The guidance represents the Agency’s current thinking on this topic. 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 requirements of the applicable statutes and regulations.

II. The Paperwork Reduction Act of 1995

This 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, and the collection of information under the guidance for industry “Special Protocol Assessment” has been approved under OMB control number 0910–0470.

III. Comments

Interested persons may submit to the Division of Dockets Management (see ADDRESSES) either electronic or written comments regarding this document. It is only necessary to send one set of comments. It is no longer necessary to send two copies of mailed 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.

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: November 22, 2010.

Leslie Kux,
Acting Assistant Commissioner for Policy.

[FR Doc. 2010–29796 Filed 11–26–10; 8:45 am]
BILLING CODE 4160–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Health Resources and Services Administration

Health Center Program

AGENCY: Health Resources and Services Administration, HHS.

ACTION: Notice of Noncompetitive Replacement Awards to Upper Room AIDS Ministry, Inc.

SUMMARY: The Health Resources and Services Administration (HRSA) will transfer Health Center Program (section 330 of the Public Health Service Act) Increased Demand for Services (IDS) and Capital Improvement Project (CIP) funds, awarded under the American Recovery and Reinvestment Act (ARRA), originally awarded to Harlem United Community AIDS Center, Inc. (HUCAC) to Upper Room AIDS Ministry, Inc. to ensure the provision of critical primary health care services and continuity of services to low-income, underserved homeless patients in New York City.

SUPPLEMENTARY INFORMATION:

For Further Information, Contact: 
Marquita Cullom-Stott via e-mail at Mcullom-Stott@hrsa.gov or 301–594–4300.

Dated: November 19, 2010.

Mary K. Wakefield,
Administrator.

[FR Doc. 2010–29866 Filed 11–26–10; 8:45 am]
BILLING CODE 4165–15–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Health Resources and Services Administration

Part C Early Intervention Services Grant under the Ryan White HIV/AIDS Program

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

ACTION: Notice of a non-competitive one-time replacement award from Ryan White HIV/AIDS Program, Part C funds for the Louisiana State University, Health Sciences Center, Viral Disease Clinic in Shreveport, Department of Medicine, Shreveport, Louisiana.

SUMMARY: HRSA will be giving a non-competitive one-time replacement award to support comprehensive primary care services for persons living with HIV/AIDS, including primary medical care, laboratory testing, oral health care, outpatient mental health and substance abuse treatment, speciality and subspeciality care, referrals for health and support services and adherence monitoring/education services to the Louisiana State University, Health Sciences Center, Viral Disease Clinic to ensure continuity of critical HIV medical care and treatment services, to clients in Shreveport, Louisiana.

SUPPLEMENTARY INFORMATION: