populations; and the extent to which the proposal timeline appears feasible. (25 points)

4. Evaluation Plan. The extent to which the evaluation plan appears capable of monitoring progress toward meeting project objectives. (25 points)

5. Program Management. The extent to which applicant demonstrates the ability to conduct and manage cancer prevention and control projects and that proposed staff appear to be qualified and possess capacity to perform the project. (20 points)

6. Budget. The extent to which each line-item budget and narrative justification are reasonable and consistent with the purpose and objectives of the program. (Not scored)

7. Human Subjects. Does the application adequately address the requirements of Title 45 CFR Part 46 for the protection of human subjects? (Not scored)

The degree to which the applicant has met the CDC Policy requirements regarding the inclusion of women, ethnic, and racial groups in the proposed research. This includes—

a. The proposed plan for the inclusion of both sexes and racial and ethnic minority populations for appropriate representation.

b. The proposed justification when representation is limited or absent.

c. A statement as to whether the design of the study is adequate to measure differences when warranted.

d. A statement as to whether the plans for recruitment and research for study participants include the process of establishing partnerships with community(ies) and recognition of mutual benefits.

H. Other Requirements

Technical Reporting Requirements

Provide CDC with the original plus two copies of the following:

1. Annual written progress report must be submitted 30 days after the end of each budget period.

2. Financial status report (FSR) must be submitted 90 days after the end of each budget period.

3. Final financial and performance reports, must be submitted 90 days after the end of the project period.

Send all reports to the Grants Management Specialist identified in the "Where to Obtain Additional Information" section of this announcement.

The following additional requirements are applicable to this program. For a complete description of each, see Attachment I in the application package.

AR-1 Human Subjects Requirement

AR–2 Requirements for Inclusion of Women and Racial and Ethnic Minorities in Research

AR–9 Paperwork Reduction Act Requirements

AR–10 Smoke-Free Workplace Requirements

AR-11 Healthy People 2010

AR-12 Lobbying Restrictions

AR-20 Conference Support

I. Authority and Catalog of Federal Domestic Assistance Number

This program is authorized under sections 301(a), 317(k)(2) of the Public Health Service Act [42 U.S.C. 241(a) and 247b(k)(2)], as amended. The Catalog of Federal Domestic Assistance Number for this program is 93.283.

J. Where To Obtain Additional Information

For this announcement and other CDC program announcements see the CDC home page on the Internet: http://www.cdc.gov.

If you have questions after reviewing the contents of all the documents, business management technical assistance may be obtained from: Cynthia Collins, Grants Management Specialist, Grants Management Branch, Procurement and Grants Office, Announcement 00145, Centers for Disease Control and Prevention (CDC), Room 3627, 2920 Brandywine Road, Atlanta, GA 30341, Telephone (770) 488–2757, E-mail address ccollins@cdc.gov.

For program technical assistance, contact: Corinne Graffunder, Chief, Section A, Program Services Branch, Division of Cancer Prevention and Control, National Center for Chronic Disease Prevention and Health Promotion, Centers for Disease Control and Prevention (CDC), 4770 Buford Highway NE., Mailstop K–57, Atlanta, GA 30341–3724, Telephone (770) 488–4880, fax (770) 488–3230. E-mail address: cgraffunder@cdc.gov.

Dated: May 31, 2000.

John L. Williams,

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

[FR Doc. 00–14097 Filed 6–5–00; 8:45 am] BILLING CODE 4163–18–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Centers for Disease Control and Prevention

[Program Announcement 00081]

Cooperative Agreements for National Organizations To Enable Postsecondary Institutions To Prevent HIV Infection and Other Important Health Problems Among Youth Notice of Availability of Funds

A. Purpose

The Centers for Disease Control and Prevention (Center for Disease Control) announces the availability of fiscal year (FY) 2000 funds for a cooperative agreement program to enable postsecondary institutions to prevent HIV infection and other important health problems among youth. Centers for Disease Control is committed to achieving the health promotion and disease prevention objectives of "Healthy People 2010", a national activity to reduce morbidity and mortality and improve the quality of life. This announcement is related to the focus areas of HIV and Sexually Transmitted Diseases. For the conference copy of "Healthy People 2010", visit the internet site: www.health.gov/healthypeople>.

The purpose of the program is to strengthen the capacity of postsecondary institutions to increase the proportion of college and university students who receive information from their institutions on each of six priority health-risk behaviors (1) sexual behaviors that result in HIV infection, other STDs, and unintended pregnancy; (2) alcohol and other drug use; (3) tobacco use; (4) dietary patterns that result in disease; (5) intentional and unintentional injury; and (6) inadequate physical activity. Applicants may apply for one of the two following priority areas, which are of equal importance:

Priority 1: Institution-wide health promotion programs. To implement strategies for policymakers and practitioners (such as professors, educators, wellness coordinators, health care providers) in colleges and universities to institutionalize comprehensive HIV/AIDS prevention methods into health promotion and disease prevention programs for youth and young adults both on campus and in the community, especially for groups disproportionately affected by HIV/ AIDS, including communities of color and youth in high risk situations in large urban areas.

Priority 2: Preservice education. To implement and evaluate strategies for

university, college and other systems which will result in prevention methods for HIV and other serious health problems of youth being included in professional development courses for individuals entering the health, education or service professions and working with groups disproportionately affected by HIV/AIDS, including communities of color in large urban areas.

As additional funds become available, Centers for Disease Control expects to support through competitive supplemental awards other priorities addressing additional health-related areas.

B. Eligible Applicants

Limited Competition

Funding will be provided only to national non-profit organizations, to include national minority organizations, that have postsecondary institutions or programs as their major focus, and that have the capacity to develop an ongoing program of activities to prevent HIV infection and other serious health problems among youth and young adults, especially those in high-risk situations.

Eligible national organizations must have affiliate offices or local, state, or regional membership constituencies in a minimum of 10 states and territories. Affiliate offices and local, state, or regional membership constituencies may not apply in lieu of, or on behalf of, their national office. Colleges and universities and for-profit organizations are not eligible to apply. To be considered a national minority organization, eligible applicants must meet the following criteria:

At least 51 percent of the persons on the governing board must be members of racial or ethnic minority populations.

The organization must possess a documented history of serving racial or ethnic minority populations through its offices, affiliates, or participating organizations at the national level for at least 12 months before the submission of the application to Centers for Disease Control. Non-governmental organizations funded for similar activities under Centers for Disease Control's Program Announcement 99023, "Cooperative Agreements for National Programs to Prevent HIV Infection and Other Important Health Problems among Youth and Strengthen Coordinated School Health Programs" are not eligible for funding under this program announcement.

Competition is limited under this program announcement because of the need for directed and concentrated

focus in the effective dissemination of information and implementation and evaluation of programs. The coordination and implementation of a national strategy for postsecondary institutions requires organizations that have the capacity and experience to influence the professional actions of their constituencies; have the capacity to provide professional development for implementation of effective programs; and can build the capacity of postsecondary institutions.

Note: Public Law 104–65 states that an organization described in section 501(c)(4) of the Internal Revenue Code of 1986 that engages in lobbying activities is not eligible to receive Federal funds constituting an award, grant, cooperative agreement, contract, loan, or any other form.

C. Availability of Funds

Approximately \$2.2 million will be available in FY 2000 to fund approximately 8 awards under the two priority areas including at least one national minority organization. It is expected that awards will range from \$200,000 to \$300,000. It is expected that the awards will begin on or about September 30, 2000 and will be made for a 12-month budget period within a project period of up to 5 years. Funding estimates may change.

Continuation awards within an approved project period will be made on the basis of satisfactory progress as evidenced by required reports and the availability of funds.

Use of Funds

Funds must be used for categorical activities to prevent behaviors that place young people at risk for HIV infection, other STDs, unintended pregnancy, and other important health problems, especially targeting groups disproportionately affected, including communities of color and youth in highrisk situations particularly in urban settings. (A list of young people considered to be in high-risk situations is included as Attachment I of this program announcement.) Funds may be used to integrate such categorical activities into broader coordinated health programs to improve the health of young people (e.g., college health programs, adolescent health programs, or coordinated school health programs).

Activities funded under this announcement are intended to build the capacity of national non-governmental organizations to promote HIV, STD, and unintended pregnancy prevention among youth and young adults and should not include any formal or informal research. In addition, funds

under this announcement are not to be used for clinical services or supplies.

Applicants may apply for funding under only one of the two priority areas and must clearly identify the specific priority area for which funding is requested. As additional funds become available, Center for Disease Control expects to support, through competitive supplemental awards, expanded efforts in other health-related areas.

D. Program Requirements

In conducting activities to achieve the purpose of this program, the recipient shall be responsible for conducting activities under 1 (Recipient Activities) and Center for Disease Control will be responsible for conducting activities under 2 (Center for Disease Control Activities).

1. Recipient Activities

a. Establish and maintain a staff position within the agency that has full-time responsibility and organizational authority for HIV prevention and other health-related activities funded under this announcement. The selected individual in this position should have specific training and experience needed for leadership and coordination of health promotion activities; knowledge and experience working in higher education; and good written and oral skills to enable them to serve as a liaison with partners in health, education, and the community.

b. Collaborate with the organization's constituents in addition to state and local education, health, and social service agencies, non-governmental organizations (especially those also funded under this program announcement), and Center for Disease Control to implement a national strategy to achieve the purposes of this program in postsecondary institutions.

c. Implement specific, measurable, and feasible goals and objectives. Evaluate the effectiveness of the program in achieving goals and objectives by providing indicators of success.

d. Participate in the Division of Adolescent and School Health (DASH) annual conference each budget year of the project for the purpose of improving health education to prevent HIV infection and reduce other important health risks that face youth and young adults.

e. Disseminate project-related information and findings through a variety of methods.

f. Implement an operational plan for the funded priority area that may include, but is not limited to, one or more of the following activities: Possible activities for Priority Area 1: (Institution-wide health promotion

programs).

(1) Form state coalitions of decisionmakers to implement health promotion programs for young people in the community, including postsecondary students, focusing on HIV prevention among youth in high-risk situations and within communities of color especially in urban settings. Assist coalitions to develop focused goals, select feasible strategies, obtain critical resources, implement effective collaborative methods, and evaluate program outcomes. The coalition should be statewide, involve other campuses, and include stakeholders from universities and their governing boards, state or local government agencies, state or local health departments, local school districts, businesses, voluntary and religious organizations, social services organizations, special population groups, community-based organizations, other organizations that serve youth, and legislators.

(2) Integrate comprehensive HIV prevention methods throughout the campus learning environment. Adopt effective, model prevention techniques into the credit curriculum; non-credit courses, programs and services; co-curricular programs; and other education reform initiatives. Foster educational experiences for postsecondary students that actively involve them in community efforts (e.g., through service learning) to prevent HIV and other serious health problems

among youth.

(3) Implement campus-wide policies regarding HIV/AIDS and other serious health problems. Include language that supports a healthy campus/community in the institution's mission, vision, and/or values statement(s). Implement policies to broaden the definition of scholarship in universities and colleges to include professional services, especially those that improve the health of children and youth, as criteria for tenure and promotion. Provide assistance to implement such policies and evaluate their effectiveness.

(4) Identify and target youth and young adults engaging in high-risk behaviors with health messages, education, resources, and services, providing particular attention to students living in communities of color especially in urban settings. Evaluate the effects of the intervention.

Possible activities for Priority Area 2: (Preservice education)

(1) Convene policymakers in state systems of higher education, and state and local education agencies to develop or modify policies dealing with university/college professional development courses so prevention of HIV and other serious health problems among youth is institutionalized in preservice training. Assist a designated work group in planning, implementing, and evaluating these changes.

(2) Train university/college instructors and professors to use effective teaching resources for HIV prevention and other serious health problems in professional development courses for educators in general, health educators, counselors, social workers, nurses, physicians and others who will work with youth. Provide technical assistance for these individuals as well as follow up evaluation of their work.

(3) Convene a cross-disciplinary consortium of accrediting bodies or professional associations whose constituencies are teachers, nurses, physicians, public health educators, counselors, social workers, and other practitioners who regularly work with youth. Devise, implement and evaluate a plan to prepare professionals to address HIV prevention/health education for youth.

(4) Form a coalition comprised of members of a pertinent discipline(s) to develop and adopt HIV and health education standards to be included in relevant credentialing guidelines for certification and licensing for youth-serving professionals.

2. Center for Disease Control Activities

a. Provide and periodically update information related to the purposes or activities of this program announcement.

b. Coordinate with national, state, and local education, health and social service agencies, as well as other relevant organizations, in planning and conducting national strategies designed to strengthen programs for preventing HIV infection, other STDs, unintended pregnancy, and other important health risks and health problems among young people.

c. Provide programmatic consultation and guidance related to program planning, implementation, and evaluation; assessment of program objectives; use of indicators; and dissemination of successful strategies, experiences, and evaluation reports.

d. Plan and conduct meetings of national, state, and local education agencies and other appropriate organizations and individuals to address issues and program activities related to improving coordinated school health programs and strengthening the capacity of postsecondary institutions and agencies that serve young people to prevent HIV infection, other STDs,

unintended pregnancies and other important health problems among young people.

e. Assist in the evaluation of program activities.

E. Application Content

Use the information in the Program Requirements, Other Requirements, and Evaluation Criteria sections to develop the application content. Your application will be evaluated on the criteria listed, so it is important to follow these in laying out your program plan.

The narrative should be no more than 42 double-spaced pages printed on one side, with one-inch margins, and unreduced font. Pages must be numbered clearly, and a complete table of contents of the application and its appendixes must be included. Begin each separate section on a new page.

Provide a concise, one page Executive Summary that clearly states the priority area being addressed and describes your organization's eligibility, including: (a) its status as a national organization, (b) number and membership of affiliate offices, and (c) experience and capacity of the organization to work with postsecondary institutions and other relevant agencies. The summary should also include the major proposed goals, objectives, and activities for implementation of the project.

Divide the body of the application into the following sections:

- 1. Background and Need (not more than 4 pages): Identify the priority area for which support is being requested and describe:
- a. The needs associated with the priority area.
- b. Your organization's background and experience in addressing the needs related to the priority area.
- c. The need for the specific activities proposed in your plan.
 - 2. Capacity (not more than 8 pages):
- a. Describe your organization's constituents and affiliates as follows:
- —Type of constituency.
- —Number of constituents and affiliates.
- Location of constituents and affiliates.
- —How the constituency can influence and work with the population identified in the priority area.
- b. Describe your organization's experience in supporting the priority area for which you are applying, including such factors as:
- —Current and previous experience related to the proposed program activities.
- —Current and previous coordination with other national organizations and

health, education, and social service agencies.

-Activities related to building alliances, networks, or coalitions.

- c. Describe your organization's structure and how it supports health promotion and education activities. Attach a copy of your organizational chart.
- 3. Operational Plan (not more than 15 pages):
- a. Goals. List goals that specifically relate to program requirements that indicate where the program will be at the end of the projected 5 year project period.
- b. Objectives. List objectives that are specific, measurable, and feasible to be accomplished during the first 12-month budget period. The objectives should relate directly to the project goals and recipient activities.
- c. Describe in narrative form and display on a timetable, specific activities that are related to each firstyear objective. Indicate when each activity will occur as well as when preparations for activities will occur. Indicate who will be responsible for each activity.
- d. List major milestones that will be accomplished during years two through
- 4. Project Management and Staffing Plan (not more than 8 pages):
- a. Describe the proposed staffing for the project and provide job descriptions for existing and proposed positions.
- b. Attach curriculum vitae (limited to 2 pages per person) for each professional staff member named in the proposal.
- c. Submit job descriptions illustrating the level of organizational responsibility for professional staff who will be assigned to the project.
- d. If a state(s) has been identified where the proposed activities will occur, provide the name of this state(s) and the name(s) of the contact person who will coordinate the activity.
- 5. Sharing experiences (not more than

Describe how project materials and accomplishments will be shared with others. Identify appropriate audiences for this information.

6. Collaboration (not more than 2 pages): Describe the purposes of proposed collaboration and the agencies and organizations with which collaboration will be conducted. If other organizations will participate in proposed activities, provide the name(s) of the organization(s), and state who in your organization will coordinate the activity. For each organization listed, provide a letter from them that acknowledges their specific role and

describes their capacity to fulfill it. Do not include letters of support from organizations that will not have specific roles in the project.

- 7. Evaluation (not more than 4 pages): Describe a plan to evaluate the project's effectiveness in meeting its objectives and goals. For each of the types of evaluation listed below, specify the evaluation question(s) to be answered, data to be obtained, the type of analyses that will be performed, to whom it will be reported, and how data will be used to improve the program. The plan should indicate the major steps in the evaluation, who will be responsible for each one, and when each will be accomplished.
- a. Process evaluation. Describe how you will evaluate the project's progress in meeting objectives and conducting activities during the budget period.
- b. Outcome evaluation. Describe how vou will assess the project's effectiveness in attaining goals at the completion of each project year and at the end of the 5 year project period. Specific, measurable indicators of project success should be developed.
- 8. Budget and Accompanying Justification: Provide a detailed budget narrative and line-item justification of all operating expenses. The budget should be consistent with the stated objectives and planned activities of the project. Budget requests should include the cost for two people for a 2 day trip to Atlanta, Georgia for a planning meeting and a 4 day trip to Atlanta, Georgia for the Division of Adolescent and School Health annual conference.

F. Submission and Deadline

Letter of Intent

The application must be preceded by an original and two copies of a letter of intent to apply. The letter of intent must be submitted on or before June 8, 2000, to the Grants Management Specialist identified in the "Where to Obtain Additional Information" section of this announcement.

Your letter of intent should include the name, address, telephone and facsimile numbers of the organization's primary contact for writing and submitting the application. The letter of intent should be limited to a simple statement of your organization's intention to apply and may not exceed one page. The letter of intent will be used to anticipate the number of applications.

Application

Submit the original and two copies of PHS Form 5161-1 (OMB Number 0937-0189). Forms are available in the

application kit. On or before June 30, 2000, submit the application to the Grants Management Specialist identified in the "Where to Obtain Additional Information" section of this announcement.

Deadline: Applications shall be considered as meeting the deadline if they are either:

- 1. Received on or before the deadline date: or
- Sent on or before the deadline date. Applicants must request a legibly dated U.S. Postal Service postmark or obtain a legibly-dated receipt from a commercial carrier or U.S. Postal Service. Private metered postmarks shall not be acceptable as proof of timely mailing.

Late Applications: Applications which do not meet the criteria in (1) or (2) above are considered late applications, will not be considered, and will be returned to the applicant.

G. Evaluation Criteria (100 points)

Each application will be evaluated individually according to the following criteria by an independent review group appointed by the Centers for Disease Control and Prevention.

1. Background and Need (10 points)

The extent to which the applicant justifies need for the program under the priority area, the organization's experience in addressing the priority area, and the need for proposed activities.

2. Capacity (30 points)

The extent to which the applicant demonstrates the capacity and ability of the organization and its constituency to address the identified needs and develop, implement, and evaluate program activities.

3. Operational Plan (25 points)

The extent to which the applicant: a. Identifies goals that are specific and feasible for the projected 5 year project period and are consistent with program

requirements.

b. Identifies objectives for the first year budget period that are specific, measurable, and feasible and are related directly to project goals.

c. Proposes activities that are likely to achieve each objective for the first budget period.

d. Proposes activities that focus on youth in high-risk situations and communities of color especially those in urban settings.

e. Provides a reasonable time line for conducting activities.

f. Outlines major milestones that will be accomplished during years two through five of the project.

4. Project Management and Staffing (15 points)

The extent to which the applicant identifies staff that have the responsibility, capability, and authority to carry out each activity, as evidenced by job descriptions, curriculum vitae, and organizational charts.

5. Sharing Experiences and Resources (5 points)

The extent to which the applicant describes plans to share effective materials and activities with appropriate audiences.

6. Collaboration (5 points)

The extent to which the applicant describes plans to collaborate with agencies such as state and local health and education departments, postsecondary institutions, and other national organizations and provides letters of specific intentions from collaborating agencies.

7. Evaluation (10 points)

The quality of the plans for both process and outcome evaluations, to include specification of indicators of program success, methods of obtaining data, ways of reporting results, use of results for programmatic decisions, and timing and staff responsibility.

8. Budget (Not Scored)

The extent to which the applicant provides a detailed and clear budget narrative consistent with the stated objectives, planned activities, and goals of the project.

H. Other Requirements

1. Technical Reporting Requirements

Provide Center for Disease Control with original plus two copies of:

- a. Annual progress reports, no more than 90 days after the end of each budget period;
- b. Financial status reports, no more than 90 days after the end of the budget period; and
- c. Final financial and performance reports, no more than 90 days after the end of the project period.

Send all reports to the Grants Management Specialist identified in section J, "Where to Obtain Additional Information".

2. Research Activities Restricted

Activities funded under this program announcement are intended to build the capacity of postsecondary institutions to promote HIV, other STDs, and unintended pregnancy prevention and to prevent other serious health problems among youth and young adults as

described in the two priority areas. Research activities will not be supported under this announcement.

The following additional requirements are applicable to this program. For a complete description of each, see Attachment III in the application kit.

AR–5—HIV Program Review Panel Requirements

AR-7—Executive Order 12372 Review AR-8—Public Health System Reporting Requirements

AR-9—Paperwork Reduction Act Requirements

AR–10—Smoke-Free Workplace Requirements

AR–11—Healthy People 2010

AR-12—Lobbying Restrictions

AR-15—Proof of Non-profit Status

I. Authority and Catalog of Federal Domestic Assistance Number

This program is authorized under sections 301(a), 317(k)(2) and 1706 [42 U.S.C. 241(a), 247b(k)(2) and 300u–5] of the Public Health Service Act, as amended. The Catalog of Federal Domestic Assistance number is 93.938.

J. Where to Obtain Additional Information

This and other Center for Disease Control announcements can be found on the Center for Disease Control home page <www.cdc.gov>. Click on Funding then click on Grants and Cooperative Agreements. To receive additional written information and to request an application kit, call (1–888–472–6874). You will be asked to leave your name and address and will be instructed to identify the announcement of interest.

If you have questions after reviewing the contents of all documents, business management assistance may be obtained from: Van A. King, Grants Management Specialist, Grants Management Branch, Procurement and Grants Office, Announcement 00081, Centers for Disease Control and Prevention, 2920 Brandywine Road, Room 3000, Atlanta, GA 30341–4146; Telephone Number (770) 488–2751; Email address vbk5@cdc.gov.

For program technical assistance, contact: Mary Vernon-Smiley, Chief, Special Populations Program Section, Division of Adolescent and School Health, National Center for Chronic Disease Prevention and Health Promotion, Centers for Disease Control and Prevention, 4770 Buford Highway, MS K–31, Atlanta, Georgia 30341–4146; Telephone Number (770) 488–325–8004; Email address mev0@cdc.gov.

Dated: May 31, 2000.

John L. Williams,

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

[FR Doc. 00–14098 Filed 6–5–00; 8:45 am]

BILLING CODE 4163-18-P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

Arthritis Advisory Committee; Notice of Meeting

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

This notice announces a forthcoming meeting of a public advisory committee of the Food and Drug Administration (FDA). The meeting will be open to the public.

Name of Committee: Arthritis Advisory Committee.

General Function of the Committee: To provide advice and recommendations to the agency on FDA's regulatory issues.

Date and Time: The meeting will be held on July 12, 2000, 8 a.m. to 5 p.m.

Location: Gaithersburg Holiday Inn, Walker and Whetstone Rooms, Two Montgomery Village Ave., Gaithersburg, MD.

Contact Person: Kathleen R. Reedy or LaNise S. Giles, Center for Drug Evaluation and Research (HFD–21), Food and Drug Administration, 5600 Fishers Lane, (for express delivery, 5630 Fishers Lane, rm. 1093) Rockville, MD 20857, 301–827–7001, or e-mail: reedyk@cder.fda.gov, or FDA Advisory Committee Information Line, 1–800–741–8138 (301–443–0572 in the Washington, DC area), code 12532. Please call the Information Line for upto-date information on this meeting.

Agenda: The Committee will discuss biologics license application (BLA) 99–1234, RemicadeTM (infliximab, Centocor) for the treatment of rheumatoid arthritis, prevention of radiographic progression and prevention of physical disability. The Committee will also discuss general issues regarding claims based on radiographic data in patients with rheumatoid arthritis.

Procedure: Interested persons may present data, information, or views, orally or in writing, on issues pending before the committee. Written submissions may be made to the contact person by July 6, 2000. Oral presentations from the public will be scheduled between approximately 11