ANNUAL BURDEN ESTIMATES—Continued

Instrument	Number of respondents	Number of responses per respondent	Average burden hours per response	Total burden hours
Legal Service Provider List for UC	58,000	1	.1	5,800
URM Application	350	1	1	350
Withdrawal of Application or Declination of Placement Form	10	1	.1/hour	1
Standard Shelter Tour Request	60	1	.1/hour	6

Estimated Total Annual Burden Hours: 172,636.

In compliance with the requirements of Section 506(c)(2)(A) of the Paperwork Reduction Act of 1995, the Administration for Children and Families is soliciting public comment on the specific aspects of the information collection described above. Copies of the proposed collection of information can be obtained and comments may be forwarded by writing to the Administration for Children and Families, Office of Planning, Research and Evaluation, 370 L'Enfant Promenade SW., Washington, DC 20447, Attn: ACF Reports Clearance Officer. Email address: *infocollection@acf.hhs.gov.* All requests should be identified by the title of the information collection.

The Department specifically requests comments on: (a) Whether the proposed collection of information is necessary for the proper performance of the functions of the agency, including whether the information shall have practical utility; (b) the accuracy of the agency's estimate of the burden of the proposed collection of information; (c) the quality, utility, and clarity of the information to be collected; and (d) ways to minimize the burden of the collection of information on respondents, including through the use of automated collection techniques or other forms of information technology. Consideration will be given to comments and suggestions submitted within 60 days of this publication.

Robert Sargis,

Reports Clearance Officer.

[FR Doc. 2015–22495 Filed 9–4–15; 8:45 am]

BILLING CODE 4184–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2012–N–0961]

Agency Information Collection Activities; Proposed Collection; Comment Request; Environmental Impact Considerations

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, including each proposed extension of an existing collection of information, and to allow 60 days for public comment in response to the notice. This notice solicits comments on the information collection entitled ''Environmental Impact Considerations.''

DATES: Submit either electronic or written comments on the collection of information by November 9, 2015.

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, including each proposed extension of an existing 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 listed below.

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.

Environmental Impact Considerations—21 CFR Part 25

OMB Control Number 0910–0322

FDA is requesting OMB approval for the reporting requirements contained in the FDA collection of information ''Environmental Impact Considerations.'' The National Environmental Policy Act (NEPA) (42 U.S.C. 4321–4347) states national environmental objectives and imposes upon each Federal Agency the duty to consider the environmental effects of its actions. Section 102(2)(C) of NEPA requires the preparation of an

environmental impact statement (EIS) for every major Federal action that will significantly affect the quality of the human environment.

FDA's NEPA regulations are in part 25 (21 CFR part 25). All applications or petitions requesting Agency action require the submission of a claim for categorical exclusion or an environmental assessment (EA). A categorical exclusion applies to certain classes of FDA-regulated actions that usually have little or no potential to cause significant environmental effects and are excluded from the requirements to prepare an EA or EIS. Sections 25.15(a) and (d) specifies the procedures for submitting to FDA a claim for a categorical exclusion. Extraordinary circumstances (§ 25.21), which may result in significant environmental impacts, may exist for some actions that are usually categorically excluded. An EA provides information that is used to determine whether an FDA action could result in a significant environmental impact. Sections 25.40(a) and (c) specifies the content requirements for EAs for non-excluded actions.

This collection of information is used by FDA to assess the environmental impact of Agency actions and to ensure that the public is informed of environmental analyses. Firms wishing to manufacture and market substances regulated under statues for which FDA is responsible must, in most instances, submit applications requesting approval. Environmental information must be included in such applications for the purpose of determining whether the proposed action may have a significant impact on the environment. Where significant adverse events cannot be avoided, the Agency uses the submitted information as the basis for preparing and circulating to the public an EIS, made available through a **Federal Register** document also filed for comment at the Environmental Protection Agency. The final EIS, including the comments received, is reviewed by the Agency to weigh environmental costs and benefits in determining whether to pursue the proposed action or some alternative that would reduce expected environmental impact.

Any final EIS would contain additional information gathered by the Agency after the publication of the draft EIS, a copy or a summary of the comments received on the draft EIS, and the Agency's responses to the comments, including any revisions resulting from the comments or other information. When the Agency finds that no significant environmental effects are expected, the Agency prepares a finding of no significant impact.

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

Estimated Annual Reporting Burden for Human Drugs (Including Biologics in the Center for Drug Evaluation and Research)

Under 21 CFR 312.23(a)(7)(iv)(*c*), 314.50(d)(1)(iii), and 314.94(a)(9)(i), each investigational new drug application (IND), new drug application (NDA), and abbreviated new drug application (ANDA) must contain a claim for categorical exclusion under § 25.30 or § 25.31, or an EA under § 25.40. Annually, FDA receives approximately 3,677 INDs from 2501 sponsors; 120 NDAs from 87 applicants; 2,718 supplements to NDAs from 399 applicants; 9 biologic license applications (BLAs) from 8 applicants; 317 supplements to BLAs from 43 applicants; 1475 ANDAs from 300 applicants; and 5448 supplements to ANDAs from 318 applicants. FDA estimates that it receives approximately 13,663 claims for categorical exclusions as required under §§ 25.15(a) and (d), and 11 EAs as required under §§ 25.40(a) and (c). Based on information provided by the pharmaceutical industry, FDA estimates that it takes sponsors or applicants approximately 8 hours to prepare a claim for a categorical exclusion and approximately 3,400 hours to prepare an EA.

TABLE 1—ESTIMATED ANNUAL REPORTING BURDEN FOR HUMAN DRUGS [1]

21 CFR section	Number of respondents	Number of responses per respondent	Total annual responses	Average burden per response	Total hours
25.15(a) and (d)	3,416	4	13,664	8	109,312
25.40(a) and (c)	11	1	11	3,400	37,400
Total					146,712

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

Estimated Annual Reporting Burden for Human Foods

Under 21 CFR 71.1, 171.1, 170.39, and 170.100, food additive petitions, color additive petitions, requests from exemption from regulation as a food additive, and submission of a food contact notification for a food contact substance must contain either a claim of categorical exclusion under § 25.30 or § 25.32 or an EA under § 25.40. Annually, FDA receives approximately 97 industry submissions. FDA received an annual average of 42 claims of categorical exclusions as required under § 25.15(a) and (d) and 33 EAs as required under §§ 25.40(a) and (c). FDA estimates that approximately 42 respondents will submit an average of 1 application for categorical exclusion and 33 respondents will submit an average of 1 EA. FDA estimates that, on average, it takes petitioners, notifiers, or requestors approximately 8 hours to prepare a claim of categorical exclusion and approximately 210 hours to prepare an EA.

TABLE 2—ESTIMATED ANNUAL REPORTING BURDEN FOR HUMAN FOODS [1]

21 CFR section	Number of respondents	Number of responses per respondent	Total annual responses	Average burden per response	Total hours
25.15(a) and (d)	42	1	42	8	336
25.40(a) and (c)	33	1	33	210	6,930

TABLE 2—ESTIMATED ANNUAL REPORTING BURDEN FOR HUMAN FOODS [1]—Continued

21 CFR section	Number of respondents	Number of responses per respondent	Total annual responses	Average burden per response	Total hours
Total					7,266

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

Estimated Annual Reporting Burden for Medical Devices

Under 21 CFR 814.20(b)(11), premarket approvals (PMAs) (original PMAs and supplements) must contain a claim for categorical exclusion under § 25.30 or § 25.34 or an EA under § 25.40. In 2012 to 2014, FDA received an average of 39 claims (original PMAs and supplements) for categorical exclusions as required under §§ 25.15(a) and (d), and 0 EAs as required under §§ 25.40(a) and (c). FDA estimates that approximately 39 respondents will submit an average of 1 application for categorical exclusion annually. Based on information provided by sponsors, FDA estimates that it takes approximately 6 hours to prepare a claim for a categorical exclusion.

TABLE 3—ESTIMATED ANNUAL REPORTING BURDEN FOR MEDICAL DEVICES [1]

21 CFR section	Number of respondents	Number of responses per respondent	Total annual responses	Average burden per response	Total hours
25.15(a) and (d)	39	1	39	6	234

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

Estimated Annual Reporting Burden for Biological Products, Drugs, and Medical Devices in the Center for Biologics Evaluation and Research

Under 21 CFR 601.2(a), BLAs as well as INDs (§ 312.23), NDAs (§ 314.50), ANDAs (§ 314.94), and PMAs (§ 814.20) must contain either a claim of categorical exclusion under § 25.30 or 25.32 or an EA under § 25.40. Annually, FDA receives approximately 34 BLAs from 18 applicants, 801 BLA supplements to license applications from 156 applicants, 345 INDs from 256 sponsors, 1 NDA from 1 applicant, 26 supplements to NDAs from 8 applicants, 1 ANDA from 1 applicant, 1 supplement to ANDAs from 1 applicant, 8 PMAs from 3 applicants, and 33 PMA supplements from 16 applicants. FDA estimates that approximately 10 percent of these supplements would be submitted with a claim for categorical exclusion or an EA.

FDA has received approximately 481 claims for categorical exclusion as required under §§ 25.15(a) and (d) annually and 2 EAs as required under §§ 25.40(a) and (c) annually. Therefore, FDA estimates that approximately 247 respondents will submit an average of 2 applications for categorical exclusion and 2 respondents will submit an average of 1 EA. Based on information provided by industry, FDA estimates that it takes sponsors and applicants approximately 8 hours to prepare a claim of categorical exclusion and approximately 3,400 hours to prepare an EA for a biological product.

TABLE 4—ESTIMATED ANNUAL REPORTING BURDEN FOR BIOLOGICAL PRODUCTS[1]

21 CFR section	Number of respondents	Number of responses per respondent	Total annual responses	Average burden per response	Total hours
25.15(a) and (d)	247	2	494	8	3,952
25.40(a) and (c)	2	1	2	3,400	6,800
Total					10,752

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

Estimated Annual Reporting Burden for Animal Drugs

Under 21 CFR 514.1(b)(14), new animal drug applications (NADAs) and abbreviated new animal drug applications (ANADAs); 21 CFR 514.8(a)(1) supplemental NADAs and ANADAs; 21 CFR 511.1(b)(10) investigational new animal drug applications (INADs), and 21 CFR 571.1(c) food additive petitions must contain a claim for categorical exclusion under § 25.30 or 25.33 or an EA under § 25.40. Annually, FDA's Center for Veterinary Medicine has received approximately 698 claims for categorical exclusion as required under §§ 25.15(a) and (d), and 10 EAs as required under §§ 25.40(a) and (c). FDA estimates that approximately 70 respondents will submit an average of 10 applications for categorical exclusion and 10 respondents will submit an average of 1 EA. FDA estimates that it takes sponsors/applicants approximately 3 hours to prepare a claim of categorical exclusion and an average of 2,160 hours to prepare an EA.

TABLE 5—ESTIMATED ANNUAL REPORTING BURDEN FOR ANIMAL DRUGS [1]

21 CFR section	Number of respondents	Number of responses per respondent	Total annual responses	Average burden per response	Total hours
25.15(a) and (d)	70	10	700	3	2,100
25.40(a) and (c)	10	1	10	2,160	21,600
Total					23,700

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

Estimated Annual Reporting Burden for Tobacco Products

Under sections 905, 910, and 911 of the Federal Food, Drugs, and Cosmetic Act (21 U.S.C. 387, 387j, and 387k), product applications and supplements (PMTAs), SEs, Exemption from SEs, and modified risk tobacco products must contain a claim for categorical exclusion or an EA. In 2015, FDA estimated it will receive approximately 5 premarket review of new tobacco PMTAs from 5 respondents, 509 reports intended to demonstrate the substantial equivalence of a new tobacco product (SEs) from 509 respondents, 15 exemption from substantial equivalence requirements applications (SE Exemptions) from 15 respondents, and 3 modified risk tobacco product applications (MRTPAs) from 3 respondents. FDA is not accepting claims for categorical exclusions at this time, and estimates that there will be 532 EAs from 532 respondents as required under §§ 25.40(a) and (c). Therefore, over the next 3 years, FDA estimates that approximately 532 respondents will submit an average of 1 application for environmental assessment. Part of the information in the EA will be developed while writing other parts of a PMTA, SE, Exemption from SE, or MRTPA. Based on FDA's experience, previous information provided by potential sponsors and knowledge that part of the EA information has already been produced in one of the tobacco product applications, FDA estimates that it takes approximately 80 hours to prepare an EA.

TABLE 6—ESTIMATED ANNUAL REPORTING BURDEN FOR TOBACCO PRODUCTS [1]

21 CFR section	Number of respondents	Number of responses per respondent	Total annual responses	Average burden per response	Total hours
25.40(a) and (c)	532	1	532	80	42,560

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

Dated: August 31, 2015.

Leslie Kux,

Associate Commissioner for Policy.

[FR Doc. 2015–22507 Filed 9–4–15; 8:45 am]

BILLING CODE 4164–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2011–D–0147]

Demonstrating the Substantial Equivalence of a New Tobacco Product: Responses to Frequently Asked Questions; Second Edition; Guidance for Industry; Availability

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is announcing a second edition of the guidance for industry entitled ''Demonstrating the Substantial Equivalence of a New Tobacco Product: Responses to Frequently Asked Questions''. FDA is issuing the second edition to provide further information on demonstrating substantial equivalence (SE) of a new tobacco product, including demonstrating SE when the new tobacco product has: A modified label that renders it distinct from, but has identical characteristics to, a valid predicate product; or a change in product quantity from, but where the per weight composition is identical to, a valid predicate product.

DATES: Submit either electronic or written comments on Agency guidances at any time.

ADDRESSES: All communications in response to this notice should be identified with Docket No. FDA–2011–D–0147. Submit electronic comments on the guidance 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: Annette Marthaler, Center for Tobacco Products, Food and Drug Administration, Document Control Center, Bldg. 71, Rm. G335, 10903 New Hampshire Ave., Silver Spring, MD 20993–0002; 1–877–287–1373, *CTPRegulations@fda.hhs.gov,* or *annette.marthaler@fda.hhs.gov.*

SUPPLEMENTARY INFORMATION:

I. Background

We are announcing the availability of the second edition of the guidance for industry entitled ''Demonstrating the Substantial Equivalence of a New Tobacco Product: Responses to Frequently Asked Questions'' (second edition SE FAQ guidance). We are issuing this guidance consistent with our good guidance practices regulation (21 CFR 10.115).

In September 2011, FDA issued draft guidance responding to frequently asked questions covering a range of topics on demonstrating the SE of a new tobacco product (September 9, 2011, 76 FR 55927). In March 2015, FDA issued a final guidance on many of the topics included in the September 2011 draft ((March 5, 2015, 80 FR 12011) (March 2015 FAQ guidance)). In May 2015, FDA announced that an interim enforcement policy would be in effect while it considered comments submitted on the March 2015 FAQ guidance. This interim enforcement policy will continue to be in effect for 30 days from the date of issuance of the