CFDA Number: 93.110.

Justification for the Exception to Competition:

The F2F HICs were legislated by Congress under the Family Opportunity Act/Budget Deficit Reduction Act. Congress specified that there be a family staffed center in each State and the District of Columbia by June 2009. The former grantee, Family Voices of Colorado, received a competitive grant in 2008 operating under the non-profit, Cerebral Palsy of Colorado. Family Voices of Colorado notified HRSA that it would be unable to continue providing services to families and providers as had been proposed in their Family-To-Family Health Information Center grant application under Cerebral Palsy of Colorado and will now be providing services under the Colorado Nonprofit Development Center.

It is critical that Family Voices of Colorado continue helping families of children and youth with special health care needs (CYSHCN) gain access to information they need to make informed health care decisions, be full partners in decision-making and access needed resources/referrals and financing for those services in the State of Colorado. It is also critical that they continue to train and support healthcare providers and other professionals in public and private agencies who serve Colorado's CYSHCN, helping them better understand the needs of children, youth and their families.

CYSHCN are defined as ''those children and youth who have or are at increased risk for a chronic physical, developmental, behavioral, or emotional condition and who also require health and related services of a type or amount beyond that required by children generally'' (American Academy of Pediatrics, 1998). This is particularly relevant since more than 28% of CYSHCN in Colorado had problems getting referrals to care. Only 22% of Colorado families of a CYSHCN identified that community-based service systems are organized for easy use. In addition, because of changes occurring in State services and their funding for CYSHNC, many families and providers alike need to be kept up to date on these changes so that they can access appropriate services. This center is urgently needed to address these gaps and disparities in information and services.

The Colorado Non-Profit Development Center was identified as an umbrella agency with a demonstrated history of providing a full array of technical assistance and fiscal management services to entities such as Family Voices of Colorado. This replacement award will ensure that Family Voices of Colorado can continue to provide critical information, referral and support services to families with children having special health care needs throughout Colorado and in a manner which avoids any disruption of services.

FOR FURTHER INFORMATION CONTACT: Diana Denboba, Integrated Services Branch Chief, Maternal and Child Health Bureau, HRSA, 5600 Fishers Lane, Rockville, MD 20857, via e-mail at *DDenboba@hrsa.gov* or via telephone at 301 443–9332.

Dated: July 22, 2009.

Mary K. Wakefield,

Administrator.

[FR Doc. E9–18125 Filed 7–29–09; 8:45 am]

BILLING CODE 4165–15–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2008–D–0128] (formerly Docket No. 2007D–0396)

Guidance for Industry on Drug-Induced Liver Injury: Premarketing Clinical Evaluation; 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 ''Drug-Induced Liver Injury: Premarketing Clinical Evaluation.'' This guidance is intended to assist the pharmaceutical industry and others engaged in new drug development in the assessment of the potential of a drug to cause severe drug-induced liver injury (DILI) during the conduct of premarketing trials. This guidance defines severe DILI as injury that is fatal or requires liver transplantation.

DATES: Submit written or electronic 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; or the Office of Communication, Outreach and Development (HFM–40), Center for Biologics Evaluation and Research, 1401 Rockville Pike, suite 200N, Rockville, MD 20852–1448. The guidance may also be obtained from the Center for Biologics Evaluation and Research by mail by calling 1–800–835–4709 or 301–827–1800. Send one self-addressed adhesive label to assist that office in processing your requests. Submit written comments on the guidance to the Division of Dockets Management (HFA–305), Food and Drug Administration, 5630 Fishers Lane, rm. 1061, Rockville, MD 20852. Submit electronic comments to *http://www.regulations.gov*. See the **SUPPLEMENTARY INFORMATION** section for electronic access to the guidance document.

FOR FURTHER INFORMATION CONTACT:

Hee Shelia Lianos, Center for Drug Evaluation and Research, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 22, rm. 5329, Silver Spring, MD 20993–0002, 301–796–4147; or

Steve Ripley, Center for Biologics Evaluation and Research (HFM–17), Food and Drug Administration, 1401 Rockville Pike, suite 200N, Rockville, MD 20852, 310–827–6210.

SUPPLEMENTARY INFORMATION:

I. Background

FDA is announcing the availability of a guidance for industry entitled ''Drug-Induced Liver Injury: Premarketing Clinical Evaluation.'' Severe DILI has been an important cause of drug marketing withdrawal. This has led FDA to pay particular attention to how the risk of severe DILI can be predicted before a drug is approved. The science of detecting and evaluating DILI during drug development is evolving, and FDA is working with industry, academia, and other government groups toward better understanding of how best to do this.

Even for drugs that prove to be significant hepatotoxins in some patients (e.g., bromfenac, troglitazone, and ximelagatran), it is unlikely that cases of severe DILI will be identified during a drug development program with only a few thousand exposed subjects. Therefore, it is critical to discover signals of a drug's potential to cause such injury during drug development by detection of lesser degrees of liver injury that may be more frequently seen. There are a number of such signals that have varying levels of sensitivity and specificity in predicting the potential for severe DILI. However, the most specific finding to date is a finding of cases of serum aminotransferase elevation together with elevated bilirubin concentration (and no evidence of biliary obstruction or impaired ability to conjugate bilirubin) in some trial subjects (i.e., Hy's Law cases).

The guidance describes the sensitivity and specificity of various indicators of hepatotoxic potential, as well as the observations needed to evaluate those indicators, including detection, confirmation and monitoring of liver test abnormalities, close evaluation and exclusion of other causes, and careful supportive care and follow-up to normality or return to baseline status. The guidance makes specific recommendations about the use of Hy's Law and interpretation of Hy's Law cases that are identified during clinical development and suggests research opportunities to learn more about what makes certain people more susceptible to DILI than are most persons exposed to the drug.

The guidance was issued in draft form in October 2007 for public comments. We received a total of 12 comments submitted to Docket No. 2007D–0396. FDA organized a public meeting in March 2008 for discussion of issues raised by the draft guidance and reopened the public comment period from March 6, 2008, to June 30, 2008, with Docket No. FDA–2008–D–0128 (formerly Docket No. 2007D–0396). One comment was submitted to Docket No. FDA–2008–D–0128. The comments are available at *http://www.fda.gov/Drugs/ScienceResearch/ResearchAreas/ucm071471.htm*. Presentations, discussion, and materials from the March 2008 public meeting also are available at the above Web site.

FDA considered written and verbal comments submitted to the dockets and at the public meeting before finalizing the guidance. The guidance reflects clarifying and editorial changes made in response to comments and at our own initiative.

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 the premarketing evaluation of a drug's potential for causing severe DILI. 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, 314, and 601 have been approved under OMB Control Numbers 0910–0014, 0910–0001, and 0910–0338, respectively.

III. Comments

Interested persons may submit to the Division of Dockets Management (see **ADDRESSES**) written or electronic comments regarding this document. Submit a single copy of electronic comments or two paper copies of any mailed comments, except that individuals may submit one paper copy. Comments are to be identified 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 *http://www.fda.gov/Drugs/GuidanceComplianceRegulatoryInformation/Guidances/default.htm*, *http://www.fda.gov/cber/guidelines.htm*, or *http://www.regulations.gov*.

Dated: July 22, 2009.

Jeffrey Shuren,

Associate Comissioner for Policy and Planning.

[FR Doc. E9–18135 Filed 7–29–09; 8:45 am]

BILLING CODE 4160–01–S

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Substance Abuse and Mental Health Services Administration

Fiscal Year (FY) 2009 Funding Opportunity

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

ACTION: Notice of intent to award a Single Source Supplement Grant to the Community Anti-Drug Coalitions of America (CADCA).

SUMMARY: This notice is to inform the public that the Substance Abuse and Mental Health Services Administration (SAMHSA) intends to award approximately $30,000 (total costs) for one year to the Community Anti-Drug Coalitions of America (CADCA). This is not a formal request for applications. Assistance will be provided only to the Community Anti-Drug Coalitions of America (CADCA) based on the receipt of a satisfactory application that is approved by an independent review group.

Funding Opportunity Title: SP–09–007.

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

Authority: Sections 509, 516 and 520A of the Public Health Service Act, as amended.

Justification: Only the Community Anti-Drug Coalitions of America (CADCA) is eligible to apply. The Substance Abuse and Mental Health Services Administration (SAMHSA) is seeking to supplement a single source grant to the Community Anti-Drug Coalitions of America (CADCA) to support a Prevention Town Hall Meeting and a Partners Meeting at CADCA's Mid-Year Training Institute. The Training Institute will disseminate knowledge and transfer state-of-the-art information, assisting community leaders in developing effective local programs, practices, and policies that support national substance abuse goals, outcomes and efforts, such as National Alcohol and Drug Addiction Recovery Month, and prevention of underage drinking. The Prevention Town Hall Meeting will provide an in-depth overview of substance abuse prevention principles, and make the link to community-level change strategies promoted by the Drug-Free Communities grant program. The Partners Meeting is intended to bring all Federal and other key constituents together to update and discuss new initiatives and ongoing projects. Grant funds will also support evaluation of the Prevention Town Hall Meeting to obtain findings and identify directions for future trainings.

The Community Anti-Drug Coalitions of America (CADCA) is uniquely qualified to carry out the activities of this program because the purpose of the program is to partner with a national organization that has special expertise and unique broad, national-level experience in working with community anti-drug coalitions. CADCA is the only national organization that annually provides training and technical assistance through a mid-year leadership conference for thousands of members of community coalitions dedicated to preventing substance abuse. CADCA currently is the sole organization that plays a major role in helping to strengthen and develop the nation's prevention infrastructure of anti-drug coalitions in support of on-going activities funded by SAMHSA's priority grant programs including: the Substance Abuse Prevention and Treatment Block Grant, the Strategic Prevention Framework State Incentive Grant, and the Drug Free Communities Support Program. CADCA is the only identified organization that currently meets this experience level and national reach to over 5,000 identified anti-drug coalitions across the country.