

Information Request Regarding pH of Tobacco Products

0910-NEW

SUPPORTING STATEMENT

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 (the Tobacco Control Act) (Public Law 111-31) into law. The Tobacco Control Act amended the Federal Food, Drug, and Cosmetic Act (the FD&C Act) by granting FDA authority to regulate the manufacture, marketing, and distribution of tobacco products to protect the public health generally and to reduce tobacco use by minors.

Section 904(b) of the FD&C Act (21 U.S.C. 387d(b)) states that, at the request of the Secretary, each tobacco product manufacturer or importer, or agents thereof, must submit:

- Any or all documents (including underlying scientific information) relating to research activities, and research findings, conducted, supported, or possessed by the manufacturer (or agents thereof) on the health, toxicological, behavioral, or physiological effects of tobacco products and their constituents (including smoke constituents), ingredients, components, and additives.
- Any or all documents (including underlying scientific or financial information) relating to research activities, and research findings, conducted, supported, or possessed by the manufacturer (or agents thereof) that relate to the issue of whether a reduction in risk to health from tobacco products can occur upon the employment of technology available or known to the manufacturer.”
- Any or all documents (including underlying scientific or financial information) relating to marketing research involving the use of tobacco products or marketing practices and the effectiveness of such practices used by tobacco manufacturers and distributors.

If the Secretary requests information from the manufacturer of a tobacco product not manufactured in the United States, the importer of the tobacco product is required to supply that information.

FDA is requesting OMB approval of an information collection under section 904(b) of the FD&C Act. To become better informed about the effects of product pH of smokeless tobacco products, FDA would request information about the effects of product pH in smokeless tobacco products from all tobacco product manufacturers. FDA would send letters to tobacco product manufacturers and importers who FDA has identified as having an obligation to respond based on information before the Agency. The requested information would include information about research requested under section 904(b) of the FD&C

Act as well as information to be provided voluntarily beyond the inquiries described in section 904(b).

Information Requested

The proposed request would include the following information:

All documents (including underlying scientific information and financial information) relating to research activities and research findings, conducted, supported, or possessed by the respondent or the respondent's agents relating to a specified set of topics listed in this document. The request includes but is not limited to documents relating to research findings and activities, if any, that the respondent possesses as the result of acquiring or merging with another company. For purposes of the request, "research" would include, but would not be limited to, focus groups, surveys, experimental clinical studies, toxicological and biochemical assays, in vivo and in vitro assays including animal testing, laboratory formulation and processing testing, taste panels, and assessments of the effectiveness of product marketing practices. The request would apply to research relating to any and all smokeless tobacco products, including but not limited to those products for research, investigational use, developmental studies, test marketing, and/or commercial marketing, and also to the components, parts, or accessories of such products. For products not manufactured in the United States, the request would apply to the extent the respondent has imported such products into the United States.

Topics

Under section 904(b) of the FD&C Act, FDA would request all documents and underlying scientific and financial information relating to research activities, research findings, and marketing research for smokeless tobacco products developed since January 1, 1980, on the following topics:

- The effect of product pH on ratio of free/bound (unprotonated/protonated) nicotine;
- the effect of product pH on user behavior;
- the effect of product pH on user subjective effects and experiences including, but not limited to, sensory effects in the mouth and throat, liking, craving and withdrawal symptoms, stimulation, concentration, and anxiety;
- the effect of product pH on user physiological responses including, but not limited to, heart rate, blood pressure, temperature, and nicotine pharmacokinetics;
- for smokeless tobacco products that have a pH of 7.2 or less, marketing research that includes attractiveness or appeal to new users, inexperienced users, and/or to persons under the age of 25.

Research and development of methodology for adjusting the pH of smokeless tobacco products would be specifically excluded from this 904(b) request.

Limitations on Types of Documents and Information

With respect to the topics listed above, FDA would request only the following documents and information:

- Study proposals, original implemented protocols (including all amendments), analysis plans, agreements, notebooks, data collection tools, including but not limited to, forms and assessment scales for planned, ongoing, or completed studies, surveys, and other research, whether for external release or internal use;
- Final data analyses and reports regarding studies, surveys, data compilations, or other research, whether for external or internal use (if there were no final analyses, interim data analyses would be included in the request);
- Posters and/or presentations exhibited or to be exhibited at external meetings or conferences if the underlying data has not been presented in other documents and information within the request;
- Manuscripts, articles, editorials, and letters that have been submitted for publication but not yet published (e.g., in review, accepted, rejected);
- Underlying data (e.g., in the form of spreadsheets, datasets, charts, tables, and diagrams) analyzed to produce any of the data analyses, reports, posters, manuscripts, or articles requested above.

FDA would request only the final versions of documents, or in the absence of a final version, the most recent draft of each document. Published (i.e., publically available) press releases, abstracts, editorials, letters, manuscripts, material safety data sheets (MSDS), and HHS correspondences, would not be requested, although FDA would appreciate a list of such publications provided as a separate appendix.

Data supporting summary reports would be included in the request, and FDA would ask that spreadsheets or datasets be submitted both in portable document format (.pdf) and in a file type and structured format that allows for meaningful review and analysis of the data e.g., Excel (.xls), comma separated values (.csv), or SAS transport (.xpt) file formats. Also, FDA would request relevant data submissions be accompanied by the name and version of the software used to create the file, and names and definitions of variables and copies of programs and macros needed to generate the analyses. FDA would also ask that respondents include any data analyses that stratify scientific results by gender, race/ethnicity, age, or other similar factors.

To provide context and background for each document, FDA would ask the respondent to include a load file containing metadata (e.g., manufacturer, date, author(s)) for each document. Also in the metadata load file, FDA would ask the respondents to identify the presence of each document in the University of California San Francisco Legacy Tobacco Documents Library (LTDL) as one of the following: Present with the Bates number (begin Bates number to end Bates number), not present, or unknown.

As an option, information responsive to the request that has been previously provided to FDA under section 904(a)(1), 904(a)(3), 904(c)(1), 904(c)(2), or 904(c)(3) of the FD&C Act would not have to be resubmitted as long as the document was fully referenced in the metadata load file.

Additional Information

FDA would ask the respondent to submit voluntarily the following additional information, as applicable, to provide context and background for FDA:

- A summary (one to five pages in length) for each of the topics above that includes the number and type of documents included, and a high-level overview of the content;
- An explanation of the scientific and business reasons, rationale or justification for developing and marketing smokeless tobacco products with different pH values, including expected and observed perception and behavior of current and potential consumers.

2. Purpose and Use of the Information Collection

FDA will use the information to assess the effects of product pH of smokeless tobacco products on consumers and the public health.

Individuals from CTP have previously reviewed available published literature on product pH of smokeless tobacco products; however, there is limited information in the published literature and CTP has identified the topics that are included in the information request as information that is important to develop policy regarding pH of smokeless tobacco products.

3. Use of Improved Information Technology and Burden Reduction

FDA is encouraging respondents to submit their response in an electronic format on CD-ROM or DVD. The information request provides guidance for preparing the submission. FDA estimates that approximately 85 percent of the documents will be submitted using this format.

4. Efforts to Identify Duplication and Use of Similar Information

To avoid the inefficiencies associated with submitting, receiving and reviewing duplicative documents or substantively identical documents, FDA requests only final document versions, or in the absence of a final version, the most recent draft of each document. This request specifically excludes (a) past iterations of a completed or more recent document, (b) document duplicates, or (c), near duplicates that only vary in minor ways (e.g. differences in addressee or changes in letterhead). As an option, FDA requests information that has been previously provided to FDA under the FD&C Act not be re-submitted, as long as the document was fully referenced in the metadata load file.

Section 904(a)(4) of the FD&C Act (tobacco health document submission) requires each tobacco product manufacturer or importer, or agent thereof, to submit all documents developed after June 22, 2009, “that relate to health, toxicological, behavioral, or

physiologic effects of current or future tobacco products, their constituents (including smoke constituents), ingredients, components, and additives.” Because the tobacco health document submission requirement pertains only to documents developed after June 22, 2009, the requested documents under this 904(b) information collection will not be duplicate documents requested under section 904(a)(4).

5. Impact on Small Businesses or Other Small Entities

This information collection does not fall disproportionately upon small businesses. The letter requesting this information will be sent to all manufacturers of tobacco products. The agency expects that small businesses will have limited studies on many of the topics, therefore, the burden on small businesses may actually be smaller. Moreover, some small companies may not have information for the effects of product pH and their only burden will be to inform FDA of that fact. All respondents, including small businesses, have been informed that failure to provide the information requested by FDA in accordance with section 904(b) of the FD&C Act is a violation of the FD&C Act and is subject to regulatory and enforcement action by FDA.

FDA continues to pursue means of reducing the reporting burden for both small and large respondents.

6. Consequences of Collecting the Information Less Frequently

FDA requires the requested information in order to better understand effects of smokeless tobacco product pH and its effects on ingredients in tobacco products and users. Collecting the information less frequently will impact FDA’s ability to better understand these effects and effectively regulate tobacco products under the FD&C Act.

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

This section is not applicable. 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 July 23, 2014 (79 FR 42797). Four commenters submitted nine comments that were PRA related.

(Comment 1) The Agency should request all document versions, including drafts, as well as comments on those versions and reasons for changes made in subsequent versions.

(Response) FDA believes the request to prepare a submission that includes drafts including related metadata will be overly burdensome for the respondent. Additionally, a

request to be provided the reason for changes made in subsequent versions is beyond the inquiries described in section 904(b). FDA clarified the request to note the original implemented protocol is to be submitted. FDA would contact manufacturers, if additional information is needed to facilitate the Agency's review of the submission.

(Comment 2) Do not limit the request to SAS datasets as to not exclude other statistical software.

(Response) It is FDA's intent that data not be excluded from the request based upon the statistical analysis software used. The proposed request asks that data be provided in a file type and structured format that allows for meaningful review and analysis of the data. The request was clarified to note that SAS.xpt is a recommended format for datasets.

(Comment 3) The Agency should request the LTDL tobacco identification (TID) number or URL since these are unique to the document.

(Response) Because the manufacturer does not assign the TID number or URL, FDA believes requesting this information would be overly burdensome for the respondent and therefore would request only the Bates number(s) as proposed, given that this information is assigned by the manufacturer.

(Comment 4) It would be overly burdensome for the respondent to locate data and provide the requested software for information dating back to January 1, 1970, and FDA should focus the information for more recent times.

(Response) FDA believes the time period for this request should coincide with the commercial availability of smokeless tobacco products with different pH values because industry research on this topic is limited in the public domain. FDA has considered the scientific value of the data and information as well as the burden on respondents to provide such information to FDA. Therefore, FDA revised the request to ask for documents developed since January 1, 1980.

(Comment 5) The burden for the collection was underestimated given that it is likely older documents may only exist in hard copy and, if found, would be in remote storage that would be mostly searched manually.

(Response) The burden was revised given that this portion of the request may be performed manually.

(Comment 6) The burden for the collection was underestimated given that respondents would need to perform document-by-document search of a third-party site to provide the requested metadata from LTDL.

(Response) The burden was revised given that this portion of the request may be performed manually.

(Comment 7) It would be overly burdensome for respondents to provide the amount of metadata requested for documents previously submitted to FDA in lieu of providing the Agency with all of the responsive documents it locates.

(Response) FDA clarified the purpose of the metadata load file and also clarified that the respondent has the option to provide metadata for previously submitted documents.

(Comment 8) It would take at least 90 days to provide a response to the request.

(Response) Given the Agency's experience with previous submissions under section 904(a)(4) and 904(b), FDA would request a response within 60 days from the date of the letter and request respondents that anticipate difficulties with the document production to contact FDA within 30 days of the date of the letter. FDA will provide assistance in resolving any technical difficulties and facilitate compliance with the timeline.

(Comment 9) The Agency previously estimated an average of 200 hours per response for the Agency's request for dissolvable tobacco products in 2011.

(Response) FDA has since learned from experience with document submissions under section 904(a)(4) and 904(b) that some respondents have electronic document systems. Thus, estimates for this collection, reflect automation capabilities for processing and managing document submissions.

9. Explanation of Any Payment or Gift to Respondents

This information collection does not provide for any payment or gift to respondents.

10. Assurance of Confidentiality Provided to Respondents

Information submitted under section 904 of the FD&C 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 information submitted under section 904 of the FD&C Act, including sections 301(j) and 906(c) of the FD&C 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 FD&C 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 FD&C Act and, when relevant, in any proceeding under the tobacco products chapter of the FD&C Act.

Section 301(j) of the FD&C 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 FD&C Act and to Congress in response to an authorized congressional request.

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 contain questions of a sensitive nature.

12. Estimates of Annualized Burden Hours and Costs

FDA is drawing from tobacco health document submissions under section 904(a)(4) and 904(b) of the FD&C Act, our interaction with the public, and our experience to inform the burden estimates associated with this information collection. Additionally, based upon comments in response to the Federal Register Notice published on July 23, 2014 (79 FR 42797), FDA is revising its initial estimates of annualized burden hours.

FDA estimates the burden for this collection of information to be 1,615 reporting hours. FDA estimates it will receive 125 submissions. Based upon the expected number of tobacco product manufacturers and importers, the burden has been broken into three tiers: 3 manufacturers and importers that have document collections in LTDL, 3 manufacturers and importers that provided health documents under section 904(a)(4); and 119 manufacturers who are only required to submit a letter indicating that they have no tobacco documents to submit.

- FDA anticipates documents for this request will be submitted by three tobacco product manufacturers and importers that have document collections within LTDL. Manufacturers one through three were estimated to take 201, 206, and 85 hours respectively, for an approximate average of 165 hours per response, to process and prepare a submission (i.e., cover letter, documents and information, and metadata load file). Total burden hours for this portion of the collection are expected to be 495 hours (3 x 165).
- FDA anticipates documents to also be submitted by three additional tobacco product manufacturers and importers that provided health documents under section 904(a)(4). Manufacturers four through six were estimated to take 304, 118, and 91 hours respectively, for an approximate average of 175 hours per response, to process and prepare a submission (i.e., cover letter, documents and information, and metadata load file). Total burden hours for this portion of the collection are expected to be 525 hours (3 x 175).
- FDA estimates that 119 manufacturers and importers will not possess documents responsive to this request. These manufacturers do not have documents, do not

manufacture smokeless tobacco products, or do not anticipate manufacturing these tobacco products and are estimated to take approximately 5 hours each to conduct a review of their records, draft and send a letter to FDA indicating that they do not have documents to submit. Total burden hours for this portion of the collection are expected to be 595 hours (119 x 5).

- Total reporting burden for this collection is estimated to be 1,615 hours (495 + 525 + 595 hours.)

FDA estimates the burden for this information collection as follows:

12 a. Annualized Hour Burden Estimate

Table 1.--Estimated Annual Reporting Burden					
Type of Respondent Gathering Product pH Information	No. of Respondent s	No. of Responses per Responde nt	Total Annual Responses	Average Burden Hours per Response	Total Hours
Tobacco product manufacturers and importers with LTDL collections	3	1	3	165	495
Additional tobacco product manufacturers and importers with previous submissions to FDA	3	1	3	175	525
Other manufacturers who have no documents, do not manufacture smokeless tobacco products, or do not anticipate manufacturing these products	119	1	119	5	595
Total					1,615

12b. Annualized Cost Burden Estimate

FDA estimates the reporting cost to respondents is \$88,825. This figure was derived by multiplying the total reporting burden hours (1,615 hours) by an hourly rate of \$55. This hourly rate is based on a 2,080 annual work hours and at an annual salary rate of \$116,000. This health care professional salary rate includes salary, benefits, overhead, technical staff, support staff, etc. This annual rate was determined by the Agency's current estimates of staff expenses for performing this type of work.

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

The capital costs associated with this collection pertain to the postage for mailing documents in electronic format. Estimating these costs is problematic because the costs would vary depending on the size of the document production (e.g. one binder of documents vs. numerous boxes of paper) and the media type (e.g., paper, CD, or DVD) chosen to submit documents.

Some sample postage costs are shown for different types of packages:

- Ten compact disks (CDs) in a flat envelope weighing 30 ounces: approximately \$9.50 using first class business mail
- Five-pound parcel containing paper documents: approximately \$14 using business parcel post mail and delivering to the furthest delivery zone
- Ten-pound parcel containing paper documents: approximately \$20 using business parcel mail and delivering to the furthest delivery zone
- Fifty-pound parcel containing paper documents: approximately \$62 using business parcel post mail and delivering to the furthest delivery zone.

We estimate the capital costs associated with this document submission to be \$274. This estimate is based upon (a) 3 submissions being submitted by mailing an average of 10 CDs per envelope (\$29), (b) 3 submissions being submitted by mailing a package of paper documents weighing an average of 50 pounds total (\$186), and (c) 119 submissions of one business class letter describing that no documents are available (119 x \$0.49 (the price of a first class business stamp), or \$59).

14. Annualized Cost to the Federal Government

Staff Costs

Full time Equivalents = 5 FTEs for 8 months.

Annual Cost per FTE = \$116,000

Total Cost = approximately \$387,000

15. Explanation for Program Changes or Adjustments

This is a new collection of information.

16. Plans for Tabulation and Publication and Project Time Schedule

We are not seeking to publish data collected during this collection of information.

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

We are not seeking approval to not display the expiration date for OMB approval of the information collection.

18. Exceptions to Certification for Paperwork Reduction Act Submissions

No exceptions to the certification statement were identified.