ACTION: Notice.

SUMMARY: The Centers for Medicare & Medicaid Services (CMS) is announcing an opportunity for the public to comment on CMS' intention to collect information from the public. 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 or reinstatement of an existing collection of information) and to allow 60 days for public comment on the proposed action. Interested persons are invited to send comments regarding our burden estimates or any other aspect of this collection of information, including any of the following subjects: (1) The necessity and utility of the proposed information collection for the proper performance of the agency's functions; (2) the accuracy of the estimated burden; (3) ways to enhance the quality, utility, and clarity of the information to be collected; and (4) the use of automated collection techniques or other forms of information technology to minimize the information collection burden.

DATES: Comments must be received by December 28, 2015.

ADDRESSES: When commenting, please reference the document identifier or OMB control number. To be assured consideration, comments and recommendations must be submitted in any one of the following ways:

1. *Electronically.* You may send your comments electronically to *http://www.regulations.gov.* Follow the instructions for ''Comment or Submission'' or ''More Search Options'' to find the information collection document(s) that are accepting comments.

2. *By regular mail.* You may mail written comments to the following address: CMS, Office of Strategic Operations and Regulatory Affairs, Division of Regulations Development, Attention: Document Identifier/OMB Control Number _____, Room C4–26–05, 7500 Security Boulevard, Baltimore, Maryland 21244–1850.

To obtain copies of a supporting statement and any related forms for the proposed collection(s) summarized in this notice, you may make your request using one of following:

1. Access CMS' Web site address at *http://www.cms.hhs.gov/PaperworkReductionActof1995.*

2. Email your request, including your address, phone number, OMB number, and CMS document identifier, to *Paperwork@cms.hhs.gov.*

3. Call the Reports Clearance Office at (410) 786–1326.

FOR FURTHER INFORMATION CONTACT: Reports Clearance Office at (410) 786–1326.

SUPPLEMENTARY INFORMATION:

Contents

This notice sets out a summary of the use and burden associated with the following information collections. More detailed information can be found in each collection's supporting statement and associated materials (see **ADDRESSES**).

CMS–10280 Home Health Change of Care Notice (HHCCN)

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. The term ''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 requires federal agencies to publish a 60-day notice in the **Federal Register** concerning each proposed collection of information, including each proposed extension or reinstatement of an existing collection of information, before submitting the collection to OMB for approval. To comply with this requirement, CMS is publishing this notice.

Information Collection

1. *Type of Information Collection Request:* Extension of a currently approved collection; *Title of Information Collection:* Home Health Change of Care Notice (HHCCN); *Use:* The Home Health Change of Care Notice (HHCCN) is used to notify original Medicare beneficiaries receiving home health care benefits of plan of care changes. Home health agencies (HHAs) must provide the HHCCN whenever they reduce or terminate a beneficiary's home health services due to physician/provider orders or limitation of the HHA in providing the specific service. Notification is required for covered and non-covered services listed in the plan of care. This iteration contains non-substantive changes which add language informing beneficiaries of their rights under Section 504 of the Rehabilitation Act of 1973 by alerting the beneficiary to CMS' nondiscrimination practices and the availability of alternate forms of this notice if needed. There are no substantive changes. *Form Number:* CMS–10280 (OMB control number: 0938–0829); *Frequency:* Occasionally; *Affected Public:* Private sector (Business or other for-profits and Not-for-profit institutions); *Number of Respondents:* 12,459; *Total Annual Responses:* 13,764,434; *Total Annual Hours:* 917,262. (For policy questions regarding this collection contact Evelyn Blaemire at 410–786–1803).

Dated: October 20, 2015.

William N. Parham, III,

Director, Paperwork Reduction Staff, Office of Strategic Operations and Regulatory Affairs.

[FR Doc. 2015–27077 Filed 10–23–15; 8:45 am]

BILLING CODE 4120–01P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2013–N–1282]

National Environmental Policy Act; Environmental Assessments for Tobacco Products; Categorical Exclusions—Small Entity Compliance Guide; Guidance for Industry; Availability

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice of availability.

SUMMARY: The Food and Drug Administration (FDA) is announcing the availability of a guidance for industry entitled ''National Environmental Policy Act; Environmental Assessments for Tobacco Products; Categorical Exclusions—Small Entity Compliance Guide.'' This guidance is intended to help small businesses understand the recent changes to FDA's National Environmental Policy Act (NEPA)-implementing regulations, which will allow certain classes of actions on tobacco product marketing applications to be excluded from the requirements to prepare an environmental assessment (EA) or an environmental impact statement (EIS). This will decrease the amount of time required for industry to complete, and for FDA to review, applications.

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

ADDRESSES: You may submit comments as follows:

Electronic Submissions

Submit electronic comments in the following way:

- *Federal eRulemaking Portal: http://www.regulations.gov.* Follow the

instructions for submitting comments. Comments submitted electronically, including attachments, to *http://www.regulations.gov* will be posted to the docket unchanged. Because your comment will be made public, you are solely responsible for ensuring that your comment does not include any confidential information that you or a third party may not wish to be posted, such as medical information, your or anyone else's Social Security number, or confidential business information, such as a manufacturing process. Please note that if you include your name, contact information, or other information that identifies you in the body of your comments, that information will be posted on *http://www.regulations.gov.*

• If you want to submit a comment with confidential information that you do not wish to be made available to the public, submit the comment as a written/paper submission and in the manner detailed (see ''Written/Paper Submissions'' and ''Instructions'').

Written/Paper Submissions

Submit written/paper submissions as follows:

• *Mail/Hand delivery/Courier (for written/paper submissions):* Division of Dockets Management (HFA–305), Food and Drug Administration, 5630 Fishers Lane, Rm. 1061, Rockville, MD 20852.

• For written/paper comments submitted to the Division of Dockets Management, FDA will post your comment, as well as any attachments, except for information submitted, marked and identified, as confidential, if submitted as detailed in ''Instructions''.

Instructions: All submissions received must include the Docket No. FDA–2013–N–1282 for ''National Environmental Policy Act; Environmental Assessments for Tobacco Products; Categorical Exclusions—Small Entity Compliance Guide.'' Received comments will be placed in the docket and, except for those submitted as ''Confidential Submissions,'' publicly viewable at *http://www.regulations.gov* or at the Division of Dockets Management between 9 a.m. and 4 p.m., Monday through Friday.

• Confidential Submissions—To submit a comment with confidential information that you do not wish to be made publicly available, submit your comments only as a written/paper submission. You should submit two copies total. One copy will include the information you claim to be confidential with a heading or cover note that states ''THIS DOCUMENT CONTAINS CONFIDENTIAL INFORMATION.'' The Agency will review this copy, including the claimed confidential information, in its consideration of comments. The second copy, which will have the claimed confidential information redacted/blacked out, will be available for public viewing and posted on *http://www.regulations.gov.* Submit both copies to the Division of Dockets Management. If you do not wish your name and contact information to be made publicly available, you can provide this information on the cover sheet and not in the body of your comments and you must identify this information as ''confidential.'' Any information marked as ''confidential'' will not be disclosed except in accordance with 21 CFR 10.20 and other applicable disclosure law. For more information about FDA's posting of comments to public dockets, see 80 FR 56469, September 18, 2015, or access the information at: *http://www.fda.gov/regulatoryinformation/dockets/default.htm.*

Docket: For access to the docket to read background documents or the electronic and written/paper comments received, go to *http://www.regulations.gov* and insert the docket number, found in brackets in the heading of this document, into the ''Search'' box and follow the prompts and/or go to the Division of Dockets Management, 5630 Fishers Lane, Rm. 1061, Rockville, MD 20852.

Submit written requests for single copies of this guidance to the Center for Tobacco Products, Food and Drug Administration, Document Control Center, Bldg. 71, Rm. G335, 10903 New Hampshire Ave., Silver Spring, MD 20993–0002. Send one self-addressed adhesive label to assist that office in processing your request or include a fax number to which the guidance document may be sent. See the **SUPPLEMENTARY INFORMATION** section for information on electronic access to the guidance.

FOR FURTHER INFORMATION CONTACT: Katherine Collins, Center for Tobacco Products, Food and Drug Administration, 10903 New Hampshire Ave., Document Control Center, Bldg. 71, Rm. G335, 10903 New Hampshire Ave., Silver Spring, MD 20993–0002, *CTPRegulations@fda.hhs.gov.*

SUPPLEMENTARY INFORMATION:

I. Background

FDA is announcing the availability of a guidance for industry entitled ''National Environmental Policy Act; Environmental Assessments for Tobacco Products; Categorical Exclusions—Small Entity Compliance Guide.'' This guidance is intended to help small businesses understand and comply with FDA's implementation of NEPA and the Council on Environmental Quality (CEQ) regulations for classes of actions for tobacco products as provided by the final rule. Specifically, this guidance is intended to help small businesses understand which classes of actions for tobacco products require at least the preparation of an EA, and how to apply for categorical exclusions if they qualify based on their particular circumstance.

NEPA and CEQ regulations require each Federal Agency to assess, as an integral part of its decisionmaking process, the environmental impacts of any proposed Federal action to ascertain the environmental consequences of that action on the quality of the human environment and to ensure that the interested and affected public is appropriately informed (42 U.S.C. 4332(2); 40 CFR 1506.6). FDA regulations governing its responsibilities under NEPA are codified at 21 CFR part 25, and the CEQ regulations are codified at 40 CFR parts 1500 to 1508.

CEQ oversees FDA's compliance with NEPA. For major Federal actions that may have a significant environmental impact, FDA can either prepare an EIS or prepare an EA. An EA provides sufficient information and analysis for FDA to determine whether to prepare an EIS or issue a finding of no significant impact (21 CFR 25.20; 40 CFR 1501.4). FDA is responsible for the scope and content of an EA and generally requires an applicant to prepare an EA and make necessary corrections to it (21 CFR 25.40(b)).

Categorically excluded actions refer to a category of actions that have been found not to individually or cumulatively have a significant effect on the quality of the human environment and which do not normally require the preparation of an EA or EIS (40 CFR 1508.4). However, as required under 21 CFR 25.21 and 40 CFR 1508.4, FDA will require preparation of at least an EA for any specific action that normally would be excluded if extraordinary circumstances are present such that the specific proposed action may have the potential to significantly affect the quality of the human environment. In compliance with section 212 of the Small Business Regulatory Enforcement Fairness Act (Pub. L. 104–121), FDA is making available this small entity compliance guide stating in plain language the legal requirements of the September 24, 2015, final rule, set forth in 21 CFR part 25.

II. Significance of Guidance

This guidance is being issued consistent with FDA's good guidance

practices regulation (21 CFR 10.115). The guidance represents the current thinking of FDA on NEPA and environmental assessments for tobacco products including categorical exclusions. It does not establish any rights for any person and is not binding on FDA or the public. You can use an alternative approach if it satisfies the requirements of the applicable statutes and regulations.

III. Electronic Access

Persons with access to the Internet may obtain an electronic version of the guidance at either *http://www.regulations.gov* or *http://www.fda.gov/TobaccoProducts/GuidanceComplianceRegulatoryInformation/default.htm.*

Dated: October 20, 2015.

Leslie Kux,

Associate Commissioner for Policy.

[FR Doc. 2015–27111 Filed 10–23–15; 8:45 am]

BILLING CODE 4164–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

National Institute of Diabetes and Digestive and Kidney Diseases Notice of Closed Meetings

Pursuant to section 10(d) of the Federal Advisory Committee Act, as amended (5 U.S.C. App.), notice is hereby given of the following meetings.

The meetings will be closed to the public in accordance with the provisions set forth in sections 552b(c)(4) and 552b(c)(6), title 5 U.S.C., as amended. The grant applications and the discussions could disclose confidential trade secrets or commercial property such as patentable material, and personal information concerning individuals associated with the grant applications, the disclosure of which would constitute a clearly unwarranted invasion of personal privacy.

Name of Committee: National Institute of Diabetes and Digestive and Kidney Diseases Special Emphasis Panel; Ancillary R01 Telephone Review SEP.

Date: November 10, 2015.

Time: 1:00 p.m. to 2:00 p.m.

Agenda: To review and evaluate grant applications.

Place: National Institutes of Health, Two Democracy Plaza, 6707 Democracy Boulevard, Bethesda, MD 20892, (Telephone Conference Call).

Contact Person: Xiaodu Guo, MD, Ph.D., Scientific Review Officer, Review Branch, DEA, NIDDK, National Institutes of Health, Room 761, 6707 Democracy Boulevard, Bethesda, MD 20892–5452, (301) 594–4719, *guox@extra.niddk.nih.gov.*

Name of Committee: National Institute of Diabetes and Digestive and Kidney Diseases Special Emphasis Panel; Treatments for Fecal Incontinence.

Date: December 2, 2015.

Time: 2:00 p.m. to 4:00 p.m.

Agenda: To review and evaluate grant applications.

Place: National Institutes of Health, Two Democracy Plaza, 6707 Democracy Boulevard, Bethesda, MD 20892, (Telephone Conference Call).

Contact Person: Maria E. Davila-Bloom, Ph.D., Scientific Review Officer, Review Branch, DEA, NIDDK, National Institutes of Health, Room 758, 6707 Democracy Boulevard, Bethesda, MD 20892–5452, (301) 594–7637, *davila-bloomm@extra.niddk.nih.gov.*

(Catalogue of Federal Domestic Assistance Program Nos. 93.847, Diabetes, Endocrinology and Metabolic Research; 93.848, Digestive Diseases and Nutrition Research; 93.849, Kidney Diseases, Urology and Hematology Research, National Institutes of Health, HHS)

Dated: October 20, 2015.

David Clary,

Program Analyst, Office of Federal Advisory Committee Policy.

[FR Doc. 2015–27061 Filed 10–23–15; 8:45 am]

BILLING CODE 4140–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

National Institute of General Medical Sciences; Notice of Closed Meetings

Pursuant to section 10(d) of the Federal Advisory Committee Act, as amended (5 U.S.C. App.), notice is hereby given of the following meetings.

The meetings will be closed to the public in accordance with the provisions set forth in sections 552b(c)(4) and 552b(c)(6), title 5 U.S.C., as amended. The grant applications and the discussions could disclose confidential trade secrets or commercial property such as patentable material, and personal information concerning individuals associated with the grant applications, the disclosure of which would constitute a clearly unwarranted invasion of personal privacy.

Name of Committee: National Institute of General Medical Sciences Special Emphasis Panel; Support of NIGMS Program Project Grants.

Date: November 16, 2015.

Time: 1:00 p.m. to 5:00 p.m.

Agenda: To review and evaluate grant applications.

Place: National Institutes of Health, Natcher Building, 45 Center Drive, Room 3An.12N, Bethesda, MD 20892, (Telephone Conference Call).

Contact Person: Margaret J. Weidman, Ph.D., Scientific Review Officer, Office of Scientific Review, National Institute of General Medical Sciences, National Institutes of Health, 45 Center Drive, Room 3An.12N, Bethesda, MD 20892, 301–594–3663, *weidmanma@nigms.nih.gov.*

Name of Committee: National Institute of General Medical Sciences Special Emphasis Panel; NIGMS Support of Competitive Research (SCORE) Awards.

Date: November 17, 2015.

Time: 1:00 p.m. to 5:00 p.m.

Agenda: To review and evaluate grant applications.

Place: National Institutes of Health, Natcher Building, 45 Center Drive, Room 3An.12N, Bethesda, MD 20892, (Telephone Conference Call).

Contact Person: Margaret J. Weidman, Ph.D., Scientific Review Officer, Office of Scientific Review, National Institute of General Medical Sciences, National Institutes of Health, 45 Center Drive, Room 3An.12N, Bethesda, MD 20892, 301–594–3663, *weidmanma@nigms.nih.gov.*

Name of Committee: National Institute of General Medical Sciences Special Emphasis Panel; Review of K99 and R01 Grant Applications.

Date: November 17, 2015.

Time: 8:00 a.m. to 5:00 p.m.

Agenda: To review and evaluate grant applications.

Place: Courtyard by Marriott Chevy Chase, 5520 Wisconsin Avenue, Chevy Chase, MD 20815.

Contact Person: Lee Warren Slice, Ph.D., Scientific Review Officer, Office of Scientific Review, National Institute of General Medical Sciences, National Institutes of Health, 45 Center Drive, Room 3An.12E, Bethesda, MD 20892, 301–435–0807, *slicelw@mail.nih.gov.*

Name of Committee: National Institute of General Medical Sciences Special Emphasis Panel; Support of Competitive Research (SCORE) Awards.

Date: November 18, 2015.

Time: 8:00 a.m. to 6:00 p.m.

Agenda: To review and evaluate grant applications.

Place: Embassy Suites at the Chevy Chase Pavilion, 4300 Military Road NW., Washington, DC 20015

Contact Person: Nina Sidorova, Ph.D., Scientific Review Officer, Office of Scientific Review, National Institute of General Medical Sciences, National Institutes of Health, 45 Center Drive, Room 3An.12K, Bethesda, MD 20892, 301–402–2783, *sidorova@nigms.nih.gov.*

(Catalogue of Federal Domestic Assistance Program Nos. 93.375, Minority Biomedical Research Support; 93.821, Cell Biology and Biophysics Research; 93.859, Pharmacology, Physiology, and Biological Chemistry Research; 93.862, Genetics and Developmental Biology Research; 93.88, Minority Access to Research Careers; 93.96, Special Minority Initiatives, National Institutes of Health, HHS)

Dated: October 20, 2015.

Melanie J. Gray,

Program Analyst, Office of Federal Advisory Committee Policy.

[FR Doc. 2015–27059 Filed 10–23–15; 8:45 am]

BILLING CODE 4140–01–P