ESTIMATED ANNUALIZED BURDEN HOURS

Respondent	Form name or module	Number of respondents	Number of responses per respondent	Average burden per response (in hours)
Household member 18 yrs or older	Eligibility Screener	1,118	1	10/60
Children ages 3–15	Baseline: Session 1 (Child Modules)	250	1	15/60
Parents of children ages 3–15	Baseline: Session 1 (Parent Modules)	250	1	1
Children ages 3–15	Baseline: Session 2 (Child Modules)	250	1	1
Parents of children ages 3–15	Baseline: Session 2 (Parent Modules)	250	1	30/60
Children ages 3–15	6-month Follow-up: Session 1 (Child Modules).	225	1	7/60
Parents of children ages 3–15	6-month Follow-up: Session 1 (Parent Modules).	225	1	40/60
Children ages 3–15	6-month Follow-up: Session 2 (Child Modules).	225	1	37/60
Parents of children ages 3–15	6-month Follow-up: Session 2 (Parent Modules).	225	1	30/60
Household member 18 yrs or older	Verification Questionnaire for Eligibility Screener (10% subsample).	112	1	2/60
Household member 18 yrs or older	Verification Questionnaire for Baseline and 6-month Follow-up Visits (9% subsample).	43	1	5/60
Household member 18 yrs or older	Mail Verification Form for Baseline and 6-month Follow-up Visits (1% subsample).	5	1	5/60

Dated: August 30, 2011.

Daniel Holcomb,

Reports Clearance Officer, Centers for Disease Control and Prevention.

[FR Doc. 2011–22788 Filed 9–6–11; 8:45 am]

BILLING CODE 4163–18–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Centers for Disease Control and Prevention

Meeting of the Task Force on Community Preventive Services

AGENCY: Centers for Disease Control and Prevention (CDC), Department of Health and Human Services (HHS).

ACTION: Notice of meeting.

SUMMARY: The Centers for Disease Control and Prevention (CDC) announces the next meeting of the Community Preventive Services Task Force (Task Force). The Task Force—an independent, nonfederal body of nationally known leaders in public health practice, policy, and research who are appointed by the CDC Director—was convened in 1996 by the Department of Health and Human Services (HHS) to assess the effectiveness of community, environmental, population, and healthcare system interventions in public health and health promotion. During this meeting, the Task Force will consider the findings of systematic reviews and issue recommendations and findings to help inform decision making about policy, practice, and research in a wide range of U.S. settings. The Task Force's recommendations, along with the systematic reviews of the scientific evidence on which they are based, are compiled in the *Guide to Community Preventive Services (Community Guide).*

DATES: The meeting will be held on Monday, October 3, 2011 from 8:30 a.m. to 5:30 p.m., EST and Tuesday, October 4, 2011 from 8:30 a.m. to 1 p.m. EST.

ADDRESSES: The Task Force Meeting will be held at the Centers for Disease Control and Prevention, Century Center, 2500 Century Parkway, Conference Rooms 1200/1201, Atlanta, Georgia 30345. Information regarding logistics will be available on the Community Guide Web site (*http://www.thecommunityguide.org*), Wednesday, September 14, 2011.

FOR FURTHER INFORMATION CONTACT: Linda Shelton, The Community Guide Branch, Epidemiology and Analysis Program Office, Office of Surveillance, Epidemiology, and Laboratory Services, Centers for Disease Control and Prevention, 1600 Clifton Road, MS–E–69, Atlanta, Georgia 30333, *phone:* (404) 498–1194), *e-mail: communityguide@cdc.gov.*

SUPPLEMENTARY INFORMATION:

Purpose: The purpose of the meeting is for the Task Force to consider the findings of systematic reviews and issue recommendations and findings to help inform decision making about policy, practice, and research in a wide range of U.S. settings.

Matters to be discussed: Updates on Tobacco, Skin Cancer, Health Equity and Cardiovascular Disease.

Meeting Accessibility: This meeting is open to the public, limited only by space availability.

Dated: August 25, 2011.

Tanja Popovic,

Deputy Associate Director for Science, Centers for Disease Control and Prevention.

[FR Doc. 2011–22801 Filed 9–6–11; 8:45 am]

BILLING CODE 4163–18–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2011–N–0619]

Agency Information Collection Activities; Proposed Collection; Comment Request; Medical Devices: Humanitarian Use Devices

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 information collection requirements for humanitarian use devices (HUDs).

DATES: Submit either electronic or written comments on the collection of information by November 7, 2011.

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.

Medical Devices: Humanitarian Use Devices—21 CFR Part 814 (OMB Control Number 0910–0332)—Extension

This collection of information implements the HUD provision of section 520(m) of the Federal Food, Drug, and Cosmetic Act (the FD&C Act) (21 U.S.C. 360j(m)) and subpart H, part 814 (21 CFR part 814). Under section 520(m) of the FD&C Act, FDA is authorized to exempt an HUD from the effectiveness requirements of sections 514 and 515 of the FD&C Act (21 U.S.C. 360d and 360e) provided that the device: (1) Is used to treat or diagnose a disease or condition that affects fewer than 4,000 individuals in the United States; (2) would not be available to a person with such a disease or condition unless an exemption is granted because there is no comparable device other than another HUD approved under this exemption that is available to treat or diagnose the disease or condition; and (3) will not expose patients to an unreasonable or significant risk of illness or injury with the probable benefit to health from using the device outweighing the risk of injury or illness from its use. This takes into account the probable risks and benefits of currently available devices or alternative forms of treatment.

The information collected will assist FDA in making determinations on the following: (1) Whether to grant HUD designation of a medical device; (2) exempt an HUD from the effectiveness requirements under sections 514 and 515 of the FD&C Act, provided that the device meets requirements set forth under section 520(m) of the FD&C Act; and (3) whether to grant marketing approval(s) for the HUD. Failure to collect this information would prevent FDA from making a determination on the factors listed previously in this document. Further, the collected information would also enable FDA to determine whether the holder of an HUD is in compliance with the HUD provisions under section 520(m) of the FD&C Act.

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

TABLE 1—ESTIMATED ANNUAL REPORTING BURDEN [1]

21 CFR Section	Number of respondents	Number of responses per respondent	Total annual responses	Average burden per response	Total hours
814.102	17	1	17	40	680
814.104	5	1	5	320	1,600
814.106	5	5	25	50	1,250
814.108	47	1	47	80	3,760
814.116(e)(3)	3	1	3	1	3
814.124(a)	22	1	22	1	22
814.124(b)	12	1	12	2	24
814.126(b)(1)	43	1	43	120	5,160
Total					12,499

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

TABLE 2—ESTIMATED ANNUAL RECORDKEEPING BURDEN [1]

21 CFR Section	Number of recordkeepers	Number of records per recordkeeper	Total annual records	Average burden per record-keeping	Total hours
814.126(b)(2)	43	1	43	2	86

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

The number of respondents in tables 1 and 2 of this document are an average from data for the previous 3 years, *i.e.,* fiscal years 2008 to 2010. The number of annual reports submitted under § 814.126(b)(1) in table 1 reflects 43 respondents with approved HUD applications. Likewise, under § 814.126(b)(2) in table 2, the number of recordkeepers is 43.

Dated: September 1, 2011.

David Dorsey,

Acting Associate Commissioner for Policy and Planning.

[FR Doc. 2011–22858 Filed 9–6–11; 8:45 am]

BILLING CODE 4160–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2011–N–0627]

Agency Information Collection Activities; Proposed Collection; Comment Request; General Administrative Procedures: Citizen Petitions; Petition for Reconsideration or Stay of Action; Advisory Opinions

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 reporting requirements contained in existing FDA regulations regarding the general administrative procedures for a person to petition the Commissioner of Food and Drugs (the Commissioner) to issue, amend, or revoke a rule; to file a petition for an administrative reconsideration or an administrative stay of action; and to request an advisory opinion from the Commissioner.

DATES: Submit either electronic or written comments on the collection of information by November 7, 2011.

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: Ila S. Mizrachi, Office of Information Management, Food and Drug Administration, 1350 Piccard Dr., PI50–400B, Rockville, MD 20850, 301–796–7726, *Ila.Mizrachi@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.

General Administrative Procedures: Citizen Petitions; Petition for Reconsideration or Stay of Action; Advisory Opinions—(OMB Control Number 0910–0183)—Extension

The Administrative Procedures Act (5 U.S.C. 553(e)), provides that every Agency shall give an interested person the right to petition for issuance, amendment, or repeal of a rule. Section 10.30 (21 CFR 10.30) sets forth the format and procedures by which an interested person may submit to FDA, in accordance with § 10.20 (21 CFR 10.20) (submission of documents to Division of Dockets Management), a citizen petition requesting the Commissioner to issue, amend, or revoke a regulation or order, or to take or refrain from taking any other form of administrative action.

The Commissioner may grant or deny such a petition, in whole or in part, and may grant such other relief or take other action as the petition warrants. Respondents are individuals or households, State or local governments, not-for-profit institutions or groups.

Section 10.33 (21 CFR 10.33) issued under section 701(a) of the Federal, Food, Drug, and Cosmetic Act (the FD&C Act) (21 U.S.C. 371(a)), sets forth the format and procedures by which an interested person may request reconsideration of part or all of a decision of the Commissioner on a petition submitted under 21 CFR 10.25 (initiation of administrative proceedings). A petition for reconsideration must contain a full statement in a well-organized format of the factual and legal grounds upon which the petition relies. The grounds must demonstrate that relevant information and views contained in the administrative record were not previously or not adequately considered by the Commissioner. The respondent must submit a petition no later than 30 days after the decision involved. However, the Commissioner may, for good cause, permit a petition to be filed after 30 days. An interested person who wishes to rely on information or views not included in the administrative record shall submit them with a new petition to modify the decision. FDA uses the information provided in the request to determine whether to grant the petition for reconsideration. Respondents to this collection of information are individuals of households, State or local governments, not-for-profit institutions, and businesses or other for-profit institutions who are requesting from the Commissioner a reconsideration of a matter.

Section 10.35 (21 CFR 10.35), issued under section 701(a) of the FD&C Act, sets forth the format and procedures by which an interested person may request, in accordance with § 10.20 (submission of documents to Division of Dockets Management), the Commissioner to stay the effective date of any administrative action.

Such a petition must do the following: (1) Identify the decision involved; (2) state the action requested, including the