

Hampshire Ave., Bldg. 51, rm. 2201, 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 guidance document.

Submit electronic comments on the guidance to <http://www.regulations.gov>. Submit written comments to the Division of Dockets Management (HFA-305), Food and Drug Administration, 5630 Fishers Lane, rm. 1061, Rockville, MD 20852.

**FOR FURTHER INFORMATION CONTACT:**

Devinder Gill, Center for Drug Evaluation and Research (HFD-630), Food and Drug Administration, 7500 Standish Pl., Rockville, MD 20855, 240-276-8483.

**SUPPLEMENTARY INFORMATION:**

**I. Background**

FDA is announcing the availability of a guidance for industry entitled "ANDAs: Impurities in Drug Products." In December 1998, FDA issued the draft guidance "ANDAs: Impurities in Drug Products," and in August 2005, FDA revised it in conformance with the "Q3B(R) Impurities in New Drug Products" guidance for industry that was announced in August 2006.

We are issuing the final guidance to: (1) Update information on listing of degradation products, setting acceptance criteria, and qualifying degradation products (thresholds and procedures) in abbreviated new drug applications (ANDAs) in conformance with the revision of the guidance for industry on Q3B(R) and (2) remove those sections of the 1998 draft guidance containing recommendations that are no longer needed because they are addressed in the more recent Q3B(R). The Q3B(R) was developed by the ICH to provide guidance on impurities in drug products for new drug applications (NDAs). However, the Agency believes that many of the recommendations provided on impurities in NDAs also apply to ANDAs.

This guidance is being issued consistent with FDA's good guidance practices regulation (21 CFR 10.115). The guidance represents the Agency's current thinking on impurities in drug products submitted as ANDAs. 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. 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.

**III. 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. 2010-29896 Filed 11-26-10; 8:45 am]

**BILLING CODE 4160-01-P**

**DEPARTMENT OF HEALTH AND HUMAN SERVICES**

**Food and Drug Administration**

[Docket No. FDA-2007-D-0150; Formerly Docket No. 2007D-0367]

**Guidance for Industry on Antibacterial Drug Products: Use of Noninferiority Trials to Support Approval; Availability**

**AGENCY:** Food and Drug Administration, HHS.

**ACTION:** Notice.

**SUMMARY:** The Food and Drug Administration (FDA) is announcing the availability of a guidance for industry entitled "Antibacterial Drug Products: Use of Noninferiority Trials to Support Approval." The purpose of this guidance is to provide information on FDA's current thinking regarding appropriate use of noninferiority (NI) clinical trial designs to evaluate antibacterial drug products. The Agency's thinking in this area has evolved in recent years in response to a number of public discussions on the use of active-controlled trials designed to show NI as the basis for approval of antibacterial drug products. This guidance finalizes the draft guidance published in the **Federal Register** of October 15, 2007.

**DATES:** Submit either electronic or written comments on Agency guidances at any time.

**ADDRESSES:** Submit written requests for single copies of this guidance to the

Division of Drug Information, Center for Drug Evaluation and Research, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 51, rm. 2201, 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 guidance document.

Submit electronic comments on the guidance to <http://www.regulations.gov>. Submit written comments to the Division of Dockets Management (HFA-305), Food and Drug Administration, 5630 Fishers Lane, rm. 1061, Rockville, MD 20852.

**FOR FURTHER INFORMATION CONTACT:**

Joseph G. Toerner, Center for Drug Evaluation and Research, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 22, rm. 6244, Silver Spring, MD 20993-0002, 301-796-1300.

**SUPPLEMENTARY INFORMATION:**

**I. Background**

FDA is announcing the availability of a guidance for industry entitled "Antibacterial Drug Products: Use of Noninferiority Trials to Support Approval." The purpose of this guidance is to inform industry, sponsors, applicants, researchers, and the public on the appropriate uses of NI clinical trial designs to evaluate antibacterial drug products and to amend ongoing or completed trials accordingly. In the **Federal Register** of October 15, 2007 (72 FR 58312), FDA announced a notice of availability of the draft guidance for industry entitled "Antibacterial Drug Products: Use of Noninferiority Studies to Support Approval" in response to numerous public discussions that focused primarily on the following indications: Acute bacterial sinusitis, acute bacterial exacerbation of chronic bronchitis, and acute bacterial otitis media. Since FDA issued the draft guidance, there have been public discussions on consistent and reliable estimates of the efficacy of active treatment to placebo for other infectious disease indications for the NI trial design. The public comments received on the draft guidance have been considered and the guidance has been revised as appropriate. The guidance emphasizes that adequate scientific evidence should be provided to support the proposed NI margin for any indication being studied in any proposed, ongoing, or completed active-controlled trial designed to show NI.

This guidance is being issued consistent with FDA's good guidance practices regulation (21 CFR 10.115).

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]

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## 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:

*Former Grantee of Record:* Harlem United Community AIDS Center, Inc.

*Original Period of Grant Support:* March 27, 2009, to March 26, 2011 (IDS) and June 29, 2009, to June 28, 2011 (CIP).

*Replacement Awardee:* Upper Room AIDS Ministry, Inc.

*Amount of Replacement Award:* \$103,317 (IDS) and \$262,740 (CIP).

*Period of Replacement Award:* The period of support for the replacement awards is March 27, 2009 to March 26, 2011 (IDS) and June 29, 2009 to June 28, 2011 (CIP).

*Authority:* Section 330(h) of the Public Health Service Act, 42 U.S.C. 245b.

*CDDA Number:* 93.703

*Justification for Exception to Competition:* Under the original grant applications approved by HRSA, Harlem United Community AIDS Center, Inc. (HUCAC) was identified as the grantee of record. HUCAC had a subrecipient agreement in place with Upper Room AIDS Ministry, Inc., a HUCAC-subsidiary organization. Through this arrangement, Upper Room AIDS Ministry, Inc. provided all services and carried out the full scope of project for the homeless program. Instead of continuing this agreement, both organizations decided that Upper Room AIDS Ministry, Inc. should become the direct grantee recipient for the ARRA IDS and CIP grants. Upper Room AIDS Ministry, Inc. competed successfully for fiscal year 2010 Service Areas Competition funding and has become the direct grant recipient of the health center homeless grant. HUCAC and the Upper Room AIDS Ministry, Inc. requested that full responsibility for the grants be transferred from HUCAC to Upper Room AIDS Ministry. Upper Room AIDS Ministry has provided documentation to HRSA that it meets Section 330 statutory and regulatory requirements as well as applicable grant management requirements.

The transfer of these grants will ensure critical primary health care services continue and remain available to low income, underserved homeless populations with no interruption in services to the target population. Transferring the funds to Upper Room AIDS Ministry, Inc. does not materially change the projects as originally proposed and funded. Upper Room AIDS Ministry, Inc. will fulfill the expectations of the former grantee's originally funded IDS and CIP grant applications. In order to ensure that critical primary health care services continue to be available to the original target population in a timely manner, these ARRA CIP and IDS awards will not be competed.

#### FOR FURTHER INFORMATION, CONTACT:

Marquita Cullom-Stott via e-mail at [MCullom-Stott@hrsa.gov](mailto: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, specialty and subspecialty 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:**