DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2009–N–0380]

Agency Information Collection Activities; Submission for Office of Management and Budget Review; Comment Request; Product Jurisdiction: Assignment of Agency Component for Review of Premarket Applications

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is announcing that a proposed collection of information has been submitted to the Office of Management and Budget (OMB) for review and clearance under the Paperwork Reduction Act of 1995.

DATES: Fax written comments on the collection of information by October 6, 2016.

ADDRESSES: To ensure that comments on the information collection are received, OMB recommends that written comments be faxed to the Office of Information and Regulatory Affairs, OMB, Attn: FDA Desk Officer, FAX: 202–395–7285, or emailed to *oira_submission@omb.eop.gov.* All comments should be identified with the OMB control number 0910–0523. Also include the FDA docket number found in brackets in the heading of this document.

FOR FURTHER INFORMATION CONTACT: FDA PRA Staff, Office of Operations, Food and Drug Administration, Three White Flint North 10A–12M, 11601 Landsdown St., North Bethesda, MD 20852, *PRAStaff@fda.hhs.gov.*

SUPPLEMENTARY INFORMATION: In compliance with 44 U.S.C. 3507, FDA has submitted the following proposed collection of information to OMB for review and clearance.

Product Jurisdiction: Assignment of Agency Component for Review of Premarket Applications—21 CFR Part 3—OMB Control Number 0910–0523—Extension

This regulation relates to Agency management and organization and has two purposes. The first is to implement section 503(g) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 353(g)), as added by the Safe Medical Devices Act of 1990 (Pub. L. 101–629), and amended by the Medical Device User Fee and Modernization Act of 2002 (Pub. L. 107–250), by specifying how FDA will determine the organizational component within FDA assigned to have primary jurisdiction for the premarket review and regulation of products that are comprised of any combination of: (1) A drug and a device; (2) a device and a biological product; (3) a biological product and a drug; or (4) a drug, a device, and a biological product.

The second purpose of this regulation is to enhance the efficiency of Agency management and operations by providing procedures for classifying and determining which Agency component is designated to have primary jurisdiction for any drug, device, or biological product where such jurisdiction is unclear or in dispute.

The regulation establishes a procedure by which an applicant may obtain an assignment or designation determination. The regulation requires that the request include the identity of the applicant, a comprehensive description of the product and its proposed use, and the applicant's recommendation as to which Agency component should have primary jurisdiction, with an accompanying statement of reasons. The information submitted would be used by FDA as the basis for making the assignment or designation decision. Most information required by the regulation is already required for premarket applications affecting drugs, devices, biological products, and combination products. The respondents will be businesses or other for-profit organizations.

In the **Federal Register** of January 28, 2016 (81 FR4921), FDA published a 60-day notice requesting public comment on the proposed collection of information. No comments were received.

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

TABLE 1—ESTIMATED ANNUAL REPORTING BURDEN [1]

21 CFR part	Number of respondents	Number of responses per respondent	Total annual responses	Average burden per response	Total hours
3	84	1	84	24	2,016

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

These burden estimates are based on the number of applications FDA received over the past fiscal year.

Dated: August 30, 2016.

Leslie Kux,

Associate Commissioner for Policy.

[FR Doc. 2016–21228 Filed 9–2–16; 8:45 am]

BILLING CODE 4164–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Health Resources and Services Administration

Senior Executive Service Performance Review Board

AGENCY: Health Resources and Services Administration (HRSA), Department of Health and Human Services (HHS).

ACTION: Notice.

SUMMARY: In this notice, the Health Resources and Services Administration (HRSA) located within the Department of Health and Human Services (HHS) publishes a list of persons who may be named to serve on the Performance Review Board that oversees the evaluation of performance appraisals for Senior Executive Service members within HRSA.

FOR FURTHER INFORMATION CONTACT: Dora Ober, Executive Resources, Office of Human Resources, 5600 Fishers Lane, Rm 12N06C, Rockville, Maryland 20857, Telephone (301) 443–0759.

SUPPLEMENTARY INFORMATION: Title 5, U.S.C. Section 4314(c)(4) of the Civil Service Reform Act of 1978, Public Law 95–454, requires that the appointment of Performance Review Board Members be published in the **Federal Register**. The following persons may be named to serve on the HRSA Performance Review Board, which will oversee the evaluation of performance appraisals of

Senior Executive Service members for the Fiscal Year 2016 review period:

Leslie Atkinson, Tonya Bowers, Adriane Burton, Tina Cheatham, Laura Cheever, Cheryl Dammons, Elizabeth DeVoss, Diana Espinosa, Catherine Ganey, Alexandra Garcia, Richard Goodman, Heather Hauck, Avril Houston, Laura Kavanagh, Martin Kramer, Sarah Linde, Rimas Liogys, Michael Lu, Dennis Malcomson, James Macrae, Thomas Morris, Kerry Nesseler, William O'Rourke, Luis Padilla, Deborah Parham Hopson, Wendy Ponton, Patricia Stroup.

Dated: August 30, 2016.

James Macrae,

Acting Administrator.

[FR Doc. 2016–21320 Filed 9–2–16; 8:45 am]

BILLING CODE 4165–15–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Health Resources and Services Administration

Request for Public Comment on Draft Health Center Program Compliance Manual

AGENCY: Health Resources and Services Administration (HRSA), Department of Health and Human Services (HHS).

ACTION: Request for public comment on Draft Health Center Program Compliance Manual.

SUMMARY: HRSA is inviting public comment on the Draft Health Center Program Compliance Manual, hereafter referred to as the Compliance Manual. The purpose of the Compliance Manual is to provide a consolidated web-based resource to assist current and prospective health centers in understanding and demonstrating compliance with requirements of the Health Center Program, a HRSA-administered program authorized under 42 U.S.C. 254b. The Compliance Manual identifies requirements found in the Health Center Program's authorizing legislation and implementing regulations, as well as certain applicable grant regulations. The Compliance Manual also addresses HRSA's approach to determining eligibility for and oversight of the Health Center Program. In addition, the Compliance Manual includes the requirements for obtaining deemed Public Health Service (PHS) employee status under the Federally Supported Health Centers Assistance Acts of 1992 and 1995, for purposes of Federal Tort Claims Act (FTCA) liability protections for the performance of medical, surgical, dental, and related functions within the scope of deemed PHS employment.

DATES: Submit written comments no later than November 22, 2016.

ADDRESSES: Written comments should be submitted through the HRSA/Bureau of Primary Health Care (BPHC) Web site at *http://bphc.hrsa.gov/programrequirements/draftcompliancemanual/index.html.*

FOR FURTHER INFORMATION CONTACT: For questions regarding this notice, contact HRSA/BPHC/Office of Policy and Program Development at *HCPComplianceManual@hrsa.gov.*

SUPPLEMENTARY INFORMATION: HRSA provides grants to eligible applicants under section 330(e), (g), (h), and/or (i) of the PHS Act, as amended (42 U.S.C. 254b), to support the delivery of preventive and primary care services to medically underserved communities and vulnerable populations. Nearly 1,400 Health Center Program-funded health centers operate approximately 9,800 service delivery sites that provide care to over 24 million patients in every U.S. state, the District of Columbia, Puerto Rico, the U.S. Virgin Islands, and the Pacific Basin. HRSA also designates eligible applicants under the Health Center Look-Alike Program (*see* Sections 1861(aa)(4)(B) and 1905(l)(2)(B) of the Social Security Act). Look-Alikes do not receive Health Center Program funding but must meet the Health Center Program statutory and regulatory requirements. Note that for the purposes of the Compliance Manual, the term ''health center'' refers to entities that receive a federal award under section 330 of the PHS Act, as amended, subrecipients, and organizations designated as look-alikes, unless otherwise stated.

HRSA also makes determinations of deemed PHS employment status for health centers funded under section 330 and their covered individuals for purposes of providing liability protections under the Health Center Federal Tort Claims Act (FTCA) Program. Section 224(g)–(n) of the PHS Act (42 U.S.C. 233(g)–(n)) authorizes the FTCA Program and affords eligibility for FTCA coverage as the exclusive civil remedy for acts or omissions arising from the performance of medical, surgical, dental, or related functions within the scope of such employment by deemed health centers and by any officers, governing board members, employees, and certain individual contractors of these entities. A favorable FTCA deeming determination requires submission of an application by the Health Center Program awardee in the form and manner specified by HRSA.

The Compliance Manual includes sections identifying the requirements found in the Health Center Program's authorizing legislation and program implementing regulations (section 330 of the PHS Act, as amended, 42 CFR part 51c, and 42 CFR part 56); certain applicable HHS grant regulations (45 CFR part 75); and the Health Center FTCA Program's authorizing legislation and implementing regulations (section 224(g)–(n) of the PHS Act, and 42 CFR part 6). Organizations receiving Health Center Program federal awards, including subrecipients, are also subject to all requirements incorporated within documents such as Funding Opportunity Announcements and Notices of Award. The Compliance Manual specifies Health Center Program non-regulatory policy issuances that would be superseded, as well as those that would remain in effect.

The first chapter of the Compliance Manual outlines HRSA's approach to determining organizational eligibility for the Health Center Program, including how to demonstrate non-profit or public agency status. The chapter also describes organizational eligibility requirements that apply only to look-alikes. The second chapter clarifies HRSA/BPHC's oversight process by providing information on how HRSA will address areas of noncompliance and impose enforcement actions, including those for serious violations that may lead to the suspension of grant activities or termination of grant funding by HRSA under 45 CFR part 75.

The Compliance Manual contains 18 chapters on Health Center Program requirements, each of which: (a) Cites the applicable statutory and regulatory authorities; (b) lists statutory and regulatory requirements; (c) describes how health centers would demonstrate compliance to HRSA; and d) includes examples of areas in which health centers have discretion or that may be helpful for health centers to consider when implementing the requirements.

The final chapter specifies the FTCA requirements for obtaining deemed PHS employment status, including how a health center would demonstrate compliance with the FTCA requirements in its annual deeming application. Please note that deemed employment status does not confer FTCA coverage in all cases, as health center providers also must comply with applicable legal eligibility requirements and covered actions must be undertaken within the scope of such deemed PHS employment (for more information, see the *Federal Tort Claims Act Health Center Policy Manual* at *http://*