

Minority Populations

- American Indian or Alaska Native
- Asian
- Black or African American
- Hispanic or Latino
- Native Hawaiian or Other Pacific Islander

(Revision to the standards for the classification of Federal Data on Race and Ethnicity, **Federal Register**, Vol. 62, No. 210, pg. 58782, October 30, 1997)

Risk Factor—The environmental and behavioral influences capable of causing ill health with or without predisposition.

Sociocultural Barriers—Policies, practices, behaviors, and beliefs that create obstacles to health care access and service delivery. Examples of sociocultural barriers include:

- Cultural differences between individuals and institutions
- Cultural differences of beliefs about health and illness
- Customs and lifestyles
- Cultural differences in languages or nonverbal communication styles

Tribal Colleges and Universities—Those institutions cited in section 532 of the Equity in Education Land-Grants Status Act of 1994 (U.S.C. 301 note) or that qualify for funding under the Tribally Controlled Community College Assistance Act of 1978, (25 U.S.C. 1801 et seq.), and Navajo Community College, authorized in the Navajo Community College Assistance Act of 1978, Public Law 95–471, Title II (25 U.S.C. 640a note).

Dated: March 8, 2001.

Nathan Stinson, Jr.,

Deputy Assistant Secretary for Minority Health.

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Centers for Disease Control and Prevention

[Program Announcement 02001]

Grants for Education Programs in Occupational Safety and Health; Notice of Availability of Funds for Fiscal Year 2002

A. Purpose

The Centers for Disease Control and Prevention (CDC) announces the availability of fiscal year (FY) 2002 funds for institutional training grants in occupational safety and health. This program addresses the “Healthy People 2010” priority area of occupational

safety and health. The goal of the program is to provide an adequate supply of qualified personnel to carry out the purposes of the Occupational Safety and Health Act. The specific program objective is to provide financial assistance to eligible institutions or agencies to assist in providing an adequate supply of qualified professional occupational safety and health personnel. Projects are supported for Occupational Safety and Health Education and Research Center Training Grants (ERCs) and for Long-Term Training Project Grants (TPGs). ERCs are funded academic institutions that provide interdisciplinary graduate training and continuing education in the industrial hygiene, occupational health nursing, occupational medicine, occupational safety, and closely related occupational safety and health fields. The ERCs also serve as regional resource centers for industry, labor, government, and the public. TPGs are funded academic institutions that primarily provide single-discipline graduate training in the industrial hygiene, occupational health nursing, occupational medicine, occupational safety, and closely related occupational safety and health fields.

B. Eligible Applicants

Any public or private educational or training agency or institution that has demonstrated competency in the occupational safety and health field and is located in a State, the District of Columbia, or U.S. Territory is eligible to apply for an institutional training grant.

Note: Public Law 104–65 states that an organization described in section 501(c)(4) of the Internal Revenue Code of 1986 that engages in lobbying activities is not eligible to receive Federal funds constituting an award, grant, cooperative agreement, contract, loan, or any other form.

C. Availability of Funds and Types of Training Awards

In FY 2002, a total of approximately \$16,200,000 is available for award. Approximately \$10,280,000 of this total is available for non-competing continuation awards. Approximately \$5,920,000 is available for competing continuation or new awards to fund ERC and TPG programs as described below:

1. For ERCs:

Approximately \$5,520,000 of the total funds available will be utilized as follows:

a. Approximately \$4,800,000 is available to award seven competing continuation or new ERC grants. This includes \$280,000 to augment the support of occupational medicine

residents. Awards range from \$400,000 to \$800,000 with the average award being \$680,000.

b. Approximately \$480,000 is available to award supplemental funds to eight competing continuation or new training grants; four of the awards are planned for \$240,000 for Hazardous Substance Academic Training (HSAT) Programs and four of the awards are planned for \$240,000 for Hazardous Substance Training (HST) Programs. The awards are to support the development and presentation of: continuing education and short courses (HST Programs) and academic curricula (HSAT Programs) for trainees and professionals engaged in the management of hazardous substances. Program support is available for faculty and staff salaries, trainee costs, and other costs to provide training and education for occupational safety and health and other professional personnel engaged in the evaluation, management, and handling of hazardous substances.

c. Approximately \$120,000 is available to award supplemental funds to two competing continuation or new training grants. These awards will support the development of specialized educational programs in agricultural safety and health within the existing core disciplines of industrial hygiene, occupational medicine, occupational health nursing, and occupational safety.

d. Approximately \$120,000 is available to award supplemental funds to two new grants to support the enhancement of the ERC research training mission through the support of pilot project research training programs. The pilot projects should be related to the National Occupational Research Agenda (NORA).

2. For TPGs:

Approximately \$400,000 of the total funds available will be utilized as follows:

To award approximately six competing continuation or new TPG grants. Awards will range from approximately \$20,000 to \$100,000, with the average award being \$65,000. This includes \$40,000 to augment the support of occupational medicine residents. These awards will support academic programs in the core disciplines (i.e., industrial hygiene, occupational health nursing, occupational/industrial medicine, and occupational safety and ergonomics) and relevant components (e.g., occupational injury prevention, industrial toxicology, ergonomics). These awards are intended to augment the scope, enrollment, and quality of training programs rather than to replace

funds already available for current operations.

3. It is expected that awards will begin on or about July 1, 2002, and will be made for a 12-month budget period within a project period of up to five years. Supplemental awards will be made for a 12-month budget period within a project period not to exceed that of the main training grant.

Continuation awards within an approved project period will be made on the basis of satisfactory progress as evidenced by required reports and the availability of funds.

D. Program Requirements

The following are applicant requirements:

1. An ERC shall be an identifiable organizational unit within the sponsoring organization. Applicants must meet the following characteristics in order to be considered responsive. If the characteristics are not met, the application will be considered non-responsive and will be returned to the applicant without a review.

(a) Cooperative arrangements with a: medical school or teaching hospital (with an established program in preventive or occupational medicine); school of nursing or its equivalent; school of public health or its equivalent; or school of engineering or its equivalent. It is expected that other schools or departments with relevant disciplines and resources shall be represented and shall contribute as appropriate to the conduct of the total program, *e.g.*, epidemiology, toxicology, biostatistics, environmental health, law, business administration, and education. Specific mechanisms to implement the cooperative arrangements between departments, schools/colleges, universities, etc., shall be demonstrated in order to assure that the intended interdisciplinary training and education will be engendered.

(b) An ERC Director who possesses a demonstrated capacity for sustained productivity and leadership in occupational health and safety education and training. The Director shall oversee the general operation of the ERC Program and shall, to the extent possible, directly participate in training activities. A Deputy Director shall be responsible for managing the daily administrative duties of the ERC and to increase the ERC Director's availability to ERC staff and to the public.

(c) Program Directors who are full-time faculty and professional staff representing various disciplines and qualifications relevant to occupational safety and health who are capable of planning, establishing, and carrying out

or administering training projects undertaken by the ERC. Each academic program, as well as the continuing education and outreach program, shall have a Program Director.

(d) Faculty and staff with demonstrated training and research expertise, appropriate facilities and ongoing training and research activities in occupational safety and health areas.

(e) A program for conducting education and training for four core disciplines: occupational physicians, occupational health nurses, industrial hygienists, and occupational safety personnel. There shall be a minimum of five full-time students or full-time equivalent students in each of the core programs, with a goal of a minimum of 30 full-time students (total in all of core and component programs together). ERCs are encouraged to recruit and train minority students to help address the under-representation of minorities among the occupational safety and health professional workforce. Although it is desirable for an ERC to have the full range of core programs, an ERC with a minimum of three academic programs of which two are in the core disciplines is eligible for support providing it is demonstrated that students will be exposed to the principles and issues of all four core disciplines. In order to maximize the unique strengths and capabilities of institutions, consideration will be given to the development of: new and innovative academic programs that are relevant to the occupational safety and health field, *e.g.*, ergonomics, industrial toxicology, occupational injury prevention, and occupational epidemiology; and to innovative technological approaches to training and education. ERCs must also document that the program covers an occupational safety and health discipline in critical need or meets a specific regional workforce need. Each core program curriculum shall include courses from non-core categories as well as appropriate clinical rotations and field experiences with public health and safety agencies and with labor-management health and safety groups. Where possible, field experience shall involve students representing other disciplines in a manner similar to that used in team surveys and other team approaches. ERCs should address the importance of providing training and education content related to special populations at risk, including minority workers and other sub-populations specified in the National Occupational Research Agenda (NORA) special populations at risk category.

(f) A specific plan describing how trainees in core and component

academic programs will be exposed to the principles of all other occupational safety and health core and allied disciplines. ERCs that apply as a consortium (contracting with other institutional partners) generally have geographic, policy and other barriers to achieving this ERC characteristic and, therefore, must give special, innovative, attention to thoroughly describing the approach for fulfilling interdisciplinary interaction between students.

(g) Demonstrated impact of the ERC on the curriculum taught by relevant medical specialties, including family practice, internal medicine, dermatology, orthopedics, pathology, radiology, neurology, perinatal medicine, psychiatry, etc., and on the curriculum of undergraduate, graduate and continuing education of primary core disciplines as well as relevant medical specialties and the curriculum of other schools such as engineering, business, and law.

(h) An outreach program to interact with and help other institutions or agencies located within the region. Programs shall be designed to address regional needs and implement innovative strategies for meeting those needs. Partnerships and collaborative relationships shall be encouraged between ERCs and TPGs. Programs to address the under-representation of minorities among occupational safety and health professionals shall be encouraged. Specific efforts should be made to conduct outreach activities to develop collaborative training programs with academic institutions serving minority and other special populations, such as Tribal Colleges and Universities, Historically Black Colleges and Universities, and Hispanic-Serving Institutions. Examples of outreach activities might include activities such as: Interaction with other colleges and schools within the ERC and with other universities or institutions in the region to integrate occupational safety and health principles and concepts within existing curricula (*e.g.*, Colleges of Business Administration, Engineering, Architecture, Law, and Arts and Sciences); exchange of occupational safety and health faculty among regional educational institutions; providing curriculum materials and consultation for curriculum/course development in other institutions; use of a visiting faculty program to involve labor and management leaders; cooperative and collaborative arrangements with professional societies, scientific associations, and boards of accreditation, certification, or licensure; and presentation of awareness seminars to undergraduate and secondary

educational institutions (e.g., high school science fairs and career days) as well as to labor, management and community associations.

(i) A specific plan for preparing, distributing and conducting courses, seminars and workshops to provide short-term and continuing education training courses for physicians, nurses, industrial hygienists, safety engineers and other occupational safety and health professionals, paraprofessionals and technicians, including personnel from labor-management health and safety committees, in the geographical region in which the ERC is located. The goal shall be that the training be made available to a minimum of 400 trainees per year representing all of the above categories of personnel, on an approximate proportional basis with emphasis given to providing occupational safety and health training to physicians in family practice, as well as industrial practice, industrial nurses, and safety engineers. Priority shall be given to establishing new and innovative training technologies, including distance learning programs and to short-term programs designed to prepare a cadre of practitioners in occupational safety and health. Where appropriate, it shall be professionally acceptable that Continuing Education Units (as approved by appropriate professional associations) may be awarded. These courses should be structured so that higher educational institutions, public health and safety agencies, professional societies or other appropriate agencies can utilize them to provide training at the local level to occupational health and safety personnel working in the workplace. Further, the ERC shall conduct periodic training needs assessments, shall develop a specific plan to meet these needs, and shall have demonstrated capability for implementing such training directly and through other institutions or agencies in the region. The ERC should establish and maintain cooperative efforts with labor unions, government agencies, and industry trade associations, where appropriate, thus serving as a regional resource for addressing the problems of occupational safety and health that are faced by State and local governments, labor and management.

(j) A Board of Advisors or Consultants representing the user and affected population, including representatives of labor, industry, government agencies, academic institutions and professional associations, shall be established by the ERC. The Board should meet at least annually to advise an ERC Executive Committee and to provide periodic

evaluation of ERC activities. The Executive Committee shall be composed of the ERC Director and Deputy Director, academic Program Directors, the Director for Continuing Education and Outreach and others whom the ERC Director may appoint to assist in governing the internal affairs of the ERC.

(k) A plan to incorporate research training into all aspects of training and, in research institutions, as documented by on-going funded research and faculty publications, a defined research training plan for training doctoral-level researchers in the occupational safety and health field. The plan will include how the ERC intends to strengthen existing research training efforts, how it will integrate research training activities into the curriculum, field and clinical experiences, how it will expand these research activities to have an impact on other primarily clinically-oriented disciplines, such as nursing and medicine, and how it will build on and utilize existing research opportunities in the institution. Each ERC is required to identify or develop a minimum of one, preferably more, areas of research focus related to work environment problems. Consideration shall be given to the CDC/NIOSH priority research areas identified in the National Occupational Health Research Agenda (NORA). Further information regarding NORA may be found at the CDC/NIOSH home page: <http://www.cdc.gov/niosh>. The research training plan will address how students will be instructed and instilled with critical research perspectives and skills. This training will emphasize the importance of developing and working on interdisciplinary teams appropriate for addressing a research issue. It should also prepare students with the skill necessary for developing research protocols, pilot studies, outreach efforts to transfer research findings into practice, and successful research proposals. Such components of research training will require the ERCs to strive toward developing the faculty composition and administrative infrastructure essential to being Centers of Excellence in Occupational Safety and Health Research Training that are required to train research leaders of the future. The plan should address the incremental growth of such elements and evaluation of the plan commensurate with funds available. In addition to the research training components, the plan will also include such items as specific strategies for obtaining student and faculty funding, plans for acquiring equipment, if appropriate, and a plan for developing research-oriented faculty.

1. Evidence in obtaining support from other sources, including other Federal grants, support from States and other public agencies, and support from the private sector including grants from foundations and corporate endowments, chairs, and gifts.

2. TPG applicants must document that the program covers an occupational safety and health discipline in critical need or meets a specific regional workforce need. There shall be a minimum of three full-time students or full-time equivalent students in each academic program. Applicants should address the importance of providing training and education content related to special populations at risk, including minority and disadvantaged workers. The types of training currently eligible for support are:

(a) Graduate training for practice, teaching, and research careers in occupational safety and health. Priority will be given to programs producing graduates in areas of greatest occupational safety and health need. Strong consideration will be given to the establishment of innovative training technologies including distance learning programs.

(b) Undergraduate and other pre-baccalaureate training providing trainees with capabilities for positions in occupational safety and health professions.

(c) Special technical or other programs for long-term training of occupational safety and health technicians or specialists.

E. Application Content

Applications will be evaluated on the basis of the Program Requirements, Other Requirements, and Evaluation Criteria sections listed, so it is important to follow them in laying out the program plan. The narrative should be no more than 15 pages per program. Prepare the application single-sided and single-spaced, staying within the margin limitations indicated on the form and continuation pages. The print must be clear and legible. Use standard size, black letters that can be clearly copied. Do not use photo reduction. Prepare all graphs, diagrams, tables, and charts in black ink. The application must contain only material that can be photocopied. Do not include course catalogue and course brochures. When additional space is needed to complete any of the items, use plain white paper (8 1/2 by 11 inches), leave 1/2 inch margin on each side, identify each item by its title, and type the name of the program director and the grant number (if the application is a competitive renewal) in the upper right corner of each page. All pages,

including Appendices should be numbered consecutively at least 1/2 in from the bottom edge.

Note: Please consult the detailed Recommended Outline for Preparation of Competing New/Renewal Training Grant Applications provided in each application kit (CDC 2.145 A).

F. Submission and Deadline

Applications should be clearly identified as an application for an ERC Training Grant or TPG Training Grant.

Application

Submit the original and two copies of CDC 2.145 A—ERC or TPG (OMB Number 0920–0261). Forms are in the application kit. Forms and instructions are also available on the CDC home page: <http://www.cdc.gov>. On or before July 5, 2001, submit the application to the Grants Management Specialist identified in Section J of this announcement, “Where to Obtain Additional Information”.

Deadline: Applications shall be considered as meeting the deadline if they are either:

(a) Received on or before the deadline date; or

(b) Sent on or before the deadline date and received in time for submission to the independent review group. (Applicants must request a legibly dated U.S. Postal Service postmark or obtain a legibly dated receipt from a commercial carrier or U.S. Postal Service. Private metered postmarks shall not be acceptable as proof of timely mailing.)

Late Applications: Applications which do not meet the criteria in (a) or (b) above are considered late applications, will not be considered, and will be returned to the applicant.

G. Evaluation Criteria

Each application will be evaluated individually against the following criteria. The initial peer review will be conducted by means of a panel meeting or site visit. The purpose of the initial review is to obtain basic information regarding elements of the proposed training grant program and to provide a technical report as input to the Special Emphasis Panel. The final official peer review will be conducted by a Special Emphasis Panel appointed by CDC.

In reviewing ERC grant applications, the evaluation criteria are as follows:

1. Plans to satisfy the regional needs for training in the areas outlined by the application, including projected enrollment, recruitment and current workforce populations. Special consideration should be given to the development of programs addressing the

under-representation of minorities among occupational safety and health professionals. Indicators of regional need should include measures utilized by the ERC such as previous record of training and placement of graduates. The need for supporting students in allied disciplines must be specifically justified in terms of user community requirements.

2. Extent to which arrangements for day-to-day management, allocation of funds and cooperative arrangements are designed to effectively achieve the “Characteristics of an Education and Research Center” (see D.1).

3. The establishment of new and innovative programs and approaches to training and education relevant to the occupational safety and health field and based on documentation that the program meets specific regional workforce needs. In reviewing such proposed programs, consideration shall be given to the developing nature of the program and its capability to produce graduates who will meet such workforce needs.

4. Extent to which curriculum content and design includes formalized training objectives, minimal course content to achieve degree, course descriptions, course sequence, additional related courses open to occupational safety and health students, time devoted to lecture, laboratory and field experience, and the nature of specific field and clinical experiences including their relationships with didactic programs in the educational process.

5. Academic training including the number of full-time and part-time students and graduates for each core and component program, the placement of graduates, employment history, and their current location by type of institution (academic, industry, labor, etc.). Previous continuing education training in each discipline and outreach activity and assistance to groups within the ERC region.

6. Methods in use or proposed methods for evaluating the effectiveness of training and outreach including the use of placement services and feedback mechanisms from graduates as well as employers, innovative strategies for meeting regional needs, critiques from continuing education courses, and reports from consultations and cooperative activities with other universities, professional associations, and other outside agencies.

7. Competence, experience and training of the ERC Director, the Deputy ERC Director, the Program Directors and other professional staff in relation to the type and scope of training and education involved.

8. Institutional commitment to ERC goals. An example of institutional commitment to the long-term stability of ERC programs is the commitment of tenured or tenure-track faculty positions to each participating academic program.

9. Academic and physical environment in which the training will be conducted, including access to appropriate occupational settings.

10. Appropriateness of the budget required to support each academic component of the ERC program, including a separate budget for the academic staff's time and effort in continuing education and outreach.

11. Evidence of the integration of research experience into the curriculum, and field and clinical experiences. In institutions seeking funds for doctoral and post-doctoral (physician training) level research training, evidence of a plan describing the research and research training the ERC proposes. This shall include goals, elements of the program, research faculty and amount of effort, support faculty, facilities and equipment available and needed, and methods for implementing and evaluating the program.

12. Evidence of success in attaining outside support to supplement the ERC grant funds including other Federal grants, support from States and other public agencies, and support from the private sector including grants from foundations and corporate endowments, chairs, and gifts.

13. Evidence of a strategy to evaluate the impact that the ERC and its programs have had on the region served by the Center. Examples could include a continuing education needs assessment, a workforce needs survey, consultation and research programs provided to address regional occupational safety and health problems, the impact on primary care practice and training, a program graduate data base to track the employment history and contributions of graduates to the occupational safety and health field, and the cost effectiveness of the program.

14. Past performance based on evaluation of the most recent CDC/NIOSH Objective Review Summary Statement and the grant application Progress Report (Competing Continuation applications only).

In reviewing supplements to ERC grants, consideration will be given to:

1. *Hazardous Substance Training Program in Education and Research Centers*—The evaluation criteria are as follows:

a. Relevance of the proposed project to each element of the characteristics of a hazardous substance training program.

b. Comprehensiveness and soundness of the training plan developed to carry out the proposed activities. This is based on a documented need for the training and evidence to support the approach used to provide the required training. It includes description of the scope and magnitude of the hazardous substance problem in the region served by the ERC and current activities and training efforts.

c. Education and experience of the Project Director, faculty, and staff assigned to this project with respect to handling, managing or evaluating hazardous substance sites and to the training of professionals in this field.

d. Creativity and innovation of the project leadership with respect to attracting the courses, structure in attracting trainees and/or providing incentives for training.

e. Extent to which the applicant considered the work of relevant agencies involved in hazardous substance activities, including EPA, and cooperated with these agencies in developing and implementing this training program.

f. Suitability of facilities and equipment available for this project.

g. Appropriateness of the budget to carry out the planned activities.

2. *Agricultural Safety and Health Education Programs in Education and Research Centers*—The evaluation criteria are as follows:

a. Evidence of a needs assessment directed to the overall contribution of the training program toward meeting the job market, especially within the applicant's region, for qualified personnel to carry out the purposes of the Occupational Safety and Health Act of 1970. The needs assessment should consider the regional requirements for outreach, continuing education, information dissemination and special industrial or community training needs that may be peculiar to the region.

b. Evidence of a plan to satisfy the regional needs for training in the areas outlined by the application, including projected enrollment, recruitment and current workforce populations. The need for supporting students in allied disciplines must be specifically justified in terms of user community requirements.

c. The extent to which arrangements for day-to-day management, allocation of funds and cooperative arrangements are designed to effectively achieve characteristics of an ERC.

d. The extent to which curriculum content and design includes formalized training objectives, minimal course content to achieve degree, course descriptions, course sequence,

additional related courses open to occupational safety and health students, time devoted to lecture, laboratory and field experience, and the nature of specific field and clinical experiences including their relationships with didactic programs in the educational process.

e. Previous record of academic training in agricultural safety and health including the number of full-time and part-time students and graduates, the placement of graduates, employment history, and their current location by type of institution (academic, industry, labor, etc.). Previous record of continuing education training in agricultural safety and health and record of outreach activity and assistance to agricultural groups within the ERC region.

f. Methods in use or proposed for evaluating the effectiveness of training and services including the use of placement services and feedback mechanisms from graduates as well as employers, critiques from continuing education courses, and reports from consultations and cooperative activities with other universities, professional associations, and other outside agencies.

g. The competence, experience and training of the Program Director and other professional staff in relation to the type and scope of training and education involved.

h. Institutional commitment to Center goals.

i. Academic and physical environment in which the training will be conducted, including access to appropriate occupational agricultural settings.

j. Appropriateness of the budget required to support the agricultural safety and health education program. This includes the budget for the academic program and the continuing education and outreach program.

k. Evidence of a plan describing the agricultural safety and health training the Center proposes. This shall include goals, elements of the program, faculty and amount of effort, support faculty, facilities and equipment available and needed, and methods for implementing and evaluating the program.

l. Evidence of success in attaining outside support to supplement the ERC grant funds including other federal grants, support from states and other public agencies, and support from the private sector including grants from foundations and corporate endowments, chairs, and gifts.

3. *Hazardous Substance Academic Training Program in Education and Research Centers*—The evaluation criteria are as follows:

a. Evidence of a needs assessment directed to the overall contribution of the proposed training program toward meeting the needs of the job market, especially within the applicant's region. The needs assessment should consider the regional requirements for hazardous substance training, information dissemination and special industrial, labor or community training needs that may be peculiar to the region.

b. Evidence of a plan to satisfy regional needs for training in the areas outlined by the application, including Program projected enrollment and recruitment and current workforce populations.

c. The extent to which the HSAT curriculum content and design includes: Formalized training objectives; minimal course content to achieve a degree or successful completion of the specialty area requirements; course descriptions; course sequence; additional related courses open to occupational safety and health students; time devoted to lecture, laboratory, and field experience; and the nature of specific field and clinical experiences including their relationships with didactic programs in the educational process.

d. Previous record of academic and/or short course training delivered in the hazardous substances field, including the number and type of students trained. Previous record of hazardous substances outreach activity and assistance to hazardous substance groups within the ERC's region.

e. Methods in use or proposed for evaluating the effectiveness of training and services including the use of placement services and feedback mechanisms from graduates as well as employers, student evaluations from academic and continuing education courses, and reports from consultations and cooperative activities with other universities, professional associations, and other outside agencies.

f. The competence, experience and training of the Program Director and other professional staff in relation to the type and scope of training and education involved.

g. Institutional commitment to HSAT Program goals.

h. Academic and physical environment in which the training will be conducted.

i. Appropriateness of the budget required to support the training courses developed, including accounting for the academic staff's time.

j. Evidence of a plan describing the hazardous substances academic training the Center proposes. This shall include goals, elements of the program, faculty and amount of effort, support faculty,

facilities and equipment available and needed, and methods for implementing and evaluating the program.

k. Evidence of success in attaining outside support to supplement the ERC grant funds including other federal grants, support from states and other public agencies, and support from the private sector including grants from foundations and corporate endowments, chairs, and gifts.

l. Extent to which the applicant has collaborated with state and federal agencies having hazardous substance management functions, including the U.S. Environmental Protection Agency, and has cooperated with the agencies in developing and implementing this program.

4. *ERC Supplemental Pilot Project Research Training Programs*—The evaluation criteria are as follows:

a. Relevance of the proposed program, including objectives that are specific and consistent.

b. Adequacy of the plan proposed to conduct the pilot projects program, including procedures for reviewing and funding projects, the scientific review mechanism, program quality assurance. Human Subjects—Are the procedures proposed adequate for the protection of human subjects and are they fully documented? Are all procedures in compliance with applicable published regulations?

c. Extent to which the applicant demonstrates collaboration with other research training institutions in the region, including NIOSH Training Project Grantees.

d. Education and experience of the proposed Research Training Program Director and faculty in the occupational safety and health field, including the utilization of pilot projects as a research training mechanism.

e. Appropriateness of the proposed budget to carry out the planned activities.

f. Adequacy of the plan to evaluate the effectiveness of the proposed pilot projects program.

g. Gender and minority issues—Are plans to include both sexes and minorities and their subgroups adequately developed (as appropriate for the scientific goals of the project)? Are strategies included for the recruitment and retention of human subjects? (See Attachment 1, AR-2—Requirements for Inclusion of Women and Racial and Ethnic Minorities in Research.)

In reviewing TPG applications, the evaluation criteria are as follows:

1. Need for training in the program area outlined by the application. This should include documentation of a plan

for student recruitment, projected enrollment, job opportunities, regional need both in quality and quantity, and for programs addressing the underrepresentation of minorities in the profession of occupational safety and health.

2. Potential contribution of the project toward meeting the needs for graduate or specialized training in occupational safety and health.

3. The establishment of new and innovative programs and approaches to training and education relevant to the occupational safety and health field and based on documentation that the program meets specific regional workforce needs. In reviewing such proposed programs, consideration shall be given to the developing nature of the program and its capability to produce graduates who will meet such workforce needs.

4. Curriculum content and design which should include formalized program objectives, minimal course content to achieve degree, course sequence, related courses open to students, time devoted to lecture, laboratory and field experience, nature and the interrelationship of these educational approaches. There should also be evidence of integration of research experience into the curriculum, and field and clinical experiences.

5. Previous records of training in this or related areas, including placement of graduates.

6. Methods proposed to evaluate effectiveness of the training.

7. Degree of institutional commitment: Is grant support necessary for program initiation or continuation? Will support gradually be assumed? Is there related instruction that will go on with or without the grant? An example of institutional commitment to the long-term stability of TPG programs is the commitment of tenured or tenure-track faculty positions to each academic program.

8. Adequacy of facilities (classrooms, laboratories, library services, books, and journal holdings relevant to the program, and access to appropriate occupational settings).

9. Competence, experience, training, time commitment to the program and availability of faculty to advise students, faculty/student ratio, and teaching loads of the program director and teaching faculty in relation to the type and scope of training involved. The program director must be a full-time faculty member.

10. Admission Requirements: Student selection standards and procedures, student performance standards and student counseling services.

11. Advisory Committee: Membership, industries and labor groups represented; how often they meet; who they advise, role in designing curriculum and establishing program need. The Committee should meet at least annually to provide advice and periodic evaluation of TPG activities.

12. Evidence of a strategy to evaluate the impact that the program has had on the region. Examples could include a workforce needs survey, consultation and research programs provided to address regional occupational safety and health problems, a program graduate data base to track the employment history and contributions of graduates to the occupational safety and health field, and the cost effectiveness of the program.

13. Past performance based on evaluation of the most recent CDC/NIOSH Objective Review Summary Statement and the grant application Progress Report (Competing Continuation applications only).

H. Other Requirements

Technical Reporting Requirements

Provide CDC with original plus two copies of:

1. Progress reports (annual and may be incorporated as component of non-competing continuation applications);

2. Financial status report, no more than 90 days after the end of the budget period; and

3. Final financial status and progress reports, no more than 90 days after the end of the project period.

Send all reports to the Grants Management Specialist identified in Section J of this announcement, "Where to Obtain Additional Information".

The following additional requirements are applicable to this program. For a complete description of each, see Attachment 1 in the application kit.

AR-1* Human Subjects Requirements

AR-2* Requirements for Inclusion of Women and Racial and Ethnic

Minorities in Research AR-

AR-3* Animal Subjects Requirements

AR-10 Smoke-Free Workplace Requirements

AR-11 Healthy People 2010

AR-12 Lobbying Restrictions

*=Applies to ERC Supplemental Pilot Project Research Training Program applications only.

Data collection initiated under this training grant program has been approved by the Office of Management and Budget under Number 0920-0261. "NIOSH Training Grants, 42 CFR part 86, Application and Regulations," Expiration Date 1/31/2004.

I. Authority and Catalog of Federal Domestic Assistance Number

This program is authorized under section 21(a) of the Occupational Safety and Health Act [29 U.S.C. 670 (a)]. The Catalog of Federal Domestic Assistance number is 93.263.

J. Where To Obtain Additional Information

This and other CDC announcements are available through the CDC homepage on the Internet at <http://www.cdc.gov>.

To receive additional written information and to request an application kit, call 1-888-GRANTS4 (1-888-472-6874). You will be asked to leave your name and address and will be instructed to identify the announcement number of interest. Please refer to Program Announcement 02001 and specify ERC or TPG when you request information. If you have questions after reviewing the contents of all the documents, business management technical assistance may be obtained from: Sonia V. Rowell, Grants Management Specialist, Grants Management Branch, Procurement and Grants Office, Announcement 02001, Centers for Disease Control and Prevention (CDC), 2920 Brandywine Road, Room 3000, Atlanta, GA 30341-4146, Telephone: (770) 488-2724, Email address: srowell@cdc.gov.

For program technical assistance, contact: John T. Talty, Principal Engineer, Office of Extramural Programs, National Institute for Occupational Safety and Health, Centers for Disease Control and Prevention (CDC), 4676 Columbia Parkway, Mailstop C-7, Cincinnati, OH 45226-1998, Telephone (513) 533-8241, Email address: jtt2@cdc.gov.

Dated: March 12, 2001.

Diane D. Porter,

Acting Director, National Institute for Occupational Safety and Health, Centers for Disease Control and Prevention (CDC).

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. 01N-0078]

Agency Information Collection Activities; Proposed Collections; Comment Request; Assessment of Physician and Patient Attitudes Toward Direct-to-Consumer Promotion of Prescription Drugs

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is announcing an opportunity for public comment on two proposed collections of certain information by the agency. Under the Paperwork Reduction Act of 1995 (the PRA), Federal agencies are required to publish notice in the **Federal Register** concerning each proposed collection of information, including each proposed extension of an existing collection of information, and to allow 60 days for public comment in response to the notice. This notice solicits comments on surveys of physicians and patients to examine the impact of direct-to-consumer (DTC) promotion of prescription drugs.

DATES: Submit written or electronic comments on the collections of information by May 18, 2001.

ADDRESSES: Submit electronic comments on the collections of information to <http://www.accessdata.fda.gov/scripts/oc/dockets/edockethome.cfm>. Submit written comments on the collections of information to the Dockets Management Branch (HFA-305), Food and Drug Administration, 5630 Fishers Lane, rm. 1061, Rockville, MD 20852. All comments should be identified with the docket number found in brackets in the heading of this document.

FOR FURTHER INFORMATION CONTACT: Karen L. Nelson, Office of Information Resources Management (HFA-250), Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857, 301-827-1482.

SUPPLEMENTARY INFORMATION: Under the PRA (44 U.S.C. 3501-3520), Federal agencies must obtain approval from the Office of Management and Budget (OMB) for each collection of information they conduct or sponsor. "Collection of information" is defined in 44 U.S.C. 3502(3) and 5 CFR 1320.3(c) and includes agency requests or requirements that members of the public submit reports, keep records, or

provide information to a third party. Section 3506(c)(2)(A) of the PRA (44 U.S.C. 3506(c)(2)(A)) requires Federal agencies to provide a 60-day notice in the **Federal Register** concerning each proposed collection of information, including each proposed extension of an existing collection of information, before submitting the collection to OMB for approval. To comply with this requirement, FDA is publishing notice of the proposed collection of information set forth in this document.

With respect to the following collection of information, FDA invites comments on: (1) Whether the proposed collection of information is necessary for the proper performance of FDA's functions, including whether the information will have practical utility; (2) the accuracy of FDA's estimate of the burden of the proposed collection of information, including the validity of the methodology and assumptions used; (3) ways to enhance the quality, utility, and clarity of the information to be collected; and (4) ways to minimize the burden of the collection of information on respondents, including through the use of automated collection techniques when appropriate, and other forms of information technology.

Assessment of Physician and Patient Attitudes Toward Direct-to-Consumer Promotion of Prescription Drugs

Under the Federal Food, Drug, and Cosmetic Act (the act), FDA is responsible for ensuring that the labeling and advertising of prescription drugs is truthful and not misleading. Section 502(n) of the act (21 U.S.C. 352(n)) prohibits the advertising of prescription drugs that is false or misleading or that fails to provide required information about product risks. Although advertising of prescription drugs was once primarily addressed to health professionals, consumers increasingly have become a primary target audience, and DTC advertising has dramatically increased in the past few years. However, DTC advertising raises many questions and issues. While it may alert consumers to new information and facilitate treatment of their medical problems, it also may confuse consumers and adversely impact the relationship between patients and their health care providers. In August 1997, when the agency issued its draft guidance on consumer-directed broadcast advertisements, FDA announced that it intended to evaluate the effects of the guidance and of DTC promotion in general within 2 years of finalizing the guidance. The guidance was finalized on August 9, 1999 (64 FR 43197). In the notice announcing