

**SUPPLEMENTARY INFORMATION:** FDA has a contract (223-92-2185) with FASEB concerning the analysis of scientific issues that bear on the safety of foods and cosmetics. The objectives of this contract are to provide information to FDA on general and specific issues of scientific fact associated with the analysis of human nutrition.

Infant formulas for infants with low birthweight are regulated as exempt infant formulas under the Infant Formula Act of 1980 and its 1986 amendments (21 U.S.C. 350a). Exempt infant formulas may have nutrients or nutrient levels that are different from those that are codified in 21 CFR 107.100, if the manufacturer of the infant formula can justify the nutrient deviation. LSRO will perform a review to consider the scientific basis for having different recommendations for energy and macronutrients (protein, fat, including long-chain polyunsaturated fatty acids (LCPUFA's), and carbohydrates) in formulas for low birthweight preterm infants.

In the Federal Register of November 15, 1996 (61 FR 58566), FDA announced that it asked FASEB, as a task under contract 223-92-2185, to provide FDA's Center for Food Safety and Applied Nutrition with both an up-to-date review of nutrient requirements of preterm infants and of the effects of new information about nutritional needs of preterm infants on recommendations for levels of nutrients in formulas for preterm infants. In response to this request, FASEB has directed LSRO to obtain state-of-the-art scientific information on infant nutrient requirements and related scientific questions on specifications for preterm infant formula. The LSRO/FASEB has undertaken a study and will prepare a documented scientific report that summarizes the available information related to these questions.

LSRO is performing a review of the scientific and medical literature with a particular emphasis on studies published since 1986, when 21 U.S.C. 350a was last amended. Requirements of other governmental bodies are also being considered in this review. Specifically, LSRO will address the following issues in its review:

(1) What scientific basis is there to support requirements for energy and macronutrients (protein, fat, and carbohydrates) in infant formulas intended for use by preterm infants as distinct from the requirements for energy and macronutrients in formulas for term infants? The American Academy of Pediatrics, the European Society for Pediatric Gastroenterology and Nutrition, and the Canadian

Pediatric Society have proposed some nutrient requirements for preterm infants distinct from those for term infants.

(2) Has scientific knowledge advanced to the point that distinct composition standards for energy and macronutrients in formulas for these preterm infants are warranted?

(3) Nutrient requirements of hospitalized preterm infants who are fed enteral formulas are sometimes described according to stages, such as a first or transition stage (between birth and 10 days of age), a stable growing stage (from about 10 days until discharge from hospital, 6 to 8 weeks after birth), and a post-discharge stage (from discharge home to approximately 1 year of age). Is there scientific evidence to support more than one set of energy and macronutrient requirements to support growth and development of the hospitalized preterm infant at the different stages of development? If so, how should the stages be defined?

(4) Are the energy and macronutrient requirements for infant formulas for term infants sufficient for healthy post-discharge preterm infants?

(5) Is there scientific evidence to support specific deviations from current nutrient standards for healthy post-discharge preterm infants, and if so, what would they be, and to what stage (age/weight) should these special formulas be given?

(6) Does available evidence establish the essentiality of addition of subcomponents of the macronutrients (specifically, taurine, carnitine, and LCPUFA's) to formulas for preterm infants, and if so, does the evidence establish what the amount and ratios of these compounds should be in the formula? For example, the Canadian *Guidelines for the Composition and Clinical Testing for Formulas for Preterm Infants* (p. 17) finds that term infant formulas that contain adequate and balanced 18:2n-6 and 18:3n-3 fatty acids do not require addition of the 20 and 22 carbon n-6 and n-3 fatty acids.

(7) Is there available evidence to suggest that this result also applies to preterm infant formulas? If so, is there an optimum level and ratio of 18:2n-6 and 18:3n-3 fatty acids in formulas for preterm infants?

(8) Does the available evidence address the issue of safety of various sources of these LCPUFA's for use in preterm infant formulas? If so, is there a safe source of LCPUFA's?

(9) Does available evidence establish the essentiality of the addition of nucleotides to formulas for preterm infants, and if so, does the evidence

establish what the amounts should be in the formulas?

LSRO will use these questions as a guide in the drafting of its report. LSRO notes that, in arriving at answers to the above questions, it will consult with the American Academy of Pediatrics' Committee on Nutrition and, to the extent possible, the Institute of Medicine's Food and Nutrition Board. LSRO will prepare a comprehensive final report that documents and summarizes the results of its evaluation.

Under its contract with FDA, FASEB will provide the agency with its scientific report on or about September 30, 1997.

Dated: January 24, 1997.

William K. Hubbard,  
Associate Commissioner for Policy  
Coordination.

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## Health Resources and Services Administration

### Ryan White Title IV; Grants for Coordinated HIV Services and Access to Research for Children, Youth, Women, and Families

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

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

**SUMMARY:** The HRSA announces that approximately \$15.5 million in fiscal year (FY) 1997 funds will be available for project grants that enhance access to clinical research trials and other research, and develop and support the provision of coordinated comprehensive services and activities for children, youth, women and families infected/affected by the Human Immunodeficiency Virus (HIV). Grants will be funded that link clinical research and other research activities with comprehensive care systems, and improve and expand the coordination of a system of comprehensive care for children, youth, women, and families who are infected/affected by HIV. These projects are authorized under Section 2671 of the Public Health Service Act, as amended by the Ryan White Comprehensive AIDS Resource Emergency (CARE) Act Amendments of 1996, Public Law 104-146 (42 U.S.C. 300f-71). Within the HRSA, Ryan White Title IV projects are administered by the Maternal and Child Health Bureau (MCHB).

The PHS is committed to achieving the health promotion and disease prevention objectives of Healthy People 2000, a PHS national activity for setting

priority areas. Title IV directly addresses the Healthy People 2000 objectives related to the priority area of HIV infection. Potential applicants may obtain a copy of *Healthy People 2000* (Full Report; Stock Number 017-001-0474-0) or *Healthy People 2000* (Summary Report; Stock No. 017-001-00473-1) through the Superintendent of Documents, Government Printing Office, Washington, DC 20402-9325 (telephone 202-512-1800).

The PHS strongly encourages all grant recipients to provide a smoke-free workplace and to promote the non-use of all tobacco products. In addition, Public Law 103-227, the Pro-Children Act of 1994, prohibits smoking in certain facilities (or in some cases any portion of a facility) in which regular routine education, library, day care, child care or early development services are provided to children.

**ADDRESSES:** Federal Register notices and application guidance for MCHB programs are available on the World Wide Web via the Internet at address: <http://www.os.dhhs.gov/hrsa/mchb>. Click on the file name you want to download to your computer. It will be saved as a self-extracting (Macintosh or WordPerfect 5.1 file). To decompress the file once it is downloaded, type in the file name followed by a <return>. The file will expand to a WordPerfect 5.1 file.

For applicants for Ryan White Title IV Grants who are unable to access application materials electronically, a hard copy (Revised PHS form 5161-1, approved under OMB clearance number 0937-0189) may be obtained from the HRSA Grants Application Center. The Center may be contacted at: Telephone Number: 1-888-300-HRSA, FAX Number: 301-309-0579, E-mail Address: [HRSA.GAC@ix.netcom.com](mailto:HRSA.GAC@ix.netcom.com). Completed applications should be returned to: Grants Management Officer (CFDA #93.153), HRSA Grants Application Center, 40 West Gude Drive, Suite 100, Rockville, Maryland 20850.

**DATES:** The application deadline date for Ryan White Title IV grants is April 18, 1997. Competing applications will be considered to be on time if they are:

- (1) Received on or before the deadline date, or
- (2) Postmarked on or before the deadline date and received in time for orderly processing.

As proof of timely mailing, applicants should obtain a legibly dated receipt from the commercial carrier or the U.S. Postal Service; private metered postmarks will not be accepted as proof of timely mailing. Late applications not

accepted for processing will be returned to the applicant.

**FOR FURTHER INFORMATION CONTACT:**

Additional information regarding technical and program issues may be obtained from: Marilyn J. Vranas, Project Officer, Division of Services for Children with Special Health Care Needs, Maternal and Child Health Bureau, Health Resources and Services Administration, Room 18-A-19, Parklawn Building, 5600 Fishers Lane, Rockville, Maryland 20857, telephone 301-443-9051. Requests for information concerning administration and business management issues should be directed to: Sandra Perry, Chief, Grants Management Branch, Maternal and Child Health Bureau, 5600 Fishers Lane, Room 18-12, Rockville, Maryland, 20857, telephone 301-443-1440.

**SUPPLEMENTARY INFORMATION:**

**Program Background and Objectives**

The Pediatric AIDS Program was initiated in 1988. The program grew from 13 projects funded at \$4.4 million to a total of 51 projects funded at \$27.4 million in FY 1995. Since 1988, the program has evolved from a primary focus on the coordination of services for the management and care of infected children and their families to also address the broader prevention and care needs of youth and women infected/affected by HIV. In FY 1994, Congress funded the Pediatric AIDS Program under section 2671, Title IV of the Ryan White Comprehensive AIDS Resources Emergency (CARE) Act 1990, Public Law 101-381 (Title IV). As a consequence of authorization under Title IV, the focus of the program was expanded to include the development of innovative models linking clinical trials offered by the National Institutes of Health (NIH) and other research entities, with systems of comprehensive primary/community-based medical and social services.

In 1994, published results from a NIH clinical trial (ACTG 076) demonstrated the potential for reducing perinatal HIV transmission by two-thirds when pregnant women and their newborns were given zidovudine (ZDV). The ZDV therapy regimen has been published in the Centers for Disease Control's Morbidity and Mortality Weekly Report (MMWR 1994:43(RR-11)).

In 1995, the CDC issued recommendations for enhanced voluntary HIV counseling and testing for women of child bearing age, and the HRSA issued an *Advisory: The Use of Zidovudine (ZDV) to Reduce Perinatal HIV Transmission in HRSA-Funded Programs*. This advisory contains

practical, specific steps for implementing PHS recommendations for offering ZDV to pregnant women. A copy of this advisory will be included in the application kit. All Title IV grantees are expected to implement the ZDV recommendations.

The 1996 amendments to the Ryan White CARE Act impose new requirements on the services to be provided or arranged by the applicant, require coordination with other providers of health care services under the Ryan White Care Act and Title V of the Social Security Act, enhance opportunities for and participation in clinical and other research by Title IV clients, specify arrangements that must exist between Title IV programs and research entities, and enhance opportunities for Title IV clients to participate in clinical research. The law requires new grantees to enroll a significant number of clients in clinical trials or other research by the end of the second grant year.

The amended Ryan White law does not define the term "significant participation". Nor does it define the type of research in which patients are to participate; it specifies only "research for the prevention and treatment of HIV disease". The law mandates the Secretary to establish a group composed of providers, consumers and researchers to recommend priority research protocols to be put on a list. Given that these two key legislative terms will not be defined prior to the application due date, we will not use significant participation in research protocols as an evaluation criterion in the review of applications for new FY 1997 grants. Rather, new applicants will be expected to have demonstrable research linkages or credible plans to link services to research; offer clients research opportunities; and support client participation in research through case management, transportation, and other required services. See REVIEW CRITERIA for the list of evaluation criteria.

**Eligible Applicants**

Ryan White Title IV grants may be made only to public and nonprofit private entities that provide primary care, directly or through contracts.

**Funding Categories**

For FY 1997, there will be a single funding category for competition: Grants for coordinated HIV services and access to research for children, youth, women, and families. Applications which do not fall within this category will not be considered for funding. Up to 23 grants,

at an estimated \$15.5 million will be awarded. The project period is 3 years.

These grants will develop and support innovative projects that foster collaboration between clinical research institutions and family-centered, primary/community-based medical and social service programs, and that coordinate systems of comprehensive HIV care for children, youth, women and their families. Projects are expected to focus on local capacity-building, making maximum use of all available public and private resources, and to strengthen existing comprehensive care infrastructures.

Activities under these grants should address the goals of:

- Increasing client access by linking HIV/AIDS clinical research trials and activities with comprehensive care; and
- Fostering the development and support of comprehensive, culturally competent, community-based and family-centered care infrastructures; and emphasizing prevention within the care system.

Preference for funding in Category (1) will be given to projects that have:

- Established and currently support a comprehensive, coordinated, system of HIV care serving either children, youth, women, or families; and
- Linked with, or initiated activities to link with, clinical trials or other research.

This means that these projects will be funded ahead of new groups of applications in this category.

Special consideration for funding may be given to projects which help to achieve an equitable geographical distribution of projects across all States and territories. This means that the score of an individual project may be favorably adjusted if it addresses this objective.

#### Special Concerns

Grantees supported by Title IV of the Ryan White CARE Act should coordinate their projects with other Federal, State, and local programs concerned with HIV and/or serving the target population of children, youth, women and families affected by or at risk for HIV, particularly: Title V Maternal and Child Health programs; Ryan White Titles I, II and III(b) programs; providers funded by the Substance Abuse and Mental Health Services Administration; the Health Resources and Services Administration; the Centers for Disease Control and Prevention efforts; and clinical trials funded by NIH or other sources.

HRSA's Maternal and Child Health Bureau places special emphasis on improving service delivery to women, children and youth from communities with limited access to comprehensive care. In order to assure access and cultural competence, it is expected that projects will involve individuals from the populations to be served in the planning and implementation of the project. The Bureau's intent is to ensure that project interventions are responsive to the cultural and linguistic needs of special populations, that services are accessible to consumers, and that the broadest possible representation of culturally distinct and historically underrepresented groups is supported through programs and projects sponsored by the MCHB.

In keeping with the goals of advancing the development of human potential, strengthening the Nation's capacity to provide high quality education by broadening participation in MCHB programs of institutions that may have perspectives uniquely reflecting the Nation's cultural and linguistic diversity, and increasing opportunities for all Americans to participate in and benefit from Federal public health programs, HRSA will place a funding priority on projects from Historically Black Colleges and Universities (HBCU) or Hispanic Serving Institutions (HSI) in all categories and subcategories in this notice for which applications from academic institutions are encouraged. This is in conformity with the Federal Government's policies in support of White House Initiatives on Historically Black Colleges and Universities (Executive Order 12876) and Educational Excellence for Hispanic Americans (Executive Order 12900). An approved proposal from a HBCU or HSI will receive a 0.5 point favorable adjustment of the priority score in a 4 point range before funding decisions are made.

#### Review Criteria

Applications will be reviewed with particular attention to inclusion of women and persons from culturally distinct populations. Funding will be provided to those which, in the Department's view, best meet the statutory purposes of the Ryan White Title IV program and address achievement of the Healthy People 2000 objectives related to HIV infection.

Applications for grants will be reviewed and rated by objective review panels according to the following weighted criteria:

- Documentation of the HIV medical and social support service needs of

children, youth, women and families (weight 15%);

- Demonstration of capacity to coordinate and support a comprehensive system of HIV care for this population (weight 20%);
- Demonstrated capacity to enhance client access to clinical trials or other research and/or to establish linkages with providers offering clinical trials or other research (weight 20%);
- The degree to which the Title IV's program priority of consumer involvement has been implemented (weight 10%);
- The degree to which the proposed plan: Addresses the issues identified in response to the first criterion on this list; reflects the legislative and programmatic priorities of the Title IV program (access to clinical trials, reduction of perinatal HIV transmission and consumer involvement); contains goals and objectives that are clear, measurable, time framed and address identified needs; and presents an evaluation strategy capable of documenting the achievement of project goals (weight 25%); and
- The degree to which the proposed budget clearly supports administrative and programmatic activities necessary to manage the program and accomplish proposed goals and activities. (weight 10%)

Review criteria will be described in further detail in the application guidance.

#### Allowable Costs

The HRSA may support reasonable and necessary costs of HIV Project grants within the scope of approved projects. Allowable costs may include salaries, equipment and supplies, travel, contractual arrangements, consultants, and others, as well as indirect costs. The HRSA adheres to administrative standards reflected in the Code of Federal Regulations (45 CFR part 92 and 45 CFR part 74). All other sources of funding to support this project must be accurately reflected in the applicant's budget.

#### Reporting Requirements

A successful applicant under this notice will submit reports in accordance with the provisions of the general regulations which apply under 45 CFR part 74, subpart J, Monitoring and Reporting of Program Performance, with the exception of State and local governments to which 45 CFR 92.40 will apply. Financial reporting will be required in accordance with 45 CFR part 74, subpart I, with the exception of State

and local governments, to which 45 CFR part 92, subpart C will apply.

#### Public Health System Reporting Requirements

This program is subject to the Public Health System Reporting Requirements (approved under OMB No. 0937-0195). Under these requirements, the community-based nongovernmental applicant must prepare and submit a Public Health System Impact Statement (PHSIS). The PHSIS is intended to provide information to State and local health officials to keep them apprised of proposed health services grant applications submitted by community-based nongovernmental organizations within their jurisdictions.

Community-based nongovernmental applicants are required to submit the following information to the head of the appropriate State and local health agencies in the area(s) to be impacted no later than the Federal application receipt due date:

- (a) A copy of the face page of the application (SF 5161).
- (b) A summary of the project (PHSIS), not to exceed one page, which provides:
  - (1) A description of the population to be served.
  - (2) A summary of the services to be provided.
  - (3) A description of the coordination planned with the appropriate State and local health agencies.

The project abstract may be used in lieu of the one-page PHSIS, if the applicant is required to submit a PHSIS.

#### Executive Order 12372

The Title IV Program has been determined to be subject to the provisions of Executive Order 12372 concerning intergovernmental review of Federal programs by appropriate health planning agencies, 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. The application packages to be made available under this notice (Form PHS 5161-1 with revised face sheet HHS Form 424 and with Program Narrative and Checklist approved under OMB 0937-0189) will contain a listing of States which have chosen to set up such a review system and will provide a single point of contact (SPOC) in the States for review. Applicants (other than federally-recognized Indian tribal governments) should contact their State SPOCs as early as possible to alert them to the prospective applications and receive any necessary instructions on the State process. For proposed projects

serving more than one State, the applicant is advised to contact the SPOC of each affected State. The due date for State process recommendations is 60 days after the application deadline for new and competing awards. The granting agency does not guarantee to "accommodate or explain" State process recommendations it receives after that date. (See part 148, Intergovernmental Review of PHS Programs under Executive Order 12372 and 45 CFR part 100 for a description of the review process and requirements.)

(The OMB Catalog of Federal Domestic Assistance number for the HIV Program for Children, Youth, Women, and Families is 93.153.)

Dated: January 27, 1997.

Ciro V. Sumaya,

*Administrator.*

[FR Doc. 97-2374 Filed 1-31-97; 8:45 am]

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#### Advisory Council; Notice of Meeting

In accordance with section 10(a)(2) of the Federal Advisory Committee Act (Public Law 92-463), announcement is made of the following National Advisory bodies scheduled to meet during the month of March, 1997.

*Name:* Advisory Commission on Childhood Vaccines (ACCV).

*Date and Time:* March 13, 1997; 9:00 a.m.—4:30 p.m.

*Place:* Parklawn Building, Conference Room E, 5600 Fishers Lane, Rockville, Maryland 20857.

The meeting is open to the public.

The first day of the meeting, Wednesday, March 12, will consist of a meeting of one of the Commission's workgroups.

*Name:* Workgroup on Intent, Provisions and Process.

*Time:* March 12, 1997; 10:00 a.m.—5:00 p.m.

*Purpose:* The Workgroup will address issues related to the operation process of the National Vaccine Injury Compensation Program.

*Agenda:* Agenda items will include, but not be limited to, discussion of the following issues: Status of recommendations from the September and December 1996 WIPP meetings; Program and policy issues related to the operation of the Vaccine Injury Compensation Program, including proposals to revise the wage loss calculation, to provide for an interim payment of attorneys fee and expenses, and to extend the statute of limitations; and a report on the Department of Justice's Process Improvement Initiatives.

The full Commission will meet on Thursday, March 13, from 9:00 a.m. to 4:30 p.m. Agenda items will include, but not be limited to: an overview of the Vaccine Injury Compensation Program; reports from the Workgroup on Intent, Provision, and Process and the Vaccine Safety Subcommittee; an update on the Proposed Vaccine Information

Statement for DTP; and routine Program reports.

Public comment will be permitted before lunch and at the end of the Workgroup meeting on March 12, as well as the full Commission meeting on March 13. Oral presentations will be limited to 5 minutes per public speaker.

Persons interested in providing an oral presentation should submit a written request, along with a copy of their presentation to: Ms. Melissa Palmer, Principal Staff Liaison, Division of Vaccine Injury Compensation, Bureau of Health Professions, Health Resources and Services Administration, Room 8A-35, 5600 Fishers Lane, Rockville, MD 20857, Telephone (301) 443-6593. Requests should contain the name, address, telephone number, and any business or professional affiliation of the person desiring to make an oral presentation. Groups having similar interests are requested to combine their comments and present them through a single representative. The allocation of time may be adjusted to accommodate the level of expressed interest. The Division of Vaccine Injury Compensation Program will notify each presenter by mail or telephone of their assigned presentation time. Persons who do not file an advance request for presentation, but desire to make an oral statement, may sign-up in Conference Room E on March 12-13. These persons will be allocated time as time permits.

Anyone requiring information regarding the Commission should contact Ms. Palmer.

Agenda Items are subject to change as priorities dictate.

Dated: January 28, 1997.

J. Henry Montes,

*Director, Office of Policy and Information Coordination, HRSA.*

[FR Doc. 97-2487 Filed 1-31-97; 8:45 am]

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#### DEPARTMENT OF HOUSING AND URBAN DEVELOPMENT

[Docket No. FR-4200-N-19]

#### Submission for OMB Review: Comment Request

**AGENCY:** Office of the Assistant Secretary for Housing, HUD.

**ACTION:** Notice.

**SUMMARY:** The proposed information collection requirement described below will be submitted to the Office of Management and Budget (OMB) for review, as required by the Paperwork Reduction Act. The Department is soliciting public comments on the subject proposal.

**DATES:** Comments due date: April 4, 1997.

**ADDRESSES:** Interested persons are invited to submit comments regarding this proposal. Comments must be received within seven days from the date of this Notice. Comments should