II. Annual AIC Adjustments

A. AIC Adjustment Formula and AIC Adjustments

As previously noted, section 940 of the MMA requires that the AIC threshold amounts be adjusted annually, beginning in January 2005, by the percentage increase in the medical care component of the consumer price index (CPI) for all urban consumers (U.S. city average) for July 2003 to July of the year preceding the year involved and rounded to the nearest multiple of $10.

B. Calendar Year 2013

The AIC threshold amount for ALJ hearing requests will increase to $140 and the AIC threshold amount for judicial review will rise to $1,400 for CY 2013. These updated amounts are based on the 40.04 percent increase in the medical care component of the CPI from July 2003 to July 2012. The CPI level was at 297.600 in July 2003 and rose to 416.759 in July 2012. This change accounted for the 40.04 percent increase. The AIC threshold amount for ALJ hearing requests changes to $140.04 based on the 40.04 percent increase. In accordance with section 940 of the MMA, this amount is rounded to the nearest multiple of $10. Therefore, the CY 2013 AIC threshold amount for ALJ hearings is $140. The AIC threshold amount for judicial review changes to $1,400.40 based on the 40.04 percent increase. This amount was rounded to the nearest multiple of $10, resulting in the CY 2013 AIC threshold amount of $1,400 for judicial review.

C. Summary Table of Adjustments in the AIC Threshold Amounts

In the following table we list the CYs 2009 through 2013 threshold amounts.

	CY 2009	CY 2010	CY 2011	CY 2012	CY 2013
ALJ Hearing	$120	$130	$130	$130	$140
Judicial Review	1,220	1,260	1,300	1,350	1,400

III. Collection of Information Requirements

This document does not impose information collection and recordkeeping requirements. Consequently, it need not be reviewed by the Office of Management and Budget under the authority of the Paperwork Reduction Act of 1995 (44 U.S.C. 35).

(Catalog of Federal Domestic Assistance Program No. 93.778, Medical Assistance Program; No. 93.773 Medicare—Hospital Insurance Program; and No. 93.774, Medicare—Supplementary Medical Insurance Program)

Dated: September 12, 2012.

Marilyn Tavenner,

Acting Administrator, Centers for Medicare & Medicaid Services.

[FR Doc. 2012–23992 Filed 9–27–12; 8:45 am]

BILLING CODE 4120–01–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 27, 2012.

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: Daniel Gittleson, Office of Information Management, Food and Drug Administration, 1350 Piccard Dr., PI50–400B, Rockville, MD 20850, 301–796–5156, *daniel.gittleson@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 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.

Environmental Impact Considerations—21 CFR Part 25 (OMB Control Number 0910–0322)—Extension)

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. Section 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. Section 25.40(a) and (c) specifies the content requirements for EAs for nonexcluded 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)(3), 21 CFR 314.50(d)(1)(iii), and 21 CFR 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. In 2011, FDA received 2,818 INDs from 2,064 sponsors, 99 NDAs from 79 applicants, 3,247 supplements to NDAs from 376 applicants, 5 biologic license applications (BLAs) from 5 applicants, 287 supplements to BLAs from 50 applicants, 895 ANDAs from 195 applicants, and 5,348 supplements to ANDAs from 299 applicants. FDA estimates that it receives approximately 12,699 claims for categorical exclusions as required under 25.15(a) and (d), and 10 EAs as required under 25.40(a) and (c). Therefore, over the next 3 years, FDA estimates that approximately 3,175 respondents will submit an average of 4 applications for categorical exclusion and 10 respondents will submit an average of 1 EA. 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)	3,175	4	12,700	8	101,600
25.40(a) and (c)	10	1	10	3,400	34,000
Total					135,600

[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. In 2011, FDA received 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). Therefore, over the next 3 years, 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 3 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

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
25.40(a) and (c)	33	1	33	210	6,930
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 (PMA) (original PMAs and supplements) must contain a claim for categorical exclusion under 25.30 or 25.34 or an EA under 25.40. In 2011, FDA received approximately 52 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). Therefore, over the next 3 years, FDA estimates that approximately 52 respondents will submit an average of 1 application for categorical exclusion. Based on information provided by less than 10 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)	52	1	52	6	312

[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

BLAs under 21 CFR 601.2(a), as well as INDs (21 CFR 312.23), NDAs (21 CFR 314.50), ANDAs (21 CFR 314.94), and PMAs (21 CFR 814.20), must contain either a claim of categorical exclusion under 25.30 or 25.32 or an EA under 25.40. In 2011, FDA received 14 BLAs from 14 applicants, 831 BLA supplements to license applications from 153 applicants, 288 INDs from 210 sponsors, 1 NDA from 1 applicant, 37 supplements to NDAs from 9 applicants, 1 ANDA from 1 applicant, 12 supplements to ANDAs from 2 applicants, and 45 PMA supplements from 11 applicants. FDA estimates that approximately 10 percent of these supplements would be submitted with a claim for categorical exclusion or an EA.

FDA estimates that it received approximately 481 claims for categorical exclusion as required under 25.15(a) and (d), and 2 EAs as required under 25.40(a) and (c). Therefore, over the next 3 years, 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. In 2011, 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). Therefore, over the next 3 years, 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, premarket tobacco applications (PMTAs), applications for substantial equivalence (SEs), Exemption from SEs, and modified risk tobacco products must contain a claim for categorical exclusion under 25.30 or 25.34 or an EA under 25.40. In 2011, FDA estimated it will receive approximately 20 PMTAs and supplements from 20 respondents, 150 reports intended to demonstrate the SE of a new tobacco product from 150 respondents, 500 exemption from SE requirements applications from 500 respondents, and 3 modified risk Tobacco product applications from 3 respondents for a total of 673 responses from 673 respondents. FDA estimates that there were 538 claims from 538 respondents for categorical exclusions as required under 25.15(a) and (d), and 135 EAs from 135 respondents as required under 25.40(a) and (c). Therefore, over the next 3 years, FDA estimates that approximately 538 respondents will submit an average of 1 application for categorical exclusion and 135 respondents will submit an average of 1 EA. Based on FDA's experience and previous information provided by potential sponsors, FDA estimates that it takes approximately 12 hours to prepare a claim for a categorical exclusion and 12 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
25.15 (a) and (d)	538	1	538	12	6,456
25.40 (a) and (c)	135	1	135	12	1,620
Total					8,076

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

TABLE 7—ESTIMATED ANNUAL TOTAL REPORTING BURDEN FOR ALL CENTERS [1]

CFR Section	Number of respondents	Number of responses per respondent	Total annual responses	Average burden per response	Total hours
25.15 (a) and (d)	4,124		14,526		114,756
25.40 (a) and (c)	190		190		70,950
Total					185,706

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

Dated: September 21, 2012.

Leslie Kux,

Assistant Commissioner for Policy.

[FR Doc. 2012–23838 Filed 9–27–12; 8:45 am]

BILLING CODE 4160–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2012–N–0977]

Agency Information Collection Activities; Proposed Collection; Comment Request; Regulations Restricting the Sale and Distribution of Cigarettes and Smokeless Tobacco To Protect Children and Adolescents

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 regulations restricting the sale and distribution of cigarettes and smokeless tobacco to protect children and adolescents.