

that it deems necessary, including institution of proceedings to revoke any existing licenses held by the applicant.

*G. Refund of Remaining Upfront Payment Balance*

186. After the auction, applicants that are not winning bidders or are winning bidders whose upfront payment exceeded the total net amount of their winning bids may be entitled to a refund of some or all of their upfront payment. All refunds will be returned to the payer of record, as identified on the FCC Form 159, unless the payor submits written authorization instructing otherwise. Bidders should not request a refund of their upfront payments before the Commission releases a public notice declaring the auction closed, identifying the winning bidders, and establishing the deadlines for submitting down payments, long-form applications, and final payments.

Federal Communications Commission.

**Gary D. Michaels,**

*Deputy Chief, Auctions and Spectrum Access Division, WTB.*

[FR Doc. E9-18198 Filed 7-29-09; 8:45 am]

**BILLING CODE 6712-01-P**

## GENERAL SERVICES ADMINISTRATION

[OMB Control No. 3090-0044]

### Public Buildings Service; Submission for OMB Review; GSA Form 3453, Application/Permit for Use of Space in Public Buildings and Grounds

**AGENCY:** Public Buildings Service, GSA.

**ACTION:** Notice of request for comments regarding a renewal to an existing OMB clearance.

**SUMMARY:** Under the provisions of the Paperwork Reduction Act of 1995 (44 U.S.C. Chapter 35), the General Services Administration will be submitting to the Office of Management and Budget (OMB) a request to review and approve a renewal of a currently approved information collection requirement regarding GSA Form 3453, Application/Permit for Use of Space in Public Buildings and Grounds. A request for public comments was published at 74 FR 19094, April 27, 2009. No comments were received.

*Public comments are particularly invited on:* Whether this collection of information is necessary and whether it will have practical utility; whether our estimate of the public burden of this collection of information is accurate, and based on valid assumptions and methodology; ways to enhance the

quality, utility, and clarity of the information to be collected.

**DATES:** Submit comments on or before: August 31, 2009.

**FOR FURTHER INFORMATION CONTACT:**

Frank Giblin, Public Buildings Service, at telephone (202) 501-1856, or via e-mail to [frank.giblin@gsa.gov](mailto:frank.giblin@gsa.gov).

**ADDRESSES:** Submit comments regarding this burden estimate or any other aspect of this collection of information, including suggestions for reducing this burden to GSA Desk Officer, OMB, Room 10236, NEOB, Washington, DC 20503, and a copy to the Regulatory Secretariat (VPR), General Services Administration, 1800 F Street, NW., Room 4041, Washington, DC 20405. Please cite OMB Control No. 3090-0044, GSA Form 3453, Application/Permit for Use of Space in Public Buildings and Grounds, in all correspondence.

**SUPPLEMENTARY INFORMATION:**

#### A. Purpose

The general public uses GSA Form 3453, Application/Permit for Use of Space in Public Buildings and Grounds, to request the use of public space in Federal buildings and on Federal grounds for cultural, educational, or recreational activities. A copy, sample, or description of any material or item proposed for distribution or display must also accompany this request.

#### B. Annual Reporting Burden

*Respondents:* 8,000.

*Responses per Respondent:* 1.

*Hours per Response:* 0.05.

*Total Burden Hours:* 400.

#### *Obtaining Copies of Proposals:*

Requesters may obtain a copy of the information collection documents from the General Services Administration, Regulatory Secretariat (VPR), 1800 F Street, NW., Room 4041, Washington, DC 20405, telephone (202) 501-4755. Please cite OMB Control No. 3090-0044, GSA Form 3453, Application/Permit for Use of Space in Public Buildings and Grounds, in all correspondence.

Dated: July 21, 2009.

**Casey Coleman,**

*Chief Information Officer.*

[FR Doc. E9-18129 Filed 7-29-09; 8:45 am]

**BILLING CODE 6820-34-P**

## DEPARTMENT OF HEALTH AND HUMAN SERVICES

### Food and Drug Administration

[Docket No. FDA-2009-D-0324]

#### International Conference on Harmonisation; Draft Guidance on E16 Genomic Biomarkers Related to Drug Response: Context, Structure, and Format of Qualification Submissions; Availability

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

**ACTION:** Notice.

**SUMMARY:** The Food and Drug Administration (FDA) is announcing the availability of a draft guidance entitled "E16 Genomic Biomarkers Related to Drug Response: Context, Structure, and Format of Qualification Submissions." The draft guidance was prepared under the auspices of the International Conference on Harmonisation of Technical Requirements for Registration of Pharmaceuticals for Human Use (ICH). The draft guidance describes recommendations regarding context, structure, and format of regulatory submissions for qualification of genomic biomarkers. The draft guidance is intended to foster consistency of applications across regions and facilitate joint discussions with and among regulatory authorities.

**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 written or electronic comments on the draft guidance by September 28, 2009.

**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; or the Office of Communication, Outreach and Development (HFM-40), Center for Biologics Evaluation and Research (CBER), Food and Drug Administration, 1401 Rockville Pike, Rockville, MD 20852-1448. The guidance may also be obtained by mail by calling CBER at 1-800-835-4709 or 301-827-1800. Send two self-addressed adhesive labels to assist the office in processing your requests. Submit written comments on the draft 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](http://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.