

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Solicitation of Potential Partners to Participate in Programs of the Office of the President's Council on Physical Fitness and Sports During 2006 50th Anniversary Celebration

AGENCY: Department of Health and Human Services, Office of the Secretary, Office of Public Health and Science, Office of the President's Council on Physical Fitness and Sports.

ACTION: Notice.

SUMMARY: The Office of the President's Council on Physical Fitness and Sports (PCPFS) is soliciting proposals for the establishment of partnerships with non-Federal public and private sector organizations, with the goal of developing, implementing, promoting, and evaluating physical activity, fitness, and sports participation activities and initiatives. These partnerships are particularly targeted at calendar year 2006, which marks the 50th anniversary of the PCPFS. This Partnership Initiative is not a grant or contract award program. It is intended to provide opportunities for the Office of the PCPFS and non-Federal public and private sector organizations to work together both to enhance and integrate existing partnerships and also to create new physical activity, fitness, and sports initiatives at the national, state, and local levels to promote better health and fitness for all Americans in a synergistic and collaborative environment. These partnerships will be voluntary, and each partner will be responsible for supporting its own activities. Potential co-sponsors must have a demonstrated interest in physical activity, fitness, and/or sports activities and be willing to participate substantively in the co-sponsored activity.

DATES: This announcement is open until June 1, 2006, and may be renewed as needed through subsequent notices. Comments expressing or confirming an interest in potential partnerships will be most useful if received within two months of the publication of this notice, but will continue to be accepted for consideration throughout the open period.

ADDRESSES: Expressions of interest, comments, or questions may be sent via e-mail, fax, or regular mail to: Melissa Johnson at mjohnson@osophs.dhhs.gov, Fax: 202-690-5211, President's Council on Physical Fitness and Sports—Partnerships, Department of Health and Human Services, Hubert H. Humphrey Building, 200 Independence Avenue,

SW., Room 738H, Washington, DC 20201.

FOR FURTHER INFORMATION CONTACT:

Melissa Johnson at Ph: 202-690-5187, e-mail: mjohnson@osophs.dhhs.gov or Christine Spain at Ph: 202-690-5148, e-mail: cpain@osophs.dhhs.gov.

SUPPLEMENTARY INFORMATION: The President's Council on Physical Fitness and Sports (PCPFS) was established by the President of the United States in 1956 and today operates under Executive Order 13265, continued by Executive Order 13385, in accordance with the Federal Advisory Committee Act. The purposes of the PCPFS are (1) to provide advice and recommendations to the President through the HHS Secretary concerning actions and initiatives to develop, implement, and coordinate national programs for physical activity, fitness, and sports; (2) to inform the general public about the importance of regular physical activity and the link between physical activity and good health.

The PCPFS serves as a catalyst to promote physical activity, fitness, and sports for Americans of all ages, backgrounds, and abilities. Since its founding in 1956, the Office of the PCPFS has sustained a productive history of relationships with both public and private sector sponsors to create and maintain opportunities for Americans to participate in physical activity, fitness, and sports initiatives on the national, state, and local levels. Co-sponsorships established for observance of the 50th anniversary of the PCPFS should raise awareness of following: (1) The physical benefits of a fit and active lifestyle; (2) model programs promoting and providing physical activity in a variety of venues, suitable for replication; (3) opportunities to work collaboratively at the grassroots level to promote physical activity, fitness, and sports; (4) gaps and barriers preventing active and functional living and aging.

The Secretary has delegated to the Office of the PCPFS certain authorities under the Public Health Service Act (PHS Act) including, but not limited to, sections 1704(1) and (2) of the PHS Act. Sections 1704(1) and (2) of the PHS Act provides the Office of the PCPFS with authority to enter into co-sponsorships with non-Federal entities for certain health promotion activities. The 50th Anniversary observance offers partners the opportunity to make recommendations for improving the health of Americans in the future and for reducing health-care costs for individuals, public agencies, and private businesses and organizations. Finally, co-sponsorship with the Office

of the PCPFS during the observance of its 50th anniversary throughout the year 2006 offers partners the opportunity to highlight their past, present, and future initiatives to promote physical activity, fitness, and/or sports and to associate their programs with the goals and objectives of the Office of the PCPFS.

Purpose and Scope

The Office of the PCPFS is extending this invitation to both existing and potential new partners to broaden the reach of PCPFS programs and to promote physical activity, fitness, and sports to all Americans in their communities and work places. The Office of the PCPFS has limited resources for implementing actions that address large-scale national, state, and local initiatives and for sponsoring campaigns to promote improvements in the status of physical activity, fitness, and the overall health of individuals and communities. The Office of the PCPFS relies upon the combined efforts of both public agencies and private organizations through co-sponsored initiatives and activities to bring about the societal and cultural adjustments necessary to influence the attitudes of individuals and communities concerning the importance of physical activity, fitness, and sports and to bring about change. The observance of the 50th Anniversary of the Office of the PCPFS offers an ideal opportunity for organizations not only to highlight longstanding successful collaborations with the Office of the PCPFS but also to establish new collaborations with the Office of the PCPFS to raise public awareness of the importance of physical activity and to develop new programs and initiatives.

In forming collaborative partnerships, the Office of the PCPFS is seeking organizations that can bring knowledge, skills, and expertise to work synergistically on physical activity, fitness, and/or sports activities during the year 2006 and beyond; the 50th anniversary celebration of the Office of the PCPFS offers an ideal opportunity to launch such collaborations. For example, the Office of the PCPFS is interested in partnerships with public and private organizations that might involve (but are not limited to) the following sponsoring or co-sponsoring examples:

(a) Develop and disseminate educational public information materials on physical activity, fitness, health and/or sports to stress the benefits of a healthy, active lifestyle; such materials might be targeted to specific populations by age, gender, ability level, cultural background, or

minority status (e.g. co-sponsorship of a publication; co-sponsorship of a Web site or Web-based materials for existing Web sites);

(b) Develop and disseminate a nationwide educational campaign, including advertisements and/or public service announcements (print, TV, and/or radio) to alert individuals and diverse media markets about the dangers of a sedentary lifestyle and to promote co-sponsored programs that might be developed in the course of this initiative. This might include but is not limited to the President's Challenge, a free, motivational tool and recognition program of the PCPFS;

(c) Create, develop, and evaluate effective programs and activities for physical activity, fitness and sports; such programs would provide evidence-based results and best practices;

(d) Co-sponsor the development and management of a CEO/Business roundtable to raise awareness of the need for a fit and healthy workforce and to stress the potential role of business in fostering and promoting healthy lifestyles among employees and their families in an effort to reduce chronic disease and health care costs;

(e) Conduct educational and/or practical physical activity, fitness, and/or sports clinics in diverse venues (e.g. after school programs; senior activity centers; parks and recreation centers; others);

(f) Create a "Road Show" celebrating 50 years of fitness by providing demonstrations and coaching lessons for all ages that can be continued at the local level;

(g) Sponsor 50th Anniversary memorabilia for distribution at such venues as health fairs, athletic events, special events, and similar occasions;

(h) Sponsor 50th Anniversary special events;

(i) Any combination or enhancement of the above activities;

(j) Other innovative ideas.

Partnership/Co-Sponsorship Agreements

This Partnership Initiative is not a grant or contract award program. Any partnership formed between the Office of the PCPFS and an outside organization will be a voluntary collaboration. Each partner will be responsible for providing the resources necessary to carry out the specified activities of mutual interest contained in the organization's proposal. The Office of the PCPFS will execute, in advance, a concise, written agreement with collaborating partner(s). The partnership/co-sponsorship agreement will identify key elements of the project

including: Goals and intended benefits; roles and responsibilities of each partner; resources each plans to commit to the project; any reporting plans; and the time period in which the partnership remains in effect.

Partnership/co-sponsorship agreements will make clear that there will be no Federal endorsement of commercial products or of particular companies. The Office of the PCPFS will have a right to review the use of any Departmental logo and statement related to the Office of the PCPFS programs or materials and products to ensure that they are suitable for the initiative and that government neutrality with respect to commercial products is maintained. When any Departmental logo is approved for use on commercial materials or products that promote the goals and mission of the Office of the PCPFS and its program activities, a disclaimer will be required. The disclaimer must be printed on, or affixed to, commercial partner materials and products and indicate that the use of the logo does not imply any Federal endorsement or warranty of a particular commercial product or of other products of a particular company.

Evaluation Criteria

After engaging in exploratory discussions of potential partnerships and partnership activities, the Office of the PCPFS will make a determination whether the Office of the PCPFS will engage in partnership activities with particular entities and the scope of those activities. The final decision to establish a partnership agreement with an outside organization will be made by the Office of the PCPFS Executive Director. The Office of the PCPFS Executive Director reserves the right to decline partnership opportunities that are not consistent with the Office of the PCPFS goals, mission, or priorities, or for reasons of limited federal resources available to appropriately manage and oversee a proposed partnership. Depending on circumstances, a variety of objective and subjective criteria may be applied. The following factors will be considered when selecting partners and determining the scope of partnership activities:

1. Is the proposed project consistent with the mission and priorities of the Office of the PCPFS and the outside organization?

2. Are the activities proposed by the offering entity likely to provide a substantial public benefit relative to the resources required?

3. Do the potential benefits of the proposed partnership outweigh any potential negative impact on the

Department and its ability to accomplish its mission? For example, the Department will avoid any appearance that an offering entity's co-sponsorship of an event would improperly influence the Department or any HHS employee in other official matters in which the offering entity may have an interest. It may be possible to structure a proposal to minimize potential issues.

4. Does the outside entity have the expertise and capacity to carry out its proposed activities?

5. Has the outside entity demonstrated a willingness to work collaboratively with other public and private sector organizations to achieve the stated goals or to advance related efforts, activities, or initiatives?

Organizations that have goals and interests consistent with the mandate of the Office of the PCPFS are encouraged to reply to this notice. Such organizations should have appropriate expertise and resources and be willing to pursue and enhance physical activity, fitness, and/or sports activities within their own organizations. Organizations that meet the criteria are encouraged to reply to this notice.

Working collaboratively with its partners, the Office of the PCPFS and its partners will provide innovative opportunities in diverse venues to improve the adoption and maintenance of regular physical activity for the enhanced health and well-being of all Americans during the 50th anniversary year and beyond.

Dated: November 7, 2005.

Melissa Johnson,

Executive Director, President's Council on Physical Fitness and Sports, Department of Health and Human Services.

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. 2004D-0555]

Draft Guidance for Industry and Food and Drug Administration Staff; Class II Special Controls Guidance Document: Labeling for Male Condoms Made of Natural Rubber Latex; Availability

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is announcing the availability of the draft guidance