

any PHS advisory committee, board, and/or peer review committee, or as a consultant.

FOR FURTHER INFORMATION CONTACT:
Director, Division of Investigative Oversight, Office of Research Integrity, 1101 Wootton Parkway, Suite 750, Rockville, MD 20852, (301) 443-5330.

Chris B. Pascal,

Director, Office of Research Integrity.

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Centers for Disease Control and Prevention (CDC)

Citizens Advisory Committee on Public Health Services Activities and Research at Department of Energy Sites: Notice of Charter Renewal

This gives notice under the Federal Advisory Committee Act (Pub. L. 92-463) of October 6, 1972, that the Citizens Advisory Committee on Public Health Services Activities and Research at Department of Energy Sites of the Department of Health and Human Services, has been renewed for a 2-year period extending through July 7, 2006.

FOR FURTHER INFORMATION CONTACT:
Joseph E. Salter, Committee Management Officer, CDC, 1600 Clifton Road, NE., m/s E-72, Atlanta, Georgia 30333. Telephone (404) 498-0090, or fax (404) 498-0011.

The Director, Management Analysis and Services Office, has been delegated the authority to sign **Federal Register** notices pertaining to announcements of meetings and other committee management activities, for both CDC and the Agency for Toxic Substances and Disease Registry.

Dated: July 14, 2004.

William J. Atkinson,

Acting Director, Management Analysis and Services Office, Centers for Disease Control and Prevention.

[FR Doc. 04-16413 Filed 7-19-04; 8:45 am]

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Centers for Disease Control and Prevention

Expansion of Psychosocial Support and Peer Counseling Services to HIV-Infected Women and Their Families in Botswana

Announcement Type: New.

Funding Opportunity Number: PA 04256.

Catalog of Federal Domestic

Assistance Number: 93.041

Dates:

Application Deadline: August 20, 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. Sections 2421 and 247b(k)(S)], as amended.

Purpose: The purpose of the program is to provide funding to technical and organizational capacity building support for the expansion of psychosocial support services and development of peer counseling programs for HIV-infected women and their families. The awardee will provide funding for technical and organizational capacity building support to no more than five civil society organizations (non-governmental, community-based and faith-based organizations) working in HIV prevention, care and support in Botswana. This can be done either directly by the awardee or by an umbrella agency designated to manage and monitor the funding to the civil society organizations.

The Botswana National Prevention of Mother to Child Transmission (PMTCT) program, which is supported technically and financially under the President's Emergency Plan for AIDS Relief (PEPFAR) and the PMTCT initiative, provides limited counseling services to women and their families during antenatal and postnatal care, and relies on non-governmental and faith-based organizations for on-going counseling for HIV-infected clients. This program addresses the urgent need to increase the role of civil society in HIV prevention, care and support in Botswana.

Botswana's HIV prevalence is the world's highest. National HIV surveillance prevalence for 2003, among women in antenatal clinics, is estimated to be 37.4 percent. There are approximately 40,000 infants born each year in Botswana, 14,960 of them to HIV-positive women. Without intervention, roughly 6,000 of these infants will be HIV-infected (approximately 40 percent transmission). Through the use of antiretroviral (ARV) drug prophylaxis and infant formula, instead of breastfeeding, this number could be reduced to approximately 750-1500 (5-10 percent transmission rate).

In 1999, Botswana started a PMTCT program to provide AZT prophylaxis to mother and infant, and free infant

formula. The program has been available in all public health facilities since November 2001. An evaluation conducted in 1999, to review the progress of the first phase of the program, identified counseling as a major area of weakness in the program. Since then, several steps have been taken to improve access to and quality of counseling, including placement of dedicated PMTCT counselors in all health facilities. These counselors, however, have limited training (four weeks) and are unable to provide the on-going, supportive counseling that is required to meet the needs of HIV-infected women. Additionally, counselors only have contact with women during their pregnancy. Where services exist, counselors are encouraged to refer women to non-governmental and faith-based organizations for on-going support. Unfortunately, Botswana has a weak, underdeveloped civil society, and psychosocial services for HIV-infected people are limited to very few cities, towns and large villages. In January 2004, Botswana began implementation of routine HIV testing in all health facilities. With this new approach, women will be tested for HIV during antenatal care along with other routine blood tests, unless they refuse. It is hoped that this will normalize HIV testing, reduce stigma and increase utilization of the PMTCT, ARV and other programs. With routine HIV testing, it is expected that the number of people knowing their positive HIV status will increase tremendously and the need for psychosocial support services will intensify accordingly.

The PMTCT program currently does not have a personal face in Botswana. Only one woman, to date, has gone public with her status after going through the PMTCT program. Support groups for pregnant, infected women, though encouraged, do not yet exist. In a recent survey, 85 percent of women expressed interest in talking to other HIV-infected women and there is general agreement that there is a great need for support groups and peer counseling 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 President's Emergency Plan for AIDS Relief (PEPFAR). Through this new initiative, CDC's Global AIDS Program (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. Botswana 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 Botswana focuses on several areas of national priority including scaling up of promising prevention and care strategies for HIV prevention, care, and treatment.

The measurable outcomes of the program will be in alignment with the following performance goals for the National Center for HIV, STD and TB Prevention (NCHSTP), GAP: To reduce HIV transmission and improve care of persons living with HIV. They will also 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 10 million HIV-infected persons and those orphaned by HIV/AIDS; and prevent seven million infections in 14 countries throughout the world.

Activities:

Awardee activities for this program are as follows: The awardee will serve as or designate an umbrella organization which will be responsible for awarding and managing grants and providing technical assistance and organizational capacity development to no more than five civil society organizations in Botswana.

Activities to be carried out by selected civil society organizations under this task order are as follows:

1. Expand psychosocial support services for HIV-positive women and their families.

- Establish counseling and psychosocial care services in three underserved (currently without non-governmental, community-based or faith-based support services for people living with HIV/AIDS (PLWHAs)) areas to include counseling and support groups for HIV + women from the PMTCT program and their families. This funding does not provide for construction, erection or renovation of buildings.

2. Establish a peer counseling program for antenatal women.

- Develop and implement a peer counseling program in which HIV-positive women who have received PMTCT services provide education, counseling and support for pregnant

women in government clinics in conjunction with existing counseling structures. This program may involve multiple local providers (up to three) and may only begin in limited sections of the country in the first year.

3. Establish a peer counseling program at ARV sites.

- Train and support PLWHAs, including HIV+ women from the PMTCT program, as ARV counselors at 15 implementing ARV sites.

The awardee will provide funding, technical assistance, and organizational capacity building support to the selected civil society organizations directly or through an umbrella organization as follows:

Funding

The awardee or umbrella organization will award grants of up to five local civil society organizations to carry out the above activities. The awardee will oversee the financial management of funds awarded and submit reports to Botswana/USA Project (BOTUSA/CDC) as required.

Technical Assistance

The awardee will provide technical expertise and guidance to the selected umbrella organization and/or civil society organizations in support of the tasks outlined above. The awardee will provide relevant staff with training to meet the needs of the project.

Organizational Capacity Building

The awardee or umbrella organization will provide on-going support to the selected civil society organizations in general management and administration, financial management, supervision, monitoring and evaluation and other areas identified. All organizational capacity building support should be coordinated with other organizations working in this area, e.g. Botswana Council of Non-Governmental Organizations (BOCONGO), Bristol-Myers Squibb Foundation (BMS), and African Comprehensive HIV/AIDS Partnerships (ACHAP).

The awardee and/or umbrella organization will provide relevant staff with training to meet the needs of the project.

The awardee will coordinate activities and receive necessary approvals from BOTUSA, with input from the Ministry of Health and a sub-committee of the PMTCT Technical Advisory Committee, specifically tasked with providing input to the awardee (hereafter known as the Reference Group). The Reference Group will be selected by the PMTCT Technical Advisory Committee. The Reference Group is responsible for

providing overall guidance and technical support to the awardee. The Reference Group will also participate in the selection of the civil society organizations.

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:

1. Collaborate in designing and implementing the activities listed above including but not limited to the provision of technical assistance to develop and implement program activities, quality assurance, data management and presentation of program methods and findings.

2. Collaborate with all relevant partners (awardee, umbrella organization and civil society organizations) in the development of program activities.

3. Monitor project and budget performance.

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: \$3,000,000.

Approximate Number of Awards: one.

Approximate Average Award: \$600,000. (This amount is for the first 12-month budget period, and includes both direct and indirect costs.) Floor of Award Range: None.

Ceiling of Award Range: \$600,000.

Anticipated Award Date: September 1, 2004.

Budget Period Length: Twelve 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 non-profit voluntary organizations, including faith-based and community-based organizations, with experience working with HIV/AIDS in Botswana.

Eligible applications will have the following qualifications:

- At least two years experience or longer in the development and

implementation of psychosocial services for PLWHAs, including supportive counseling, peer counseling and support groups.

- Program staff should have expertise in psychology, social work, management, monitoring and evaluation, supervision and training, organizational capacity development.

- PLWHAs should be included on the team.

- Experience working in Africa.

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.

Note: Title 2 of the United States Code Section 1611 states that an organization described in Section 501(c)(4) of the Internal Revenue Code that engages in lobbying activities is not eligible to receive Federal funds constituting an award, grant, or loan.

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, 17303 (March 28, 2001).

All recipients must insert provisions implementing the applicable parts of this section, "Prostitution and Related Activities," in all sub-agreements under this award. These provisions must be express terms and conditions of the sub-agreement, 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."

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 submit 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.
- **Double spaced.**
- **Paper size:** 8.5 by 11 inches.
- **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.

Your narrative should address activities to be conducted over the entire project period, and must include the following items in the order listed:

- Goals and Objectives.
- Activities and timeline.
- Staffing Plan with Level of Effort.
- Methods of Evaluation.
- Summary Budget by line item along

with a budget justification (this will not be counted against the stated page limit).

Additional information may be included in the application appendices. The appendices will not be counted toward the narrative page limit. This additional information includes:

- Curriculum Vitae or Resumes for Proposed Staff.
- Organizational Charts.
- Letters of Support.

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 19, 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 carrier's 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:

- Antiretroviral Drugs—The purchase of antiretrovirals, reagents, and laboratory equipment for antiretroviral treatment projects requires 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, 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 organization 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.

- You must obtain an annual audit of these CDC funds (program-specific audit) 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.

- A fiscal Recipient Capability Assessment may be required, prior to or post award, in order to review the applicant's business management and fiscal capabilities regarding the handling of U.S. Federal funds.

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 #04256, 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:

Technical Approach and Methodology (40 points)

Provide a detailed description of the proposed methodology for development and implementation of the activities as

outlined above. Include a 12-month timeline and budget.

Personnel and Management Plan (35 points)

Provide a description and history of the organization, including personnel. Include their experience, education, skills and qualifications. If sub-contractors are proposed, provide information to support their qualifications and experience as well.

Document recent successful experience in managing similar or related work that is comparable, especially work performed in Botswana that demonstrates capacity for achieving the above objective.

Understanding of the Problem and Statement of Work (25 points)

Provide a detailed and comprehensive statement of the problem, scope and purpose of the project to demonstrate complete understanding of the intent and requirements of the agreement and potential problems, which may be encountered.

V.2. Review and Selection Process

Applications will be reviewed for completeness by the Procurement and Grants Office (PGO) staff, and for responsiveness by 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.

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-6—Patient Care
 - AR-10—Smoke-Free Workplace Requirements
 - AR-12—Lobbying Restrictions
 - AR-15—Proof of Non-Profit Status
 - AR-21—Small, Minority, and Women-Owned Business
 - AR-22—Research Integrity
 - AR-23—States and Faith-Based Organizations
 - AR-25—Release and Sharing of Data
- 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. 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.
2. Financial status report, no more than 90 days after the end of the budget period.
3. 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.

Additionally, the awardee shall submit quarterly progress reports to BOTUSA/MOH covering both technical and financial aspects of the task order. Following receipt of the report, a meeting shall be held between the contractor and BOTUSA (MOH will be in attendance) to discuss progress.

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: Thierry Roels, Project Officer, c/o American Embassy, Plot 5348 Dithakore Way, Extension 12, Gaborone, Botswana, telephone: 011 267 390 1696, e-mail: tbr6@cdc.gov.

For financial, grants management, or budget assistance, contact: Shirley Wynn, Grants Management Specialist, CDC Procurement and Grants Office, 2920 Brandywine Road, Atlanta, GA 30341, telephone: 770/488-1515, e-mail: Zbx6@cdc.gov.

Dated: July 14, 2004.

William P. Nichols,

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

[FR Doc. 04-16412 Filed 7-19-04; 8:45 am]

BILLING CODE 4163-18-P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. 2004N-0286]

Withdrawal of Six Guidances on the Clinical Evaluation or Requirements for Approval of Certain Classes of Drugs

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice; withdrawal.

SUMMARY: The Food and Drug Administration (FDA) is announcing the withdrawal of six guidances on the clinical evaluation or the requirements for approval of radiopharmaceuticals, antacids, antidiarrheals, laxatives, gastric secretory depressants, and drugs to treat superficial bladder cancer. The guidances are being withdrawn because they are out of date and of little use to the drug industry. The agency has developed other guidances and/or resources to assist the industry in obtaining information on the clinical evaluation and the requirements for approval of these classes of drugs.

DATES: General comments on agency guidance documents are welcome at any time.

ADDRESSES: Submit written comments to the Division of Dockets Management (HFA-305), Food and Drug Administration, 5630 Fishers Lane, rm. 1061, Rockville, MD 20852. Submit