and ineligible screener completes). As a result, it is not possible to route participants to the screener exit if they screen out as ineligible before collecting their e-mail address.

Reason for collecting date of birth (PII): We will cross-reference reported age and date of birth to ensure matching to reduce fraudulent responses.

Reason for collecting IP Address: To reduce the potential of participants completing multiple screeners and to reduce non-U.S. based youth from completing screeners, IP addresses from outside of the U.S. will be blocked from taking the screener. Additionally, we may maintain a list of IP addresses from which we receive repeated fraudulent activity as defined above. IP addresses appearing on this list may be blocked from accessing the screener.

This study is funded by the FDA, a Department of Health and Human Services supported agency, and is covered by a Certificate of Confidentiality (CoC). Section 2012 of the 21st Century Cures Act includes significant amendments, to the previous statutory authority for such

protections, to enhance privacy protections for individuals who are the subjects of federally funded research, under subsection 301(d) of the Public Health Service Act (42 U.S.C. 241). Specifically, the amended authority requires the FDA to issue a CoC to investigators or institutions engaged in research funded by the Federal government to protect the privacy of individuals who are subjects of this research. We will notify participants in the assent form (and parental permission form) of the protections that the Certificate provides.

11. **Justification for Sensitive Questions**

Most questions asked will not be of a sensitive nature. However, it will be necessary to ask some questions that may be considered of a sensitive nature in order to assess specific health behaviors, such as tobacco use. Asking such questions is critical to the objectives to this information collection.

Some questions about tobacco use are potentially sensitive because tobacco use among adolescents under age 18 is illegal in a few states, and sales to individuals under age 21 are illegal nationwide. These questions are essential to the objectives of this information collection.

Demographic questions such as race and ethnicity, country of origin/national background, gender identity, and sexual orientation could be considered sensitive. The purpose of these questions is to ensure a representative respondent sample that enables assessing potential differences in receptivity of tobacco messages through subgroup comparisons.

Decades of research has shown significant disparities in tobacco use by race (e.g., Harlow et al., 2019; Odani et al, 2018), gender identity (e.g., Johnson et al, 2019; Delahanty et al, 2019). We ask about country of origin/national background when asking about Hispanic/Latino ethnicity because an abundance of data shows disparities in tobacco use and susceptibility depending on Hispanic/Latino country of origin (Slobig, 2014; Kaplan et al., 2014; Parrinello et al., 2015; Bandiera et al., 2015). Response options include the top 5 countries of origin based on the 2020 U.S. Census data. Given that nearly one in 5 (18.7%) Americans identify as Hispanic/Latino it is important for CTP to capture this information to ensure our efforts in smoking cessation and prevention are not only reflective of U.S. population characteristics but can reach and reflect the needs of this sizeable segment of the population.

Research has also shown significant disparities in tobacco use by sexual orientation and gender identity (e.g., Johnson et al, 2019; McCabe et al., 2018). The 2021 National Youth Tobacco Survey (NYTS) found that adolescents who identified as sexual or gender minority had higher rates of tobacco use than their heterosexual or cisgender counterparts. For example, 17% of high school students in the NYTS who identified as gay, lesbian, or bisexual currently used tobacco, compared to 11% of heterosexual students. Approximately 25% of transgender high school students in NYTS 2021 currently used tobacco, compared to 12% of non-transgender students. Therefore, collecting detailed information on these demographic characteristics among our sample will allow us to measure subgroup differences in tobacco education message receptivity with the goal of reducing these disparities.

Currently, there is no federal requirement for one uniform question to assess sexual orientation or gender identity (SOGI). For example, the most recent federal guidance from the White House Office of the Chief Statistician of the United States (OCS) on assessing LGBTQ+ identity in federal surveys states that their guidance, “does not mandate any particular approach or create

any new requirements for agencies. In the future, Federal agencies may need to diverge from the recommendations in this report to reflect new, evidence-based best practices."[4] It also states that the recommendations in its recent guidance are not intended to "limit the continued evolution and improvement of SOGI data collection methods." The gender identity and sexual orientation questions included in this protocol are based on OMB control number 0910-0914 options for the Monthly Monitoring Study.

We recognize that many studies assess sex assigned at birth, especially those that are focused on clinical or medical information. However, in this study, FDA is not collecting data for clinical/medical purposes and does not need to know the status of respondent's sex assigned at birth. For the purposes of FDA's campaign efforts, we are only able to craft messages, tailor campaigns, and tailor media strategy by gender identity (not sex). Our focus only on gender identity aligns with the 2022 NASEM[5] report's argument that, "in many contexts...collection of data on gender is more relevant than collection of data on sex as a biological variable, particularly for the purposes of assessing inclusion and monitoring discrimination and other forms of disparate treatment." Additionally, gender identity questions should contain a non-binary option (to encompass identities such as non-binary, genderqueer, gender non-conforming), as multiple studies of youth and young adults have shown that approximately 12%-32% of their samples identified with non-binary identities (e.g., The Human Rights Campaign 2018 LGBTQ+ Youth Report; The Trevor Project 2020 National Survey on LGBT Youth Mental Health; CTP's evaluation of This Free Life campaign; Kosciw, 2021). Non-binary identities are also recognized federally, as people in the United States can select "X" as their gender marker on their passport (U.S. Department of State, 2022).

CTP's research has shown the need to provide an expanded set of options for sexual orientation. Data from FDA/CTP's This Free Life LGBTQ+ tobacco campaign evaluation (sample n=12,324) (OMB control number 0910-0808, fielded from 2016 to 2019) showed that nearly 10% of the sample identified with a sexual orientation other than lesbian, gay, or bisexual of which most reported using another label such as pansexual or queer. A recently published intersectional analysis using data from this study found important variations in tobacco use across different sexual and gender minority subgroups,[6] underscoring the need to ensure appropriate inclusion and measurement of these groups in tobacco research.

Participants may exit the screener or survey instrument at any time without penalty should they not wish to answer a question or longer wish to participate. If respondents are uncomfortable with any of the questions, they can terminate the screener or survey instrument at any time without penalty.

To address any concerns about inadvertent disclosure of sensitive information, respondents will be fully informed of the applicable privacy safeguards. The assent form will apprise respondents that the topic of tobacco use will be covered during the survey. This study includes a number of procedures and methodological characteristics that will minimize potential negative reactions to these types of questions, including the following:

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[4] Office of the Chief Statistician of the United States. (2023). Recommendations on the best practices for the collection of sexual orientation and gender identity data on federal statistical surveys. https://www.whitehouse.gov/wp-content/uploads/2023/01/SOGI-Best-Practices.pdf

[5] National Academies of Sciences, Engineering, and Medicine 2022. Measuring Sex, Gender Identity, and Sexual Orientation. Washington, DC: The National Academies Press. https://doi.org/10.17226/26424.

[6]

- Respondents will be informed that they do not need participate and that if they choose to participate, they do not need answer any question on the survey (aside from required screening questions) that makes them feel uncomfortable or that they simply do not wish to answer.
- The web survey is entirely self-administered to maximize respondent privacy without the need to verbalize responses.
- Participants will be provided with a specific toll-free phone number for the RTI Office of Research Protection and the RTI Principal Investigator to contact in case they have a question or concern about the sensitive issue.

The project team will not conduct or report on statistical analysis for demographic groups for which there is insufficient statistical power.

12. **Estimates of Annualized Burden Hours and Costs**

12a. ***Annualized Hour Burden Estimate***

An estimated one-time reporting burden for both adults and youth combined for this collection will be approximately 1,000 hours (Table 1). This includes a reporting burden of approximately 250 hours for adults and approximately 750 hours for youth. The total time burden for adults includes time associated with the parental consent process, which we anticipate will require 5 minutes per response to complete (0.0833 hours). Among youth, we anticipate the assent process will also require 5 minutes per response to complete (0.0833 hours), screening will require 5 minutes per response to complete (0.0833 hours), and the survey will require 20 minutes per response to complete (0.3333 hours).

To obtain a final sample of 900 youth aged 13-17 who have either used e-cigarettes or cigarettes or are susceptible to e-cigarette or cigarette use, we estimate administering the study invitation and parental consent to 3,000 parents of potential participants. Based on experience from previous surveys, we anticipate about 60% of parents who review the parental consent form will provide permission for their child to participate in the study. For social media recruitment directly to youth ages 15-17, based on previous experience, we anticipate about 10% of youth exposed to a recruitment ad impression will click through. Of the potential youth participants, we anticipate approximately 40% have either used e-cigarettes or cigarettes or are susceptible to e-cigarette use or cigarette smoking and will consent to participate.

Table 1. Estimated Annual Reporting Burden

Type of Respondent	Activity	Number of Respondents	Number of Responses per Respondent	Total Responses	Average Burden per Response (in hours)	Total Hours
Youth aged 15-17	Social media recruitment ad impression	4,500	1	4,500	0.0166 (1 min)	**75**
Adult, general population	Invitation and Parental Consent	3,000	1	3,000	0.0833 (5 min)	**250**
Screened Potential Participants						
Youth aged 13 to 17	Youth Assent	2,250	1	2,250	0.0833 (5 min)	**187.5**
Youth aged 13 to 17	Youth Screening	2,250	1	2,250	0.0833 (5 min)	**187.5**
Survey Participants						
Youth aged 13 to 17	Survey	900	1	900	0.3333 (20 min)	**300**
Total Annualized Hours						**1,000**

12b. *Annualized Cost Burden Estimate*

Respondents participate on a purely voluntary basis and, therefore, are subject to no direct costs other than time to participate. There are also no start-up or maintenance costs. The estimated value of respondents' time for participating in the information collection is $13,572. To calculate this cost, the mean hourly wage of $7.25 was used for youth and $28.01 was used for parents. The youth price represents the minimum wage, and the parental costs represent the Department of Labor estimated mean for state, local, and private industry earnings. There are no direct costs to respondents associated with participation in this information collection. Thus, assuming an average hourly wage of $7.25 and $28.01 (youth and parent), and doubling this to account for benefits and overhead, yielding an hourly wage rate of $14.50 for youth and $56.02 for parents, the estimated one-year annualized cost to participants will be $24,880. The estimated value of respondents' time for participating in the information collection is summarized in Table 2.

Table 2. Estimated Annual Cost

Type of Respondent	Activity	Annual Burden Hours	Doubled Hourly Wage Rate	Total Cost
Parent	Invitation and Parental Permission Form	250	$ 56.02	$14,005
Youth	Assent, Screener, and Survey	750	$ 14.50	$10,875
Total		**1,000**		**$24,880**

13. **Estimates of Other Total Annual Costs to Respondents and/or Recordkeepers/Capital Costs**

No capital, start-up, operating, or maintenance costs are associated with this information collection.

14. **Annualized Cost to the Federal Government**

The total estimated cost to the Federal Government for this study is $127,099.00 as shown in Table 3. Contractor costs attributable to this information collection are $96,143. This includes costs to program the survey, draw the sample, and collect the data. Other contractor activities outside this data collection estimate include coordination with FDA to develop the instrument and deliver the final data set and reporting deliverables.

Table 3. Itemized Cost to the Federal Government

Government Personnel	Time Commitment	Average Annual Salary	Total
GS-13	20%	$119,482	$23,896.40
GS-14	5%	$141,192	$7,059.60
Total Salary Costs			$30,956.00
Contractor Costs			$96,143.00
Total			**$127,099.00**

15. **Explanation for Program Changes or Adjustments**

This is a new data collection.

16. **Plans for Tabulation and Publication and Project Time Schedule**

The project schedule is shown in Table 4. Future development and research activities are dependent on the timely completion of the present study.

Table 4. Project Schedule

Activity	Approximate Date
Data Collection	August 2023
Draft Reporting Deliverables	October 2023
Final Reporting Deliverables	November 2023

17. **Reason(s) Display of OMB Expiration Date is Inappropriate**

FDA is not requesting an exemption for display of the OMB expiration date and is also not seeking OMB approval to exclude the expiration date for this information collection. The OMB approval and expiration date will be displayed on the relevant materials associated with the study.

18. **Exceptions to Certification for Paperwork Reduction Act Submissions**

There are no exceptions to the certification.