

DEPARTMENT OF HEALTH AND HUMAN SERVICES

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Certifier R. LEDESMA

Food and Drug Administration

State Health Fraud Task Force Grants; Availability of Funds for Fiscal Year  
2004: Request for Applications

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

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**SUMMARY:** The Food and Drug Administration (FDA) is announcing the availability of grant funds for State Health Fraud Task Force Grant Program support. Grant funds will be used to assist law enforcement agencies in identifying and prosecuting perpetrators of health fraud; obtain and disseminate information on the use of fraudulent drugs and therapies; disseminate information on approved drugs and therapies; and provide health fraud information obtained by the State Health Fraud Task Force to State health agencies, community based organizations, and FDA staff. Approximately \$300,000 will be available for this program in fiscal year 2004. FDA anticipates making approximately 20 awards, not to exceed \$15,000 in direct costs only per award per year. Support of these grants will be for up to 3 years. The number of grants awarded will depend on the quality of the applications received and the availability of Federal funds to support the grant. These grants are not intended to fund food, medical device, or drug inspections.

**DATES:** The application receipt date is [*insert date 45 days after date of publication in the Federal Register*].

**ADDRESSES:** Application kits are available from, and completed applications should be mailed, hand-carried, or commercially delivered to Cynthia M. Polit, Division of Contracts and Grants Management (HFA-531), Food and Drug Administration, 5630 Fishers Lane, rm. 2142, Rockville, MD 20852, 301-827-7180, e-mail: [cpolit@oc.fda.gov](mailto:cpolit@oc.fda.gov). Application forms PHS-5161-1 (7/00) are available via the Internet at <http://www.psc.gov/forms>. Do not send the application to the Center for Scientific Review, National Institutes of Health (NIH). An application not received by FDA in time for orderly processing will be returned to the applicant without consideration. FDA cannot receive an application electronically.

**FOR FURTHER INFORMATION CONTACT:**

*Regarding the administrative and financial management aspects of this notice:* Cynthia M. Polit (see **ADDRESSES**).

*Regarding the programmatic aspects of this notice:* Stephen Toigo, Division of Federal-State Relations (HFC-150), Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857, 301-827-6906, e-mail: [dfs@ora.fda.gov](mailto:dfs@ora.fda.gov). Internet site: [http://www.fda.gov/ora/fed\\_state/default.htm](http://www.fda.gov/ora/fed_state/default.htm).

**SUPPLEMENTARY INFORMATION:**

**I. Introduction**

FDA will support projects covered by this notice under sections 1702 through 1706 of title XVII of the Public Health Service Act (42 U.S.C. 300u-1 through 300u-5). FDA's project program is described in the Catalog of Federal Domestic Assistance, No. 93.447, and applicants are limited to States that have an existing State Health Fraud Task Force or States that are in the process of developing a task force.

Only one award will be made per State. A fiscal agent, who will be responsible for the administrative responsibilities for grant funds to conduct their activities, must be identified on the application. A program director, also known as the State Health Fraud Task Force Chair, must be identified as being responsible for submission of the application, and a complete listing of all State Health Fraud Task Force members and their credentials must be included in the application.

## **II. Background**

The mission of the State Health Fraud Task Force is as follows: (1) To assist health professionals and persons with serious illnesses and to educate them about the dangers and magnitude of health fraud; (2) to assist law enforcement agencies in identifying and prosecuting perpetrators of health fraud; (3) to obtain and disseminate information on the fraudulent drugs and therapies being used and the consequences of their use; (4) to disseminate information on approved drugs and therapies; and (5) to provide health fraud information obtained by the State Health Fraud Task Force to State health agencies, community based organizations, and FDA staff.

## **III. Project Goals, Definitions, and Examples**

State Health Fraud Task Force grants will be awarded only for direct costs incurred to accomplish the mission of the State Health Fraud Task Force Program in educating and combating health fraud.

Examples of direct costs may include the following items: (1) Conferences/workshops sponsored by the task force, (2) development of public service announcements/campaigns, (3) health fraud brochures, and (4) travel expenses for face-to-face State Health Fraud Task Force meetings. Grant funds may be used to cover the cost of the program director, or task force chair, to attend one non-FDA sponsored health fraud related meeting and one FDA-sponsored

National Health Fraud Task Force Steering Committee meeting per year. Grant funds may not be used to purchase meals in conjunction with any activities sponsored by the State Health Fraud Task Force or for any Federal employee to travel to any task force meeting or to participate in any task force activity. FDA region/district representatives may be invited to be liaisons or advisors of the State Health Fraud Task Force but each task force should develop its own guidelines for work, consensus decision making, size and format.

The Division of Federal-State Relations will provide meeting guidelines and organization documents as requested. State Health Fraud Task Force grants will be awarded for up to 3 years based on availability of funds and satisfactory performance. The budgets for all years of requested support must be fully justified in the original application.

#### **IV. Reporting Requirements**

Semi-annual progress reports as well as a final program progress report are required. The grantee must submit a progress report and two copies to FDA's grants management officer in the middle of each budget period and also within 90 days after the end of each budget period. The final progress report, due 90 days after the end of the project period, must provide full written documentation of the project, copies of any results (as described in the grant application), and an analysis and evaluation of the results of the project.

An annual financial status report (FSR) is due 90 days after the end of each budget period. The final FSR is due 90 days after the end of the project period.

Program monitoring of recipients will be conducted on an ongoing basis and written reports will be reviewed and evaluated at least semi-annually by the project officer. Project monitoring may also be in the form of telephone

conversations between the project officer/grants management specialist and the principal investigator and/or a site visit with appropriate officials of the recipient organization. The results of these monitoring activities will be recorded in the official file and may be available to the recipient upon request.

## **V. Mechanism of Support**

### *A. Award Instrument*

Support for this program will be in the form of a grant. These grants will be subject to all policies and requirements that govern the project grant programs of FDA, including the provisions of 42 CFR part 52, 45 CFR parts 74 and 92, and the Public Health Service (PHS) Grants Policy Statement. The regulations issued under Executive Order 12372 also apply to this program and are implemented through Department of Health and Human Services (HHS) regulations at 45 CFR part 100. Executive Order 12372 sets up a system for State and local government review of applications for Federal financial assistance. Applicants (other than Federally recognized Indian tribal governments) should contact the State's single point of contact (SPOC) as early as possible to alert the SPOC to the prospective application(s) and to receive any necessary instructions on the State's review process. A current listing of SPOCs is included in the application kit. The SPOC should send any State review process recommendations to the FDA administrative contact (see **ADDRESSES**). The due date for the State process recommendations is no later than 60 days after the deadline date for the receipt of applications. FDA does not guarantee that we will accommodate or explain SPOC comments that are received after the 60-day cutoff.

### *B. Eligibility*

This grant program is only available to one State Health Fraud Task Force per State (see **SUPPLEMENTARY INFORMATION**). This program is primarily intended for previously established Health Fraud Task Forces. However, consideration will be given to newly formed task forces that meet the requirements of this request for applications (RFA).

### *C. Length of Support*

It is anticipated that FDA will fund these grants at a level requested but not exceeding \$15,000 total direct costs only for the first year. An additional 2 years of support up to approximately \$15,000 total direct costs only each year will be available, depending upon the following factors: (1) Performance during the preceding year, (2) compliance with regulatory requirements of the award, and (3) availability of Federal funds.

### *D. Funding Plan*

The number of grants funded will depend on the quality of the applications received, their relevance to the FDA mission, priorities, and the availability of funds.

## **VI. Review Procedure and Criteria**

All applications submitted in response to this RFA will first be reviewed by grants management and program staffs for responsiveness. Responsiveness is defined as submission of a complete application with original signatures on or before the required submission date as listed earlier in this document. If an application is found to be nonresponsive, it will be returned to the applicant without further consideration. An application will be considered nonresponsive if any of the following circumstances are not met: (1) If it is received after the specified receipt date; (2) if the total dollar amount requested

from FDA exceeds \$15,000 per year; (3) if all required original signatures are not on the face, assurance, or certification pages of the application; (4) if there is no original signature copy; (5) if it is illegible; (6) if the material presented is insufficient to permit an adequate review; (7) if the application demonstrates an inadequate understanding of the intent of the RFA.

Responsive applications will be reviewed and evaluated for scientific and technical merit by an ad hoc panel of experts in the subject field of the specific application. Applications will be considered for funding on the basis of their overall technical merit as determined through the review process. Other award criteria will include availability of funds and overall program balance. Funding decisions will be made by the Commissioner of Food and Drugs or his designee.

Applicants are strongly encouraged to contact FDA to resolve any questions regarding criteria prior to the submission of their applications. All questions of a technical or programmatic nature must be directed to the Office of Regulatory Affairs program staff (see **ADDRESSES**) and all questions of an administrative or financial nature must be directed to the grants management staff (see **ADDRESSES**).

Applications will be given an overall score and judged based on all of the following criteria: (1) The content/subject matter and how current and appropriate it is for FDA's mission; (2) the educational outreach plan and how thorough, reasonable, and appropriate it is for accomplishing the mission of the program; (3) the experience, training, and competence of the program director and task force members as described in the application; (4) the reasonableness of the proposed budget given the plan for achieving the objective of the mission of the State Health Fraud Task Force Program; (5) a

plan for self-sustaining the task force program in the event that Federal funding were to become unavailable in the future; (6) a brief history of the existing State Health Fraud Task Force and its accomplishments, not to exceed two typewritten pages; (7) a description of the structure of the existing State Health Fraud Task Force including such items as nonprofit organizational status, membership guidelines, or other relevant information to demonstrate the task force as a recognizable structured entity.

## **VII. Submission Requirements**

The original and two copies of the completed grant application Form PHS-5161-1 (revised 07/00) for State and local governments should be delivered to the Grants Management Office (see **ADDRESSES**). The application receipt date is 45 days after date of publication in the **Federal Register**, for the first year, and that anniversary date for each subsequent year this program is in effect. No supplemental material or addenda will be accepted after the receipt date.

## **VIII. Method of Application**

### *A. Submission Instructions*

Applications will be accepted during working hours, 8 a.m. to 4:30 p.m., Monday through Friday, on or before the established receipt date. Applications will be considered received on time if sent or mailed on or before the receipt date as evidenced by a legible U.S. Postal Service dated postmark or a legible date receipt from a commercial carrier, unless they arrive too late for orderly processing. Private metered postmarks shall not be acceptable as proof of timely mailing. Applications not received on time will not be considered for review and will be returned to the applicant. Applicants should note that the U.S. Postal Service does not uniformly provide dated postmarks. Before relying on this method, applicants should check with their local post office.

Do not send applications to the Center for Scientific Research, NIH. Any application sent to NIH that is then forwarded to FDA and not received in time for orderly processing will be deemed unresponsive and returned to the applicant. FDA is unable to receive applications via the Internet.

The outside of the mailing package and item 2 of the application face page should be labeled "Response to RFA-FDA-ORA-04-2." You must submit only one application, an original and two copies, per package.

### *B. Format for Application*

When using Form PHS 5161-1 (rev 07/00), all instructions for the enclosed Standard Form 424 (SF424) should be followed using the nonconstruction application pages. A properly formatted sample application for grants can be accessed on the Internet at [http://www.fda.gov/ora/fed\\_state/Innovative\\_Grants.html](http://www.fda.gov/ora/fed_state/Innovative_Grants.html).

The face page of the application should indicate "Response to RFA-FDA-ORA-04-2." The outside of the mailing package should also be labeled "Response to State Health Fraud Task Force Grant Program."

Data included in the application, if restricted with the legend specified later in this document, may be entitled to confidential treatment as trade secret or confidential commercial information within the meaning of the Freedom of Information Act (FOIA) (5 U.S.C. 552(b)(4)) and FDA's implementing regulations (21 CFR 20.61).

Information collection requirements requested on PHS Form 5161-1 were approved and issued under Office of Management and Budget Circular A-102.

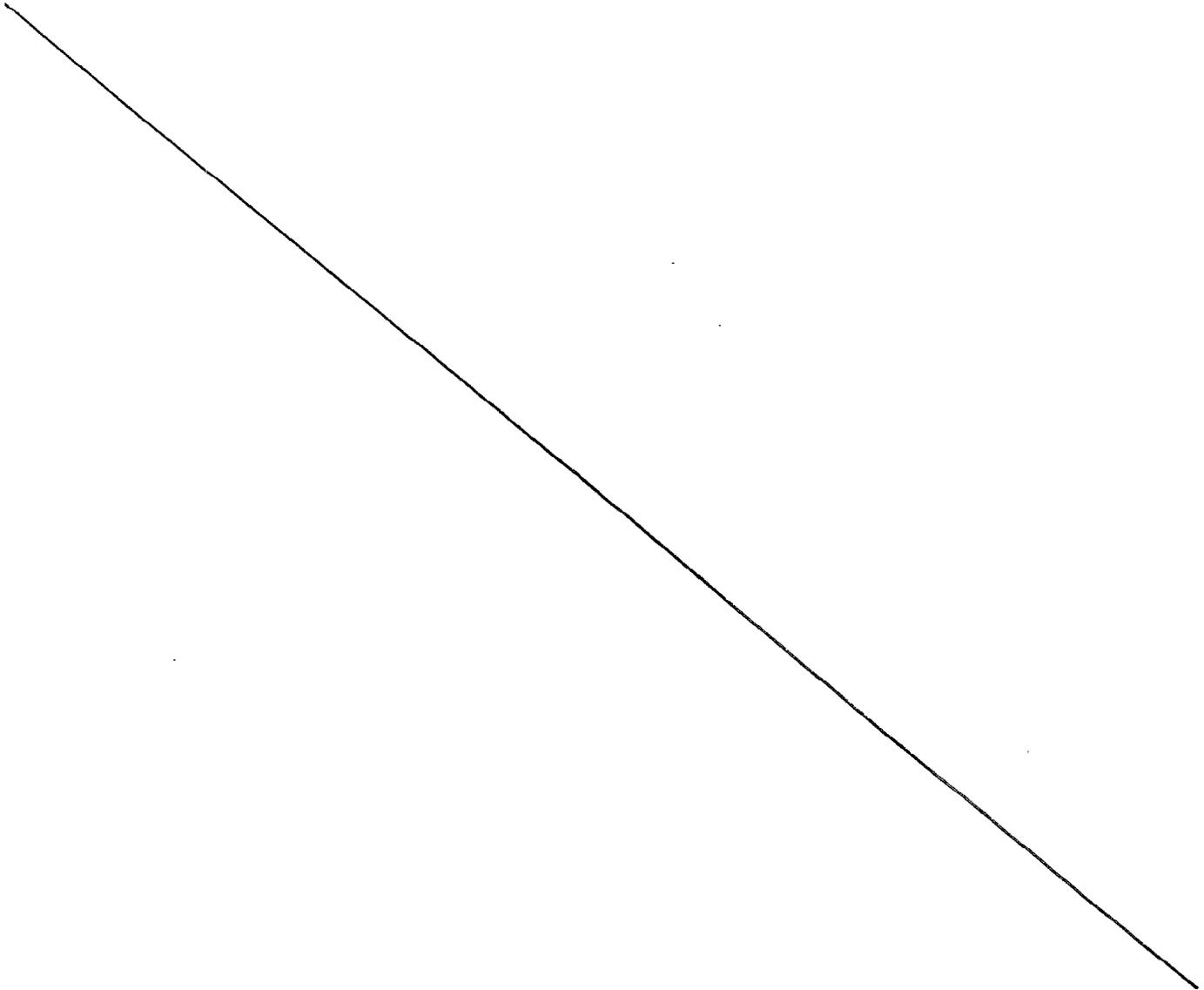
### **IX. Dun and Bradstreet Number (DUNS) Requirement**

Beginning October 1, 2003, applicants will be required to have a DUNS number to apply for a grant or cooperative agreement from the Federal

government. The DUNS number is a 9-digit identification number, which uniquely identifies business entities. Obtaining a DUNS number is easy and there is no charge. To obtain a DUNS number, call 1-866-705-5711. Be certain that you identify yourself as a Federal grant applicant when you contact Dun and Bradstreet.

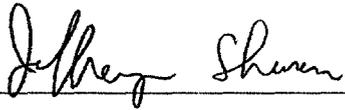
**X. Legend**

Unless disclosure is required by FOIA as amended (5 U.S.C. 552), as determined by the freedom of information officials of HHS or by a court, data contained in the portions of an application which have been specifically identified by page number, paragraph, etc., by the applicant as containing



restricted and/or proprietary information shall not be used or disclosed except for evaluation purposes.

Dated:           JUN 22 2004          



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Jeffrey Shuren,  
Assistant Commissioner for Policy.

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