0920–0212) and the National Hospital Ambulatory Medical Care Survey (NHAMCS) (OMB No. 0920–0278) may investigate the addition of facility and patient information especially as it relates to insurance and electronic medical records.

Discussion is underway with the DHHS Office of Minority Health on the possibility of conducting a study to collect data on the awareness, adoption and implementation of the Enhanced National Standards on Culturally and Linguistically Appropriate Services (CLAS) in physician offices. The study may be preceded by a feasibility study.

The National Health Care Surveys collect critical, accurate data that are used to produce reliable national estimates—and in recent years, state-level estimates—of clinical services and of the providers who delivered those services in inpatient, outpatient, ambulatory, and long-term care settings. The data from these surveys are used by providers, policy makers and researchers to address important topics of interest, including the quality and disparities of care among populations, epidemiology of medical conditions, diffusion of technologies, effects of policies and practice guidelines, and changes in health care over time. Research studies need to be conducted to improve existing and proposed survey design and procedures of the National Health Care Surveys, as well as to evaluate alternative data collection approaches particularly due to the expansion of electronic health record use, and to develop new sample frames of currently out-of-scope providers and settings of care. There is no cost to respondents other than their time to participate. Average burdens are designed to cover 15–40 min interviews as well as 90 minute focus groups, longer on-site visits, and situations where organizations may be preparing electronic data files. The total estimated annualized burden is 7,085 hours.

ESTIMATED ANNUALIZED BURDEN HOURS

Type of respondents	Form name	Number of respondents	Number of responses per respondent	Average burden per response (in hours)
Health Care Providers and Business entities	Interviews, surveys, focus groups, experiments (in person, phone, internet, postal/electronic mail).	6,667	1	1
Health Care Providers,State/local government agencies, and business entities.	Interviews, surveys, focus groups, experiments (in person, phone, internet, postal/electronic mail).	167	1	2.5

Leroy Richardson,

Chief, Information Collection Review Office, Office of Scientific Integrity, Office of the Associate Director for Science, Office of the Director, Centers for Disease Control and Prevention.

[FR Doc. 2014–17328 Filed 7–22–14; 8:45 am]

BILLING CODE 4163–18–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2014–N–1009]

Agency Information Collection Activities; Proposed Collection; 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 an opportunity for public comment on the proposed collection of certain information by the Agency. Under the Paperwork Reduction Act of 1995 (the PRA), Federal Agencies are required to publish notice in the **Federal Register** concerning each proposed collection of information and to allow 60 days for public comment in response to the notice. This notice solicits comments on the collection of information regarding pH of smokeless tobacco products.

DATES: Submit either electronic or written comments on the collection of information by September 22, 2014.

ADDRESSES: Submit electronic comments on the collection of information to *http://www.regulations.gov.* Submit written comments on the collection of information to the Division of Dockets Management (HFA–305), Food and Drug Administration, 5630 Fishers Lane, Rm. 1061, Rockville, MD 20852. All comments should be identified with the 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: Under the PRA (44 U.S.C. 3501–3520), Federal Agencies must obtain approval from the Office of Management and Budget (OMB) for each collection of information they conduct or sponsor. ''Collection of information'' is defined in 44 U.S.C. 3502(3) and 5 CFR 1320.3(c) and includes Agency requests or requirements that members of the public submit reports, keep records, or provide information to a third party. Section 3506(c)(2)(A) of the PRA (44 U.S.C. 3506(c)(2)(A)) requires Federal Agencies to provide a 60-day notice in the **Federal Register** concerning each proposed collection of information before submitting the collection to OMB for approval. To comply with this requirement, FDA is publishing notice of the proposed collection of information set forth in this document.

With respect to the following collection of information, FDA invites comments on these topics: (1) Whether the proposed collection of information is necessary for the proper performance of FDA's functions, including whether the information will have practical utility; (2) the accuracy of FDA's estimate of the burden of the proposed collection of information, including the validity of the methodology and assumptions used; (3) ways to enhance the quality, utility, and clarity of the information to be collected; and (4) ways to minimize the burden of the collection of information on respondents, including through the use of automated collection techniques, when appropriate, and other forms of information technology.

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, 1970, 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, 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, SAS 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 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 SAS 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.

Information responsive to the request that has been previously provided to FDA under the FD&C Act would not have to be resubmitted as long as the document was fully referenced in the metadata load file. For documents 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, FDA would ask that the respondent provide the following additional information in the metadata load file: The file name and file extension, Bates number (begin Bates number to end Bates number) and relevant page numbers, date of submission, section under which the document was submitted, tobacco product brand/subbrand name, and product identification number. FDA would also ask that respondents 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.

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.

V. Burden Estimate

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	120	360	$29
Additional tobacco product manufacturers and importers with previous submissions to FDA	3	1	3	125	375	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					1,330	274

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

We estimate the capital costs associated with this document submission 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 developed its reporting burden estimates from the expected volume of documents to be received based upon broad searches of LTDL, the Agency's experience with previous information collection requests under section 904(b) of the FD&C Act, and submissions received as health documents under section 904(a)(4).

FDA estimates the burden for this one-time collection of information to be 1,330 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:

- FDA anticipates documents for this request will be submitted by three tobacco product manufacturers and importers that have related document collections within LTDL. Manufacturers 1 through 3 were estimated to take 140, 142, and 80 hours respectively, for an approximate average of 120 hours per response, to process and prepare a submission (i.e., cover letter, documents and information, and metadata load file). Total estimated burden hours for this portion of the collection are expected to be 360 hours.
- FDA anticipates documents will also be submitted by three additional tobacco product manufacturers and importers that provided health documents under section 904(a)(4) of the FD&C Act. Manufacturers 4 through 6 were estimated to take 194, 96, and 83 hours respectively, for an approximate average of 125 hours per response, to process and prepare a submission (i.e., cover letter, documents and information, and metadata load file). Total estimated burden hours for this portion of the collection are expected to be 375 hours.
- FDA estimates that 119 manufacturers and importers will not have documents responsive to this request and are estimated to take approximately 5 hours each to conduct a review of their records and to draft and send a letter to FDA indicating that they do not have documents to submit. These manufacturers do not have documents, do not manufacture smokeless tobacco products, or do not anticipate manufacturing these tobacco products. Total estimated burden hours for this portion of the collection are expected to be 595 hours.

Dated: July 18, 2014.

Leslie Kux,

Assistant Commissioner for Policy.

[FR Doc. 2014–17294 Filed 7–22–14; 8:45 am]

BILLING CODE 4164–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2013–N–1496]

Agency Information Collection Activities; Announcement of Office of Management and Budget Approval; Generic Food and Drug Administration Rapid Response Surveys

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is announcing that a collection of information entitled ''Generic FDA Rapid Response Surveys'' has been approved by the Office of Management and Budget (OMB) under the Paperwork Reduction Act of 1995.

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: On April 23, 2014, the Agency submitted a proposed collection of information entitled ''Generic FDA Rapid Response Surveys'' to OMB for review and clearance under 44 U.S.C. 3507. An Agency may not conduct or sponsor, and a person is not required to respond to, a collection of information unless it displays a currently valid OMB control number. OMB has now approved the information collection and has assigned OMB control number 0910–0500. The approval expires on July 31, 2017. A copy of the supporting statement for this information collection is available on the Internet at *http://www.reginfo.gov/public/do/PRAMain.*

Dated: July 18, 2014.

Leslie Kux,

Assistant Commissioner for Policy.

[FR Doc. 2014–17292 Filed 7–22–14; 8:45 am]

BILLING CODE 4164–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2007–D–0369]

Draft and Revised Draft Guidances for Industry Describing Product-Specific Bioequivalence Recommendations; Availability

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is announcing the availability of additional draft and revised draft product-specific bioequivalence (BE) recommendations. The recommendations provide product-specific guidance on the design of BE studies to support abbreviated new drug applications (ANDAs). In the **Federal Register** of June 11, 2010, FDA announced the availability of a guidance for industry entitled ''Bioequivalence Recommendations for Specific Products,'' which explained the process that would be used to make product-specific BE recommendations available to the public on FDA's Web site. The BE recommendations identified in this notice were developed using the process described in that guidance.

DATES: Although you can comment on any guidance at any time (see 21 CFR 10.115(g)(5)), to ensure that the Agency considers your comments on these draft and revised draft guidances before it begins work on the final versions of the guidances, submit either electronic or written comments on the draft and revised draft product-specific BE recommendations listed in this notice by September 22, 2014.

ADDRESSES: Submit written requests for single copies of the individual BE guidances to the Division of Drug Information, Center for Drug Evaluation and Research, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 51, rm. 2201, Silver Spring, MD 20993–0002. Send one self-addressed adhesive label to assist that office in processing your requests. See the **SUPPLEMENTARY INFORMATION** section for electronic access to the draft guidance recommendations.

Submit electronic comments on the draft product-specific BE recommendations 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.

FOR FURTHER INFORMATION CONTACT: Kris André, Center for Drug Evaluation and Research, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 75, rm. 1615, Silver Spring, MD 20993–0002, 240–402–7959.

SUPPLEMENTARY INFORMATION:

I. Background

In the **Federal Register** of June 11, 2010 (75 FR 33311), FDA announced the availability of a guidance for industry entitled ''Bioequivalence Recommendations for Specific Products'' which explained the process that would be used to make product-specific BE recommendations available to the public on FDA's Web site at *http://www.fda.gov/Drugs/GuidanceComplianceRegulatoryInformation/Guidances/default.htm.*

As described in that guidance, FDA adopted this process as a means to develop and disseminate product-specific BE recommendations and provide a meaningful opportunity for the public to consider and comment on those recommendations. Under that process, draft recommendations are posted on FDA's Web site and announced periodically in the **Federal Register**. The public is encouraged to submit comments on those recommendations within 60 days of their announcement in the **Federal Register**. FDA considers any comments received, and either publishes final recommendations or publishes revised draft recommendations for comment. Recommendations were last announced in the **Federal Register** on April 2, 2014 (79 FR 18561). This notice announces draft product-specific recommendations, either new or revised, that are posted on FDA's Web site.

II. Drug Products for Which New Draft Product-Specific BE Recommendations Are Available

FDA is announcing the availability of a new draft guidance for industry on product-specific BE recommendations for drug products containing the following active ingredients:

TABLE 1—NEW DRAFT PRODUCT-SPECIFIC BE RECOMMENDATIONS FOR DRUG PRODUCTS

A	Alogliptin benzoate.
	Alogliptin benzoate; Metformin hydrochloride (HCl).
	Alogliptin benzoate; Pioglitazone HCl.
	Amoxicillin (multiple reference listed drugs).
	Atenolol; Chlorthalidone.
C	Canagliflozin.
	Carbidopa.
	Carbinoxamine maleate.