

TRANSACTIONS GRANTED EARLY TERMINATION, 04/24/2000–05/05/2000—Continued

Transaction No.	Acquiring person	Acquired person	Acquired entities
20002858	Q-Media Services Corporation	Estate of Pierre Peladeau	Print Northwest L.P.
20002862	IT Group, Inc	W&H Pacific, Inc	W&H Pacific, Inc.
20002864	Welsh, Carson, Anderson & Stowe VIII, L.P.	Politic Acquisition Corp	Politic Acquisition Corp.
20002865	WCAS Capital Partners III, L.P	Politic Acquisition Corp	Politic Acquisition Corp.
20002866	Science Applications International Corporation.	VeriSign, Inc	VeriSign, Inc.
20002892	National Bank of Egypt	Arab American Bank	Arab American Bank
20002895	Berkshire Fund V, Limited Partner- ship.	USA Jet Airlines, Inc	USA Jet Airlines, Inc.
20002902	Einhorn Verwaltungsgesellschaft	Gerald L. Lennard	PGP Industries, Inc.
20002908	International Business Machines Corporation.	Scott A. Blum Separate Property Trust U/D/T 8/2/95.	eDevelopments.com Inc.
20002916	Prime 66 Partners, L.P	The Warnaco Group, Inc	The Warnaco Group, Inc.
20002917	Centennial Fund IV, L.P	24/7 Media, Inc	24/7 Media, Inc.
20002918	Great Plains Software, Inc	Solomon Software, Inc	Solomon Software, Inc.
20002925	Activated Communications Limited Partnership.	Mr. Arthur Liu	Way Broadcasting, Inc.
20002926	Mr. Arthur Liu	Activated Communications Limited Partnership.	Activated Communications Limited Partnership.
20002929	Agfa-Gevaert N.V	Emerson Electric, Co	Krautkramer-Branson.
20002935	HNC Software, Inc	Simon B. Ruddick	High Touch Technologies.
20002939	eGain Communications Corporation	Inference Corporation	Inference Corporation.
20002944	GS Capital Partners III, L.P	SiPix Group Limited	SiPix Group Limited.
20002955	Dial Corporation (The)	Procter & Gamble Company, (The)	Procter & Gamble Company, (The).

FOR FURTHER INFORMATION CONTACT:

Sandra M. Peay or Parcellena P. Fielding, Contact Representatives, Federal Trade Commission, Premierer Notification Office, Bureau of Competition, Room 303, Washington, DC 20580, (202) 326–3100.

By Direction of the Commission.

Donald S. Clark,

Secretary.

[FR Doc. 00–12127 Filed 5–12–00; 8:45 am]

BILLING CODE 6750–01–M

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Centers for Disease Control and Prevention

[Program Announcement 00083]

National Trauma Information and Exchange Program; Notice of Availability of Funds

A. Purpose

The Centers for Disease Control and Prevention (CDC) announces the availability of funds in Fiscal Year (FY) 2000 for a grant to develop a National Trauma Information and Exchange Program (TIEP).

The purpose of TIEP is to make data and information on trauma care in the United States more accessible to a broad spectrum of individuals and organizations, including trauma care professionals and professional associations, trauma centers and other

acute care hospitals, trauma care systems, emergency medical services (EMS) systems, injury researchers and research organizations, public health agencies, health care payers, and the general public. CDC is committed to achieving the health promotion and disease prevention objectives of “Healthy People 2010.”

This announcement is related to Injury and Violence Prevention focus areas.

B. Eligible Applicants

Applications may be submitted by public and private nonprofit organizations and by governments and their agencies; that is, universities, colleges, research institutions, hospitals, other public and private nonprofit organizations, State and local governments or their bona fide agents, and Federally recognized Indian tribal governments, Indian tribes, or Indian tribal organizations.

C. Availability of Funds

Approximately \$387,500 is available in FY 2000 to fund one new award. It is expected that the award will begin on or about September 30, 2000, and will be made for a 12-month budget period within a project period of up to 3 years. Funding estimates may change.

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

In conducting the activities to achieve the purpose of this program, the recipient will be responsible for the following activities:

1. Provide a full-time director/coordinator with authority and responsibility to carry-out the requirements of the program.

2. Provide qualified staff, other resources, and knowledge to implement the components of the program.

3. Develop and implement a comprehensive plan to periodically update a detailed description of trauma centers in the United States, including key personnel, as well as their capabilities.

4. Develop and implement a plan that enables an exchange of information among trauma centers and trauma organizations nationwide.

5. Develop and implement a plan for a uniform surveillance system for trauma centers that will enable researchers and research organizations to conduct research on quality of trauma care and trauma center and trauma system effectiveness.

6. Develop and implement a plan for the dissemination of available information on trauma, trauma centers, and trauma care systems to the public, researchers and healthcare practitioners.

E. Application Content

Use the information in the Program Requirement, Other Requirements, and Evaluation Criteria sections to develop the application content. Your

application will be evaluated on the criteria listed, so it is important to follow them in laying out your program plan. The narrative should be no more than 30 pages double-spaced, printed on one side, with one inch margins, and un-reduced font. The application must include a one-page abstract and summary of the proposed effort.

F. Submission and Deadline

Application

Submit the original and two copies of PHS 5161-1 (OMB Number 0937-0189).

Forms are in the application kit. On or before July 14, 2000, submit the application to the Grants Management Specialist identified in the "Where To Obtain Additional Information" section of this announcement.

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 an independent review. (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 by an independent review group appointed by CDC.

1. Background and Need (40 percent)

The extent to which the applicant describes the background and need for a comprehensive trauma information program including; development, current challenges in organizing and delivering trauma care, challenges of developing and maintaining trauma systems, implementation and evaluation of a plan to periodically update a detailed description of trauma centers in the United States, development of a plan to exchange information and link resources of trauma centers and a plan for a uniform surveillance program.

2. Methods (30 percent)

The extent to which the applicant provides a detailed description of all proposed activities required to implement a comprehensive trauma

information and exchange program including letters of support and collaboration needed to achieve each objective and the overall program goal(s). The extent to which the applicant provides a reasonable, logically sequenced and complete schedule for implementing all activities. The extent to which position descriptions, lines of command, and collaborations are appropriate to accomplishing the program goal(s) and objectives. The extent to which the applicant describes a plan and implementation dissemination of available trauma information.

3. Evaluation (10 percent)

The extent to which the proposed evaluation plan is detailed and capable of documenting program process and outcome measures. The extent to which the applicant demonstrates staff and/or collaborator availability, expertise, and capacity to perform the evaluation.

4. Staff and Resources (20 percent)

The extent to which the applicant can provide adequate facilities, staff and/or collaborators, including a full-time coordinator and resources to accomplish the proposed goal(s) and objectives during the project period. The extent to which the applicant demonstrates staff and/or collaborator availability, expertise, previous experience, and capacity to perform the undertaking successfully.

5. Budget and Justification (not scored)

The extent to which the applicant provides a detailed budget and narrative justification consistent with the stated objectives and planned program activities. CDC may not approve or fund all proposed activities. The applicant should be precise about the program purpose of each budget item. Proposed contracts should identify the name of the contractor, if known; describe the services to be performed; provide an itemized budget and justification for the estimated costs of the contract; specify the period of performance, and method of selection.

H. Other Requirements

Technical Reporting Requirements

Provide CDC with original plus two copies of:

1. Semi-annual progress reports;
2. Financial status report, no more than 90 days after the end of the budget period; and
3. Final financial status and performance reports, no more than 90 days after the end of the project period. Send all reports to the Grants Management Specialist identified in the

"Where To Obtain Additional Information" Section of this announcement.

The following additional requirements are applicable to this program. For a complete description of each, see Attachment

I. (List all applicable requirements by number and title. The Grants Management Branch will include the applicable descriptions in the application kit.)

AR-10 Smoke-Free Workplace Requirements

AR-11 Healthy People 2010

AR-12 Lobbying Restrictions

AR-13 Prohibition on Use of CDC Funds for Certain Gun Control Activities

AR-14 Accounting System Requirements

AR-15 Proof of Non-Profit Status

I. Authority and Catalog of Federal Domestic Assistance Number

This program is authorized under section 301(a), 317(k)(2), 391, 392, 394, and 394A (42 U.S.C. 241(a), 247b(k)(2), 280b, 280b-1, 280b-2, 280b-3) of the Public Health Service Act, as amended. The Catalog of Federal Domestic Assistance number is 93.136.

J. Where to Obtain Additional Information

See the CDC home page on the Internet: <http://www.cdc.gov> for this and other program announcements, click on funding.

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 00083 when you request information. After reviewing the Program Announcement for business management assistance contact: Sheryl Heard, Grants Management Specialist, Grants Management Branch, Procurement and Grants Office, Announcement 00083, Centers for Disease Control and Prevention (CDC), 2920 Brandywine Road, Suite 3000, Atlanta, GA, 30341-4146, Telephone (770) 488-2723, Email address: Sheard@cdc.gov

For program technical assistance contact: Paul Burlack Centers for Disease Control and Prevention (CDC), National Center for Injury Prevention and Control, 4770 Buford Highway NE, Mailstop F-41, Atlanta, GA, 30341-3724, Telephone (770) 488-4031, Email address: pburlack@cdc.gov.

Dated: May 9, 2000.

John L. Williams,

*Director, Procurement and Grants Office,
Centers for Disease Control and Prevention
(CDC).*

[FR Doc. 00-12107 Filed 5-12-00; 8:45 am]

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. 00N-1219]

Biological Products; Bacterial Vaccines and Related Biological Products; Implementation of Efficacy Review; Proposed Order

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is issuing a proposed order to accept the conclusions and recommendations of advisory review panels concerning the safety, effectiveness, and labeling of certain bacterial vaccines and related biological products that were previously classified into Category IIIA (remaining on the market pending further studies in support of effectiveness). On the basis of the advisory review panel findings, FDA is proposing to reclassify the relevant Category IIIA products into Category I (safe, effective, and not misbranded) or Category II (unsafe, ineffective, or misbranded). This action is being taken under the reclassification procedures.

DATES: Submit written comments on this proposed order and the reclassification of products should be submitted by August 13, 2000. Data and information submitted to FDA in connection with these reclassified products will be made publicly available after June 14, 2000. Comments concerning confidentiality should be received by FDA before June 14, 2000.

ADDRESSES: Submit written comments on the proposed order to the Dockets Management Branch (HFA-305), Food and Drug Administration, 5630 Fishers Lane, rm. 1061, Rockville, MD 20852. Comments may also be submitted electronically at www.fda.gov/ohrms/dockets. Copies of the reports from the Vaccines and Related Biological Products Advisory Committee (April 1984) and the Panel on Review of Allergenic Extracts (December 1983) can be obtained from the Office of Communication, Training and Manufacturers Assistance (HFM-40), Center for Biologics Evaluation and Research, Food and Drug

Administration, 1401 Rockville Pike, Rockville, MD 20852-1448. Requests for copies that are accompanied by a self-addressed adhesive label will assist that office in processing your requests. The documents may also be obtained by mail either by calling the CBER Voice Information System at 1-800-835-4709 or 301-827-1800 or by submitting a request electronically at www.CBER_INFO@CBER.FDA.GOV, or by fax by calling the FAX Information System at 1-888-CBER-FAX or 301-827-3844.

FOR FURTHER INFORMATION CONTACT:

Steven Falter, Center for Biologics Evaluation and Research (HFM-17), Food and Drug Administration, 1401 Rockville Pike, Rockville, MD 20852-1448, 301-827-6343.

SUPPLEMENTARY INFORMATION:

I. Background

A. The Review Procedures (21 CFR 601.25)

On July 1, 1972, responsibility for regulating biological products under section 351 of the Public Health Service Act (PHS Act) (42 U.S.C. 262) was transferred from the National Institutes of Health to FDA (37 FR 12865, June 29, 1972). Section 351 of the PHS Act provides statutory authority to license biological products. In 1973, FDA established a procedure to review the safety, effectiveness, and labeling of all biological products licensed prior to July 1, 1972 (38 FR 4319, February 13, 1973). This process was eventually codified in § 601.25 (21 CFR 601.25) (38 FR 32048 at 32052, November 20, 1973). Under § 601.25, the Commissioner of Food and Drugs assigned responsibility for the initial review of all biological products licensed prior to 1972 to nine independent advisory review panels. These panels consisted of qualified nonFDA experts in order to ensure public confidence in, and objectivity of the reviews. Each of the advisory review panels was assigned to review a specific category of biological products.

In the **Federal Register** of June 19, 1974 (39 FR 21176), FDA eliminated three previously planned panels (The Panel on Review of In Vitro Diagnostic Reagents; The Panel on Review of Immune Serums, Antitoxins, and Antivenins; and the Panel on Review of Miscellaneous Biological Products) and reassigned the review of the biological products originally intended for review by these three panels to the remaining six advisory review panels: The Panel on Review of Bacterial Vaccines and Toxoids with Standards of Potency, The Panel on Review of Bacterial Vaccines and Bacterial Antigens with "no U.S.

Standards of Potency," the Panel on Review of Skin Test Antigens, The Panel on Review of Allergenic Extracts, The Panel on Review of Viral and Rickettsial Vaccines, and the Panel on Review of Blood and Blood Derivatives. The advisory review panels for bacterial vaccines and bacterial antigens with "no U.S. standard of potency," bacterial vaccines and toxoids with standards of potency, and skin test antigens reviewed the products that are the subject of this notice.

Under the review and classification procedures specified in § 601.25, each advisory review panel was charged with preparing a report to the agency that: (1) Evaluated the safety and effectiveness of the biological product; (2) reviewed the labeling of the biological product; and (3) advised FDA on which biological products under review were safe, effective, and not misbranded. Each advisory review panel report was to include a statement classifying the products into Category I, Category II, or Category III. Category I designated those biological products determined to be safe, effective, and not misbranded. Category II designated those biological products determined to be unsafe, ineffective or misbranded. Category III designated those biological products that did not fall within either Category I or Category II because of insufficient data and for which further testing was therefore required. Category III products were assigned to one of two subcategories. Category IIIA products were those that would be permitted to remain on the market pending the completion of further studies. Category IIIB products were those for which the panel report recommended license revocation on the basis of the panel's assessment of potential risks and benefits.

After reviewing the conclusions and recommendations of the panels, FDA would publish in the **Federal Register** a proposed order containing: (1) A statement designating the biological products reviewed into Categories I, II, IIIA or IIIB; (2) a description of the testing necessary for Category IIIA biological products; and (3) the complete panel report. Under the proposed order, FDA would revoke the licenses of those products designated into Category II and Category IIIB. After reviewing public comments, FDA would publish a final order on the matters covered in the proposed order.