

If deviations from your written policies or standard commercial sales practices disclosed in the chart on the Commercial Sales Practices Format are so significant and/or frequent that the Contracting Officer cannot establish whether the price(s) offered is fair and reasonable, then you may be asked to provide additional information. The Contracting Officer may ask for information to demonstrate that you have made substantial sales of the item(s) in the commercial market consistent with the information reflected on the chart on the Commercial Sales Practice Format, a description of the conditions surrounding those sales deviations, or other information that may be necessary in order for the Contracting Officer to determine whether your offered price(s) is fair and reasonable. In cases where additional information is requested, the Contracting Officer will target the request in order to limit the submission of data to that needed to establish the reasonableness of the offered price.

(End of White Paper)

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Solicitation of Nominations for Membership on the Secretary's Advisory Committee on Human Research Protections

AGENCY: Department of Health and Human Services, Office of the Secretary, Office of Public Health and Science.

ACTION: Notice.

Authority: 42 U.S.C. 217a, section 222 of the Public Health Service Act, as amended. The committee is governed by the provisions of Public Law 92-463, as amended (5 U.S.C. Appendix 2), which sets forth standards for the formation and use of advisory committees.

SUMMARY: The Office for Human Research Protections (OHRP), a program office in the Office of Public Health and Science, Department of Health and Human Services (HHS), is seeking nominations of qualified candidates to be considered for appointment as members of the Secretary's Advisory Committee on Human Research Protections (SACHRP). SACHRP provides advice and recommendations to the Secretary, HHS, and the Assistant Secretary for Health on matters pertaining to the continuance and improvement of functions within the authority of HHS directed toward protections for human subjects in research. SACHRP was established by the Secretary, HHS, on October 1, 2002. OHRP is seeking nominations of qualified candidates to fill three positions on the Committee membership that will become vacant on January 1, 2006.

DATES: Nominations for membership on the Committee must be received no later than 5 p.m. EST on October 1, 2005, at the address listed below.

ADDRESSES: Nominations should be mailed or delivered to: Dr. Bernard

Schwetz, Director, Office for Human Research Protections, Department of Health and Human Services, 1101 Wootton Parkway, Suite 200; Rockville, MD 20852. Nominations will not be accepted by e-mail or by facsimile.

FOR FURTHER INFORMATION CONTACT: Ms. Catherine Slatinshek, Executive Director, SACHRP, Office for Human Research Protections, 1101 Wootton Parkway, Suite 200, Rockville, MD 20852. Telephone: 1-240-453-6900. A copy of the Committee charter and list of the current membership can be obtained by contacting Ms. Slatinshek or by accessing the SACHRP Web site at <http://www.hhs.gov/ohrp/sachrp>, or requesting via e-mail at sachrp@osophs.dhhs.gov.

SUPPLEMENTARY INFORMATION: The Committee shall advise on matters pertaining to the continuance and improvement of functions within the authority of HHS directed toward protections for human subjects in research. Specifically, the committee will provide advice relating to the responsible conduct of research involving human subjects with particular emphasis on: Special populations, such as neonates and children, prisoners, and the decisionally impaired; pregnant women, embryos, and fetuses; individuals and populations in international studies; populations in which there are individually identifiable samples, data, or information; and investigator conflicts of interest.

In addition, the Committee is responsible for reviewing selected ongoing work and planned activities of the OHRP and other offices/agencies within HHS responsible for human subjects protection. These evaluations may include, but are not limited to, a review of assurance systems, the application of minimal research risk standards, the granting of waivers, education programs sponsored by OHRP, and the ongoing monitoring and oversight of institutional review boards and the institutions that sponsor research.

Nominations: The Office for Human Research Protections is requesting nominations to fill three positions for voting members of SACHRP. The positions will become vacant on January 1, 2006. Nominations of potential candidates for consideration are being sought from a wide array of fields, including, but not limited to: public health and medicine; behavioral and social sciences; health administration; biomedical ethics. To qualify for consideration of appointment to the Committee, an individual must possess demonstrated experience and expertise in any of the several disciplines and fields pertinent to human subjects protection and/or clinical research.

The individuals selected for appointment to the Committee will serve as voting members. The individuals selected for appointment to the Committee can be invited to serve a term of up to four years. Committee members receive a stipend for attending Committee meetings and conducting other business in the interest of the Committee, including per diem and reimbursement for travel expenses incurred.

Nominations should be typewritten. The following information should be included in the package of material submitted for each individual being nominated for consideration: (1) A letter of nomination that clearly states the name and affiliation of the nominee, the basis for the nomination (*i.e.*, specific attributes which qualify the nominee for service in this capacity), and a statement that the nominee is willing to serve as a member of the Committee; (2) the nominator's name, address and daytime telephone number, and the home and/or work address, telephone number, and email address of the individual being nominated; and (3) a current copy of the nominee's curriculum vitae. The names of Federal employees should not be nominated for consideration of appointment to this Committee.

The Department makes every effort to ensure that the membership of HHS Federal advisory committees is fairly balanced in terms of points of view

represented and the committee's function. Every effort is made to ensure that a broad representation of geographic areas, females, ethnic and minority groups, and the disabled are given consideration for membership on HHS Federal advisory committees. Appointment to this Committee shall be made without discrimination on the basis of age, race, ethnicity, gender, sexual orientation, disability, and cultural, religious, or socioeconomic status.

Nominations must state that the nominee is willing to serve as a member of SACHRP and appears to have no conflict of interest that would preclude membership. Potential candidates are required to provide detailed information concerning such matters as financial holdings, consultancies, and research grants or contracts to permit evaluation of possible sources of conflict of interest.

Dated: August 16, 2005.

Bernard A. Schwetz,

Director, Office for Human Research Protections, Executive Secretary, Secretary's Advisory Committee on Human Research Protections.

[FR Doc. 05-16506 Filed 8-19-05; 8:45 am]

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. 2005N-0311]

Critical Path Initiative; Developing Prevention Therapies; Planning of Workshop; Correction

AGENCY: Food and Drug Administration, HHS.

ACTION: Request for comments; correction.

SUMMARY: The Food and Drug Administration is correcting a notice that appeared in the **Federal Register** of August 3, 2005 (70 FR 44660). The document announced the planning of a workshop as part of its Critical Path Initiative and requested comments. The document was published with an incorrect docket number. This document corrects that error.

FOR FURTHER INFORMATION CONTACT:

Joyce Strong, Office of Policy and Planning (HF-27), Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857, 301-827-7010.

SUPPLEMENTARY INFORMATION: In FR Doc. 05-15282, appearing on page 44660 in the **Federal Register** of Wednesday, August 3, 2005, the following correction is made:

1. On page 44660, in the second column, in the headings section of the document, "[Docket No. 2004N-0355]" is corrected to read "[Docket No. 2005N-0311]".

Dated: August 12, 2005.

Jeffrey Shuren,

Assistant Commissioner for Policy.

[FR Doc. 05-16504 Filed 8-19-05; 8:45 am]

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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, 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: Application for Certification and Recertification as a Federally Qualified Health Center (FQHC) Look-Alike (OMB No. 0915-0142): Extension

HRSA proposes to extend the application guide used by organizations applying for certification or recertification as a Federally Qualified Health Center (FQHC) Look-Alike for purposes of cost-based reimbursement under the Medicaid and Medicare programs. The requirements described in the application guide are for health centers that serve a population that is medically underserved as defined in section 330 of the Public Health Service (PHS) Act. The estimated burden is as follows:

Form	Number of respondents	Responses per respondent	Hours per response	Total Burden Hours
Application	40	1	100	4,000
Recertification	100	1	15	1,500
Total	140	5,500

Comments and recommendations concerning the proposed information collection should be sent within 30 days of this notice to: John Kraemer, Human Resources and Housing Branch, Office of Management and Budget, New Executive Office Building, Room 10235, Washington, DC 20503.

Dated: August 15, 2005.

Tina M. Cheatham,

Director, Division of Policy Review and Coordination.

[FR Doc. 05-16503 Filed 8-19-05; 8:45 am]

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Health Resources and Services Administration

Advisory Commission on Childhood Vaccines; Notice of Meeting

In accordance with section 10(a)(2) of the Federal Advisory Committee Act (Pub. L. 92-463), notice is hereby given of the following meeting: