guidance no longer cites the Redbook, we continue to recommend the use of the dietary exposure assessment methodology and some toxicology tests that are also used for the evaluation of food additives because these are standard scientific methods not specific to any particular safety assessment paradigm. Finally, we added a new question at the end of section VI.C to emphasize that this draft guidance contains recommendations about safety information to include in an NDI notification, but these recommendations are not requirements.

• *Other changes*—We made clarifying changes, explanatory changes, and editorial changes throughout the document. We also updated references and links and added new references where appropriate.

## II. Paperwork Reduction Act of 1995

Under the Paperwork Reduction Act of 1995 (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. This draft guidance contains proposed collections of information. ''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 publish a 60-day notice in the **Federal Register** soliciting public comment on each proposed collection of information before submitting the collection to OMB for approval. To comply with this requirement, we intend to publish a 60-day notice on the proposed collections of information in this draft guidance in a future issue of the **Federal Register**.

This draft guidance also refers to previously approved collections of information found in FDA regulations. These collections of information are subject to review by OMB under the PRA. The collections of information in 21 CFR part 111 have been approved under OMB control number 0901–0606, and the collections of information in § 190.6 have been approved under OMB control number 0910–0330.

## III. Other Issues for Consideration

Although FDA welcomes comments on any aspect of this draft guidance, we particularly invite comment on the following:

• What processes alter the identity of an ingredient marketed prior to October 15, 1994, and thus create an NDI? We are especially interested in recommendations for clearer examples or criteria to differentiate changes in manufacturing methods and starting materials that alter the identity of the ingredient from changes that do not.

• What processes ''chemically alter'' an ingredient within the meaning of section 413(a)(1) of the FD&C Act, and why? Conversely, what processes do not cause chemical alteration, and why? Are there certain processes, such as tinctures, that sometimes result in chemical alteration and sometimes do not? What criteria should be used to evaluate whether an ingredient has been chemically altered? We are especially interested in receiving scientific information that shows whether a particular process actually results in chemical alteration.

• What method of compiling independent and verifiable data on the marketing of dietary ingredients before October 15, 1994, would be most effective? How should an authoritative list of ''grandfathered'' ingredients based on such data be developed and implemented?

As FDA considers the development of final guidance, we will review comments received on this revised version, as well as comments on the 2011 draft guidance that are still relevant.

## IV. Electronic Access

Persons with access to the Internet may obtain the guidance at either *http://www.fda.gov/FoodGuidances* or *http://www.regulations.gov.* Use the FDA Web site listed in the previous sentence to find the most current version of the draft guidance.

## V. References

The following references are on display in the Division of Dockets Management (see **ADDRESSES**) and are available for viewing by interested persons between 9 a.m. and 4 p.m., Monday through Friday; they are also available electronically at *http://www.regulations.gov.* FDA has verified the Web site addresses, as of the date this document publishes in the **Federal Register**, but Web sites are subject to change over time.

1. International Programme on Chemical Safety, ''Principles and Methods for the Risk Assessment of Chemicals in Food,'' *Environmental Health Criteria* 240 (2009), available at: *http://www.who.int/foodsafety/publications/chemical-food/en/.*

2. The official name of the Redbook is ''Guidance for Industry and Other Stakeholders: Toxicological Principles for the Safety Assessment of Food Ingredients,'' available at: *http://www.fda.gov/Food/GuidanceRegulation/GuidanceDocumentsRegulatoryInformation/IngredientsAdditivesGRASPackaging/ucm2006826.htm.*

Dated: August 9, 2016.

**Jeremy Sharp,**

*Deputy Commissioner for Policy, Planning, Legislation, and Analysis.*

[FR Doc. 2016–19306 Filed 8–11–16; 8:45 am]

**BILLING CODE 4164–01–P**

## DEPARTMENT OF HEALTH AND HUMAN SERVICES

### Health Resources and Services Administration

### Agency Information Collection Activities: Submission to OMB for Review and Approval; Public Comment Request; Health Center Program Application Forms

**AGENCY:** Health Resources and Services Administration, HHS.

**ACTION:** Notice.

**SUMMARY:** In compliance with Section 3507(a)(1)(D) of the Paperwork Reduction Act of 1995, the Health Resources and Services Administration (HRSA) has submitted an Information Collection Request (ICR) to the Office of Management and Budget (OMB) for review and approval. Comments submitted during the first public review of this ICR will be provided to OMB. OMB will accept further comments from the public during the review and approval period.

**DATES:** Comments on this ICR should be received no later than September 12, 2016.

**ADDRESSES:** Submit your comments, including the ICR Title, to the desk officer for HRSA, either by email to *OIRA_submission@omb.eop.gov* or by fax to 202–395–5806.

**FOR FURTHER INFORMATION CONTACT:** To request a copy of the clearance requests submitted to OMB for review, email the HRSA Information Collection Clearance Officer at *paperwork@hrsa.gov* or call (301) 443–1984.

**SUPPLEMENTARY INFORMATION:**

*Information Collection Request Title:* Health Center Program Application Forms OMB No. 0915–0285—Revision.

*Abstract:* Health centers (those entities funded under Public Health Service Act section 330 and Health Center Program look-alikes) deliver comprehensive, high quality, cost-effective primary health care to patients regardless of their ability to pay. Health centers are an essential primary care provider for America's most vulnerable populations. Health centers provide

coordinated, comprehensive, and patient-centered primary and preventive health care. Nearly 1,400 health centers operate more than 9,800 service delivery sites that provide care in every state, the District of Columbia, Puerto Rico, the U.S. Virgin Islands, and the Pacific Basin.

The Health Center Program is administered by HRSA's Bureau of Primary Health Care (BPHC). BPHC uses multiple Health Center Program-specific forms (see table below) to oversee the Health Center Program.

*Need and Proposed Use of the Information:* Health Center Program-specific forms are critical to Health Center Program grant and non-grant award processes and for Health Center Program oversight. The purpose of these forms is to provide HRSA staff and objective review committee panels information essential for application evaluation, funding recommendation, approval, designation, and monitoring. These forms also provide HRSA staff with information essential for ensuring compliance with Health Center Program legislative and regulatory requirements. These application forms are used by existing health centers and other organizations to apply for various grant and non-grant opportunities, renew their grant or non-grant designation, and change their scope of project.

Most of the Health Center Program-specific forms do not require any significant changes with this revision. HRSA intends to revise some of the forms to streamline and clarify data already being requested (Form 1A, 1B, 2, 3, 5A, 5B, 6A, 8, Performance Measures, Project Work Plan, Outreach and Enrollment Progress Report) and change several form names (changing Form 3A to Look-Alike Budget Information, Form 10 to Emergency Preparedness Report, and Increased Demand for Services to Expanded Services). HRSA also intends to add seven new forms. The Supplemental Information form and Summary Page will consolidate important application information that is usually found distributed throughout the application, including eligibility criteria and projected goals. These forms will require applicant confirmation that the information provided is accurate. Two of these new forms will include the Program Narrative Update, used to report progress for renewal of Health Center Program awards, and the Substance Abuse Progress Report, used to report quarterly progress for award recipients of Substance Abuse Expansion supplemental funding. Two other forms, the Health Center Controlled Networks Work Plan and Progress Report, are forms that have been used in the past (under another OMB control number) to collect application baseline data and progress metrics for grantees. An additional new form, Zika Progress Report, will collect quarterly progress on Zika-related projects.

*Likely Respondents:* Health Center Program award recipients and look-alikes, state and national technical assistance organizations, and other organizations seeking funding.

*Burden Statement:* Burden in this context means the time expended by persons to generate, maintain, retain, disclose or provide the information requested. This includes the time needed to review instructions; to develop, acquire, install and utilize technology and systems for the purpose of collecting, validating and verifying information, processing and maintaining information, and disclosing and providing information; to train personnel and to be able to respond to a collection of information; to search data sources; to complete and review the collection of information; and to transmit or otherwise disclose the information. The total annual burden hours estimated for this ICR are summarized in the table below.

TOTAL ESTIMATED ANNUALIZED BURDEN—HOURS

| Form name | Number of respondents | Number of responses per respondent | Total responses | Average burden per response (in hours) | Total burden hours |
|---|---|---|---|---|---|
| Form 1A: General Information Worksheet | 1,700 | 1 | 1,700 | 1.0 | 1,700 |
| Form 1B: BPHC Funding Request Summary | 450 | 1 | 450 | 0.75 | 337.5 |
| Form 1C: Documents on File | 1,000 | 1 | 1,000 | 0.5 | 500 |
| Form 2: Staffing Profile | 1,700 | 1 | 1,700 | 1.0 | 1,700 |
| Form 3: Income Analysis | 1,900 | 1 | 1,900 | 2.5 | 4,750 |
| Form 3A: Look-Alike Budget Information | 100 | 1 | 100 | 1.0 | 100 |
| Form 4: Community Characteristics | 1,000 | 1 | 1,000 | 1.0 | 1,000 |
| Form 5A: Services Provided | 1,700 | 1 | 1,700 | 1.0 | 1,700 |
| Form 5B: Service Sites | 1,200 | 1 | 1,200 | 0.75 | 900 |
| Form 5C: Other Activities/Locations | 1,000 | 1 | 1,000 | 0.5 | 500 |
| Form 6A: Current Board Member Characteristics | 1,000 | 1 | 1,000 | 0.5 | 500 |
| Form 6B: Request for Waiver of Governance Requirements | 100 | 1 | 100 | 1.0 | 100 |
| Form 8: Health Center Agreements | 600 | 1 | 600 | 0.75 | 450 |
| Form 9: Need for Assistance Worksheet | 500 | 1 | 500 | 4.5 | 2,250 |
| Form 10: Emergency Preparedness Report | 1,000 | 1 | 1,000 | 1.0 | 1,000 |
| Form 12: Organization Contacts | 1,000 | 1 | 1,000 | 0.5 | 500 |
| Clinical Performance Measures | 1,000 | 1 | 1,000 | 3.5 | 3,500 |
| Financial Performance Measures | 1,000 | 1 | 1,000 | 1.0 | 1,000 |
| Implementation Plan | 900 | 1 | 900 | 3.0 | 2,700 |
| Project Work Plan | 200 | 1 | 200 | 5.0 | 1,000 |
| Proposal Cover Page | 400 | 1 | 400 | 1.0 | 400 |
| Project Cover Page | 400 | 1 | 400 | 1.0 | 400 |
| Equipment List | 400 | 1 | 400 | 1.0 | 400 |
| Other Requirements for Sites | 400 | 1 | 400 | 0.5 | 200 |
| Funding Sources | 400 | 1 | 400 | 0.5 | 200 |
| Project Qualification Criteria | 400 | 1 | 400 | 1.0 | 400 |
| O&E Supplemental | 1,200 | 1 | 1,200 | 1.0 | 1,200 |
| O&E Progress Report | 1,200 | 1 | 1,200 | 1.0 | 1,200 |
| Checklist for Adding a New Service Delivery Site | 700 | 1 | 700 | 1.5 | 1,050 |
| Checklist for Deleting Existing Service Delivery Site | 700 | 1 | 700 | 1.0 | 700 |

TOTAL ESTIMATED ANNUALIZED BURDEN—HOURS—Continued

| Form name | Number of respondents | Number of responses per respondent | Total responses | Average burden per response (in hours) | Total burden hours |
|---|---|---|---|---|---|
| Checklist for Adding New Service | 700 | 1 | 700 | 1.0 | 700 |
| Checklist for Deleting Existing Service | 700 | 1 | 700 | 1.0 | 700 |
| Checklist for Adding a New Target Population | 50 | 1 | 50 | 0.5 | 25 |
| Expanded Services | 1,400 | 1 | 1,400 | 1.0 | 1,400 |
| Federal Object Class Categories | 1,400 | 1 | 1,400 | 0.25 | 350 |
| Supplemental Information (NEW) | 2,000 | 1 | 2,000 | 0.5 | 1,000 |
| Summary Page (NEW) | 1,700 | 1 | 1,700 | 0.25 | 425 |
| Program Narrative Update (NEW) | 900 | 1 | 900 | 4.0 | 3,600 |
| Substance Abuse Progress Report (NEW) | 300 | 4 | 1,200 | 1.0 | 1,200 |
| Health Center Controlled Networks Progress Report (NEW) | 93 | 1 | 93 | 25 | 2,325 |
| Health Center Controlled Networks Work Plan (NEW) | 93 | 1 | 93 | 5.0 | 465 |
| Zika Progress Report (NEW) | 20 | 4 | 80 | 1.0 | 80 |
| Total | 34,606 | | 35,566 | | 44,608 |

**Jason E. Bennett,**

*Director, Division of the Executive Secretariat.*

[FR Doc. 2016–19301 Filed 8–11–16; 8:45 am]

**BILLING CODE 4165–15–P**

## DEPARTMENT OF HEALTH AND HUMAN SERVICES

### National Institutes of Health

### National Institute of Biomedical Imaging and Bioengineering; 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 Biomedical Imaging and Bioengineering Special Emphasis Panel; Rapid Assessment of Zika Virus Complications (2017/01).

*Date:* September 12, 2016.

*Time:* 10:00 a.m. to 4:00 p.m.

*Agenda:* To review and evaluate grant applications.

*Place:* National Institutes of Health, Two Democracy Plaza, Suite 920, 6707 Democracy Boulevard, Bethesda, MD 20892, (Telephone Conference Call).

*Contact Person:* Dennis Hlasta, Ph.D., Scientific Review Officer, National Institute of Biomedical Imaging and Bioengineering, National Institutes of Health, 6707 Democracy Blvd., Bethesda, MD 20892, (301) 451–4794, *dennis.hlasta@nih.gov*.

*Name of Committee:* National Institute of Biomedical Imaging and Bioengineering Special Emphasis Panel; 2017–01 R25 Application Review.

*Date:* September 28, 2016.

*Time:* 10:00 a.m. to 4:00 p.m.

*Agenda:* To review and evaluate grant applications.

*Place:* National Institutes of Health, Two Democracy Plaza, Suite 920, 6707 Democracy Boulevard, Bethesda, MD 20892, (Virtual Meeting).

*Contact Person:* Ruixia Zhoua, Ph.D., Scientific Review Officer, 6707 Democracy Boulevard, Democracy Two Building, Suite 957, Bethesda, MD 20892, (301) 496–473, *zhour@mail.nih.gov*.

Dated: August 8, 2016.

**David Clary,**

*Program Analyst, Office of Federal Advisory Committee Policy.*

[FR Doc. 2016–19191 Filed 8–11–16; 8:45 am]

**BILLING CODE 4140–01–P**

## DEPARTMENT OF HEALTH AND HUMAN SERVICES

### National Institutes of Health

### National Institute of Arthritis and Musculoskeletal and Skin Diseases; Notice of Meeting

Pursuant to section 10(d) of the Federal Advisory Committee Act, as amended (5 U.S.C. App.), notice is hereby given of a meeting of the National Arthritis and Musculoskeletal and Skin Diseases Advisory Council.

The meeting will be open to the public as indicated below, with attendance limited to space available. Individuals who plan to attend and need special assistance, such as sign language interpretation or other reasonable accommodations, should notify the Contact Person listed below in advance of the meeting.

The meeting 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 Arthritis and Musculoskeletal and Skin Diseases Advisory Council.

*Date:* September 13, 2016.

*Open:* 8:30 a.m. to 12:00 p.m.

*Agenda:* Discussion of program policies.

*Place:* National Institutes of Health, Building 31, 31 Center Drive, 6th Floor, C Wing, Conference Room 6, Bethesda, MD 20892.

*Closed:* 1:00 p.m. to 4:00 p.m.

*Agenda:* To review and evaluate grant applications.

*Place:* National Institutes of Health, Building 31, 31 Center Drive, 6th Floor, C Wing, Conference Room 6, Bethesda, MD 20892.

*Contact Person:* Laura K. Moen, Ph.D., Director, Division of Extramural Research Activities, NIAMS/NIH, 6700 Democracy Boulevard, Suite 800, Bethesda, MD 20892, 301–451–6515, *moenl@mail.nih.gov*.

Any interested person may file written comments with the committee by forwarding the statement to the Contact Person listed on this notice. The statement should include the name, address, telephone number and when applicable, the business or professional affiliation of the interested person.

In the interest of security, NIH has instituted stringent procedures for entrance onto the NIH campus. All visitor vehicles, including taxicabs, hotel, and airport shuttles will be inspected before being allowed on campus. Visitors will be asked to show one form of identification (for example, a government-issued photo ID, driver's license,