www.regulations.gov. See the **SUPPLEMENTARY INFORMATION** section for electronic access to the draft guidance document.

FOR FURTHER INFORMATION CONTACT:

Regarding the guidance: Federico Goodsaid, Center for Drug Evaluation and Research, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 51, rm. 2148, Silver Spring, MD 20903–0002, 301–796–1535; or Jennifer Catalano, Center for Biologics Evaluation and Research (HFM–735), Food and Drug Administration, 1401 Rockville Pike, Rockville, MD 20852–1448, 301–827–0706.

Regarding the ICH: Michelle Limoli, Office of International Programs (HFG–1), Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857, 301–827–4480.

SUPPLEMENTARY INFORMATION:

I. Background

In recent years, many important initiatives have been undertaken by regulatory authorities and industry associations to promote international harmonization of regulatory requirements. FDA has participated in many meetings designed to enhance harmonization and is committed to seeking scientifically based harmonized technical procedures for pharmaceutical development. One of the goals of harmonization is to identify and then reduce differences in technical requirements for drug development among regulatory agencies.

ICH was organized to provide an opportunity for tripartite harmonization initiatives to be developed with input from both regulatory and industry representatives. FDA also seeks input from consumer representatives and others. ICH is concerned with harmonization of technical requirements for the registration of pharmaceutical products among three regions: The European Union, Japan, and the United States. The six ICH sponsors are the European Commission; the European Federation of Pharmaceutical Industries Associations; the Japanese Ministry of Health, Labour, and Welfare; the Japanese Pharmaceutical Manufacturers Association; the Centers for Drug Evaluation and Research and Biologics Evaluation and Research, FDA; and the Pharmaceutical Research and Manufacturers of America. The ICH Secretariat, which coordinates the preparation of documentation, is provided by the International Federation of Pharmaceutical Manufacturers Associations (IFPMA).

The ICH Steering Committee includes representatives from each of the ICH sponsors and the IFPMA, as well as observers from the World Health Organization, Health Canada, and the European Free Trade Area.

In June 2009, the ICH Steering Committee agreed that a draft guidance entitled ''E16 Genomic Biomarkers Related to Drug Response: Context, Structure, and Format of Qualification Submissions'' should be made available for public comment. The draft guidance is the product of the E16 Expert Working Group of the ICH. Comments about this draft will be considered by FDA and the E16 Expert Working Group.

The use of biomarkers in drug discovery, development, and postapproval has the potential to facilitate development of safer and more effective medicines, to guide dose selection, and to enhance the benefit-risk profile of approved medicines. This draft guidance describes recommendations regarding context, structure, and format of regulatory submissions for qualification of genomic biomarkers. To support the evaluation of genomic biomarkers, the draft guidance describes and defines a submission standard applicable across regions. The recommendations are based on previous experiences in the various regions with submissions containing genomic biomarker data. Such submissions have been either stand-alone biomarker qualification applications or a component of medicinal product-related regulatory process. Where appropriate, the proposed document format is expected to facilitate incorporation of genomic biomarker data into specific product-related applications.

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 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. Comments

Interested persons may submit to the Division of Dockets Management (see **ADDRESSES**) written or electronic comments on the draft guidance. 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.

III. Electronic Access

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

Dated: July 23, 2009.

Jeffrey Shuren,

Associate Commissioner for Policy and Planning.

[FR Doc. E9–18227 Filed 7–29–09; 8:45 am]

BILLING CODE 4160–01–S

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Health Resources and Services Administration

Family-To-Family Health Information Center Program

AGENCY: Health Resources and Services Administration, HHS.

ACTION: Notice of noncompetitive replacement award to Colorado Non-Profit Development Center.

SUMMARY: The Health Resources and Services Administration (HRSA) will be transferring Family Voices Colorado Family-To-Family Health Information Center (F2F HIC) grant (H84 MC 09577) from Cerebral Palsy of Colorado to the Colorado Non-Profit Development Center in Denver in order to ensure the continued provision of health resources, financing, related services and parent-to-parent support for families with children and youth with special health care needs in the State of Colorado.

SUPPLEMENTARY INFORMATION:

Former Grantee of Record: Cerebral Palsy of Colorado.

Original Period of Grant Support: June 1, 2008, to May 31, 2011.

Replacement awardee: Colorado Non-Profit Development Center.

Amount of Replacement Award: $153,572 for year 2 and $95,700 for year 3 of the remaining project period.

Period of Replacement Award: The period of support for the replacement award is July 1, 2009, to May 31, 2011.

Authority: Section 501(c)(1)(A) of the Social Security Act.

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).