an NDA. This guidance document is not intended to provide recommendations on studies conducted in support of demonstrating comparability or biosimilarity for biological products licensed under section 351 of the Public Health Service Act (42 U.S.C. 262).

Studies to measure BA and/or establish BE of a product are important elements in support of INDs, NDAs, and NDA supplements. BA means the rate and extent to which the active ingredient or active moiety is absorbed from a drug product and becomes available at the site of action (21 CFR 320.1(a)). BA data provide an estimate of the fraction of the drug absorbed, as well as provide information related to the pharmacokinetics of the drug. BA for orally administered drug products can be documented by a systemic exposure profile obtained by measuring concentrations of active ingredients and/or active moieties over time and, when appropriate, active metabolites over time in samples collected from the systemic circulation as compared to that of a suitable reference.

BE means the absence of a significant difference in the rate and extent to which the active ingredient or active moiety in pharmaceutical equivalents or pharmaceutical alternatives becomes available at the site of drug action when administered at the same molar dose under similar conditions in an appropriately designed study (21 CFR 320.1(e)). Studies to establish BE between two products are important for certain formulation or manufacturing changes occurring during the drug development and postapproval stages. In BE studies, the systemic exposure profile of a test drug product is compared to that of a reference drug product.

In the **Federal Register** of March 19, 2003 (68 FR 13316), FDA announced the availability of a final guidance entitled ''Bioavailability and Bioequivalence Studies for Orally Administered Drug Products—General Considerations'' (March 2003 BA and BE guidance). Since the March 2003 guidance was issued, FDA has determined that separating guidances according to application type will be beneficial to sponsors. Thus, FDA is issuing this draft BA and BE guidance for NDAs, and has also issued a draft guidance entitled ''Bioequivalence Studies with Pharmacokinetic Endpoints for Drugs Submitted Under an ANDA'' (draft BE guidance for ANDAs) (December 5, 2013; 78 FR 73199). This draft BA and BE guidance for NDAs revises those parts of the March 2003 BA and BE guidance relating to BA and BE studies for INDs, NDAs, and NDA supplements. This draft guidance also provides additional information in the section on modified-release products, and adds new sections including the following topics: (1) Concomitant administration of drug products and combination drug products, (2) alcoholic beverage effects on modified-release dosage forms, (3) endogenous substances, and (4) drug products with high intrasubject variability. This draft guidance should be useful for applicants planning to conduct BA and/or BE studies during the IND period for submissions to an NDA, and BA and BE studies conducted in the postapproval period for certain changes in NDAs.

This draft guidance is being issued consistent with FDA's good guidance practices regulation (21 CFR 10.115). The draft guidance represents the Agency's current thinking on conducting BA and BE studies for INDs and NDAs. It does not create or confer any rights for or on any person and does not operate to bind FDA or the public. An alternative approach may be used if such approach satisfies the requirement of the applicable statutes and regulations.

II. Comments

Interested persons may submit either electronic comments regarding this document to *http://www.regulations.gov* or written comments to the Division of Dockets Management (see **ADDRESSES**). It is only necessary to send one set of comments. Identify comments with the docket number found in brackets in the heading of this document. Received comments may be seen in the Division of Dockets Management between 9 a.m. and 4 p.m., Monday through Friday, and will be posted to the docket at *http://www.regulations.gov.*

III. Paperwork Reduction Act of 1995

This draft guidance refers to previously approved collections of information that are subject to review by the Office of Management and Budget (OMB) under the Paperwork Reduction Act of 1995 (44 U.S.C. 3501–3520). The collection of information submitted under 21 CFR part 312 (investigational new drug applications) has been approved under OMB control number 0910–0014. The collection of information submitted under 21 CFR part 314 (new drug applications) has been approved under OMB control number 0910–0001.

IV. Electronic Access

Persons with access to the Internet may obtain the document at either *http://www.fda.gov/Drugs/GuidanceComplianceRegulatoryInformation/Guidances/default.htm* or *http://www.regulations.gov.*

Dated: March 12, 2014.

Peter Lurie,

Acting Associate Commissioner for Policy and Planning.

[FR Doc. 2014–05849 Filed 3–17–14; 8:45 am]

BILLING CODE 4160–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Health Resources and Services Administration

National Advisory Committee on Rural Health and Human Services; Notice of Meeting

In accordance with section 10(a)(2) of the Federal Advisory Committee Act (Pub. L. 92–463), announcement is made of the following National Advisory body scheduled to meet during the month of April 2014.

The National Advisory Committee on Rural Health will convene its seventy fifth meeting in the time and place specified below:

Name: National Advisory Committee on Rural Health and Human Services.

Dates and Time: April 28, 2014, 8:45 a.m.–5:30 p.m. April 29, 2014, 9:00 a.m.–5:00 p.m. April 30, 2014, 8:30 a.m.–10:30 a.m.

Place: University of Nebraska Medical Center, Michael F. Sorrell Center for Health Science Education, 649 South 42nd Street, Omaha, NE 68105, (402) 559–8550.

Status: The meeting will be open to the public.

Purpose: The National Advisory Committee on Rural Health and Human Services (the Committee) provides counsel and recommendations to the Secretary with respect to the delivery, research, development, and administration of health and human services in rural areas.

Agenda: Monday morning, at 8:45 a.m., the meeting will be called to order by the Chairperson of the Committee: the Honorable Ronnie Musgrove. The Committee will assess how rural residents are served by the new insurance coverage opportunities afforded by the Affordable Care Act. The Committee will also examine the issue of rural homelessness. The day will conclude with a period of public comment at approximately 5:00 p.m.

Tuesday morning at approximately 9:00 a.m., the Committee will break into Subcommittees and depart for site visits to health care and human services' providers in Iowa and Nebraska. One panel from the Health Subcommittee will visit Nemaha County Hospital in Auburn, Nebraska. Another panel from the Health Subcommittee will visit Myrtue Medical Center in Harlan, Iowa. The Human Services Subcommittee will visit the Northeast Nebraska Community Action Partnership, in Fremont, Nebraska. The day will conclude at the Sorrell Center for Health Science Education with a period

of public comment at approximately 5:15 p.m.

Wednesday morning at 8:30 a.m., the Committee will meet to summarize key findings and develop a work plan for the next quarter and the following meeting.

FOR FURTHER INFORMATION CONTACT: Steve Hirsch, MSLS, Executive Secretary, National Advisory Committee on Rural Health and Human Services, Health Resources and Services Administration, Parklawn Building, Room 5A–05, 5600 Fishers Lane, Rockville, MD 20857, telephone (301) 443–7322, fax (301) 443–2803.

Persons interested in attending any portion of the meeting should contact Kristen Lee at the Office of Rural Health Policy (ORHP) via telephone at (301) 443–6884 or by email at klee1@hrsa.gov. The Committee meeting agenda will be posted on ORHP's Web site *http://www.hrsa.gov/advisorycommittees/rural/*.

Dated: March 12, 2014.

Jackie Painter,

Deputy Director, Division of Policy and Information Coordination.

[FR Doc. 2014–05950 Filed 3–17–14; 8:45 am]

BILLING CODE 4165–15–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

Proposed Collection; 60-Day Comment Request; Generic Clearance for the Collection of Qualitative Feedback on Agency Service Delivery (NCI)

AGENCY: National Institutes of Health, HHS.

ACTION: Notice.

SUMMARY: In compliance with the requirement of Section 3506(c)(2)(A) of the Paperwork Reduction Act of 1995, for opportunity for public comment on proposed data collection projects, the National Cancer Institute (NCI), National Institutes of Health (NIH), will publish periodic summaries of proposed projects to be submitted to the Office of Management and Budget (OMB) for review and approval.

Written comments and/or suggestions from the public and affected agencies are invited on one or more of the following points: (1) Whether the proposed collection of information is necessary for the proper performance of the function of the agency, including whether the information will have practical utility; (2) The accuracy of the agency'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 those who are to respond, including the use of appropriate automated, electronic, mechanical, or other technological collection techniques or other forms of information technology.

DATES: Comments Due: Comments regarding this information collection are best assured of having their full effect if received by May 19, 2014.

FOR FURTHER INFORMATION CONTACT: To obtain a copy of the data collection plans and instruments, submit comments in writing, or request more information on the proposed project, contact: Vivian Horovitch-Kelley, Office of Management Policy and Compliance, National Cancer Institute, 9609 Medical Center Drive, Bethesda, MD 20892–9760 or call non-toll-free number 240–276–6850 or Email your request *horovitchkellv@mail.nih.gov.* Formal requests for additional plans and instruments must be requested in writing.

SUPPLEMENTARY INFORMATION:

Proposed Collection: Generic Clearance for the Collection of Qualitative Feedback on Agency Service Delivery (NCI), 0925–0642, Expiration Date 9/31/2014, EXTENSION, National Cancer Institute (NCI), National Institutes of Health (NIH).

Need and Use of Information Collection: There are no changes being requested for this submission. The information collection activity is garnering qualitative customer and stakeholder feedback in an efficient, timely manner, in accordance with the Administration's commitment to improving service delivery. This generic provides information about the National Cancer Institute's customer or stakeholder perceptions, experiences and expectations, provide an early warning of issues with service, or focus attention on areas where communication, training or changes in operations might improve delivery of products or services. It also allows feedback to contribute directly to the improvement of program management. Feedback collected under this generic clearance provides useful information but it will not yield data that can be generalized to the overall population.

OMB approval is requested for 3 years. There are no costs to respondents other than their time. The total estimated burden hours are 8,750.

ESTIMATED ANNUALIZED BURDEN HOURS

Type of collection	Number of respondents	Number of responses per respondent	Average burden per response (in hours)	Total burden hours
Surveys	1000	1	30/60	500
In-Depth Interviews (IDIs) or Small Discussion Groups	500	1	90/60	750
Focus Groups	2000	1	90/60	3,000
Website or Software Usability Tests	3000	1	90/60	4,500

Dated: March 11, 2014.

Karla Bailey,

NCI Project Clearance Liaison, National Institutes of Health.

[FR Doc. 2014–05962 Filed 3–17–14; 8:45 am]

BILLING CODE 4140–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

Center for Scientific Review Amended; Notice of Meeting

Notice is hereby given of a change in the meeting of the Center for Scientific Review Special Emphasis Panel, March 03, 2014, 02:00 p.m. to March 03, 2014, 05:00 p.m., National Institutes of Health, 6701 Rockledge Drive, Bethesda, MD, 20892 which was published in the **Federal Register** on February 25, 2014, 78 FR 10541 pg. 10541–10542.

The meeting will be held at the National Institutes of Health, 6701 Rockledge Drive, Bethesda, MD 20892. The meeting will start on April 1, 2014