

Dated: July 2, 2004.

**Jeffrey Shuren,**

*Assistant Commissioner for Policy.*

[FR Doc. 04-15711 Filed 7-9-04; 8:45 am]

BILLING CODE 4160-01-S

## DEPARTMENT OF HEALTH AND HUMAN SERVICES

### Food and Drug Administration

[Docket No. 1999E-5116]

#### Determination of Regulatory Review Period for Purposes of Patent Extension; XOPENEX

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

**ACTION:** Notice.

**SUMMARY:** The Food and Drug Administration (FDA) has determined the regulatory review period for XOPENEX and is publishing this notice of that determination as required by law. FDA has made the determination because of the submission of an application to the Director of Patents and Trademarks, Department of Commerce, for the extension of a patent that claims that human drug product.

**ADDRESSES:** Submit written comments and petitions 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.fda.gov/dockets/ecomments>.

**FOR FURTHER INFORMATION CONTACT:** Claudia V. Grillo, Office of Regulatory Policy (HFD-013), Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857, 240-453-6699.

**SUPPLEMENTARY INFORMATION:** The Drug Price Competition and Patent Term Restoration Act of 1984 (Public Law 98-417) and the Generic Animal Drug and Patent Term Restoration Act (Public Law 100-670) generally provide that a patent may be extended for a period of up to 5 years so long as the patented item (human drug product, animal drug product, medical device, food additive, or color additive) was subject to regulatory review by FDA before the item was marketed. Under these acts, a product's regulatory review period forms the basis for determining the amount of extension an applicant may receive.

A regulatory review period consists of two periods of time: A testing phase and an approval phase. For human drug products, the testing phase begins when the exemption to permit the clinical investigations of the drug becomes effective and runs until the approval

phase begins. The approval phase starts with the initial submission of an application to market the human drug product and continues until FDA grants permission to market the drug product. Although only a portion of a regulatory review period may count toward the actual amount of extension that the Director of Patents and Trademarks may award (for example, half the testing phase must be subtracted, as well as any time that may have occurred before the patent was issued), FDA's determination of the length of a regulatory review period for a human drug product will include all of the testing phase and approval phase as specified in 35 U.S.C. 156(g)(1)(B).

FDA recently approved for marketing the human drug product XOPENEX (levulbuterol). XOPENEX is indicated for the treatment or prevention of bronchospasm in adults, adolescents, and children 6 years of age or older with reversible obstructive airway disease. Subsequent to this approval, the Patent and Trademark Office received a patent term restoration application for XOPENEX (U.S. Patent No. 5,362,755) from Sepracor, Inc., and the Patent and Trademark Office requested FDA's assistance in determining this patent's eligibility for patent term restoration. In a letter dated December 30, 2002, FDA advised the Patent and Trademark Office that this human drug product had undergone a regulatory review period and that the approval of XOPENEX represented the first permitted commercial marketing or use of the product. Thereafter, the Patent and Trademark Office requested that FDA determine the product's regulatory review period.

FDA has determined that the applicable regulatory review period for XOPENEX is 1,458 days. Of this time, 824 days occurred during the testing phase of the regulatory review period, while 634 days occurred during the approval phase. These periods of time were derived from the following dates:

1. The date an exemption under section 505(i) of the Federal Food, Drug, and Cosmetic Act (the act) (21 U.S.C. 355(i)) became effective: March 30, 1995. The applicant claims February 28, 1995, as the date the investigational new drug application (IND) became effective. However, FDA records indicate that the IND effective date was March 30, 1995, which was 30 days after FDA receipt of the IND.

2. The date the application was initially submitted with respect to the human drug product under section 505(b) of the act: June 30, 1997. FDA has verified the applicant's claim that the new drug application (NDA) for

XOPENEX (NDA 20-837) was initially submitted on June 30, 1997.

3. The date the application was approved: March 25, 1999. FDA has verified the applicant's claim that NDA 20-837 was approved on March 25, 1999.

This determination of the regulatory review period establishes the maximum potential length of a patent extension. However, the U.S. Patent and Trademark Office applies several statutory limitations in its calculations of the actual period for patent extension. In its application for patent extension, this applicant seeks 502 days of patent term extension.

Anyone with knowledge that any of the dates as published is incorrect may, submit to the Division of Dockets Management (see **ADDRESSES**) written or electronic comments and ask for a redetermination by September 10, 2004. Furthermore, any interested person may petition FDA, for a determination regarding whether the applicant for extension acted with due diligence during the regulatory review period by January 10, 2005. To meet its burden, the petition must contain sufficient facts to merit an FDA investigation. (See H. Rept. 857, part 1, 98th Cong., 2d sess., pp. 41-42, 1984.) Petitions should be in the format specified in 21 CFR 10.30.

Comments and petitions should be submitted to the Division of Dockets Management. Three copies of any mailed information are to be submitted, except that individuals may submit one copy. Comments are to be identified with the docket number found in brackets in the heading of this document. Comments and petitions may be seen in the Division of Dockets Management between 9 a.m. and 4 p.m., Monday through Friday.

Dated: June 21, 2004.

**Jane A. Axelrad,**

*Associate Director for Policy, Center for Drug Evaluation and Research.*

[FR Doc. 04-15712 Filed 7-9-04; 8:45 am]

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## DEPARTMENT OF HEALTH AND HUMAN SERVICES

### Health Resources and Services Administration

[CFDA Number 93.224; HRSA-05-024]

#### Fiscal Year 2005 Competitive Application Cycle for Service Area; Competition for the Consolidated Health Center Program (CHCP)

**AGENCY:** Health Resources and Services Administration, HHS.

**ACTION:** Notice of availability of funds.

**SUMMARY:** The Health Resources and Services Administration (HRSA) announces that approximately \$355,000,000 is available in fiscal year (FY) 2005 funds to promote the continued operation of community-based primary health care service systems in medically underserved areas for medically underserved populations. It is expected that each application submitted to serve one of these areas will present a clear focus on maintaining access to care and reducing health disparities identified in the target population.

Potential applicants must obtain and respond to the FY 2005 Service Area Competition guidance in order to apply for funding. This announcement does not contain sufficient information in itself to use for developing an application.

**Authorizing Legislation:** Section 330 of the Public Health Service Act, as amended (42 U.S.C. 254b).

**DATES:** The intended timelines for application submission are as follows:

Project period ending:	Application deadline
October 31, 2004 .....	Aug. 16, 2004.
November 30, 2004 .....	Aug. 16, 2004.
January 31, 2005 .....	Sept. 1, 2004.
February 28, 2005 .....	Sept. 1, 2004.
March 31, 2005 .....	Oct. 25, 2004.
May 31, 2005 .....	Jan. 3, 2005.
June 30, 2005 .....	Jan. 3, 2005.
August 31, 2005 .....	Jan. 3, 2005.

For FY 2005, applications received or postmarked by August 16, 2004, will be reviewed with funding decision announced on or about November 1, 2004. Applications received or postmarked by September 1, 2004, will be reviewed with funding decision announced on or about February 1, 2005. Applications received or postmarked by October 25, 2004, will be reviewed with funding decision announced on or about April 1, 2005. Applications received or postmarked by January 3, 2005, will be reviewed with funding decision announced on or about June 1, 2005.

Applications will be considered as meeting the deadline if they are: (1) Received on or before the established date and received in time for the Independent Committee Review; or (2) postmarked or E marked on or before the deadline date given in the **Federal Register** Notice. Late applications will be returned to the applicant. Applicants should obtain a legibly U.S. Postal Service dated postmark or a legible date receipt from a commercial carrier.

Private metered postmarks shall not be acceptable as proof of timely mailing. Applications sent to any address other than that specified below are subject to being returned.

**Application Requests:** To receive a complete application kit (*i.e.*, application instructions, necessary forms, and application review criteria), contact the HRSA Grants Application Center at: The Legin Group, Inc., The HRSA Grants Application Center, Attn: Service Area Competition, Program Announcement No: HRSA 05-024, CFDA No. 93.224, 901 Russell Avenue, Suite 450, Gaithersburg, MD 20879, Telephone: 1-877-477-2123, Fax: 1-877-477-2345, E-mail: [hrsagac@hrsa.gov](mailto:hrsagac@hrsa.gov).

When contacting the HRSA Grants Application Center (GAC), please use the following program announcement when requesting application materials: HRSA 05-024.

**Eligible Applicants:** Applicants are limited to currently funded Section 330 grantees whose project periods expire during fiscal year 2005 and public and private non-profit organizations, including faith-based and community based organizations, proposing to serve the same areas and populations being served by these existing centers. Listed below are the service areas with project periods that expire during fiscal year 2005.

Community/Migrant Health Centers, Health Care for the Homeless, Public Housing Primary Care, and School Based Health Centers

Organizations interested in these competitive opportunities are encouraged to contact the listed program officials for more information. Contact: Jack Egan 301-594-4339.

City	State	Expiration date
Hyannis .....	MA	10/31/2004
Portsmouth .....	NH	10/31/2004
Pascoag .....	RI	10/31/2004
Newark .....	NJ	10/31/2004
St. George .....	WV	10/31/2004
Harrisville .....	WV	10/31/2004
New York .....	NY	11/30/2004
White Plains .....	NY	11/30/2004
Washington .....	DC	11/30/2004
Camden-on-Gauley .....	WV	11/30/2004
Hartford .....	CT	12/31/2004
Roxbury .....	MA	12/31/2004
Lubec .....	ME	12/31/2004
Brockport .....	NY	12/31/2004
Glens Falls .....	NY	12/31/2004
Buffalo .....	NY	12/31/2004
Arrington .....	VA	12/31/2004
Richmond .....	VA	12/31/2004
Bridgeport .....	CT	01/31/2005
Provincetown .....	MA	01/31/2005

City	State	Expiration date
Turner Falls .....	MA	01/31/2005
Bronx .....	NY	01/31/2005
Mayaguez .....	PR	01/31/2005
Chester .....	PA	01/31/2005
Saltville .....	VA	01/31/2005
Fairmont .....	WV	01/31/2005
Gary .....	WV	01/31/2005
Spencer .....	WV	01/31/2005
Waterbury .....	CT	02/28/2005
Asbury Park .....	NJ	02/28/2005
Egg Harbor .....	NJ	02/28/2005
New York .....	NY	02/28/2005
Toa Alto .....	PR	02/28/2005
Hagerstown .....	MD	02/28/2005
Pittsburgh .....	PA	02/28/2005
Franklin .....	WV	02/28/2005
New Haven .....	CT	03/31/2005
New Canton .....	VA	03/31/2005
Beckley .....	WV	03/31/2005
Worcester .....	MA	03/31/2005
Mattapan .....	MA	03/31/2005
Patten .....	ME	03/31/2005
Harrington .....	ME	03/31/2005
Brooklyn .....	NY	03/31/2005
San Juan .....	PR	03/31/2005
Dover .....	DE	03/31/2005
Harrisburg .....	PA	03/31/2005
Coalport .....	PA	03/31/2005
Boston .....	MA	05/31/2005
Worthington .....	MA	05/31/2005
Worcester .....	MA	05/31/2005
Quincy .....	MA	05/31/2005
Lawrence .....	MA	05/31/2005
Schenectady .....	NY	05/31/2005
Philadelphia .....	PA	05/31/2005
Onancock .....	VA	05/31/2005
Dungannon .....	VA	05/31/2005
Laurel Fork .....	VA	05/31/2005
Burlington .....	VT	06/30/2005
Arroyo .....	PR	06/30/2005
Wilmington .....	DE	06/30/2005
Baltimore .....	MD	06/30/2005
Brandywine .....	MD	06/30/2005
Portsmouth .....	VA	06/30/2005
Man .....	WV	06/30/2005

Contact: Jerri Regan, 301-594-4283.

City	State	Expiration date
Port St. Joe .....	FL	10/31/2004
Talbot .....	TN	10/31/2004
Pittsburgh .....	KS	10/31/2004
Mantachie .....	MS	11/30/2004
Tylertown .....	MS	11/30/2004
Dade City .....	FL	11/30/2004
Vancebury .....	KY	11/30/2004
Boone .....	NC	11/30/2004
Ft. Myers .....	FL	12/31/2004
W. Palm Beach ..	FL	12/31/2004
Junction City .....	KS	12/31/2004
Cape Girardeau ..	MO	12/31/2004
Montgomery .....	AL	01/31/2005
Trenton .....	GA	01/31/2005
Newport .....	KY	01/31/2005
Brandon .....	MS	01/31/2005
Liberty .....	MS	01/31/2005
Clairfield .....	TN	01/31/2005
Des Moines .....	IA	01/31/2005
St. Louis .....	MO	01/31/2005
Jackson .....	MS	02/28/2005
Washington .....	NC	02/28/2005

City	State	Expiration date
Jackson	NC	02/28/2005
Sumter	SC	02/28/2005
Columbus	NE	02/28/2005
Tuskegee	AL	03/31/2005
Troy	AL	03/31/2005
Sumterville	FL	03/31/2005
W. Palm Beach	FL	03/31/2005
Whitesburg	KY	03/31/2005
Meridian	MS	03/31/2005
Hendersonville	NC	03/31/2005
Raleigh	NC	03/31/2005
Charlotte	NC	03/31/2005
Conway	SC	03/31/2005
Maynardville	TN	03/31/2005
New Madrid	MO	03/31/2005
Selma	AL	05/31/2005
Mobile	AL	05/31/2005
Atlanta	GA	05/31/2005
Canton	MS	05/31/2005
Port Gibson	MS	05/31/2005
Shubuta	MS	05/31/2005
Durham	NC	05/31/2005
Greenwood	SC	05/31/2005
Des Moines	IA	05/31/2005
Ellington	MO	05/31/2005
Wrightsville	GA	06/30/2005
Greenville	KY	06/30/2005
Bolivar	TN	06/30/2005
Shawnee	KS	06/30/2005

Contact: Lisa Tonrey, 301-594-1327.

City	State	Expiration date
Battle Creek	MI	10/31/2004
Bismarck	ND	10/31/2004
Cheyenne	WY	10/31/2004
Portland	OR	10/31/2004
Seattle	WA	10/31/2004
Toledo	OH	11/30/2004
Akron	OH	11/30/2004
Chicago	IL	11/30/2004
Anchorage	AK	11/30/2004
Chicago	IL	12/31/2004
E. St. Louis	IL	12/31/2004
Cleveland	OH	12/31/2004
Cincinnati	OH (2)	12/31/2004
Lisbon	OH	12/31/2004
Lamar	CO	12/31/2004
Salt Lake City	UT	12/31/2004
Anna	IL	01/31/2005
Marquette	MI	01/31/2005
Kalamazoo	MI	01/31/2005
Moorehead	MN	01/31/2005
Norwood	CO	01/31/2005
Butte	MT	01/31/2005
Anderson	IN	02/28/2005
Muskegon	MI	02/28/2005
Jackson	MI	02/28/2005
Duluth	MN	02/28/2005
Minneapolis	MN	02/28/2005
Chinook	MT	02/28/2005
Pierre	SD	02/28/2005
Saginaw	MI	03/31/2005
Traverse City	MI	03/31/2005
Sterling	MI	03/31/2005
Temperance	MI	03/31/2005
Freemont	OH	03/31/2005
Wild Rose	WI	03/31/2005
Milwaukee	WI	03/31/2005
Greeley	CO	03/31/2005
Isabel	SD	03/31/2005

City	State	Expiration date
Casper	WY	03/31/2005
Cornelius	OR	03/31/2005
Wenatchee	WA	03/31/2005
Seattle	WA	03/31/2005
Kent	WA	03/31/2005
Chicago	IL	05/31/2005
Lincoln	MI	05/31/2005
Grand Marais	MN	05/31/2005
Cook	MN	05/31/2005
Ft. Lupton	CO	05/31/2005
Glenns Ferry	ID	05/31/2005
Medford	OR	05/31/2005
Lafayette	IN	06/30/2005
Ft. Wayne	IN	06/30/2005
Battle Creek	MI	06/30/2005
Minneapolis	MN	06/30/2005
Cashton	WI	06/30/2005
Boulder	CO	06/30/2005
Bicknell	UT	06/30/2005
Sitka	AK	06/30/2005
Fairbanks	AK	06/30/2005
Pocatello	ID	06/30/2005
Plummer	ID	06/30/2005
Cave Junction	OR	06/30/2005
Tillamook	OR	06/30/2005

Contact: Rashad Al Mahdaoui, 301-594-4335.

City	State	Expiration date
Hulbert	OK	10/31/2004
Houston	TX	10/31/2004
Prescott	AZ	10/31/2004
Sacramento	CA	10/31/2004
San Mateo	CA	10/31/2004
Humboldt	CA	10/31/2004
Los Angeles	CA	10/31/2004
Gonzales	TX	11/30/2004
Phoenix	AZ	11/30/2004
San Fernando	CA	11/30/2004
Madera	CA	11/30/2004
San Mateo	CA	11/30/2004
Los Angeles	CA	11/30/2004
Augusta	AR	12/31/2004
Hidalgo	TX	12/31/2004
Houston	TX	12/31/2004
Marana	AZ	12/31/2004
San Francisco	CA	12/31/2004
Union City	CA	12/31/2004
Bloomington	CA	12/31/2004
Pohnpei	FM	12/31/2004
Greenville	TX	01/31/2005
San Antonio	TX	01/31/2005
Pleasanton	TX	01/31/2005
San Francisco	CA	01/31/2005
Porterville	CA	01/31/2005
Luling	LA	02/28/2005
Ft. Sumner	NM	02/28/2005
River Ridge	LA	02/28/2005
Los Angeles	CA (2)	02/28/2005
Ft. Bragg	CA	02/28/2005
Torrance	CA	02/28/2005
Honokaa	HI	02/28/2005
La Marque	TX	03/31/2005
Port Arthur	TX	03/31/2005
Laredo	TX	03/31/2005
Cotulla	TX	03/31/2005
San Antonio	TX	03/31/2005
San Jose	CA	03/31/2005
San Francisco	CA	03/31/2005
Oakland	CA	03/31/2005

City	State	Expiration date
Agana	GU	03/31/2005
Honolulu	HI	03/31/2005
New Iberia	LA	05/31/2005
Konawa	OK	05/31/2005
Levelland	TX	05/31/2005
Olivehurst	CA	05/31/2005
Susanville	CA	05/31/2005
El Rito	NM	06/30/2005
Waco	TX	06/30/2005
San Joaquin	CA	06/30/2005
Kahului	HI	06/30/2005
Reno	NV	06/30/2005
Elfrido	AZ	06/30/2005
Monroe	LA	08/31/2005
San Diego	CA	08/31/2005

**Application Review and Funding Criteria:** The following Review Criteria will be used by the Independent Review Committee (IRC) to evaluate the merits of the proposed plan presented in each SAC application.

The seven (7) Review Criteria for the SAC funding opportunity and maximum points awarded

**Criterion 1: Need (10 Points)**

1. Applicant describes the service area(s)/community(ies) being served, including:

(a) The service area population, *i.e.* urban, rural, sparsely populated [7 people or less per square mile].

(b) The counties, census tracts, minor civil divisions, schools/school districts, etc., (as appropriate) in the service area.

(c) Any Medically Underserved Areas (MUAs), Medically Underserved Populations (MUPs), High Impact Areas, and Health Professional Shortage Areas (HPSAs), as applicable.

2. Applicant describes the target population(s) (*e.g.*, general community members, migrant/seasonal agricultural workers, residents of public housing, homeless persons, low-income school children, etc.) within the service area/community, including:

(a) The unserved and underserved populations in the community, including any other populations that are in need of access to primary health care (*e.g.*, elderly population, immigrant population, migrant/seasonal farmworkers, homeless populations, residents of public housing, low-income school children/adolescents and their families, etc.).

(b) The unique demographic characteristics of the target population (*e.g.*, age, gender, insurance status, unemployment, poverty level, ethnicity/culture, education, etc.).

(c) The relevant access to care and health status indicators of the target population/community.

3. Applicant identifies how many people are currently being served by the

organization. Applicant also discusses how many will be served and the number of projected encounters that will be generated through the proposed project. This information should be consistent with the information presented on Form 1-A: General Information Worksheet.

4. Applicant identifies and describes the most significant barriers to care, gaps in services, significant health disparities and the major health care problems in the community. This should include a description of:

(a) Any culturally specific characteristics that impact access to and the delivery of health care services.

(b) Any relevant geographic barriers to care and other factors impacting access to care.

(c) Any major and/or unique health care needs of the target population(s). (The Health Care and Business Plans should present goals and measurable, time-framed objectives to address the identified needs.)

5. Applicant demonstrates and understanding of the most common causes of mortality, and the incidence and prevalence of chronic and infectious diseases in the target population.

6. Applicant describes any significant changes over the past year in the service area or population being served (*i.e.*, influx of refugee population, or closing of local factory, etc.) impacting on the need for services. This should include a description of any significant changes for each target population type served (*i.e.*, CHC, MHC, HCH, PHPC, and/or SBHC).

7. Applicant identifies any health care providers of care (including all other FQHCs and section 330 grantees), resources and/or services of other public and private organizations within the proposed service area that are providing care to the target population(s). The applicant should also evaluate the effectiveness of available resources and/or services in providing care to the target community/population.

8. Applicant demonstrates a thorough understanding of the health care environment including:

(a) The impact in the State of the implementation of SCHIP, 1115 and 1915(b) waivers, State Medicaid prospective payment system; Medicaid managed care, State laws, current and proposed welfare reform initiatives, etc.;

(b) The impact that these changes have had on the access to services or demand for services among the target population(s), on the ability to respond to patient demand, and/or on the fiscal stability of the organization;

*In addition to the above, applicants requesting funding for one or more types of health centers authorized under the section 330 program, should also address the following:*

*For MHC Applicants*

(a) Applicant describes the major agricultural environment, the crops and growing seasons, including a discussion of any impact on the demand for services among migrant and seasonal farmworkers (*e.g.*, the need for hand labor or the number of temporary workers, etc.).

*For HCH Applicants*

(a) Applicant describes the availability of housing in the community and the impact of this and other factors on the demand for services among homeless individuals and families.

*For PHPC Applicants*

(a) Applicant describes any recent changes in the availability of public housing to serve area residents and the impact on the demand for services among residents in the targeted public house communities served.

*For SBHC Applicants*

(a) Applicant describes any changes to the number or type of students enrolled in the targeted schools and the impact on the demand for services in these locations.

**Criterion 2: Response (20 Points)**

1. Applicant describes the proposed service delivery model (*e.g.*, freestanding, single or multi-site, migrant voucher, mobile site, school-based location, or combination), and locations/settings where services are provided. Applicant should include a discussion of how services will be provided at each proposed service site (*e.g.* via contract, referral system, etc.) and access problems the model would address and resolve.

2. Applicant demonstrates that the proposed model is most appropriate and responsive to the identified community health care needs (*i.e.*, the service delivery plan addresses the priority health and social problems of the target population(s) for all the major life cycles).

3. Applicant demonstrates that the required primary, preventive and supplemental health services (*e.g.*, enabling services, eligibility assistance, outreach, and transportation) will be available and accessible to all lifecycles of the target population either directly on-site or through established

arrangements without regard to ability to pay.

4. Applicant demonstrates a clear and defined plan for providing oral health care that assures availability and accessibility to the target population either directly on-site or through established arrangements (*e.g.*, contract, referral, etc.) without regard to ability to pay.

5. Applicant demonstrates a clear and defined plan for providing mental health care and substance abuse services that assures availability and accessibility to the target population either directly on-site or through established arrangements (*e.g.*, contract, referral, etc.) without regard to ability to pay.

6. Applicant addresses the chronic disease incidences within the target population, and participation in a formal disease/care management and system improvement program, such as the BPHC-supported or sponsored Health Disparities Collaborative.

7. Applicant describes and demonstrates that the services will be culturally and linguistically appropriate.

8. Applicant demonstrates comprehensiveness and continuity of care, including a discussion of the following:

(a) Hours of operation that assure services are available and accessible at times meeting the needs of the population including evenings and weekends as appropriate;

(b) Mechanism to assure professional coverage during the hours when the health center is closed;

(c) Performance improvement system that includes eliminating disparities in health outcomes, reducing patient risk, improving patient satisfaction, credentialing and privileging, incident reporting, etc., that integrates planning, management, leadership and governance into the evaluation processes of program effectiveness; and

(d) Case management system that demonstrates care coordination at all levels of health care, including arrangements for referrals, hospital admissions discharge planning and patient tracking.

9. Applicant demonstrates collaboration and coordination of services with other providers including other existing FQHCs and section 330 grantees in the area (*e.g.* contracts, MOUs, letters of support, etc.)

10. Applicant discusses the extent to which project activities are coordinated and integrated with the activities of other federally-funded, State and local health services delivery projects and programs serving the same

population(s). This should include a description of both formal and informal collaborative and partner arrangements, which assure a seamless continuum of care and access to appropriate specialty care for the target population(s). Applicant should have provided copies of relevant contracts, MOUs, letters of commitment or investment (e.g., from the school board, local hospital, public health department, etc.), as part of the application attachments.

11. Applicant demonstrates that the proposed clinical staffing pattern (e.g., number and mix of primary care physicians and other providers and clinical support staff, language and cultural appropriateness, etc.) is appropriate for the level and mix of services to be provided.

12. Applicant describes a detailed plan for recruiting and retaining appropriate health care providers as appropriate for achieving the proposed staffing pattern.

*In addition to the above, applicants requesting funding for one or more types of health centers authorized under the section 330 program, should also address the following:*

*For MHC Applicants*

(a) Applicant describes the response to health care needs associated with the environmental and/or occupational hazards to which farmworkers and their families are exposed, and how these needs will be met.

(b) Applicant describes the setting(s) in which health and enabling services will be provided, i.e., special arrangements to provide services at camps and/or farms; use of mobile teams and/or vans; extended hours/ weekend services; etc.

(b) Applicant describes an outreach program that will increase access to primary and preventive health care services and how the outreach program is integrated into the primary care delivery system.

*For HCH Applicants*

(a) Applicant describes the arrangements for providing required substance abuse services.

(b) Applicant demonstrates the mechanism for informing homeless people of the availability of services and the features of its outreach program.

(c) Applicant describes the coordination of services with providers of housing, job training, and other essential supports for persons who are homeless. The applicant must also describe its relationship with homeless coalitions, advocacy groups, and the existing continuum of care organizations in their community.

(d) Applicant describes the nature and scope of its expanded case management services.

*For PHPC Applicants*

(a) Applicant provides documentation that the location of the service site(s) is (are) in or directly adjacent to the public housing community(ies) being targeted.

(b) Applicant provides a formal agreement with the local public housing authority that demonstrates access to on-site space, where applicable.

(c) Applicant describes how residents will be involved in the administration of the program.

*For SBHC Applicants*

(a) Applicant provides evidence of on-site care through established arrangements with the school staff and providers (e.g., school nurse, school psychologist, etc.) when applicable.

(b) Applicant provides documentation of access to health care during the summer and other times when the school is closed (e.g. vacations, weekends).

(c) Applicant provides written documentation of an agreement with the school system to permit access to the school facility for the SBHC should be included.

**Criterion 3: Evaluative Measures (5 Points)**

1. Applicant demonstrates the ability to monitor the quality and outcomes of the services provided (e.g., adequate management information systems, established quality assurance program, patient feedback).

2. Applicant demonstrates the ability to evaluate the quality and outcomes of the services provided including an evaluation plan that includes specific time framed, measurable outcomes and clear methods/action steps.

3. Applicant describes the mechanism(s) by which the organization identifies and responds to the community and its needs (e.g., patient surveys, needs assessments).

4. Applicant demonstrates a performance improvement system that includes eliminating disparities in health outcomes, reducing patient risk, improving patient satisfaction, credentialing and privileging, incident reporting, etc., that integrates planning, management, leadership and governance into the evaluation processes of program effectiveness.

5. Applicant demonstrates through the health care plan that both goals and time-framed, measurable objectives are in place that address the identified needs and disparities of the target population.

6. Applicant demonstrates through the Business Plan that operational issues will be addressed and that the administrative, financial and clinical systems are appropriate for the proposed project.

7. Applicant discusses any issues identified in the Notice of Grant Award (NGA), Primary Care Effectiveness Review (PCER), Office of Performance Review (OPR) or Joint Commission on Accreditation of Healthcare Organizations (JCAHO) reviews, pre-application guidance letter (PAGL) or other findings, as applicable. This should include a discussion of the organization's response to the listed findings.

**Criterion 4: Impact (15 Points)**

1. Applicant describes the organization's role and relationships within the community including: (a) How the organization fits into the community and its service delivery network; (b) The role of clients, community, staff and Board of Directors in establishing and evaluating the organization's objectives and priorities; and (c) Partnerships and collaborations with other providers in the community.

2. Applicant demonstrates and provides evidence of the community's support for the organization. Letters of support and MOUs and/or a list of additional letters of commitment, MOUs, etc. on file at the health center, as appropriate should be included in the Appendices.

3. Applicant discusses the extent to which the proposed health center will address the priority health care needs, improve access to primary health care services and reduce health disparities for the medically underserved in the community/target population(s).

4. Applicant describes how the proposed project correlates to the goals and objectives of the Healthy People 2010 initiative, specifically to (1) increase the quality and years of a healthy life; and (2) eliminate our country's health disparities.

5. Applicant describes the goals and objectives of the existing project (i.e. existing approved "Scope of Project" for existing grantees). This should include a discussion of outcomes, both positive and negative, or unanticipated issues that may be important, and the organization's response.

6. Applicant discusses the short- and long-term strategic planning process including any proposed plans for future activities such as plans to expand into new areas, and how such activities will be integrated into the current service delivery system.

In addition to the above, applicants requesting funding for one or more types of health centers authorized under the section 330 program, should also address the following:

*For MHC Applicants*

(a) Applicant discusses any network of care for migrant health. This should include a discussion of linkages (e.g., MOAs, MOUs, contracts, etc.) with other migrant health organizations such as Migrant Education, Migrant Head Start, and Migrant WIC programs. Copies of appropriate signed agreements, contracts, etc should have been submitted in the Appendix.

*For HCH Applicants*

(a) Applicant documents the relationship with housing providers and other local organizations that provide services and support to homeless persons. (b) Applicant documents the degree of participation in community-wide planning on behalf of homeless persons through participation with the local continuum of care or other entities.

*For PHPC Applicants*

(a) Applicant documents the relationship with the local public housing authority and with public housing resident groups within the community.

**Criterion 5: Resources/Capabilities (30 Points)**

1. Applicant discusses why it is the appropriate entity to receive funding (e.g. staff skills, capacity, clinical outcomes, cultural and linguistic competence, evaluation capabilities, etc.).

2. Applicant discusses the history and status as a designated Federally Qualified Health Center, where applicable, including eligibility for malpractice coverage under the Federal Tort Claims Act, and years of uninterrupted services to the target area and populations.

3. Applicant demonstrates how the structure, management system and lines of authority are appropriate and adequate for the size and scope of the proposed project.

4. Applicant demonstrates that the organization structure (including sponsorship or corporate affiliation, etc.) is in compliance with 330 requirements and appropriate for the proposed project.

5. Applicant demonstrates that the proposed staffing plan is appropriate and adequate given the scope of the proposed project.

6. Applicant demonstrates that the key management staff (e.g. CEO, CFO, CMO) of the health center are appropriate and that the process for hiring key management staff is in accordance with Health Center Program Expectations. This should include a description of any specific leadership for each health center type (i.e. CHC, MHC, HCH, PHPC or SBHC) as applicable.

7. Applicant describes any key management staff changes during the last year, and/or any long-term vacancy, as applicable.

8. Applicant describes the current facility(ies), and demonstrates that it is appropriate for the proposed service delivery plan.

9. Applicant identifies unique characteristics and significant accomplishments of the organization.

10. Applicant describes prior experiences and expertise in:

(a) Working with the target population(s);

(b) Addressing the identified health care needs; and

(c) Developing and implementing appropriate systems and services to meet the needs of the community.

11. Applicant identifies any section 330 funding received over the last five years, including participation in any special initiatives (e.g., integrated service network, dental pilot, etc.) and urgent supplemental funds and/or funds received from other related Federal programs such as Healthy Start, Housing and Urban Development Homeless resources, etc.

12. Applicant demonstrates financial viability and accounting and internal controls in accord with sound financial management procedures that are appropriate to the size of the organization, funding requirements, and staff skills available.

**Criterion 6: Support Requested (10 Points)**

1. Applicant demonstrates that the budget presentation (an annualized budget for each 12 month period for which funding is requested of the new project period) is appropriate and reasonable in terms of:

(a) The level of requested Federal grant funds versus total budget for each year;

(b) The total resources required to achieve the goals and objectives of the applicant's proposed service delivery plan (i.e., total project budget);

(c) The maximization of non-grant revenue relative to the proposed plan and other Federal/State/local/in-kind resources applied to the project;

(d) The projected patient income is reasonable based on the patient mix and number of projected users and encounters;

(e) The number of proposed users and encounters;

(f) The total cost per user and encounter;

(g) The total Federal section 330 grant dollars per user.

2. Applicant demonstrates that the Federal grant funds requested are being used to leverage other sources of funding.

3. Applicant demonstrates that the business plan goals and objectives are targeted and demonstrate appropriate financial planning in the development of the proposal and for the long-term success of the project.

4. Applicant describes how the proposed health center is a cost-effective approach to meeting the primary care needs of the target population given the health care needs of the target population and the level of health care resources currently available in the community.

**Criteria 7: Governance (10 Points)**

Applicants must provide a copy of the signed bylaws demonstrating compliance with and reflecting all functions and responsibilities cited in section 330, as appropriate.

1. Applicant describes the structure of the Board in terms of size, expertise, and representativeness of the communities/populations served (e.g. appropriate racial/ethnic, economic status, and gender representation, 51% consumer majority, etc.).

2. Applicant discusses measures for assuring that the Board is compliant with appropriate and applicable regulations and BPHC guidance.

3. Applicant discusses the mechanism of continued Board training, including training new governing board members in appropriate responsibilities and requirements of the Federal grant.

4. Applicant describes the provision for ensuring monthly meetings of the Board or an alternate mechanism if a waiver is requested.

5. Applicant describes the mechanism for quality assurance, including a mechanism to evaluate Board effectiveness.

6. Applicant demonstrates that the Board has appropriate oversight responsibilities, specifically the responsibility to:

(a) Directly employ, select/dismiss and evaluate the CEO/Executive Director;

(b) Adopt policies and procedures for personnel and financial management;

(c) Establish center priorities and activities;

- (d) Approve annual budget; and
- (e) Schedule hours of operation.

*In addition to the above, applicants requesting funding for one or more types of health centers authorized under the section 330 program, should also address the following:*

*HCH, PHPC, and MHC Applicants*

(a) All HCH, PHPC and/or MHC applicants that are also requesting CHC and/or SBHC funding must demonstrate that at least one member of its Board is representative of the special population.

(b) Applicant clearly identifies a request for a waiver of governance requirements, if applicable.

*Estimated Amount of Available Funds:* Up to \$355,000,000 will be available in fiscal year 2005 for this program.

*Estimated Project Period:* Up to 5 Years.

*Estimated Number of Awards:* It is estimated that 277 awards will be issued.

*For Further Information Contact:*

Preeti Kanodia, Public Health Analyst, Division of Health Center Development, Bureau of Primary Health Care, HRSA, 4350 East-West Highway, 3rd Floor, Bethesda, MD 20814, Telephone: 301.594.4300, Fax: 301.480.7225.

*Executive Order 12372*

This program has been determined to be subject to provisions of Executive Order 12372, as implemented by 45 CFR Part 100. Executive Order 12372 allows States the option of setting up a system for reviewing applications from within their States for assistance under certain Federal programs. Application kits made available under this guidance will contain a listing of States that have chosen to set up such a review system, and will provide a State Single Point of Contact (SPOC) for the review. Information on States affected by this program and State Points of Contact may also be obtained from the Grants Management Officer listed in the AGENCY Contact(s) section, as well as from the following Web site: <http://www.whitehouse.gov/omb/grants/spoc.html>. All applicants other than federally recognized Native American Tribal Groups should contact their SPOC as early as possible to alert them to the prospective applications and receive any necessary instructions on the State process used under this Executive Order. Letters from the SPOC in response to Executive Order 12372 are due sixty days after the application due date.

Dated: July 2, 2004.

**Stephen R. Smith,**

*Senior Advisor to the Administrator.*

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**BILLING CODE 4165-15-U**

**DEPARTMENT OF HEALTH AND HUMAN SERVICES**

**Indian Health Service**

**American Indians Into Psychology; Notice of Competitive Grant Applications for American Indians Into Psychology Program**

*Funding Opportunity Number:* HHS-IHS-PSYCH-2004-0001.

*CFDA Number:* 93.970.

*Key Dates:*

*Application Deadline:* August 13, 2004.

*Application Review:* August 19, 2004.

*Application Notification:* August 25, 2004.

*Anticipated Award Start Date:* September 20, 2004.

**I. Funding Opportunity Description**

The Indian Health Service (IHS) announces that competitive grant applications are being accepted for the American Indians Into Psychology Program. These grants are established under the authority of section 217 of the Indian Health Care Improvement Act, Pub. L. 94-437, as amended by Pub. L. 102-573. The purpose of the Indians into Psychology program is to augment the number of Indian health professional serving Indians by encouraging Indians to enter the health professions and removing the multiple barriers to their entrance into IHS and private practice among Indians. This program is described at 93.970 in the Catalog of Federal Domestic Assistance. Costs will be determined in accordance with applicable Office of Management and Budget Circulars. The Public Health Service (PHS) is committed to achieving the health promotion and disease prevention objectives of *Healthy People 2010*, a PHS-led activity for setting priority areas.

This program announcement is related to the priority area of Educational and Community-based programs. Potential applicants may obtain a copy of *Healthy People 2010*, summary report in print, Stock No. 017-001-00547-9, or via CD-ROM, Stock No. 107-001-00549-5, through the Superintendent of Documents, Government Printing Office, P.O. Box 371954, Pittsburgh, PA 15250-7945, (202) 512-1800. You may access this information via the Internet at the

following Web site: <http://www.health.gov/healthypeople/publication>.

The Public Health Service strongly encourages all grant and contract recipients to provide a smoke-free workplace and promote the non-use of all tobacco products. In addition, Pub. L. 103-227, the Pro-Children Act of 1994, prohibits smoking in certain facilities (or in some cases, any portion of the facility) in which regular or routine education, library, day care, health care, or early childhood development services are provided to children. This is consistent with the PHS mission to protect and advance the physical and mental health of the American people.

**II. Award Information**

The Indians into Psychology program has been appropriated \$686,994 for Fiscal Year (FY) 2004. It is anticipated that approximately \$250,000.00 per year will be available for a three year award. The anticipated start date of the grant will be September 20, 2004, in order to begin recruitment for the 2004-2005 academic year. Projects will be awarded for a budget term of 12 months, with a maximum project period of up to three (3) years. Grant funding levels include both direct and indirect costs. Funding of succeeding years will be based on the FY 2004 level, continuing need for the program, satisfactory performance, and the availability of appropriations in those years.

**III. Eligibility Information**

*1. Eligible Applicants*

Public and nonprofit private colleges and universities are eligible to apply for a grant. However, only one grant will be awarded and funded to a college or university per funding cycle.

*2. Cost Sharing/Matching*

This announcement does not require matching funds or cost sharing to participate in the competitive grant process.

*3. Other Requirements*

**Required Affiliations**—The grant applicant must submit official documentation indicating a Tribe's cooperation with and support of the program within the schools on its reservation and its willingness to have a Tribal representative serving on the program advisory board. Documentation must be in the form prescribed by the Tribes governing body, *i.e.*, letter of support or Tribal resolution. Documentation must be submitted from every Tribe involved in the grant program.