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Submit written requests for single copies of the draft guidance to the Division of Drug Information, Center for Drug Evaluation and Research, Food and Drug Administration, 10001 New Hampshire Ave., Hillandale Building, 4th Floor, Silver Spring, MD 20993–0002. Send one self-addressed adhesive label to assist that office in processing your requests. See the **SUPPLEMENTARY INFORMATION** section for electronic access to the draft guidance document.

FOR FURTHER INFORMATION CONTACT: Kevin Bugin, Center for Drug Evaluation and Research, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 22, Rm. 5232, Silver Spring, MD 20993–0002, 301–796–2302.

SUPPLEMENTARY INFORMATION:

I. Background

FDA is announcing the availability of a draft guidance for industry entitled ''Ulcerative Colitis: Clinical Trial Endpoints.'' The purpose of this draft guidance is to assist sponsors in the clinical development of drugs for the treatment of UC in adult and pediatric patients. Specifically, this draft guidance addresses FDA's current thinking regarding efficacy endpoints for UC clinical trials.

UC is a chronic, relapsing disease characterized by diffuse mucosal inflammation of the colon. UC involves the rectum and it may extend proximally in a contiguous pattern to affect part of the colon or the entire colon. Clinical manifestations of active disease include bloody diarrhea (with or without mucus), urgency, tenesmus, abdominal pain, weight loss, fever, and malaise. In patients with extensive or severe inflammation, acute complications such as severe bleeding and toxic megacolon may occur. There is an increased risk of colorectal cancer in UC patients compared to the general population; risk factors include long duration of disease, extensive colonic involvement, severe inflammation and epithelial dysplasia, and childhood-onset disease. The signs and symptoms of UC in adults and children are similar; however, abdominal pain, disease involving the entire colon, extra-intestinal manifestations, proctitis (among girls), and disease severity necessitating colectomy are more common in children.

This draft guidance is being issued consistent with FDA's good guidance practices regulation (21 CFR 10.115). The draft guidance, when finalized, will represent the current thinking of FDA on clinical trial endpoints for UC. 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.

II. The 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 collections of information in 21 CFR parts 312 and 314 have been approved under OMB control numbers 0910–0014 and 0910–0001, respectively.

IV. Electronic Access

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

Dated: August 3, 2016.

Leslie Kux,

Associate Commissioner for Policy.

[FR Doc. 2016–18716 Filed 8–5–16; 8:45 am]

BILLING CODE 4164–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Health Resources and Services Administration

Statement of Organization, Functions and Delegations of Authority

This notice amends Part R of the Statement of Organization, Functions and Delegations of Authority of the Department of Health and Human Services (HHS), Health Resources and Services Administration (HRSA) (60 FR 56605, as amended November 6, 1995; as last amended at 81 FR 25680 dated April 29, 2016).

This notice reflects organizational changes in the Health Resources and Services Administration (HRSA), HIV/AIDS Bureau (RV). Specifically, this notice: (1) Establishes the Office of Program Support; (RV3); (2) transfers the organizational development, training and technological functions from the Office of Operations and Management (RV2) and the communications, grantee oversight and customer service functions from the Office of the Associate Administrator (RV) to the newly established Office of Program Support (RV3); and (3) updates the functional statement for the Office of Operations and Management (RV2), the Division of Administrative Operations (RV21), and the Office of the Associate Administrator (RV).

Chapter RV—HIV/AIDS Bureau

Section RV–10, Organization

Delete the organization for the Office of the Associate Administrator (RA) in its entirety and replace with the following:

The HIV/AIDS Bureau is headed by the Associate Administrator, who reports directly to the Administrator, Health Resources and Services Administration.

(1) Office of the Associate Administrator (RV);

(2) Office of Operations and Management (RV2);

a. Division of Administrative Operations (RV21);

(3) Office of Program Support (RV3);

(4) Division of Policy and Data (RVA);

(5) Division of Metropolitan HIV/AIDS Programs (RV5);

(6) Division of State HIV/AIDS Programs (RVD);

(7) Division of Community HIV/AIDS Programs (RV6); and

(8) Office of HIV/AIDS Training and Capacity Development (RVT);

a. Division of Domestic Programs; and

b. Division of Global Programs.

Section RV–20, Functions

This notice reflects organizational changes in the Health Resources and Services Administration (HRSA), HIV/AIDS Bureau (RV). Specifically, this notice: (1) Establishes the Office of Program Support; (RV3); (2) transfers the organizational development, training and technological functions from the Office of Operations and Management (RV2) and the communications, grantee oversight and customer service functions from the Office of the Associate Administrator (RV) to the newly established Office of Program Support (RV3); and (3) updates the functional statement for the Office of Operations and Management (RV2), the Division of Administrative Operations (RV21), and the Office of the Associate Administrator (RV).

Delete the function for the following: (1) Office of the Associate Administrator (RV); (2) Office of Operations and Management (RV2); and the Division of

Administrative Operations (RV21); replace in their entirety.

Office of the Associate Administrator (RV)

The Office of the Associate Administrator provides leadership and direction for the HIV/AIDS programs and activities of the Bureau and oversees its relationship with other national health programs. Specifically: (1) promotes the implementation of the National HIV/AIDS Strategy within the Agency and among Agency-funded programs; (2) coordinates the formulation of an overall strategy and policy for programs established by Title XXVI of the PHS Act as amended by the Ryan White HIV/AIDS Treatment Extension Act of 2009, P.L. 111–87; (3) coordinates the internal functions of the Bureau and its relationships with other Agency Bureaus and Offices; (4) establishes HIV/AIDS program objectives, alternatives, and policy positions consistent with broad Administration guidelines; (5) provides leadership for and oversight of the Bureau's budgetary development and implementation processes; (6) provides clinical leadership to Ryan White-funded programs and global HIV/AIDS programs; (7) oversees the implementation of the Global HIV/AIDS Program as part of the President's Emergency Plan for AIDS Relief; (8) serves as a principal contact and advisor to the Department and other parties on matters pertaining to the planning and development of HIV/AIDS-related health delivery systems; (9) reviews HIV/AIDS related program activities to determine their consistency with established policies; (10) develops and oversees operating policies and procedures for the Bureau; (11) oversees and directs the planning, implementation, and evaluation of special studies related to HIV/AIDS and public health within the Bureau; (12) prioritizes technical assistance needs in consultation with each division/office; (13) plans, implements, and evaluates the Bureau's national technical assistance resource training center Web site and other distance learning modalities; (14) represents the Agency in HIV/AIDS related conferences, consultations, and meetings with other Operating Divisions, Office of the Assistant Secretary for Health, the Department of State, and the White House; and (15) oversees Bureau Executive Secretariat functions and coordinates HRSA responses and comments on HIV/AIDS-related reports, position papers, guidance documents, correspondence, and related issues, including Freedom of Information Act requests.

Office of Operations and Management (RV2)

The Office of Operations and Management provides expertise guidance, leadership, and support in the areas of general administration, fiscal operations, and contract administration. The Office of Operations and Management is responsible for providing direction on all budgetary, administrative, human resources, operations, facility management and contracting functions for the HIV/AIDS Bureau. The Office also oversees and coordinates all Bureau program integrity activities.

Division of Administrative Operations (RV21)

The Division of Administrative Operations is responsible for the administrative, human resources operations, facility management and contracting functions for the Bureau. Specifically, these functions are carried out in the Administrative Services and Contracting Services Team.

Office of Program Support (RV3)

The Office of Program Support provides expertise, guidance, leadership, and support in the areas of organizational development, communications, grantee oversight, and customer service to support program implementation. Specifically, the Office of Program Support: (1) enhances the coordination of program support, grants management, and technical assistance across the entire Bureau; (2) plans, implements and evaluates HAB staff development and education to enable employees to meet the mission of the Bureau; (3) streamlines communications, clearance activities and development of consistent, quality presentations; (4) improves the Bureau's external facing communication efforts; (5) facilitates transparency in sharing the Bureau's data using internal and external resources; (6) provides leadership for and oversees Bureau's grants processes; (7) coordinates the grants liaison activities; (8) supports grantee oversight and improves customer service and technical assistance to grantees; (9) serves as the Bureau's primary liaison with the Office of Federal Assistance Management; (10) supports systems development to improve program efficiencies and management; (11) provides support with the implementation of staff development, organizational development and training activities; (12) plans, develops, implements and evaluates the Bureau's organizational and staff development, and staff training activities inclusive of guiding action steps addressing annual Employee Viewpoint Survey results; and (13) coordinates the development and distribution of all Bureau communication activities, materials and products internally and externally.

Delegations of Authority

All delegations of authority and re-delegations of authority made to HRSA officials that were in effect immediately prior to this reorganization, and that are consistent with this reorganization, shall continue in effect pending further re-delegation.

This reorganization is effective upon date of signature.

Dated: August 1, 2016.

James Macrae,

Acting Administrator.

[FR Doc. 2016–18730 Filed 8–5–16; 8:45 am]

BILLING CODE 4165–15–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

National Institute on Alcohol Abuse and Alcoholism, 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 on Alcohol Abuse and Alcoholism Initial Review Group; Biomedical Research Review Subcommittee.

Date: October 18, 2016.

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

Agenda: To review and evaluate grant applications.

Place: National Institute of Alcohol Abuse and Alcoholism, National Institutes of Health, Conference Room 3002–3004, 5635 Fishers Lane, Rockville, MD 20852.

Contact Person: Philippe Marmillot, Ph.D., Scientific Review Officer, National Institute on Alcohol Abuse and Alcoholism, National Institutes of Health, 5635 Fishers Lane, Room