TABLE 2—ESTIMATED ANNUAL RECORDKEEPING BURDEN [1]—Continued

21 CFR section	Number of recordkeepers	Number of records per recordkeeper	Total annual records	Average burden per recordkeeping	Total hours
600.80(c)(1) and 600.80(i)	131	1,718.60	225,137	1	225,137
Total					485,817

[1] There are no capital costs or operating and maintenance costs associated with this collection of information.
[2] The recordkeeping requirements in § 610.18(b) are included in the estimate for § 600.12.

Dated: October 23, 2014.

Leslie Kux,

Assistant Commissioner for Policy.

[FR Doc. 2014–25637 Filed 10–28–14; 8:45 am]

BILLING CODE 4164–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2014–N–1009]

Agency Information Collection Activities; Submission for Office of Management and Budget Review; Comment Request; Information Request Regarding pH of Smokeless Tobacco Products

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is announcing that a proposed collection of information has been submitted to the Office of Management and Budget (OMB) for review and clearance under the Paperwork Reduction Act of 1995.

DATES: Fax written comments on the collection of information by November 28, 2014.

ADDRESSES: To ensure that comments on the information collection are received, OMB recommends that written comments be faxed to the Office of Information and Regulatory Affairs, OMB, Attn: FDA Desk Officer, FAX: 202–395–7285, or emailed to *oira_submission@omb.eop.gov.* All comments should be identified with the OMB control number 0910–NEW and title ''Information Request Regarding pH of Smokeless Tobacco Products.'' Also include the FDA docket number found in brackets in the heading of this document.

FOR FURTHER INFORMATION CONTACT: FDA PRA Staff, Office of Operations, Food and Drug Administration, 8455 Colesville Rd., COLE–14526, Silver Spring, MD 20993–0002, *PRAStaff@fda.hhs.gov.*

SUPPLEMENTARY INFORMATION: In compliance with 44 U.S.C. 3507, FDA has submitted the following proposed collection of information to OMB for review and clearance.

Information Request Regarding pH of Smokeless Tobacco Products—(OMB Control Number 0910–NEW)

On June 22, 2009, President Obama signed the Family Smoking Prevention and Tobacco Control Act (the Tobacco Control Act) (Pub. L. 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 the 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 impact of the use of tobacco products on the public health, 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).

I. 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.

II. 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; and
- 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.

III. Limitations on Types of Documents and Information

With respect to the topics listed, 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); and
- 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 previously in this notice.

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, and Department of Health and Human Services 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 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 sections 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.

IV. 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 previously mentioned in this notice, that includes the number and type of documents included, and a high level overview of the content; and
- 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.

This is a new collection of information. FDA would use the information to assess the effects of pH of smokeless tobacco products on consumers and the public health. In the **Federal Register** of July 23, 2014 (79 FR 42797), FDA published a 60-day notice requesting public comment on the proposed collection of information. 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) of the FD&C Act, 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) of the FD&C Act that some respondents have electronic document systems. Thus, estimates for this collection reflect automation capabilities for processing and managing document submissions.

FDA estimates the burden of this collection of information as follows:

TABLE 1—ESTIMATED ANNUAL REPORTING BURDEN [1]

Type of respondent gathering product pH information	Number of respondents	Number of responses per respondent	Total annual responses	Average burden hours per response	Total hours	Total capital costs
Tobacco product manufacturers and importers with LTDL collections	3	1	3	165	495	$29
Additional tobacco product manufacturers and importers with previous submissions to FDA	3	1	3	175	525	186
Other manufacturers who have no documents, do not manufacture smokeless tobacco products, or do not anticipate manufacturing these products	119	1	119	5	595	59
Total					1,615	274

[1] There are no operating and maintenance costs associated with this collection of information.

We estimate the capital costs associated with this document to be $274. This estimate is based upon: (1) 3 Submissions being submitted by mailing an average of 10 CDs per envelope ($29), (2) 3 submissions being submitted by mailing a package of paper documents weighing an average of 50 pounds total ($186), and (3) 119 submissions of 1 business class letter describing that no documents are available (119 × $0.49 (the price of a first class business stamp), or $59).

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, FDA is revising its initial estimates of annualized burden hours.

FDA estimates the burden for this collection of information to be 1,615 hours. FDA estimates it will receive 125 submissions. Based upon the expected number of tobacco product manufacturers and importers, their burden has been broken into three tiers:

- 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.
- 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.
- 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.

Dated: October 23, 2014.

Leslie Kux,

Assistant Commissioner for Policy.

[FR Doc. 2014–25638 Filed 10–28–14; 8:45 am]

BILLING CODE 4164–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2014–N–1575]

Best Practices for Communication Between the Food and Drug Administration and Investigational New Drug Sponsors During Drug Development; Request for Comments

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice; establishment of docket, request for comments.

SUMMARY: The Food and Drug Administration (FDA) is announcing the establishment of a docket to receive suggestions, recommendations, and comments from interested parties, including academic institutions, regulated industry, and other interested organizations on best practices for communication between FDA and investigational new drug application (IND) sponsors during drug development. These comments will help FDA identify and ultimately establish best practices to be included in a draft guidance for industry and review staff.

DATES: Submit either electronic or written comments by December 29, 2014.

ADDRESSES: Submit electronic comments to *http://www.regulations.gov.* Submit written comments to the Division of Dockets Management (HFA–305), Food and Drug Administration, 5630 Fishers Lane, Rm. 1061, Rockville, MD 20852. Identify comments with the docket number found in brackets in the heading of this document.

FOR FURTHER INFORMATION CONTACT: Rachel E. Hartford, Center for Drug Evaluation and Research, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 22, Rm. 6312, Silver Spring, MD 20993–0002, 301–796–0331, email: *ONDEnhancedComm@fda.hhs.gov;* or Stephen Ripley, Center for Biologics Evaluation and Research, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 71, Rm. 7301, Silver Spring, MD 20993–0002, 240–402–7911.

SUPPLEMENTARY INFORMATION:

I. Background

One of FDA's performance commitments made as part of the fifth authorization of the Prescription Drug User Fee Act (PDUFA) under Title I of the Food and Drug Administration Safety and Innovation Act (Pub. L. 112–144), related to promoting innovation through enhanced communication between FDA and sponsors during drug (including biological product) development, is for FDA to publish draft guidance for industry and review staff describing best practices for communication between FDA and IND sponsors during drug development. (A copy of the PDUFA Reauthorization Performance Goals and Procedures; Fiscal Years 2013 Through 2017 is available on the FDA Web site at *http://www.fda.gov/downloads/forindustry/userfees/prescriptiondruguserfee/ucm270412.pdf.*)

The guidance will describe FDA's philosophy regarding timely interactive communication with IND sponsors as a core activity and the scope of appropriate interactions between the review team and the sponsor, outline the types of advice that are appropriate for sponsors to seek from FDA in pursuing their drug development program, describe the general expectations for the timing of FDA response to IND sponsor inquiries of simple and clarifying questions or referral of more complex questions to the formal meeting process, and describe best practices and communication methods (including the value of person-to-person scientific dialogue) to facilitate interactions between the FDA review team and the IND sponsor during drug development. We anticipate that the best practices will include expectations and agreement on appropriate methods (e.g., when teleconferencing or secure email may be the most appropriate means of communication) and frequency of such communications.

II. Establishment of a Docket and Request for Comments

To help FDA identify and ultimately establish best practices to be included in a draft guidance, FDA is requesting public suggestions, recommendations, and comments for each aspect of the best practices mentioned above. FDA will consider all comments submitted. FDA generally will not respond directly to the person or organization submitting the comment.

III. Comments

Interested persons may submit either electronic comments regarding this document to *http://www.regulations.gov* or written comments to the Division of Dockets Management (see **ADDRESSES**). It is only necessary to send one set of comments. Identify comments with the docket number found in brackets in the heading of this document. Received comments may be seen in the Division of Dockets Management between 9 a.m. and 4 p.m., Monday through Friday, and will be posted to the docket at *http://www.regulations.gov.*

Dated: October 22, 2014.

Leslie Kux,

Assistant Commissioner for Policy.

[FR Doc. 2014–25641 Filed 10–28–14; 8:45 am]

BILLING CODE 4164–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Office of Inspector General

Solicitation of Information and Recommendations for Revising OIG's Non-Binding Criteria for Implementing Permissive Exclusion Authority Under Section 1128(b)(7) of the Social Security Act

AGENCY: Office of Inspector General (OIG), HHS.

ACTION: Notice; Extension of comment period.

SUMMARY: This document announces an extension of the public comment period for the OIG **Federal Register** notice published on July 11, 2014 (79 FR 40114). The notice solicited input from the public on revising the criteria used by OIG in implementing its permissive exclusion authority under Section 1128(b)(7) of the Social Security Act. Due to a technical problem, the public may have been unable to submit comments at *http://www.regulations.gov* during the comment period. Accordingly, we are extending the comment period to ensure that the public has an opportunity to provide input.

DATES: To ensure consideration, public comments must be delivered to the address provided below by no later than 5 p.m. on December 29, 2014.

ADDRESSES: In commenting, please refer to file code OIG–1271–N. Because of staff and resource limitations, we cannot