

ANNUAL BURDEN ESTIMATES—Continued

Instrument	Number of respondents	Number of responses per respondent	Average burden hours per response	Total burden hours
DD Council: Group Interview with Recipients of Self-Advocacy and Leadership Education and Training .....	100	1	0.75	75
DD Council: Group Interview with Recipients of Education and Training to Improve Community Capacity .....	100	1	0.75	75
DD Council: Self-administered Form .....	20	1	8	160
DD Council Estimate of Total Burden Hours for Activities to Support Administration of Proposed Information Collection Instruments .....	20	1	33.50	670
P&A Estimate of Total Burden Hours for Activities to Support Administration of Proposed Information Collection Instruments .....	20	1	33.50	670
UCEDD Estimate of Total Burden Hours for Activities to Support Administration of Proposed Information Collection Instruments .....	20	1	33.50	670
ADD Assessment Survey .....	60	1	0.75	45

Estimated Total Annual Burden Hours: 4,120.

In compliance with the requirements of Section 506(c)(2)(A) of the Paperwork Reduction Act of 1995, the Administration for Children and Families is soliciting public comment on the specific aspects of the information collection described above. Copies of the proposed collection of information can be obtained and comments may be forwarded by writing to the Administration for Children and Families, Office of Administration, Office of Information Services, 370 L'Enfant Promenade, SW., Washington, DC 20447, Attn: ACF Reports Clearance Officer. E-mail address: [infocollection@acf.hhs.gov](mailto:infocollection@acf.hhs.gov). All requests should be identified by the title of the information collection.

The Department specifically requests comments on: (a) Whether the proposed collection of information is necessary for the proper performance of the functions of the agency, including whether the information shall have practical utility; (b) the accuracy of the agency's estimate of the burden of the proposed collection of information; (c) the quality, utility, and clarity of the information to be collected; and (d) ways to minimize the burden of the collection of information on respondents, including through the use of automated collection techniques or

other forms of information technology. Consideration will be given to comments and suggestions submitted within 60 days of this publication.

Dated: June 7, 2010.

**Robert Sargis,**

*Reports Clearance Officer.*

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**DEPARTMENT OF HEALTH AND HUMAN SERVICES**

**Health Resources and Services Administration**

**Agency Information Collection Activities: Submission for OMB Review; Comment Request**

Periodically, the Health Resources and Services Administration (HRSA) publishes abstracts of information collection requests under review by the Office of Management and Budget (OMB), in compliance with the Paperwork Reduction Act of 1995 (44 U.S.C. Chapter 35). To request a copy of the clearance requests submitted to OMB for review, e-mail [paperwork@hrsa.gov](mailto:paperwork@hrsa.gov) or call the HRSA Reports Clearance Office on (301) 443-1129.

The following request has been submitted to the Office of Management

and Budget for review under the Paperwork Reduction Act of 1995:

**Proposed Project: Federally Qualified Health Centers (FQHC) Application Forms: (OMB No. 0915-0285)—Revisions**

HRSA's Bureau of Primary Health Care administers grants to Health Centers receiving funding under section 330 of the Public Health Service Act and has an approval process for organizations seeking to qualify as Federally Qualified Health Center (FQHC) Look Alikes. These Health Centers and FQHC Look Alikes provide preventive and primary health care services to low-income and other vulnerable populations, regardless of their ability to pay and whether or not they have health insurance. Many Health Centers and FQHC Look-Alikes offer dental, mental health and substance abuse care.

HRSA uses the following application forms to administer Section 330 Health Centers grants and the FQHC Look Alike application process. These application forms are used by new and existing Health Centers and FQHC Look-Alikes to apply for grant and non-grant opportunities, renew their grant or non-grant opportunities or change their scope of project.

Estimates of annualized reporting burden are as follows:

Type of application form	Number of respondents	Responses per respondent	Total responses	Hours per response	Total burden hours
General Information Worksheet .....	1,034	1	1,034	2.0	2,068
Planning Grant: General Information Worksheet .....	250	1	250	2.5	625
BPHC Funding Request Summary .....	1,034	1	1,034	2.0	2,068
Documents on File .....	1,034	1	1,034	1.0	1,034
Proposed Staff Profile .....	1,034	1	1,034	2.0	2,068
Income Analysis Form .....	1,034	1	1,034	5.0	5,170
Community Characteristics .....	1,034	1	1,034	1.0	1,034
Health Care Plan (Competing) .....	800	1	1,034	4.0	4,136
Health Care Plan (Non-Competing) .....	1,034	1	1,034	2.0	2,068
Business Plan (Competing) .....	800	1	1,034	4.0	4,136

Type of application form	Number of respondents	Responses per respondent	Total responses	Hours per response	Total burden hours
Business Plan (Non-Competing) .....	1,034	1	1,034	2.0	2,068
Services Provided .....	1,034	1	1,034	1.0	1,034
Sites Listing .....	1,034	1	1,034	1.0	1,034
Other Site Activities .....	700	1	700	0.5	350
Change In Scope (CIS) Site Add Checklist .....	300	1	300	1.0	300
CIS Site Delete Checklist .....	200	1	200	1.0	200
CIS Relocation Checklist .....	200	1	200	1.5	300
CIS Service Add Checklist .....	100	1	200	1.0	200
CIS Service Delete Checklist .....	100	1	100	1.0	100
Board Member Characteristics .....	1,034	1	1,034	1.0	1,034
Request for Waiver of Governance Requirements .....	150	1	150	1.0	150
Health Center Affiliation Certification .....	250	1	250	1.0	250
Need for Assistance .....	900	1	900	3.0	2,700
Emergency Preparedness Form .....	1,034	1	1,034	1.0	1,034
Points of Contact .....	800	1	800	0.5	400
EHR Readiness Checklist .....	250	1	250	1.0	250
Environmental Information and Documentation (EID) .....	400	1	400	2.0	800
Capital Improvement/Investment Proposal Cover Page ...	700	1	700	1.0	700
Assurances .....	900	1	900	.5	450
Capital Improvement/Investment Project Cover .....	700	1	700	1.0	700
Capital Improvement/Investment Project Impact .....	700	1	700	.5	350
Equipment List .....	900	1	900	1.0	900
Other Requirements for Sites .....	900	1	900	.5	450
<b>Total</b> .....	<b>1,138</b>	<b>1</b>	<b>23,976</b>	.....	<b>40,161</b>

Written comments and recommendations concerning the proposed information collection should be sent within 30 days of this notice to the desk officer for HRSA, either by email to [OIRA\\_submission@omb.eop.gov](mailto:OIRA_submission@omb.eop.gov) or by fax to 202-395-6974. Please direct all correspondence to the "attention of the desk officer for HRSA."

Dated: June 7, 2010.

**Sahira Rafiullah,**

*Director, Division of Policy and Information Coordination.*

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## DEPARTMENT OF HEALTH AND HUMAN SERVICES

### Food and Drug Administration

[Docket No. FDA-2007-D-0433] (formerly Docket No. 2007D-0169)

#### Guidance for Industry on Bioequivalence Recommendations for Specific Products; 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 "Bioequivalence Recommendations for Specific Products." This guidance describes a new process for making available

recommendations on how to design product-specific bioequivalence (BE) studies to support abbreviated new drug applications (ANDAs). Under this process, applicants planning to carry out such studies in support of their ANDAs are able to access BE study guidance on the FDA Web site. FDA believes that making this information available on the Internet will streamline the guidance process and will provide a meaningful opportunity for the public to consider and comment on product-specific BE study recommendations.

**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:** Doan T. Nguyen, Center for Drug Evaluation and Research (HFD-600),

Food and Drug Administration, 7519 Standish Pl., Rockville, MD 20855, 240-276-9314.

#### **SUPPLEMENTARY INFORMATION:**

##### **I. Background**

FDA is announcing the availability of a guidance for industry entitled "Bioequivalence Recommendations for Specific Products." This guidance describes a new process for making available recommendations on how to design product-specific BE studies to support ANDAs. Under this process, draft and final BE recommendations are posted on FDA's Web site (<http://www.fda.gov/Drugs/Guidance/ComplianceRegulatoryInformation/Guidances/default.htm>, Individual Product Bioequivalence Recommendations) and announced periodically in the **Federal Register**. For draft BE recommendations, the **Federal Register** notice will identify a comment period. The public is encouraged to submit comments on the draft BE recommendations, and the agency will consider received comments in developing final BE recommendations. FDA adopted this process as a means to develop and disseminate product-specific BE recommendations and provide an opportunity for the public to consider and comment on those recommendations.

In the **Federal Register** of May 31, 2007 (72 FR 30388), FDA announced the availability of a draft version of this guidance entitled "Bioequivalence Recommendations for Specific