Regulatory Affairs, *OIRA_submission@omb.eop.gov* or by fax to 202–395–6974, *Attention:* Desk Officer for NIH. To request more information on the proposed project or to obtain a copy of the data collection plans and instruments, contact Dr. Linda Kupfer, Fogarty International Center, National Institutes of Health, 16 Center Drive, Bethesda, MD 20892, or call non-toll-free number 301–496–3288, or e-mail your request, including your address to: *Linda.Kupfer@nih.gov*.

Comments Due Date: Comments regarding this information collection are best assured of having their full effect if received within 30 days of the date of this publication.

Dated: August 23, 2010.

Timothy J. Tosten,

Executive Officer, John E. Fogarty International Center, National Institutes of Health.

[FR Doc. 2010–21350 Filed 8–26–10; 8:45 am]

BILLING CODE 4140–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2010–D–0433]

Draft Guidance for Industry on Acute Bacterial Skin and Skin Structure Infections: Developing Drugs for Treatment; Availability

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is announcing the availability of a draft guidance for industry entitled "Acute Bacterial Skin and Skin Structure Infections: Developing Drugs for Treatment." The purpose of this draft guidance is to assist clinical trial sponsors and investigators in the development of antimicrobial drugs for the treatment of acute bacterial skin and skin structure infections (ABSSSI), impetigo, and minor cutaneous abscesses. FDA's thinking in this area has evolved in recent years, and this draft guidance, when finalized, will inform sponsors of the changes in the definitions of ABSSSI and the recommendations for clinical drug development.

DATES: Although you can comment on any guidance at any time (see 21 CFR 10.115(g)(5)), to ensure that the agency considers your comment on this draft guidance before it begins work on the final version of the guidance, submit either electronic or written comments on the draft guidance by November 26, 2010.

ADDRESSES: Submit written requests for single copies of the draft guidance to the Division of Drug Information, Center for Drug Evaluation and Research, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 51, rm. 2201,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 draft guidance document.

Submit electronic comments on the draft 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 draft guidance for industry entitled "Acute Bacterial Skin and Skin Structure Infections: Developing Drugs for Treatment." The purpose of this draft guidance is to assist clinical trial sponsors and investigators in the development of antimicrobial drugs for the treatment of ABSSSI, impetigo, and minor cutaneous abscesses. This guidance revises the draft guidance regarding uncomplicated and complicated skin and skin structure infections published in 1998. The guidance also addresses the clinical development of new drugs to treat drug-resistant bacterial pathogens implicated in ABSSSI, such as methicillin-resistant *Staphylococcus aureus*.

The definitions of ABSSSI and the designs of ABSSSI clinical trials were discussed at a meeting of the Anti-Infective Drugs Advisory Committee on November 18, 2008. In addition, other advisory committee meetings have focused on the development of specific drugs for this indication. As a result of these public discussions, as well as review of applications at FDA, the agency's thinking in this area has evolved in recent years and this draft guidance informs sponsors of the changes in our recommendations. Specifically, the guidance defines the clinical disease entities and provides a justification for a noninferiority margin for the design of active-controlled clinical trials that can be used to provide evidence of efficacy for the treatment of ABSSSI. The guidance describes a new responder efficacy endpoint for noninferiority trials that is based on the historical studies used to justify the noninferiority margin. Currently, there are ongoing efforts in the scientific community to develop and evaluate new efficacy endpoints for ABSSSI. The guidance also defines the clinical disease entities of skin infections for which a superiority trial is recommended.

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 agency's current thinking on developing drugs for the treatment of ABSSSI. 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 under the Paperwork Reduction Act of 1995 (44 U.S.C. 3501–3520). The collections of information in 21 CFR part 312 have been approved under OMB control number 0910–0014 and the collections of information in 21 CFR part 314 have been approved under OMB control number 0910–0001.

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: August 23, 2010.

Leslie Kux,

Acting Assistant Commissioner for Policy.

[FR Doc. 2010–21328 Filed 8–26–10; 8:45 am]

BILLING CODE 4160–01–S

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Substance Abuse and Mental Health Services Administration

Fiscal Year (FY) 2010 Funding Opportunity

AGENCY: Substance Abuse and Mental Health Services Administration, HHS.

ACTION: Notice of Intent to award a Single Source Supplement Grant to the National Center for Mental Health Promotion and Youth Violence Prevention at Educational Development Corporation (EDC) of Newton, Massachusetts.

SUMMARY: This notice is to inform the public that the Substance Abuse and Mental Health Services Administration (SAMHSA) intends to award approximately $250,000 for up to fifteen months to expand grant activities funded under the Technical Assistance Center for Mental Health Promotion and Youth Violence Prevention to implement a Back to School media campaign targeted at the Gulf Coast schools impacted by the Deepwater oil spill. This is not a formal request for applications. This award is contingent upon the availability of funding. Assistance will be provided only to the current grantee of the Technical Assistance Center for Mental Health Promotion and Youth Violence Prevention based on the receipt of a satisfactory application that is approved by an independent review group.

Funding Opportunity Title: SM–10–020.

Catalog of Federal Domestic Assistance (CFDA) Number: 93.243.

Authority: Sections 501(d)(5), 501(d)(18), 520A, 231, of the Public Health Service (PHS) Act [42 U.S.C. 290aa; 42 U.S.C. 290bb–32, 42 U.S.C. 238, respectively].

Justification: Only an application from the current grantee, National Center for Mental Health Promotion and Youth Violence Prevention at Educational Development Corporation (EDC), will be considered for funding under this announcement. Fifteen-months funding may become available to implement a Back to School Media Support for Gulf Coast States Impacted by the Deepwater Oil Spill grant. The current grantee will provide technical assistance and is in a unique position to address the needs of communities rapidly. This Center currently provides technical assistance and training to strengthen the capacity of active Safe Schools/Healthy Students grantees to sustain the use of evidence-based strategies for mental health promotion and school violence prevention. There is no other potential organization with the required access and expertise.

Eligibility for this program supplement is restricted to the current grantee, National Center for Mental Health Promotion and Youth Violence Prevention at Educational Development Corporation (EDC). Eligibility is limited because the magnitude of the Deepwater Horizon oil spill and its impact on the residents of the Gulf Coast region have led to an urgent need for disaster behavioral health communications services targeting school aged children, youth and their families. This supplement will serve to maximize efficiencies created under the current services infrastructure. It would be inefficient and duplicative to fund additional technical assistance services for a Back to School Media Support for Gulf Coast States Impacted by the Deepwater Oil Spill grant through a second organization.

Contact: Shelly Hara, Substance Abuse and Mental Health Services Administration, 1 Choke Cherry Road, Room 8–1095, Rockville, MD 20857; *telephone:* (240) 276–2321; E-mail: *shelly.hara@samhsa.hhs.gov.*

Dated: August 23, 2010.

Toian Vaughn,

SAMHSA Committee Management Officer.

[FR Doc. 2010–21339 Filed 8–26–10; 8:45 am]

BILLING CODE 4162–20–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

Government-Owned Inventions; Availability for Licensing

AGENCY: National Institutes of Health, Public Health Service, HHS.

ACTION: Notice.

SUMMARY: The inventions listed below are owned by an agency of the U.S. Government and are available for licensing in the U.S. in accordance with 35 U.S.C. 207 to achieve expeditious commercialization of results of Federally-funded research and development. Foreign patent applications are filed on selected inventions to extend market coverage for companies and may also be available for licensing.

ADDRESSES: Licensing information and copies of the U.S. patent applications listed below may be obtained by writing to the indicated licensing contact at the Office of Technology Transfer, National Institutes of Health, 6011 Executive Boulevard, Suite 325, Rockville, Maryland 20852–3804; *telephone:* 301/496–7057; *fax:* 301/402–0220. A signed Confidential Disclosure Agreement will be required to receive copies of the patent applications.

System and Method for Producing Nondiffracting Light Sheets that Improves the Performance of Selective Plane Illumination Microscopy (SPIM)

Description of Invention: The technology offered for licensing relates to a system and method of producing nondiffracting beams of light that spatially overlap, but do not interfere with each other when intersecting the detection plane of an optical arrangement. The system includes an illumination source (*i.e.* ultrafast laser) for transmitting a beam of light through the optical arrangement that includes a diffraction grating for diffracting the light beam to produce beams of light having different wavelengths, which are then passed through an annular aperture that transforms the beams of light into nondiffracting beams having different wavelengths. The method can be readily utilized in Selective Plane Illumination Microscopy (SPIM), a system that provides optical sectioning of a sample that is labeled with fluorescent dyes. SPIM can provide quantitative three-dimensional maps of the distribution of a flurophore within the sample with high spatiotemporal resolution and an excellent signal-to-noise ratio. The standard SPIM technique however produces nonuniform axial resolution, which is caused by the diffraction of the laser beam through the sample, causing degradation in the optical sectioning, and forcing a compromise between field of view and axial resolution. Techniques for decoupling field of view and axial resolution have previously utilized nondiffracting beams (*e.g.* Bessel beams) for sample illumination. The resulting interference from multiple nondiffracting beams degrades the quality of optical sectioning and the quality of the image. The present technology utilizing nondiffracting noninterfering beams is intended to alleviate the problems associated with the currently used SPIM techniques.

Applications: In Selective Plane Illumination Microscopy (SPIM) used for optical sectioning and imaging of biological samples.

Development Status: Proof of concept has been demonstrated.