Estimated Costs to the Federal Government

The total cost to the government for its proposal review activity is estimated to be $500,000 annually.

Request for Comments

In accordance with the above-cited legislation, comments on the AHRQ's information collection are requested with regard to any of the following: (a) Whether the proposed collection of information is necessary for the proper performance of health care improvement and information dissemination functions of AHRQ, including whether the information requested will have practical utility; (b) the accuracy of AHRQ's estimate of burden (including hours and costs) of the proposed collection(s) of information; (c) ways to enhance the quality, utility, and clarity of information to be collected; and (d) ways to minimize the burden of the collection of information upon the respondents, including the use of automated collection techniques or other forms of information technology.

Comments submitted in response to this notice will be summarized and included in the request for OMB approval of the proposed information collection. All comments will become a matter of public record.

Dated: July 30, 2007.

Carolyn M. Clancy,

Director.

[FR Doc. 07–3814 Filed 8–2–07; 8:45 am]

BILLING CODE 4160–90–M

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

Food Safety and Security Monitoring Project—Radiological Health; Availability of Cooperative Agreements Under a Limited Competition; Request for Applications: FD07–005; Catalog of Federal Domestic Assistance Number: 93.448

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

I. Funding Opportunity Description

The Food and Drug Administration (FDA), Office of Regulatory Affairs (ORA), Division of Federal-State Relations, is announcing the availability of cooperative agreements for equipment, supplies, personnel, training, and facility upgrades to Food Emergency Response Laboratory Network (FERN) radiological laboratories of State, local, and tribal governments. The cooperative agreements are to enable the analyses of foods and food products in the event that redundancy and/or additional laboratory surge capacity is needed by FERN for analyses related to radiological terrorism or other emergency situations. These cooperative agreements are also intended to expand participation in networks to enhance Federal, State, local, and tribal governmental food safety and security efforts. This notice supersedes the request for applications that published in the **Federal Register** of August 24, 2006 (71 FR 50068).

A. Background

ORA is the primary inspection and analysis component of FDA and has approximately 1,600 investigators, inspectors, and analysts who cover the country's approximately 95,000 FDA-regulated businesses. These investigators inspect more than 15,000 facilities per year and ORA laboratories analyze several thousand samples per year. ORA conducts special investigations, conducts food inspection recall audits, performs consumer complaint inspections, and collects samples of regulated products. Increasingly, ORA has been called upon to expand the testing program that addresses the increasing threat to food safety and security through intentional radiological terrorism events. Toward this end, ORA has developed radiological screening and analysis methodologies that are used to evaluate foods and food products in such situations. However, in the event of a large-scale emergent incident, analytical sample capacity in ORA field laboratories has a finite limit. Information from ongoing relationships with State partners indicates limited redundancy in State food testing laboratories; both in terms of analytical capabilities and analytical sample capacity. Several State food testing laboratories lack the specialized equipment to perform the analyses, and/or the specific methodological expertise in the types of analyses performed for screening foods and food products involving radiological terrorism events.

The events of September 11, 2001, reinforced the need to enhance the security of the U.S. food supply. Congress responded by passing the Bioterrorism Act, which President George W. Bush signed into law on June 12, 2002. The Bioterrorism Act is divided into the following five titles:

Title I—National Preparedness for Bioterrorism and Other Public Health Emergencies,

Title II—Enhancing Controls on Dangerous Biological Agents and Toxins,

Title III—Protecting Safety and Security of Food and Drug Supply,

Title IV—Drinking Water Security and Safety, and

Title V—Additional Provisions.

Subtitle A of the Bioterrorism Act, ''Protection of Food Supply,'' section 312, ''Surveillance and Information Grants and Authorities,'' amends part B of Title III of the Public Health Service Act to authorize the Secretary of Health and Human Services to award grants to States and Indian tribes to expand participation in networks to enhance Federal, State, and local food safety efforts. This may include meeting the costs of establishing and maintaining the food safety surveillance, technical, and laboratory capacity needed for such participation.

FDA will support the projects covered by this document under the authority of section 312 of the Public Health Security and Bioterrorism Preparedness and Response Act of 2002 (the Bioterrorism Act) (Public Law 107–188). This program is described in the Catalog of Federal Domestic Assistance under number 93.448.

B. Program Research Goals

The goal of ORA's cooperative agreement program is to complement, develop, and improve State, local, and Indian tribal food safety and security testing programs. This will be accomplished through the provision of equipment, supplies, personnel, facility upgrades, training in current food testing methodologies, participation in proficiency testing to establish additional reliable laboratory sample analysis capacity, analysis of surveillance samples, and, in cooperation with FDA, participation in method enhancement activities designed to extend analytical capabilities. In the event of a large-scale radiological terrorism event affecting foods or food products, the recipient may be required to perform selected radiological analyses of domestic and imported food samples collected and supplied to the laboratory by FDA or other Federal agencies through FDA. These samples may consist of, but are not limited to, the following: Vegetables and fruits (fresh and packaged), juices (concentrate and diluted), grains and grain products, seafood and other fish products, milk and other dairy products, infant formula, baby foods, bottled water, condiments, and alcoholic products (beer, wine, scotch).

All grant application projects that are developed at State, local, and tribal governmental levels must have national implication or application that can enhance Federal food safety and security programs. At the discretion of FDA, successful project formats will be made available to interested Federal, State, local, and tribal government FERN laboratories.

There are two key project areas identified for this effort:

1. The use of gamma spectrometry analysis for the screening and identification of gamma-emitting radionuclides in foods, and

2. The use of beta spectrometry analysis for the screening and identification of beta-emitting radionuclides in foods.

It should be emphasized that in all of the projects, there is a particular desire to promote a continuing, reliable capability and capacity for laboratory sample analyses of foods and food products for the rapid detection and identification of radionuclides. With this in mind, it is desirable that sample analyses will be completed within 2 weeks of receipt, and the results will be reported to FERN. The format and reporting media will be established by FERN. Shorter timeframes may be sought for special testing such as proficiency tests or special assignments.

II. Award Information

Support will be in the form of cooperative agreements. Substantive involvement by the awarding agency is inherent in the cooperative agreement awards. Accordingly, FDA will have substantial involvement in the program activities of the project funded by the cooperative agreement. Substantive involvement includes, but is not limited to, the following: (1) How often samples will be sent, (2) directions on how tests should be executed, (3) onsite monitoring, (4) supply of equipment, (5) FDA training on processes, and (6) enhancement and extension of analytical methodology.

FDA will provide specific procedures and protocols for the two project areas (see section I of this document) to be used for the analysis of collected food samples. FDA will provide guidance on the specific foods to be collected and analyzed by the successful applicant. State personnel will be responsible for the collection and analysis of surveillance samples.

Proposed projects designed to fulfill the specific objectives of any one or more of the project areas will be considered for funding. Applicants may also apply for facility upgrades, personnel, training, and surveillance sample collection.

A. Award Amount

The total amount of funding available in fiscal year 2007 is $750,000. Cooperative agreements will be awarded up to $250,000 in total (direct plus indirect) costs per year for up to 3 years. It is anticipated that 3 awards will be made. Support of these cooperative agreements will be for the funding of supplies, facility upgrades, surveillance sample collection, personnel, the provision of training in current analytical methodology, and for the analysis of foods and food products. Funds may be requested in the budget to travel to FDA for meetings with program staff about the progress of the project and to travel for training. If the applicant does not have the necessary equipment available for these projects, all major needed equipment will be provided on loan from FDA and will not be included in the award amount.

B. Length of Support

The length of support is 3 years and all applicants must apply for the full 3 years of currently projected funding and program objectives. The initial competitive review and award process will provide all awardees with 1 year of funding. The second and third year of funding of noncompetitive continuation of support will based on performance during the preceding year and availability of Federal funds.

C. Equipment

FDA will purchase and have all needed major equipment for the two project areas delivered to the awardee's laboratory. The equipment purchased by FDA will remain the property of FDA under loan to the awardee's laboratory for a minimum of 5 years at which point in time it may or may not be released as surplus property. FDA may terminate the loan at any time. The equipment may not be transferred by the awardee's laboratory to a third party, and the awardee's laboratory assumes full responsibility and liability for any claims that may arise as a result of operation of this equipment for the period it is in the possession of the awardee's laboratory.

D. Funding Plan

It is anticipated that FDA will make three awards in fiscal year 2007 for this program. The number of projects funded will depend on the quality of the applications received and is subject to availability of Federal funds to support the projects.

III. Eligibility Information

A. Eligible Applicants

Due to the sensitive counterterrorism nature of this project it is imperative that only State government entities with the regulatory authority to conduct onsite inspections be participatory members of this cooperative agreement program. This is to ensure that any regulatory action and/or laboratory analysis that must be completed in an emergent situation can be carried out in the most expeditious manner. Therefore, this cooperative agreement program is available only to current FERN radiological laboratories at the time of the submission of this application also fall into one of the following categories: State laboratories, State regulatory agencies with the required lab capacity and university laboratories that are currently State adjunct laboratories connected to State laboratory and/or regulatory agencies with the required State regulatory authority.

B. Cost Sharing or Matching

Cost sharing is not required.

C. Other

The entity and/or any or all person(s) involved in any aspect of the design, implementation, and/or evaluation of a successful Food Safety and Security Monitoring Project—Radiological Health cooperative program application may at any time at FDA's discretion be subject to requirements under 42 CFR parts 72 and 73 (70 FR 13294, March 18, 2005), the Bioterrorism Act, and the USA Patriot Act, including but not limited to security risk assessments and security clearances.

Dun & Bradstreet Number (DUNS): As of October 1, 2003, applicants are 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 that 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 & Bradstreet, Inc.

IV. Application and Submission

A. Addresses to Request Application

FDA is only accepting applications for this program electronically via Grants.gov by visiting the Web site *http://www.grants.gov*[1] and following

[1] (FDA has verified the Web site address, but FDA is not responsible for subsequent changes to the

the instructions under ''APPLY.'' In order to apply electronically, the applicant must have a DUNS number (see section III.C of this document) and register in the Central Contractor Registration (CCR) database as described in section IV.F of this document.

The required application, SF424 can be completed and submitted online. We strongly encourage using the ''Tips'' posted on *http://www.grants.gov*[1] under the announcement number when preparing your submission. If you experience technical difficulties with your online submission you should contact either the Grants.gov Customer Response Center at *http://www.grants.gov/contactus/contactus.jsp*[1] or Michelle Caraffa, Food and Drug Administration, 301–827–7025, e-mail: *michelle.caraffa@fda.hhs.gov*.

To comply with the President's Management Agenda, the Department of Health and Human Services (HHS) is participating as a partner in the new governmentwide Grants.gov application site. Users of Grants.gov will be able to download a copy of the application package, complete it offline, and then upload and submit the application via the Grants.gov Web site. When you enter the Grants.gov Web site, you will find information about submitting an application electronically through the Web site. In addition, this process is similar to the R01 Grant Application process currently used at the National Institutes of Health. You can visit the following Web site for helpful background on preparing to apply, preparing an application, and submitting an application to Grants.gov: *http://era.nih.gov/ElectronicReceipt/*.[1]

In unusual circumstances, additional information may be considered, on a case-by-case basis, for inclusion in the ad hoc expert panel review (see section V.A.2 of this document), however, FDA cannot assure inclusion of any information after the receipt date, other than evidence of final Institutional Review Board (IRB) approval, Federal-Wide Assurance (FWA), and certification of adequate supply of study product.

If an application for the same grant was submitted in response to a previous request for applications but has not yet been funded, an application in response to this document will be considered a request to withdraw the previous application. The applicant for a resubmitted application should address the issues presented in the summary statement from the previous review and include a copy of the summary statement itself as part of the resubmitted application.

The submitted electronic application package is posted under the ''APPLY'' section for this announcement at *http://www.grants.gov*.[1] The required application SF424, which is part of the PHS 5161–1 form, should be completed and submitted online.

B. Content and Form of Application

1. Content of Application

The ad hoc expert panel will review the application based on the following criteria that each applicant should address in their cooperative agreement application:

a. *The rationale and design to meet the goals of the cooperative agreement*. A full description of the prospective project's intended goals and objectives and how each will guide a full project plan. This section should lay a foundation for the entire program.

b. *Expertise in the use of gamma or beta spectroscopy in the analysis of foods or animal tissues*. Specifically address and provide the qualifications of all personnel that will be assigned to the project. Curriculum vitae/resumes for key laboratory personnel, including information on personnel that have experience in gamma and beta spectroscopy, must be provided.

c. *Sample analysis commitment*. The variety and number of samples analyzed in the current food or animal tissue programs. The laboratory will be required to analyze surveillance and emergency response food samples. Therefore, an estimate of the number of food samples that can be analyzed for radionuclides by each project area (i.e., gamma spectroscopy, beta spectroscopy), must be submitted. This estimate should be for a 3-year period. The estimate should also address the number of samples that can be analyzed in a 2-week period. The procedures to be used will be supplied by FDA. This information will be provided after the award is given, so recipients will be aware of requirements/responsibilities. In addition, if a cooperative agreement is awarded, awardees will be informed of any additional documentation that should be submitted to FERN.

d. *The adequacy of facilities, support services, and quality control and quality assurance procedures and practices for food and animal tissue analysis*. This section should include:

- A summary description of procedures in place to monitor sample workflow, including the tracking and monitoring of sample analyses and a description of the current quality assurance program.
- A discussion of the laboratory's ability to complete and report on a given sample analysis within the required 2-week time frame.
- The name and address of the laboratory facility where the equipment will be installed and the name of the responsible individual at the facility.
- A complete description of the laboratory facility, specifically addressing the following information:
  - Floor diagrams of the current laboratory;
  - A description of the envisaged space, to include a floor-plan diagram;
  - Area where the equipment is to be installed. The installation of equipment in a laboratory will require adequate and appropriate space and physical plant supplies, such as power, water, etc.;
  - A detailed description of the proposed facilities upgrade including drawings and cost estimates;
  - Operational support areas to be used for the project, including details about the availability of ancillary laboratory safety and support equipment and facilities, such as the numbers and types of chemical fume hoods available;
  - Details describing the sample receiving and sample storage areas and a description of any existing chain-of-custody procedures;
  - A detailed description of laboratory access procedures, including a description of practices and systems which limit access to laboratory space by unauthorized personnel. Additional procedures for access to the space(s) dedicated to the equipment provided, if any, should also be included.

e. *Laboratory management practices*. Abilities and procedures in place to recall personnel and establish extended work weeks and commitment to analyze emergency response samples. For the laboratory, the following management information must be provided:

- A summary description of any quality management system defined, in development, or in place as it relates to quality control and quality assurance procedures and practices;
- A summary description of staffing management, specifically to include abilities and procedures in place to recall personnel, establish extended work weeks, etc.; and
- A summary description of any security procedures or processes to evaluate the background of laboratory personnel. This should include any procedures to evaluate subcontractors who have access to laboratory space, such as cleaning personnel.

Web site after this document publishes in the **Federal Register**.)

2. Format for Application

All applications must be submitted electronically through Grants.gov. Paper applications will not be accepted. The application must be an SF424. The title of the proposed grant must include the name of the product and the investigational drug (IND)/ investigational device exemption (IDE) number. The narrative portion, excluding appendices, of the application may not exceed 100 pages in length and must be single-spaced in 12-point font. The appendices should also not exceed 100 pages in length (separate from the narrative portion of the application).

Data and information included in the application will generally not be available publicly prior to the funding of the application. After funding has been awarded, data and information included in the application will be given confidential treatment to the extent permitted by the Freedom of Information Act (5 U.S.C. 552(b)(4)) and FDA's implementing regulations (including 21 CFR 20.61, 20.105, and 20.106). By accepting funding, the applicant agrees to allow ORA to publish specific information about the grant.

The requirements requested on form PHS 5161–1 (revised 7/00) have been sent by PHS to the Office of Management and Budget (OMB) and have been approved and assigned OMB control number 0248–0043.

C. Submission Dates and Times

The application receipt date is August 24, 2007. Applications must be received by the close of business on the established receipt date. Applications not received on time will not be considered for review and will generally be returned to the applicant. However, late applications may be accepted under extreme circumstances beyond the control of the applicant. No addendum material will be accepted after the receipt date.

D. Intergovernmental Review

The regulations issued under Executive Order 12372, Intergovernmental Review of Department of Health and Human Services Programs and Activities (45 CFR part 100) apply to the Food Safety and Security Monitoring Project. 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 or at *http://www.whitehouse.gov/omb/grants/spoc.html*.[1] The SPOC should send any State review process recommendations to the FDA administrative contact (see section VII of this document). The due date for the State process recommendations is no later than 60 days after the application receipt date. FDA does not guarantee to accommodate or explain SPOC comments that are received after the 60-day cutoff.

E. Funding Restrictions

These grants are not to fund or conduct food inspections for food safety regulatory agencies. They may not be utilized for new building construction, however, remodeling of existing facilities is allowed, provided that remodeling costs do not exceed 25 percent of the grant award amount.

F. Other Submission Requirements

In anticipation of the Grants.gov electronic application process applicants are encouraged to register with the CCR database. This database is a governmentwide warehouse of commercial and financial information for all organizations conducting business with the Federal Government. Registration with CCR will eventually become a requirement and is consistent with the governmentwide management reform to create a citizen-centered Web presence and build e-gov infrastructures in and across agencies to establish a ''single face to industry.'' The preferred method for completing a registration is via the Internet at *http://www.ccr.gov*.[1] This Web site provides a CCR handbook with detailed information on data needed prior to beginning the online registration, as well as steps to walk applicants through the registration process. The applicant must have a DUNS number (see section III.C of this document) to begin registration.

In order to access Grants.gov an applicant will be required to register with the Credential Provider. Information about this requirement is available at *http://www.grants.gov/CredentialProvider*.[1]

V. Application Review Information

A. Criteria

1. General Information

FDA grants management and program staff will review applications sent in response to this document. To be responsive, an application must be submitted in accordance with the requirements of this document.

If an application is found to be nonresponsive, it will be returned to the applicant without further consideration. Applicants are strongly encouraged to contact FDA to resolve any questions about criteria before submitting an application. Please direct all questions of a technical or scientific nature to ORA program staff and all questions of an administrative or financial nature to the grants management staff (see section VII of this document).

To be a FERN radiological laboratory, an applicant institution must have an approval letter from the FERN National Program Office approving the applicant institution as a FERN Radiological laboratory prior to the application receipt date of August 24, 2007.

2. Scientific/Technical Review Criteria

Applications will be considered for funding on the basis of their overall technical merit as determined through the review process. Program criteria will include availability of funds and overall program balance in terms of geography with respect to existing and projected laboratory sample analysis and testing capacity and capability. Final funding decisions will be made by the Commissioner of Food and Drugs or his designee.

A responsive application 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. Funding decisions will be made by the Commissioner or his designee.

A score will be assigned to each responsive application based on the scientific/technical review criteria. The review panel may advise the program staff about the appropriateness of the proposal to the goals of the Division of Federal-State Relations cooperative agreement.

3. Program Review Criteria

All grant application projects that are developed at State, local, and tribal levels must have national implication or application that can enhance Federal food safety and security programs. At the discretion of FDA, successful project formats will be made available to interested Federal, State, local, and tribal government FERN laboratories.

B. Anticipated Announcement and Award

It is anticipated that notification regarding the results of the review in the form of a summary statement will be sent to the applicant by September 26, 2007. It is anticipated that all awards will be made by September 30, 2007.

VI. Award Administration Information

A. Award Notices

FDA's grants management office will notify applicants who have been selected for an award. A Notice of Grant Award will be signed by the FDA Chief Grants Management Officer and be sent to the applicant by mail or transmitted electronically.

B. Administrative and National Policy

Please note as of October 1, 2006, the HHS Grants Policy Statement (GPS) (available at *http://www.hhs.gov/grantsnet/adminis/gpd/index.htm*[1]) supersedes in its entirety the Public Health Service (PHS) GPS, dated April 1, 1994, and addendum dated January 24, 1995.

Awards issued through this program are subject to the HHS GPS requirements that are applicable to you based on the type of organization and the purpose of the award. This includes any requirements in Parts I and II of the HHS GPS that apply to an award.

Although consistent with the HHS GPS and applicable statutory and regulatory requirements, these agreements will be subject to all policies and requirements that govern the research grant programs of PHS, including provisions of 42 CFR part 52, 45 CFR parts 74 and 92, and the HHS GPS.

Applicants must adhere to the requirements of this document. Special terms and conditions regarding FDA regulatory requirements and adequate progress of the study may be part of the awards notice.

PHS strongly encourages all grant recipients to provide a smoke-free workplace and to discourage the use of all tobacco products. This is consistent with the PHS mission to protect and advance the physical and mental health of the American people.

FDA is committed to achieving the health promotion and disease prevention objectives of ''Healthy People 2010,'' a national effort designed to reduce morbidity and mortality and to improve quality of life. Applicants may obtain a paper copy of the ''Healthy People 2010'' objectives, vols. I and II, for $70 ($87.50 foreign) S/N 017–000–00550–9, by writing to the Superintendent of Documents, P.O. Box 371954, Pittsburgh, PA 15250–7954. Telephone orders can be placed to 202–512–2250. The document is also available in CD–ROM format, S/N 017–001–00549–5 for $19 ($23.50 foreign) as well as on the Internet at *http://www.healthypeople.gov*[1] under ''Publications.''

C. Reporting

1. Reporting Requirements

The original and two copies of an annual Financial Status Report (FSR) (SF–269) must be sent to FDA's grants management officer within 90 days of the budget period end date of the grant. Failure to file the FSR in a timely fashion will be grounds for suspension or termination of the grant. A final FSR will be due 90 days after the expiration of the project period as noted on the Notice of Grant Award.

For continuing cooperative agreements, quarterly reports and an annual program progress report are also required. For such cooperative agreements, the noncompeting continuation application (PHS 5161–1) will be considered the program progress report for the fourth quarter of the budget period.

Quarterly progress reports must contain, but are not limited to the following:

- A status report on the installation, training, and operational readiness of any equipment that is provided;
- A summary report on any proficiency testing performed;
- A summary status of samples analyzed and time to complete individual sample testing; and
- A summary description of any other testing performed on the equipment.

A final program progress report, final FSR, and a final invention statement must be submitted within 90 days after the expiration of the project period as noted on the Notice of Grant Award.

The final program progress report must provide full written documentation of the project and summaries of laboratory operations, as described in the grant application. The documentation must contain sufficient detail such that other State, local, and tribal government FERN laboratories could reproduce the final project.

2. Monitoring Activities

The program project officer will monitor grantees periodically. The monitoring may be in the form of telephone conversations, e-mails, or written correspondence between the project office/grants management office and the principal investigator. Periodic site visits with officials of the grantee organization may also occur. The results of these monitoring activities will be recorded in the official grant file and will be available to the grantee upon request consistent with applicable disclosure statutes and with FDA disclosure regulations. Also, the grantee organization must comply with all special terms and conditions of the cooperative agreement, including those which state that future funding of the study will depend on recommendations from the project officer. The scope of the recommendation will confirm that: (1) There has been acceptable progress on the project; (2) there is continued compliance with all FDA regulatory requirements; (3) if necessary, there is an indication that corrective action has taken place; and (4) assurance that any replacement of personnel will meet the testing requirements.

VII. Agency Contacts

Regarding administrative and financial management aspects of this notice please contact: Michelle Caraffa, Office of Acquisition Support and Grants (HFA–500), Food and Drug Administration, 5630 Fishers Lane, rm. 2105, Rockville, MD 20857, 301–827–7025, FAX: 301–827–7101, e-mail *Michelle.Caraffa@FDA.HHS.gov*.

Regarding the programmatic or technical aspects of this notice: April D. Kidd, Division of Federal-State Relations (HFC–150), Food and Drug Administration, 5600 Fishers Lane, rm. 12–07, Rockville, MD 20857, 301–827–2913, e-mail: *april.kidd@fda.hhs.gov*.

VIII. Other Information

Data included in the application may be entitled to confidential treatment as trade secret or confidential commercial information within the meaning of the Freedom of Information Act and FDA's implementing regulations (21 CFR 20.61).

Unless disclosure is required under the Freedom of Information Act 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 the application that have been specifically identified by page number, paragraph, etc., by the applicant as containing restricted information, shall not be used or disclosed except for evaluation purposes.

Dated: July 27, 2007.

Jeffrey Shuren,

Assistant Commissioner for Policy.

[FR Doc. E7–15061 Filed 8ndash;2–07; 8:45 am]

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