U.S. Food and Drug Administration

Center for Tobacco Products

Tobacco Product Establishment Registration and Listing

OMB Control Number 0910-0650

SUPPORTING STATEMENT

**Terms of Clearance:** None

## A. Justification

1. Circumstances Making the Collection of Information Necessary

On June 22, 2009, the Family Smoking Prevention and Tobacco Control Act (Tobacco Control Act) (Public Law 111-31) was signed into law. The Tobacco Control Act amended the Federal Food, Drug, and Cosmetic Act (the FD&C Act) by adding, among other things, a chapter granting U.S. Food and Drug Administration (FDA) important authority to regulate the manufacture, marketing, and distribution of tobacco products to protect the public health generally and to reduce tobacco use by minors. The Tobacco Control Act created many requirements for the tobacco industry. Section 101 of the Tobacco Control Act amended the act by adding sections 905 and 904.

**Registration and Listing (Section 905)**

Section 905 of the FD&C Act requires the annual registration of any "establishment in any State engaged in the manufacture, preparation, compounding, or processing of a tobacco product or tobacco products." Section 905 requires this registration be completed by December 31 of each year. The Secretary of Health and Human Services has delegated to the Commissioner of the Food and Drug Administration the responsibility for administering the act, including section 905.

Section 905 of the act requires owners or operators of each establishment to register:

1) their name (905(b))
2) places of business (905(b))
3) a list of all tobacco products which are manufactured by that person (905(i)(1))
4) a copy of all labeling and a reference to the authority for the marketing of any tobacco product subject to a tobacco product standard under section 907 or to premarket review under section 910 (905(i)(1)(A))
5) a copy of all consumer information and other labeling (905(i)(1)(B))
6) a representative sampling of advertisements(905(i)(1)(B))
7) upon request made by the Secretary for good cause, a copy of all advertisements for a particular tobacco product (905(i)(1)(B))
8) upon request made by the Secretary, if the registrant has determined that a tobacco product contained in the product list is not subject to a tobacco product standard

established under section 907, a brief statement of the basis upon which the registrant made such determination (905(i)(1)(C)).

FDA collects the information submitted pursuant to section 905 through an electronic portal, and through a paper form (Form FDA 3741 and 3741a) for those individuals who choose not to use the electronic portal. In the future FDA will be seeking OMB approval to update form 3741 to incorporate NTN products. In the electronic portal and paper form FDA is requesting the following information:

- Registrant information
  - role of registrant
- Owner information
  - owner name, title, address, email, and position title
  - company name, address, telephone & fax number, owner Dun and Bradstreet D-U-N-S number (optional), any other owner company business name, type of business structure, list of corporate officers and director, and state of incorporation
- Establishment information
  - establishment name, address, telephone & fax number, establishment Dun and Bradstreet D-U-N-S number (optional), and functions performed by establishment
- Operator information
  - Operator name, address, operator Dun and Bradstreet D-U-N-S number (optional), any other operator business name, type of business structure, name of individuals associated with business structure, and state of incorporation
- Product listing, details
  - unique product name, intended use, category, and flavor
- Product listing, labeling
  - all labeling for each product including identification of type of labeling, internal identification number, UPC code, and date label was first published
- Product listing, consumer information
  - all consumer information for each product including type of material, internal identification number, and date material was first disseminated
- Product listing, advertising
  - a representative sampling of advertising for each product including type of advertising material, internal identification number, and date advertisement was first disseminated
- Confirmation statement
  - certification of truth and accuracy
  - authorized agent name, title, address, email, and position title
  - authorized agent company name, address, and telephone & fax number.

FDA has also published a guidance for industry entitled “Registration and Product Listing for Owners and Operators of Domestic Tobacco Product Establishments.” This guidance is intended to assist persons making tobacco product establishment registration and product listing submission to FDA.

**Ingredient Listing (Section 904)**

Section 904(a)(1) of the act requires that each tobacco product manufacturer or importer submit "a listing of all ingredients, including tobacco, substances, compounds, and additives that are, as of such date, added by the manufacturer to the tobacco, paper, filter, or other part of each tobacco product by brand and by quantity in each brand and subbrand" by December 22, 2009. This section applies only to those tobacco products manufactured and distributed before June 22, 2009, and which are still manufactured as of the date of the ingredient listing submission.

Section 904(c) of the act requires that a tobacco product manufacturer: 1) Provide all information required under section 904(a) to FDA "at least 90 days prior to the delivery for introduction into interstate commerce of a tobacco product not on the market on the date of enactment" of the Tobacco Control Act; 2) Advise the FDA in writing at least 90 days prior to adding any new tobacco additive or increasing in quantity an existing tobacco additive, except for those additives that have been designated by the FDA through regulation as not a human or animal carcinogen, or otherwise harmful to health under intended conditions of use; 3) Advise the FDA in writing at least 60 days prior to eliminating or decreasing an existing additive, or adding or increasing an additive that has been designated by the FDA through regulation as not a human or animal carcinogen, or otherwise harmful to health under intended conditions of use.

FDA collects the information submitted pursuant to section 904(a)(1) and 904(c) through an electronic portal, and through a paper form (Form FDA 3742) for those individuals who choose not to use the electronic portal. In the future FDA will be seeking OMB approval to update form 3742 to incorporate NTN products. In the electronic portal and paper form, FDA is requesting the following information:

- Type of submission
  - new submission, ingredient listing for tobacco products on the market as of June 22, 2009 *(for cigarettes, cigarette tobacco, RYO, and smokeless tobacco)* or as of August 8, 2016 *(for deemed tobacco products)* or as of April 14, 2022 *(for tobacco products containing nicotine that is not made or derived from tobacco)*
  - new submission, ingredient listing for new tobacco product
  - update to previous submission to add, delete, or change the quantity of an additive
- Manufacturer (or importer) identification
  - submitter type, company name, address, country, company headquarters Dun and Bradstreet D-U-N-S number (optional), and company headquarters FEI number
- Authorized representative
  - Contact name, title, position title, mailing address, email, telephone, and fax
- Tobacco product identification

    - FDA assigned tracking number, tobacco product brand/sub-brand name or other commercial name, submission tracking number (STN) if appropriate, product identification number, type of product identification number, intended use of product, product category and subcategory, and whether the product is co-packaged
- Component identification
    - Component type, manufacturer name, and manufacturer's uniquely identifying component name and/or number

- Ingredient listing
    - product name, ingredient name, ingredient number, and alternative ingredient using the ingredient number
    - ingredient identification,
        - for a single chemical substance: unique scientific name or code, type of code, and identification of reaction product
        - for leaf tobacco: type, variety, cure method, heat source, and identification of genetic or transgenic manipulation
        - for complex purchased ingredients: manufacturers name, unique identifying item name and or numbers used by manufacturer, and identification if ingredient is made to submitter's specifications
    - ingredient details including quality, expected functions
    - quantity of ingredient including unit of measurement and how quantity is determined, limit of detection, quantity of additive increase or decrease with date of change, or date of introduction to market
- Confirmation statement
    - identification and signature of authorized representative including name, company name, address, position title, email, telephone, and fax.

In addition to the development of the electronic portal and paper form, FDA published a guidance entitled "Listing of Ingredients in Tobacco Products." This guidance is intended to assist persons making tobacco product ingredient listing submissions. FDA also provides a technical guide, embedded hints, and a web tutorial to the electronic portal.

**D-U-N-S Number**

The FDA Standards Council has designated Dun and Bradstreet's Data Universal Numbering System (D-U-N-S®) Number as the business entity standard, to be used along with FDA's internal tracking numbers. Electronic registration for submitting Registration and Listing and Product Identifier information now will accept a DUNS number and it can be used as an optional Center for Tobacco Products (CTP) registration number. However, the DUNS number is not required to be used for CTP transactions. Obtaining a DUNS number allows each business to be uniquely identified by FDA and is specific for each corporate entity and place of business.

**Deeming tobacco products**

The Food and Drug Administration (FDA) issued a final rule to deem products meeting the statutory definition of "tobacco product" to be subject to the FD&C Act. The FD&C Act provides FDA authority to regulate cigarettes, cigarette tobacco, roll-your-own tobacco, smokeless tobacco, and any other tobacco products that the Agency by regulation deems to be subject to the law. This final rule extends the Agency's "tobacco product" authorities to all other categories of products that meet the statutory definition of "tobacco product" in the FD&C Act, except accessories of such newly deemed tobacco products. This final rule also prohibits the sale of "covered tobacco products" to individuals under the minimum age of sale and requires the display of health warnings on cigarette tobacco, roll-your own tobacco, and covered tobacco product packages and in advertisements. The rule also provides that manufacturers, distributors, importers, and retailers are responsible for ensuring that the covered tobacco products (in addition to cigarettes and smokeless tobacco) they manufacture, label, advertise, package, distribute, import, sell, or otherwise hold for sale comply with all applicable requirements. FDA is taking this action to reduce the death and disease from tobacco products.

**Tobacco products containing nicotine that is not made or derived from tobacco**

The Consolidated Appropriations Act of 2022 (the Appropriations Act), enacted on March 15, 2022, amended the definition of the term "tobacco product" in section 201(rr) of the FD&C Act to include products that contain nicotine from any source. As a result, non-tobacco nicotine (NTN) products that were not previously subject to the FD&C Act (e.g., products containing synthetic nicotine) are now subject to all of the tobacco product provisions in the FD&C Act beginning on April 14, 2022.

2. Purpose and Use of the Information Collection

FDA will use the information collected under these provisions of the act to meet inspection requirements, and the information will inform FDA's development of good manufacturing practices and review standards for new tobacco products, among others.

The information collected by FDA will be used to register new and update existing tobacco product establishments required under section 905 of the act and to register new product ingredient listings and update existing product ingredient listing required under sections 904(a)(1) and 904(c) of the act. The collection of the DUNS number information is optional, and the information can be used by FDA to identify tobacco establishments who must comply with the act.

If this data is not able to be collected, FDA would be unable to effectively regulate portions of the Tobacco Control Act.

Respondents to this collection are expected to be tobacco product establishment for-profit businesses or their representatives from the private sector.

3. Use of Improved Information Technology and Burden Reduction

FDA collects the registration and product listing information through electronic portals and through paper forms. In 2020, FDA launched the Tobacco Registration & Product Listing Module – Next Generation (TRLM-NG) (https://www.fda.gov/tobacco-products/manufacturing/tobacco-registration-and-listing-module-next-generation-trlm-ng-instructions) replacing the . the FDA Unified Registration and Listing System (FURLS) system. TRLM-NG allows establishments to upload and view their data at any time. Establishments no longer need to download an electronic submission program to their computers, can submit their information online from the website; can update files for product labeling, advertising, and consumer information without resubmitting the entire listing; and can report no changes to their registration or product listing by simply checking a box.

Ingredient listings may be submitted electronically through the CTP portal (https://www.fda.gov/tobacco-products/manufacturing/submit-ingredient-listing-tobacco-products) or if unable to submit ingredients electronically then by mail using FDA form 3742.

FDA estimates that approximately 99% of the respondents will use the electronic portals to fulfill the agency's request for registration and listing (Form FDA 3741 and 3741a), and product ingredient listing (Form FDA 3742).

4. Efforts to Identify Duplication and Use of Similar Information

This information collection is not duplicative, and the Tobacco Control Act requires the submission of this information. FDA is the only Federal agency responsible for the collection of such information and is the primary federal regulatory authority with respect to the manufacture, marketing, and distribution of tobacco products. Therefore, no duplication of data exists.

FDA also has extensive contacts with other agencies that have collected or are currently collecting tobacco data, and no similar registration and listing or product ingredient listing data is known to be available to respondents of this collection of information.

5. Impact on Small Businesses or Other Small Entities

The information submission requirements in sections 905 and 904 do not fall disproportionately upon small businesses as the Tobacco Control Act requires the submission of this information from all owners and operators of a tobacco product establishment. FDA is providing an alternative paper form for those individuals who are unable, or choose not to, use the electronic portals. FDA continues to pursue means of reducing the reporting burden for both small and large respondents and will continue to employ the latest technology for receiving these submissions, consistent with the intent of the legislation.

FDA aids small business in dealing with the information submission requirements of sections 905 and 904 by providing guidance, which further describes the statutory requirement, for submitting this information. FDA also offers assistance to small tobacco businesses through the Center for Tobacco Products' Office of Small Business Assistance (OSBA), and TRLM-NG Support.

6. Consequences of Collecting the Information Less Frequently

The Tobacco Control Act requires the registration information submission under section 905 of the act to be completed annually by December 31 of each year. As of the effective date of the deeming rule, those persons who own or operate domestic manufacturing establishments engaged in manufacturing newly deemed tobacco products (including those that engage in the blending of pipe tobacco and the mixing of e-liquids) will be required to register with FDA and submit product listings under section 905. This deeming rule will not require foreign manufacturing establishments to register their establishments or to list their tobacco products in order to sell them in the United States. However, foreign manufacturing establishments will be required to comply with the registration and listing requirements of section 905 of the FD&C Act after a registration and listing rule is final and effective.

A less frequent collection of information would not satisfy the requirements of the act. The Tobacco Control Act requires the ingredient listing information submission under section 904(a)(1) of the act to be completed by December 22, 2009, and submissions under 904(c) to be submitted according to a clearly identified timeline. A less frequent collection of this information would also not satisfy the requirements of the act.

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

There are no special circumstances for this collection of information.

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

In accordance with 5 CFR 1320.8(d), FDA published a 60-day notice for public comment in the FEDERAL REGISTER of 01/28/2022 (87 FR 4622). FDA received one comment that was not PRA related.

9. Explanation of Any Payment or Gift to Respondents

There are no incentives, payments or gifts associated with this information collection.

10. Assurance of Confidentiality Provided to Respondents

Among the laws governing the disclosure of registration and listing data submitted under section 905 of the act are the Freedom of Information Act (FOIA) (5 U.S.C. 552) and section 905(f) of the act (21 U.S.C. 387e(f)), as well as FDA's implementing regulations. Under FOIA, the public has broad access to agency records, unless the records (or a part of the

records) are protected from disclosure by any of the law's nine exemptions. Under section 905(f) of the act, FDA shall make available for inspection, to any person so requesting, any registration filed under section 905 of the act.

Information submitted under section 904 of the act may include, but is not limited to, a company's non-public trade secret or confidential commercial information. Several laws govern the confidentiality of ingredient information submitted under section 904 of the act, including sections 301(j) and 906(c) of the act (21 U.S.C. 331(j) and 387f(c)), the Trade Secrets Act (18 U.S.C. 1905), and the Freedom of Information Act (FOIA) (5 U.S.C. 552), as well as FDA's implementing regulations.

Section 906(c) of the act prohibits FDA from disclosing any information reported to or otherwise obtained by FDA under section 904, among other provisions, if that information is confidential commercial or trade secret information exempt from disclosure under FOIA Exemption 4 (5 U.S.C. 552(b)(4)). The provision contains exceptions allowing disclosure of the information to other officers or employees concerned with carrying out the tobacco products chapter of the act and, when relevant, in any proceeding under the tobacco products chapter of the act. Section 301(j) of the act generally prohibits release of trade secret information obtained by FDA under section 904, among other provisions, outside of the Department of Health and Human Services, except to courts when relevant in any judicial proceeding under the act and to Congress in response to an authorized Congressional request.

CTP consulted with FDA's Privacy office, which conducted a Privacy Impact Assessment (PIA). CTP received HHS approval on the privacy impact assessment and was assigned PIA ID 2060831.

FDA's general regulations concerning the public availability of FDA records are contained in 21 CFR Part 20.

11. Justification for Sensitive Questions

This information collection does not involve questions of a sensitive nature.

12. Estimates of Annualized Burden Hours and Costs

12 a. Annualized Hour Burden Estimate
FDA estimates the burden for this information collection as follows:

Table 1.--Estimated Annual Reporting Burden[1]

| FDA Form/Activity/TCA Section | No. of Respondents | No. of Responses per Respondent | Total Annual Responses | Hours per Response | Total Hours |
|---|---|---|---|---|---|
| Tobacco Product Establishment Initial Registration and Listing; Form FDA 3741 Registration and Product Listing for Owners and Operators of Domestic Establishments (Electronic and Paper submissions); Sections 905(b), 905(c), 905(d), 905(h), or 905(i) | 200 | 1 | 200 | 1.6 (96 minutes) | 320 |
| Tobacco Product Establishment Renewal Registration and Listing; Form FDA 3741 Registration and Product Listing for Owners and Operators of Domestic Establishments (Electronic and Paper submissions); Sections 905(b), 905(c), 905(d), 905(h), or 905(i) | 2,572 | 1 | 2,572 | .16 (10 minutes) | 412 |
| Tobacco Product Listing; Form FDA 3742 Listing of Ingredients (Electronic and Paper submissions); Section 904(a)(1) | 16 | 1 | 16 | 2 (120 minutes) | 32 |
| Tobacco Product Listing; Form FDA 3742 Listing of Ingredients (Electronic and Paper submissions); Section 904(c) | 37 | 10 | 370 | 0.40 (24 minutes) | 148 |
| Obtaining a Dun and Bradstreet D-U-N-S Number | 100 | 1 | 100 | 0.5 (30 minutes) | 50 |
| Total | | | | | 0 |

The PRA burden estimates fully incorporate the use of an electronic system known as Tobacco Registration & Product Listing Module Next Generation (TRLM NG) for submitting registration and product listing information to FDA. With the TRLM NG, manufacturers can enter information quickly and easily. For example, product label pictures can be uploaded directly. We anticipate that most, if not all companies, already have electronic versions of their labels for printing, sales, or marketing purposes.

Product listing information is provided at the time of registration. Currently, registration and listing requirements only apply to domestic establishments engaged in the manufacture, preparation, compounding, or processing of a tobacco product. This includes importers to the extent that they engage in the manufacture, preparation, compounding, or processing of a tobacco product, including repackaging or otherwise changing the container, wrapper, or labeling of any tobacco product package. Foreign establishments are not required to register and list until FDA issues regulations establishing such requirements in accordance with section 905(h) of the FD&C Act. To account for the foregoing, we include both domestic manufacturing establishments and importers in our estimates.

The deadline for initial establishment registration and product listing for both statutorily regulated and deemed products has passed. However, on March 15, 2022, President Biden signed H.R. 2471 – the Consolidated Appropriations Act, 2022. As a result, the FD&C Act now includes specific language that makes clear the FDA has the authority to regulate tobacco products containing nicotine from any source, which includes synthetic On April 14, 2022, the owners and operators of establishments engaged in the manufacture, preparation, compounding, or processing of tobacco products containing non-tobacco nicotine (NTN) must register with the FDA and list all these tobacco products that they manufacture, prepare, compound, or process for commercial distribution.
FDA estimates up to 200 new establishments will submit one initial establishment registration and product listing report each year. Such new establishments potentially include manufacturers of NTN products, new vape shop locations that mix or assemble tobacco products on the market as of the final deeming rule effective date. The Agency estimates that up to 200 tobacco establishments will each submit 1 initial establishment registration and product listing report each year, which is expected to take 1.6 hours, for a total 160 burden hours.

FDA estimates that the confirmation or updating of establishment registration and product listing information as required by section 905 of the FD&C Act will take 10 minutes annually per confirmation or update per establishment. Based on FDA's experience with current establishment registration and product listings submitted to the Agency, the Agency estimates that on average 2,572 establishments will each submit one confirmation or updated report each year, which is expected to take 0.16 hour (10 minutes) for a total 412 burden hours.

FDA estimates that the submission of ingredient listings required by section 904(a)(1) of the FD&C Act for each establishment will take 2 hours initially. We expect all section 904(a)(1) tobacco ingredient submissions to have been received prior to 11/8/2018 for small manufacturers and large manufacturers, 5/8/18, for cigarettes, cigarette tobacco, RYO, smokeless tobacco, and deemed tobacco products. While all manufacturers have been expected to submit 904(a)(1) tobacco ingredient submissions, there may be a small number of firms that have missed this deadline. We are estimating approximately 3 manufacturers may have missed their deadline. This is based on estimates of how many late submissions FDA has received after the deadline. Because this burden estimate covers 3 years, we are dividing by 3, to yield 1 respondent as a yearly average for this estimate. Additionally, manufacturers for tobacco products containing nicotine that is not made or derived from tobacco must complete initial tobacco ingredient submissions for such products per section 904(a)(1). Therefore, FDA estimates that 16

establishments will initially submit one report annually at 2 hours per report, for a total of 32 hours.

Submissions under 904(c) of the FD&C Act are for any new product that is not yet on the market (e.g., if on the market due to deeming compliance period, deemed product manufacturers should have submitted under section 904(a)(1) of the FD&C Act). This includes any statutorily regulated product that would receive a marketing authorization, any new deemed product not subject to the deeming compliance period, and any new NTN products not on the market as of April 14, 2022. For deemed product categories and NTN products, there is a portion of these applicants who will have reported their ingredients under section 904(a)(1) as most of these submissions are expected to be for products subject to section 904(a)(1) requirements.

Based on FDA's experience and the number of new products authorized to be introduced or delivered for introduction into interstate commerce submitted over the past 3 years, FDA estimates that 37 establishments will each submit 10 reports (one every 6 months). FDA also estimates that the confirmation or updating of product (ingredient) listing information required by section 904(c) of the FD&C Act is expected to take 0.40 hour (24 minutes) per response for ten confirmations or updates per establishment, for a total 148 burden hours. FDA estimates that obtaining a DUNS (data universal numbering system) number will take 30 minutes. FDA assumes that all new establishment facilities that will be required to initially register under section 905 of the FD&C Act would obtain a DUNS number. FDA estimates that up to 100 establishments that would need to obtain this number each year. The total industry burden to obtain a DUNS number is 50 hours.

12b. Annualized Cost Burden Estimate

The estimated annual reporting cost to respondents for this collection of information is $59,932.60. This estimate assumes that tobacco industry (all occupations) will account for the submissions at an average wage of $31.15 (Department of Labor's Bureau of Labor Statistics for Tobacco Manufacturers (The Bureau of Labor Statistics (BLS) May 2021 average (mean) hourly wage for all occupations - NAICS 312200 - Tobacco Manufacturing (https://www.bls.gov/oes/current/naics4_312200.htm). We double this to account for benefits and overhead, yielding an hourly wage rate of $62.30.

| Type of Respondent | Total Burden Hours | Hourly Wage Rate | Total Respondent Costs |
|---|---|---|---|
| Tobacco Product Establishment Employees | 962 | $62.30 | $59,932.60 |
| Total | | | $59,932.60 |

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

There are no additional capital costs associated with this collection of information.

14. Annualized Cost to the Federal Government

FDA anticipates that the Federal Government will incur the following costs:

Staff Costs

Full time Equivalents = 8
Annual Cost per FTE = $117,505
Total Annual Cost = $940,040

As noted above, FDA anticipates that 2 FTEs will maintain the electronic portals, and 6 FTE's will review, process, and approve applications submitted to the system or submitted on paper form under this collection of information. Using as a basis salary and wage data for the Washington DC-Metropolitan area found at www.opm.gov for a GS-13/4 employee, we calculate a total cost of $940,040 ($117,505 x 8).

15. Explanation for Program Changes or Adjustments

We have adjusted our burden estimate, which has resulted in an increase of 132 hours to the currently approved burden. FDA now estimates the total burden for this collection to be 962 hours. The Consolidated Appropriations Act of 2022 (the Appropriations Act), enacted on March 15, 2022, amended the definition of the term "tobacco product" in section 201(rr) of the FD&C Act to include products that contain nicotine from any source. As a result, non-tobacco nicotine (NTN) products that were not previously subject to the FD&C Act (e.g., products containing synthetic nicotine) are now subject to all of the tobacco product provisions in the FD&C Act beginning on April 14, 2022. Based on this new authority the owners and operators of establishments engaged in the manufacture, preparation, compounding, or processing of tobacco products containing non-tobacco nicotine (NTN) must register with the FDA and list all these tobacco products that they manufacture, prepare, compound, or process for commercial distribution. As such we have revised the estimates in the burden chart to account for products containing non-tobacco nicotine (NTN). We have therefore revised the number of respondents and burden hours in this information collection.

16. Plans for Tabulation and Publication and Project Time Schedule

Collected information will not be published or tabulated.

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

FDA is not requesting an exemption for display of the OMB expiration date.

Consistent with established practice FDA will publish a *Federal Register* notice announcing OMB approval of the information collection associated with this guidance document and will display in that notice both the OMB control number and its current expiration date. In addition, the OMB control number will be displayed on the guidance document cover page and include a link to www.reginfo.gov to identify the current expiration date

18. Exceptions to Certification for Paperwork Reduction Act Submissions

There are no exceptions to the certification.