

## DEPARTMENT OF HEALTH AND HUMAN SERVICES

### Centers for Disease Control and Prevention

#### HIV Prevention and Care Services for Young People in Kenya

*Announcement Type:* New.

*Funding Opportunity Number:* PA 04265.

*Catalog of Federal Domestic Assistance Number:* 93.941.

*Dates:* Application Deadline: August 9, 2004.

#### I. Funding Opportunity Description

*Authority:* This program is authorized under Sections 307 and 317(k)(2) of the Public Health Service Act, (42 U.S.C. 242l and 247b(k)(2)), as amended, and under Public Law 108-25 (United States Leadership Against HIV/AIDS, Tuberculosis and Malaria Act of 2003) (22 U.S.C. 7601).

*Purpose:* The Centers for Disease Control and Prevention (CDC) announces the availability of fiscal year (FY) 2004 funds for a cooperative agreement program to implement model programs for youth interventions in Kisumu, Kitale, Makindu, and other towns in Kenya. This program should include community centers and/or services, and outreach activities that target youth. The program should also involve members of the community, including parents and religious leaders, to reduce risk of HIV infection in young people in Kenya.

The Global AIDS Program (GAP) has established field operations to support national HIV/AIDS control programs in 25 countries. The CDC's GAP exists to help prevent HIV infection, improve care and support, and build capacity to address the global AIDS pandemic. CDC/GAP provides financial and technical assistance through partnerships with governments, community and faith-based organizations, the private sector, and national and international entities working in the 25 resource-constrained countries. CDC/GAP works with the Health Resources and Services Administration (HRSA), the National Institutes of Health (NIH), the U.S. Agency for International Development (USAID), the Peace Corps, the Departments of State, Labor and Defense, and other agencies and organizations. These efforts complement multilateral efforts, including UNAIDS, the Global Fund to Combat HIV, TB and Malaria, World Bank funding, and other private sector donation programs.

The U.S. Government seeks to reduce the impact of HIV/AIDS in specific countries within sub-Saharan Africa, Asia, and the Americas through the Presidential Emergency Plan for AIDS Relief (PEPFAR). Through this new initiative, CDC's GAP will continue to work with host countries to strengthen capacity and expand activities in the areas of: (1) Primary HIV prevention; (2) HIV care, support, and treatment; and (3) capacity and infrastructure development, especially for surveillance and training. Targeted countries represent those with the most severe epidemics where the potential for impact is greatest and where U.S. government agencies are already active. Kenya is one of these targeted countries.

To carry out its activities in these countries, CDC is working in a collaborative manner with national governments and other agencies to develop programs of assistance to address the HIV/AIDS epidemic. CDC's program of assistance to Kenya focuses on several areas of national priority including scaling up activities and funding for HIV prevention, care, and treatment; improvement of the national blood safety program; and support for the National AIDS and STD Control Program.

The highest rates of HIV infection in Kenya occur in Kisumu and Nyanza Province. A survey, in 1997, found 23 percent of young women aged 15 to 19 to be HIV infected, compared to 3.5 percent of young men. CDC Kenya has supported a rural intervention for youth, but now wishes to support a more urban oriented intervention program for young people in Kisumu. In addition, CDC Kenya proposes to support youth prevention and care efforts in other areas of Kenya, including Kitale, Makindu, the Mukuru slum and environs in Nairobi, and elsewhere.

The measurable outcomes of the program will be in alignment with goals of the GAP to reduce HIV transmission and improve care of persons living with HIV. They also will contribute to the goals of the PEPFAR which are: within five years treat more than two million HIV-infected persons with effective combination anti-retroviral therapy; care for seven million HIV-infected and affected persons including those orphaned by HIV/AIDS; and prevent ten million new infections. Some of the specific measurable outcomes from this program will be: the number of young people receiving HIV behavior change services; the number of persons trained to provide HIV behavior change services for youth; the number of community leaders, religious leaders, and parents involved with the program; the number

of young people who receive voluntary counseling and testing (VCT) services as a result of activities sponsored by the program; and the number of HIV+ young people linked to care and treatment services.

#### Activities

Awardee activities for this program are as follows:

- Establish or maintain youth centers and/or programs intended to help young people reduce their risk of HIV infection.

- Provide training in targeted HIV behavior change for youth, including training related to abstinence and delay of sexual debut.

- Implement community outreach activities targeting youth, parents, and community and religious leaders; and provide opportunities for young people to participate in community outreach.

- Develop formal relationships or linkages with other programs and services providing VCT, sexually transmitted infections (STI) care, and AIDS care and treatment; and ensure that these services are provided in a manner which is "youth friendly."

- If not available nearby, provide youth friendly VCT, STI prevention and treatment, and AIDS care and treatment services.

- Provide directly, or collaborate with, partner organizations for the delivery of mobile VCT services targeting young people.

- Collect and analyze data on all of these services to track and evaluate program progress.

- Conduct regular and periodic assessments to determine the effectiveness of the program in achieving specific targets relating to the outcomes listed above, including the number of youth served and trained, and the number of youth learning HIV status, etc. Applicants may also propose to study the effectiveness of the interventions in changing behavior, such as median age of first sex and rates of abstinence and faithfulness.

Awardee should ensure that all of the above activities integrate into the national HIV/AIDS strategy and support the CDC/GAP Kenya mission priorities.

In a cooperative agreement, CDC staff is substantially involved in the program activities, above and beyond routine grant monitoring.

CDC Activities for this program are as follows:

- Provide technical assistance in youth interventions, youth oriented counseling, training, data management, and program development, monitoring and evaluation.

- Assist in the development of referral networks, information exchange, and dissemination of lessons learned with other CDC-supported youth interventions and care programs.

- Assist, as needed, in monitoring and evaluation of interventions funded by the program, and in development of further appropriate initiatives.

- Monitor project and budget performance to ensure satisfactory progress towards the goals of the project.

## II. Award Information

*Type of Award:* Cooperative Agreement.

CDC involvement in this program is listed in the Activities Section above.

*Fiscal Year Funds:* 2004.

*Approximate Total Funding:* \$8,000,000.

(This amount is the approximate total funding amount for the entire five-year project period.)

*Approximate Number of Awards:* 4 to 6.

*Approximate Average Award:* \$250,000.

(This amount is for the first 12-month budget period, and includes direct costs.)

*Floor of Award Range:* \$100,000.

*Ceiling of Award Range:* \$500,000.

*Anticipated Award Date:* September 1, 2004.

*Budget Period Length:* 12 months.

*Project Period Length:* Five years.

Throughout the project period, CDC's commitment to continuation of awards will be conditioned on the availability of funds, evidence of satisfactory progress by the recipient (as documented in required reports), and the determination that continued funding is in the best interest of the Federal Government.

## III. Eligibility Information

### III.1. Eligible Applicants

Applications may be submitted by public nonprofit organizations, private nonprofit organizations, universities or colleges, and faith-based organizations that meet the following criteria:

1. Have at least three years of documented experience in conducting HIV prevention interventions in Kenya.

2. Have an existing program in Kenya at the selected site because it is critical that these activities commence quickly. Kisumu, Kitale, Makindu, and the Mukuru slum area of Nairobi are priority sites, though programs proposed for other locations will be considered.

### III.2. Cost Sharing or Matching

Matching funds are not required for this program.

### III.3. Other

If you request a funding amount greater than the ceiling of the award range, your application will be considered non-responsive, and will not be entered into the review process. You will be notified that your application did not meet the submission requirements.

If your application is incomplete or non-responsive to the requirements listed in this section, it will not be entered into the review process. You will be notified that your application did not meet submission requirements.

## IV. Application and Submission Information

### IV.1. Address To Request Application Package

To apply for this funding opportunity use application form PHS 5161.

Application forms and instructions are available on the CDC web site, at the following Internet address: <http://www.cdc.gov/od/pgo/forminfo.htm>.

If you do not have access to the Internet, or if you have difficulty accessing the forms on-line, you may contact the CDC Procurement and Grants Office Technical Information Management Section (PGO-TIM) staff at: 770-488-2700. Application forms can be mailed to you.

### IV.2. Content and Form of Submission

*Application:* You must include a project narrative with your application forms. The narrative must be submitted in the following format:

- Maximum number of pages: 15. If your narrative exceeds the page limit, only the first pages which are within the page limit will be reviewed.
- Font size: 12 point un-reduced.
- Paper size: 8.5 by 11 inches.
- Double spaced.
- Page margin size: One inch.
- Printed only on one side of page.
- Held together only by rubber bands or metal clips; not bound in any other way.

- All pages should be numbered, and a complete index to the application and any appendices must be included.

- Submitted in English.

Your narrative should address activities to be conducted over the entire project period, and should consist of, as a minimum, a plan, objectives, activities, methods, an evaluation framework, a budget highlighting any supplies mentioned in the Program Requirements and any proposed capital expenditure. The budget justification will not be counted in the page limit stated above. Guidance for completing your budget can be found on the United

States government Web site at the following address: <http://www.cdc.gov/od/pgo/funding/budgetguide.htm>.

Additional information is optional and may be included in the application appendices. The appendices will not be counted toward the narrative page limit. Additional information could include but is not limited to: organizational charts, curriculum vitas, letters of support, etc.

You are required to have a Dun and Bradstreet Data Universal Numbering System (DUNS) number to apply for a grant or cooperative agreement from the Federal government. The DUNS number is a nine-digit identification number, which uniquely identifies business entities. Obtaining a DUNS number is easy and there is no charge. To obtain a DUNS number, access <http://www.dunandbradstreet.com> or call 1-866-705-5711.

For more information, see the CDC Web site at: <http://www.cdc.gov/od/pgo/funding/pubcomm.htm>.

If your application form does not have a DUNS number field, please write your DUNS number at the top of the first page of your application, and/or include your DUNS number in your application cover letter.

Additional requirements that may require you to submit additional documentation with your application are listed in section "VI.2. Administrative and National Policy Requirements."

### IV.3. Submission Dates and Times

Application Deadline Date: August 9, 2004.

#### *Explanation of Deadlines:*

Applications must be received in the CDC Procurement and Grants Office by 4 p.m. eastern time on the deadline date. If you send your application by the United States Postal Service or commercial delivery service, you must ensure that the carrier will be able to guarantee delivery of the application by the closing date and time. If CDC receives your application after closing due to: (1) Carrier error, when the carrier accepted the package with a guarantee for delivery by the closing date and time, or (2) significant weather delays or natural disasters, you will be given the opportunity to submit documentation of the carriers guarantee. If the documentation verifies a carrier problem, CDC will consider the application as having been received by the deadline.

This announcement is the definitive guide on application submission address and deadline. It supersedes information provided in the application instructions. If your application does

not meet the deadline above, it will not be eligible for review, and will be discarded. You will be notified that your application did not meet the submission requirements.

CDC will not notify you upon receipt of your application. If you have a question about the receipt of your application, first contact your courier. If you still have a question, contact the PGO-TIM staff at: 770-488-2700. Before calling, please wait two to three days after the application deadline. This will allow time for applications to be processed and logged.

#### *IV.4. Intergovernmental Review of Applications*

Executive Order 12372 does not apply to this program.

#### *IV.5. Funding Restrictions*

Restrictions, which must be taken into account while writing your budget, are as follows:

- Funds may be used for: Hiring of staff needed to establish and operate the center or program; hiring and/or renovating facilities to ensure adequate and appropriate premises for the center or program; coordination and evaluation of the program; and purchase of supplies, equipment, vehicles, and commodities needed to provide the services.

- Antiretroviral Drugs—The purchase of antiretrovirals, reagents, and laboratory equipment for antiretroviral treatment projects require pre-approval from the GAP headquarters.

- Needle Exchange—No funds appropriated under this Act shall be used to carry out any program of distributing sterile needles or syringes for the hypodermic injection of any illegal drug.

- Funds may be spent for reasonable program purposes, including personnel, training, travel, supplies and services. Equipment may be purchased and renovations completed if deemed necessary to accomplish program objectives; however, prior written approval by CDC officials must be requested in writing.

- All requests for funds contained in the budget shall be stated in U.S. dollars. Once an award is made, CDC will not compensate foreign grantees for currency exchange fluctuations through the issuance of supplemental awards.

- The costs that are generally allowable in grants to domestic organizations are allowable to foreign institutions and international organizations, with the following exception: With the exception of the American University, Beirut, and the World Health Organization, Indirect

Costs will not be paid (either directly or through sub-award) to organizations located outside the territorial limits of the United States or to international organizations regardless of their location.

- The applicant may contract with other organizations under this program, however, the applicant must perform a substantial portion of the activities, including program management and operations, and delivery of prevention and care services for which funds are requested.

- An annual audit of these funds is required by a U.S. based audit firm with international branches and current licensure/authority in-country, and in accordance with International Accounting Standards or equivalent standard(s) approved in writing by CDC. The audit should specify the use of funds and the appropriateness and reasonableness of expenditures.

- A fiscal Recipient Capability Assessment may be required with the potential awardee, pre or post award, in order to review their business management and fiscal capabilities regarding the handling of U.S. Federal funds.

- Prostitution and Related Activities: The U.S. Government is opposed to prostitution and related activities, which are inherently harmful and dehumanizing, and contribute to the phenomenon of trafficking in persons.

Any entity that receives, directly or indirectly, U.S. Government funds in connection with this document ("recipient") cannot use such U.S. Government funds to promote or advocate the legalization or practice of prostitution or sex trafficking. Nothing in the preceding sentence shall be construed to preclude the provision to individuals of palliative care, treatment, or post-exposure pharmaceutical prophylaxis, and necessary pharmaceuticals and commodities, including test kits, condoms, and, when proven effective, microbicides. A recipient that is otherwise eligible to receive funds in connection with this document to prevent, treat, or monitor HIV/AIDS shall not be required to endorse or utilize a multisectoral approach to combating HIV/AIDS, or to endorse, utilize, or participate in a prevention method or treatment program to which the recipient has a religious or moral objection. Any information provided by recipients about the use of condoms as part of projects or activities that are funded in connection with this document shall be medically accurate and shall include the public health benefits and failure rates of such use.

In addition, any foreign recipient must have a policy explicitly opposing, in its activities outside the United States, prostitution and sex trafficking, except that this requirement shall not apply to the Global Fund to Fight AIDS, Tuberculosis and Malaria, the World Health Organization, the International AIDS Vaccine Initiative or to any United Nations agency, if such entity is a recipient of U.S. government funds in connection with this document.

The following definitions apply for purposes of this clause:

- Sex trafficking means the recruitment, harboring, transportation, provision, or obtaining of a person for the purpose of a commercial sex act. 22 U.S.C. 7102(9).

- A foreign recipient includes an entity that is not organized under the laws of any State of the United States, the District of Columbia or the Commonwealth of Puerto Rico. Restoration of the Mexico City Policy, 66 FR 17303, (March 28, 2001).

All recipients must insert provisions implementing the applicable parts of this section, "Prostitution and Related Activities," in all subagreements under this award. These provisions must be express terms and conditions of the subagreement, acknowledge that each certification to compliance with this section, "Prostitution and Related Activities," are a prerequisite to receipt of U.S. government funds in connection with this document, and must acknowledge that any violation of the provisions shall be grounds for unilateral termination of the agreement prior to the end of its term. In addition, all recipients must ensure, through contract, certification, audit, and/or any other necessary means, all the applicable requirements in this section, "Prostitution and Related Activities," are met by any other entities receiving U.S. government funds from the recipient in connection with this document, including without limitation, the recipients' sub-grantees, sub-contractors, parents, subsidiaries, and affiliates. Recipients must agree that HHS may, at any reasonable time, inspect the documents and materials maintained or prepared by the recipient in the usual course of its operations that relate to the organization's compliance with this section, "Prostitution and Related Activities."

All primary grantees receiving U.S. Government funds in connection with this document must certify compliance prior to actual receipt of such funds in a written statement referencing this document (e.g., "[Recipient's name] certifies compliance with the section, 'Prostitution and Related Activities.'")

addressed to the agency's grants officer. Such certifications are prerequisites to the payment of any U.S. Government funds in connection with this document.

Recipients' compliance with this section, "Prostitution and Related Activities," is an express term and condition of receiving U.S. government funds in connection with this document, and any violation of it shall be grounds for unilateral termination by HHS of the agreement with HHS in connection with this document prior to the end of its term. The recipient shall refund to HHS the entire amount furnished in connection with this document in the event it is determined by HHS that the recipient has not complied with this section, "Prostitution and Related Activities."

Awards will not allow reimbursement of pre-award costs.

Guidance for completing your budget can be found on the CDC Web site at the following Internet address: <http://www.cdc.gov/od/pgo/funding/budgetguide.htm>.

#### IV.6. Other Submission Requirements

**Application Submission Address:** Submit the original and two hard copies of your application by mail or express delivery service to: Technical Information Management—PA 04265, CDC Procurement and Grants Office, 2920 Brandywine Road, Atlanta, GA 30341.

Applications may not be submitted electronically at this time.

### V. Application Review Information

#### V.1. Criteria

You are required to provide measures of effectiveness that will demonstrate the accomplishment of the various identified objectives of the cooperative agreement. Measures of effectiveness must relate to the performance goals stated in the "Purpose" section of this announcement. Measures must be objective and quantitative, and must measure the intended outcome. These measures of effectiveness must be submitted with the application and will be an element of evaluation.

Your application will be evaluated against the following criteria:

1. Understanding the Issues Relating to the Prevalence of HIV Infection in Young People in Kenya, and Developing a Creative and Innovative Approach to Preventing HIV Infection in This Population (30 points)

Does the applicant demonstrate an understanding of the social, behavioral, and contextual issues relating to the

high risk of HIV infection in young people in Kenya? Does the applicant demonstrate creative and innovative ideas for addressing this multi-sectoral problem? Does the applicant provide evidence that the proposed approach has been effective in changing behavior of young people in Kenya or elsewhere, or that it is based on best practices in HIV prevention?

2. Ability To Carry Out the Proposal (25 points)

Does the applicant demonstrate the capability to achieve the purpose of this proposal? Does the applicant demonstrate an ability to set up and operate an intervention program in Kenya? Does the applicant demonstrate an ability, and a reasonable plan, to scale up activities quickly and reach large numbers of young people with HIV prevention messages and services?

3. Personnel (20 points)

Are the technical personnel involved in this project qualified, including evidence of at least three years' experience in providing HIV interventions for youth? Do the technical personnel have demonstrated capacity for creative approaches to complex problems?

4. Plans for Administration, Management, and Evaluation of the Project (15 points)

Does the applicant describe activities that are realistic, achievable, time-framed and appropriate to complete this program? Are the plans for monitoring and evaluating the project appropriate and consistent with monitoring requirements associated with the PEPFAR?

5. Administrative and Accounting Plan (10 points)

Is there a plan to account for, prepare reports, monitor and audit expenditures under this agreement; manage the resources of the program; and produce, collect and analyze performance data?

6. Budget (not scored, but evaluated)

Is the itemized budget for conducting the project, along with justification, reasonable and consistent with stated objectives and planned program activities?

#### V.2. Review and Selection Process

Applications will be reviewed for completeness by the Procurement and Grants Office (PGO) staff, and for responsiveness by the National Center for HIV, STD and TB Prevention (NCHSTP). Incomplete applications and applications that are non-responsive to

the eligibility criteria will not advance through the review process. Applicants will be notified that their application did not meet submission requirements.

An objective review panel will evaluate complete and responsive applications according to the criteria listed in the "V.1. Criteria" section above.

No award will be made without the concurrence of the U.S. Embassy and the CDC representative in Kenya.

#### V.3. Anticipated Announcement and Award Date

September 1, 2004.

### VI. Award Administration Information

#### VI.1. Award Notices

Successful applicants will receive a Notice of Grant Award (NGA) from the CDC Procurement and Grants Office. The NGA shall be the only binding, authorizing document between the recipient and CDC. The NGA will be signed by an authorized Grants Management Officer, and mailed to the recipient fiscal officer identified in the application.

Unsuccessful applicants will receive notification of the results of the application review by mail.

#### VI.2. Administrative and National Policy Requirements

45 CFR Part 74 and Part 92

For more information on the Code of Federal Regulations, see the National Archives and Records Administration at the following Internet address: <http://www.access.gpo.gov/nara/cfr/cfr-table-search.html>.

The following additional requirements apply to this project:

- AR-1—Human Subjects Requirements.
- AR-4—HIV/AIDS Confidentiality Provisions.
- AR-6—Patient Care.
- AR-8—Public Health System Reporting Requirements.
- AR-10—Smoke-Free Workplace Requirements.
- AR-14—Accounting System Requirements.

Additional information on these requirements can be found on the CDC Web site at the following Internet address: <http://www.cdc.gov/od/pgo/funding/ARs.htm>.

#### VI.3. Reporting Requirements

You must provide CDC with an original, plus two hard copies of the following reports:

1. Semi-annual progress reports, no more than 30 days after the end of the budget period.

2. Interim progress report, no less than 90 days before the end of the budget period. The progress report will serve as your non-competing continuation application, and must contain the following elements:

- a. Current Budget Period Activities Objectives.
  - b. Current Budget Period Financial Progress.
  - c. New Budget Period Program Proposed Activity Objectives.
  - d. Budget.
  - e. Additional Requested Information.
  - f. Measures of Effectiveness.
3. Financial status report, no more than 90 days after the end of the budget period.
4. Final financial and performance reports, no more than 90 days after the end of the project period.

These reports must be mailed to the Grants Management or Contract Specialist listed in the "Agency Contacts" section of this announcement.

#### VII. Agency Contacts

For general questions about this announcement, contact: Technical Information Management Section, CDC Procurement and Grants Office, 2920 Brandywine Road, Atlanta, GA 30341, telephone: 770-488-2700.

For program technical assistance, contact: Elizabeth Marum, Ph.D., Project Officer, Global Aids Program [GAP], Kenya Country Team, National Center for HIV, STD and TB Prevention, Centers for Disease Control and Prevention [CDC], PO Box 606 Village Market, Nairobi, Kenya, telephone: 256-20-271-3008, e-mail: [emarum@cdcnairobi.mimcom.net](mailto:emarum@cdcnairobi.mimcom.net).

For budget assistance, contact: Diane Flournoy, Contract Specialist, CDC Procurement and Grants Office, 2920 Brandywine Road, Atlanta, GA 30341, telephone: 770-488-2072, e-mail: [dmf6@cdc.gov](mailto:dmf6@cdc.gov).

Dated: July 2, 2004.

**William P. Nichols,**

*Acting Director, Procurement and Grants Office, Centers for Disease Control and Prevention.*

[FR Doc. 04-15602 Filed 7-8-04; 8:45 am]

**BILLING CODE 4163-18-P**

## DEPARTMENT OF HEALTH AND HUMAN SERVICES

### Food and Drug Administration

[Docket No. 2004N-0049]

#### Agency Information Collection Activities; Submission for Office of Management and Budget Review; Comment Request; Control of Communicable Diseases; Restrictions on African Rodents, Prairie Dogs, and Certain Other Animals

**AGENCY:** Food and Drug Administration, HHS.

**ACTION:** Notice.

**SUMMARY:** The Food and Drug Administration (FDA) is announcing that a proposed collection of information has been submitted to the Office of Management and Budget (OMB) for review and clearance under the Paperwork Reduction Act of 1995.

**DATES:** Fax written comments on the collection of information by August 9, 2004.

**ADDRESSES:** OMB is still experiencing significant delays in the regular mail, including first class and express mail, and messenger deliveries are not being accepted. To ensure that comments on the information collection are received, OMB recommends that written comments be faxed to the Office of Information and Regulatory Affairs, OMB, Attn: Fumie Yokota, Desk Officer for FDA, FAX: 202-395-6974.

**FOR FURTHER INFORMATION CONTACT:** Jonna Capezzuto, Office of Management Programs (HFA-250), Food and Drug

Administration, 5600 Fishers Lane, Rockville, MD 20857, 301-827-4659.

**SUPPLEMENTARY INFORMATION:** In compliance with 44 U.S.C. 3507, FDA has submitted the following proposed collection of information to OMB for review and clearance.

#### Control of Communicable Diseases; Restrictions on African Rodents, Prairie Dogs, and Certain Other Animals (OMB Control Number 0910-0519)—Extension

Under § 1240.63(a)(2)(ii) (21 CFR 1240.63(a)(2)(ii)), an individual must submit a written request to seek permission to capture, offer to capture, transport, offer to transport, sell, barter, or exchange, offer to sell, barter, or exchange, distribute, offer to distribute, and/or release into the environment any of the following animals:

- Prairie dogs (*Cynomys sp.*),
- African Tree squirrels (*Heliosciurus sp.*),
- Rope squirrels (*Funisciurus sp.*),
- African Dormice (*Graphiurus sp.*),
- Gambian giant pouched rats (*Cricetomys sp.*),
- Brush-tailed porcupines (*Atherurus sp.*),
- Striped mice (*Hybomys sp.*), or
- Any other animal so prohibited by order of the Commissioner of Food and Drugs (the Commissioner) because of that animal's potential to transmit the monkeypox virus.

The request may not seek written permission to sell, barter, or exchange, or offer to sell, barter, or exchange, as a pet, the animals listed previously or any animal covered by an order of the Commissioner.

The request must state, among other things, the reasons why an exemption is needed, describe the animals involved, and explain why an exemption will not result in the spread of monkeypox within the United States.

FDA estimates the burden of this collection of information as follows:

TABLE 1.—ESTIMATED ANNUAL REPORTING BURDEN<sup>1</sup>

| 21 CFR Section    | No. of Respondents | Annual Frequency per Response | Total No. of Responses | Hours per Response | Total Hours |
|-------------------|--------------------|-------------------------------|------------------------|--------------------|-------------|
| 1240.63(a)(2)(ii) | 120                | 1                             | 120                    | 4                  | 480         |

<sup>1</sup> There are no capital costs or operating and maintenance costs associated with this collection of information.

Our estimates are based on our experience to date with the interim final rule. To estimate the number of respondents, we examined the number of requests we have received since the June 11, 2003, order. FDA has received approximately 65 requests in a 7-month

period, and most requests involved requests to move an animal from one location to another. As the agency cannot predict how the monkeypox outbreak will be resolved, FDA will tentatively estimate that 120 respondents would be affected.

Furthermore, based on FDA's experience with requests submitted thus far, and the parties submitting those requests, the agency estimates that each respondent will need 4 hours to complete its request for an exemption. Therefore, the total reporting burden