

Review Officer, CDC, 4770 Buford Highway NE., Mailstop F-46, Atlanta, Georgia 30341, Telephone: (770) 488-3585, EEO6@cdc.gov.

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 the Centers for Disease Control and Prevention and the Agency for Toxic Substances and Disease Registry.

Dana Redford,

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

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Centers for Disease Control and Prevention

[Docket No. CDC-2013-0003]

Walking as a Way for Americans To Get the Recommended Amount of Physical Activity for Health

AGENCY: Centers for Disease Control and Prevention (CDC), Department of Health and Human Services (HHS).

ACTION: Request for information.

SUMMARY: To address the public health problem of physical inactivity, the Centers for Disease Control and Prevention (CDC), within the Department of Health and Human Services (HHS) announces the opening of a docket to obtain information from the public on walking as an effective way to be sufficiently active for health. The information obtained will be used to frame an anticipated Surgeon General's call to action on this issue.

DATES: Individuals and organizations interested in providing information must submit their written comments on or before May 1, 2013.

ADDRESSES: Comments may be submitted by any of the two following methods:

- *Internet:* Electronic comments may be sent via: <http://www.regulations.gov>, docket number CDC-2013-0003. Please follow the instructions on the site to submit comments; or
- *Mail:* Comments may also be sent by mail to the attention of Joan Dorn, Ph.D., Chief, Physical Activity and Health Branch, Division of Nutrition, Physical Activity, and Obesity, Centers for Disease Control and Prevention, 4770 Buford Highway NE., MS-K46, Atlanta, Georgia, 30341-3717.

Instructions: All information received in response to this notice must include the agency name and docket number (CDC-2013-0003).

All relevant comments received will be posted without change to <http://www.regulations.gov>, including any personal information provided.

FOR FURTHER INFORMATION CONTACT: Joan Dorn, Ph.D., Chief, Physical Activity and Health Branch, Division of Nutrition, Physical Activity, and Obesity, Centers for Disease Control and Prevention, 4770 Buford Highway NE., MS-K46, Atlanta, Georgia, 30341-3717 by telephone (770-488-5692) or email (jrnwalking@cdc.gov).

SUPPLEMENTARY INFORMATION:

Scope of the problem: Less than half (48%) of all U.S. adults (1) meet the 2008 Physical Activity Guidelines, which will be included in the docket as a supporting document, and less than 3 in 10 high school students get at least 60 minutes of physical activity every day (2). Only 13 percent of children walk or bike to school, compared with 44 percent a generation ago (3). More than a quarter of trips made by car are within one mile of home (4). Observed differences in physical activity levels among some population groups include: physical activity levels decline with age (5); activity levels are lower in low-income communities and among racial/ethnic minorities (6); and, in general, persons with disabilities are less active than those without disabilities (7). Causes for lower physical activity levels vary but may in part be due to a lack of available and/or accessible places for safe and enjoyable physical activity. Walking can be an enjoyable recreational, occupational or purposeful (e.g., for transportation) physical activity in which many Americans can engage. It can enhance health and quality of life and can also serve as a gateway to other enjoyable types of physical activity.

Approach: HHS/CDC works to increase health-related physical activity through population-based approaches. The agency also conducts physical activity related surveillance, applied research and evaluation, and translates and disseminates associated best practices to inform efforts to improve opportunities and support for physical activity. Consistent with these activities, HHS/CDC is assisting the Office of the Surgeon General in the Department of Health and Human Services to issue a call to action to increase attention to the promotion of walking and walkability to help Americans become more physically active. The intent of the Surgeon General's call to action is to

identify opportunities and actions that can be taken by all levels of government, civic organizations, health care providers, educational institutions, worksites, industry, service providers, individuals and others to increase walking and walkability throughout the nation by providing access to safe, attractive and convenient places to walk (and wheelchair roll) and creating a culture that supports walking for Americans of all ages and abilities.

We invite comments and information on environmental or systems strategies; interventions that increase walkability of communities and walking for individuals; and national-, state-, tribal-, territorial-, community-, organizational-, and individual-level actions. We are particularly interested in strategies that consider individuals with developmental and chronic disease-related disabilities, and groups having health and physical activity disparities or lack resources and opportunities to be physically active.

Areas of Focus: Many factors can contribute to low levels of walking and physical inactivity, including lack of access to safe and convenient places to walk, lack of signage and directional information, long distances to destinations, lack of public transportation, and lack of the inclusion of persons with mobility limitations in walking campaigns and programs. HHS/CDC and the Office of the Surgeon General are interested in receiving information on the following topics:

(1) Barriers to walking for youth; adults; seniors; persons with developmental, injury, and chronic disease-related disabilities; racial and ethnic minorities; and low-income individuals.

(2) Evidence-based strategies for overcoming those barriers and their reach and impact to increase physical activity at the population level and among the above mentioned subpopulations.

References

- (1) Schiller JD, Lucas JW, Ward BW, Peregoy JA. Summary health statistics for U.S. adults: National Health Interview Survey, 2010. *Vital Health Stat* 2012;10(252).
- (2) CDC. Youth Risk Behavior Surveillance—United States, 2011. *MMWR* 2012;61(SS-4).
- (3) Centers for Disease Control and Prevention. The association between school based physical activity, including physical education, and academic performance. Atlanta, GA: U.S. Department of Health and Human Services; 2010. Available at http://www.cdc.gov/healthyyouth/health_and_academics/pdf/pa-pe_paper.pdf. Accessed May 17, 2011.

- (4) Nationwide Personal Transportation Survey. U.S. Department of Transportation, Federal Highway Administration, Research and Technical Support Center. Lanham, MD: Federal Highway Administration, 1997.
- (5) Trost SG, Owen N, Bauman AE, et al. Correlates of adults' participation in physical activity: Review and update, 1996–2001. *Med Sci Sports Exerc.* 2002 Dec;34(12). Available at <http://www.healthypeople.gov/2020/topicsobjectives2020/overview.aspx?topicid=33>. Accessed May 16, 2011.; U.S. Department of Health and Human Services 2008 Physical Activity Guidelines for Americans. Available from <http://www.health.gov/paguidelines>. Accessed May 16, 2011.
- (6) Sallis JF, Prochaska JJ, Taylor WC. A review of correlates of physical activity of children and adolescents. *Med Sci Sports Exerc.* 2000; 32: 963–75.
- (7) Centers for Disease Control and Prevention. Physical activity among adults with a disability—United States 2005. *MMWR.* 2007;56(39):1021–1024.

Dated: March 18, 2013.

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*Deputy Associate Director for Science,
Centers for Disease Control and Prevention.*

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2013–D–0286]

Draft Guidance for Industry on Formal Meetings Between FDA and Biosimilar Biological Product Sponsors or Applicants; Availability

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is announcing the availability of a draft guidance for industry entitled “Formal Meetings Between the FDA and Biosimilar Biological Product Sponsors or Applicants.” This draft guidance provides recommendations to industry on formal meetings between FDA and sponsors or applicants relating to the development and review of biosimilar biological products regulated by the Center for Drug Evaluation and Research (CDER) and the Center for Biologics Evaluation and Research (CBER). The guidance assists sponsors and applicants in generating and submitting a meeting request and the associated meeting package to FDA for biosimilar biological products.

DATES: Although you can comment on any guidance at any time (see 21 CFR 10.115(g)(5)), to ensure that the Agency considers your comment on this draft guidance before it begins work on the final version of the guidance, submit either electronic or written comments on the draft guidance by May 31, 2013. Submit either electronic or written comments concerning the proposed collection of information by May 31, 2013.

ADDRESSES: Submit written requests for single copies of the draft guidance to the Division of Drug Information, Center for Drug Evaluation and Research, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 51, Rm. 2201, Silver Spring, MD 20993–0002, or Office of Communication, Outreach, and Development (HFM–40), Center for Biologics Evaluation and Research (CBER), Food and Drug Administration, 1401 Rockville Pike, Suite 200N, Rockville, MD 20852–1448. Send one self-addressed adhesive label to assist that office in processing your requests. See the **SUPPLEMENTARY INFORMATION** section for electronic access to the draft guidance document.

Submit electronic comments on the draft guidance to <http://www.regulations.gov>. Submit written comments to the Division of Dockets Management (HFA–305), Food and Drug Administration, 5630 Fishers Lane, Rm. 1061, Rockville, MD 20852.

FOR FURTHER INFORMATION CONTACT: Neel Patel, Center for Drug Evaluation and Research, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 22, Rm. 6483, Silver Spring, MD 20993–0002, 301–796–0970; or Stephen Ripley, Center for Biologics Evaluation and Research (HFM–17), Food and Drug Administration, 1401 Rockville Pike, Suite 200N, Rockville, MD 20852–1448, 301–827–6210.

SUPPLEMENTARY INFORMATION:

I. Background

FDA is announcing the availability of a draft guidance for industry entitled “Formal Meetings Between the FDA and Biosimilar Biological Product Sponsors or Applicants.” This draft guidance provides recommendations to industry on formal meetings between FDA and sponsors or applicants relating to the development and review of biosimilar biological products regulated by CDER and CBER. For the purposes of this draft guidance, “formal meeting” includes any meeting that is requested by a sponsor or applicant following the request procedures provided in this draft guidance and includes meetings conducted in any format (i.e., face-to-

face meeting, teleconference, or videoconference).

The Biologics Price Competition and Innovation Act of 2009 amended the Public Health Service (PHS) Act and other statutes to create an abbreviated licensure pathway in section 351(k) of the PHS Act (42 U.S.C. 262(k)) for biological products shown to be biosimilar to, or interchangeable with, an FDA-licensed biological product (see sections 7001 through 7003 of the Patient Protection and Affordable Care Act (Pub. L. 111–148)). The Biosimilar User Fee Act of 2012 (BsUFA), enacted as part of the Food and Drug Administration Safety and Innovation Act (Pub. L. 112–144), amended the Federal Food, Drug, and Cosmetic Act (the FD&C Act) to authorize a new user fee program for biosimilar biological products. FDA has committed to meeting certain performance goals in connection with the new user fee program. The performance goals, which are set forth in a letter from the Secretary of Health and Human Services to the Chairman of the Committee on Health, Education, Labor, and Pensions of the Senate and the Chairman of the Committee on Energy and Commerce of the House of Representatives,¹ include meeting management goals for formal meetings that occur between FDA and sponsors or applicants during the development phase of a biosimilar biological product. This draft guidance describes the Agency's current thinking on how it intends to interpret and apply certain provisions of BsUFA, and also provides information on specific performance goals for the management of meetings associated with the development and review of biosimilar biological products.

This draft guidance reflects a unified approach to all formal meetings between sponsors or applicants and FDA for biosimilar biological product development (BPD) programs. It is intended to assist sponsors and applicants in generating and submitting a meeting request and the associated meeting package to FDA for biosimilar biological products. This draft guidance does not apply to new drug or abbreviated new drug applications under section 505 of the FD&C Act or to biologics license applications (BLAs) under section 351(a) of the PHS Act.

FDA expects that review staff will participate in many meetings with biosimilar biological product sponsors

¹ See <http://www.fda.gov/downloads/Drugs/DevelopmentApprovalProcess/HowDrugsareDevelopedandApproved/ApprovalApplications/TherapeuticBiologicApplications/Biosimilars/UCM281991.pdf>.