abilities, partnerships will be established; each partner will be responsible for providing the resources necessary to carry out specified activities of mutual interest.

As partners with HHS, both public and private sector organizations can bring their respective ideas and expertise, administrative capabilities, and production and material resources, that are consistent with the goals of the *Steps* initiative, to, for example:

(a) Share in the development of educational health information and its distribution to employees or to the public, *e.g.*, promoting healthy lifestyles to prevent chronic diseases, programs aimed at improving consumers' understanding of how proper dietary choices and physical activity can improve health and prevent obesity and other chronic diseases or providing practical guidance and information on how to obtain diagnostic and treatment services. Public education efforts could include Web-site and software development, work with local or national media, and sponsorship of health promotion events, each activity generally enhancing consumer understanding of health information related to health promoting behaviors and chronic disease prevention and control;

(b) Foster the creation and maintenance of effective health and wellness and physical activity programs that provide clear measurable results;

(c) Participate in the development of health professional educational activities, including conference co-sponsorship or co-publication and dissemination of professional educational materials, such as reports of proceedings and any resulting recommendations; and

(d) Conduct or support chronic disease prevention research, or undertake scientific testing and evaluation of commercial products related to the Steps initiative, such as interactive computer software and media tools.

Partnership agreements will make clear that there will be no Federal endorsement of commercial products or of particular companies. HHS will have a right to review the use of Department logos and statements related to *Steps* on such materials and products to ensure that they are suitable for the initiative and that government neutrality with respect to commercial products is maintained. When the *Steps* logo is approved for use on commercial materials or products that promote healthier lifestyles or foster other *Steps* objectives and are incorporated in *Steps* initiative activities, a disclaimer will be required to be printed on, or affixed to commercial partner materials and products indicating 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 with respondents, the following considerations will be used by HHS officials, as appropriate and relevant, to determine whether HHS will engage in partnership activities with particular entities and the scope of those activities.

1. Are the activities proposed by the offering entity likely to provide a substantial public health benefit, consistent with HHS goals and the *Steps to a HealthierUS* Initiative?

2. Does the proposed partnership's potential for public health benefit outweigh any potential negative impact on the agency and its ability to accomplish its missions? What adjustments if any, would make the proposal acceptable?

3. Is there an identifiable and appropriate role for HHS?

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 *Steps to a HealthierUS* goals or to advance related efforts, activities, or initiatives?

Given the *Steps* Initiative's objectives, entities who have similar goals and consistent interests, appropriate expertise and resources, and would like to pursue chronic disease prevention and health promotion activities within their own organizations, or on a broader scale, in collaboration with the Department, are encouraged to reply to this notice. Working together, it is intended that these partnerships will provide innovative opportunities to promote healthier living.

Dated: October 16, 2003.

**Cristina V. Beato,**

*Acting Assistant Secretary for Health.*

[FR Doc. 03–26628 Filed 10–21–03; 8:45 am]

**BILLING CODE 4150–32–P**

## DEPARTMENT OF HEALTH AND HUMAN SERVICES

### Agency for Healthcare Research and Quality

### Meeting of the National Advisory Council for Healthcare Research and Quality

**AGENCY:** Agency for Healthcare Research and Quality (AHRQ).

**ACTION:** Notice of public meeting.

**SUMMARY:** In accordance with section 10(a) of the Federal Advisory Committee Act, this notice announces a meeting of the National Advisory Council for Healthcare Research and Quality.

**DATES:** The meeting will be held on Friday, November 7, 2003, from 9 a.m. to 4 p.m. and is open to the public.

**ADDRESSES:** The meeting will be held at the Hubert H. Humphrey Building, Department of Health and Human Services (HHS), 200 Independence Avenue, Room 800, Washington, DC 20201.

**FOR FURTHER INFORMATION CONTACT:** Anne Lebbon, Coordinator of the Advisory Council, at the Agency for Healthcare Research and Quality, 540 Gaither Road, Rockville, Maryland, 20850, (301) 427–1215. For press-related information, please contact Karen Migdail at (301) 427–1855.

If sign language interpretation or other reasonable accommodation for a disability is needed, please contact Mr. Donald L. Inniss, Director, Office of Equal Employment Opportunity Program, Program Support Center, on (301) 443–1144 no later than October 31, 2003.

Agenda, roster, and minutes are available from Ms. Bonnie Campbell, Committee Management Officer, Agency for Healthcare Quality and Research, 540 Gaither Road, Rockville, Maryland, 20850. Her phone number is (301) 427–1554. Minutes will be available after November 21, 2003.

**SUPPLEMENTARY INFORMATION:**

**I. Purpose**

Section 921 of the Public Health Service Act (42 U.S.C. 299c) established the National Advisory Council for Healthcare Research and Quality. In accordance with its statutory mandate, the Council is to advise the Secretary of the Department of Health and Human Services and the Director, Agency for Healthcare Research and Quality (AHRQ), on matters related to actions of the Agency to enhance the quality, improve the outcomes, reduce the costs of health care services, improve access to such services through scientific

research, and to promote improvements in clinical practice and in the organization, financing, and delivery of health care services. The Council is composed of members of the public appointed by the Service and Federal ex-officio members.

**II. Agenda**

On Friday, November 7, 2003, the meeting will begin at 9 a.m., with the call to order by the Council Chair. The Director, AHRQ, will present the status of the Agency's current research, programs, and initiatives. Tentative agenda items include a discussion of Improving Efficiency and Quality through Health System Design, AHRQ's Efforts Directed to Improve Decisions Regarding the Purchase, Cost, and Effectiveness of Prescribed Medicines, the National Healthcare Qualtity Report, and the National Healthcare Disparities Report. The official agenda will be available on AHRQ's Web site a *http://www.ahrq.gov* no later than October 17, 2003. The meeting will adjourn at 4 p.m.

Dated: October 14, 2003.

**Carolyn M. Clancy,**

*Director.*

[FR Doc. 03–26567 Filed 10–21–03; 8:45 am]

**BILLING CODE 4160–90–M**

## DEPARTMENT OF HEALTH AND HUMAN SERVICES

### Food and Drug Administration

**[Docket No. 2003D–0465]**

### Draft Guidance for Industry on Providing Regulatory Submissions in Electronic Format—General Considerations; 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 ''Providing Regulatory Submissions in Electronic Format—General Considerations.'' The draft guidance discusses general issues common to all types of electronic regulatory submissions and updates the guidance of the same name, issued in January 1999. The update now includes information for the Center for Devices and Radiological Health (CDRH), the Center for Food Safety and Applied Nutrition (CFSAN), and the Center for Veterinary Medicine (CVM) and reflects advances in technology as well as lessons learned from experience with electronic submissions received over the past several years.

**DATES:** Submit written or electronic comments on the draft guidance by December 22, 2003. General comments on agency guidance documents are welcome at any time.

**ADDRESSES:** Submit written requests for single copies of the draft guidance to the Office of Training and Communications, Division of Communications Management, Division of Drug Information (HFD–240), Center for Drug Evaluation and Research (CDER), 5600 Fishers Lane, Rockville, MD 20857, or to the Office of Communication, Training, and Manufacturers Assistance (HFM–40), Center for Biologics Evaluation and Research (CBER), Food and Drug Administration, 1401 Rockville Pike, Rockville, MD 20852–1448, or to the Communications Staff (HFV–12), Center for Veterinary Medicine, Food and Drug Administration, 7500 Standish Pl., Rockville, MD 20855. Send one self-addressed adhesive label to assist that office in processing your requests. Submit telephone requests to 800–835–4709 or 301–827–1800. Submit written comments on the draft guidance to the Division of Dockets Management (HFA–305), Food and Drug Administration, 5630 Fishers Lane, rm. 1061, Rockville, MD 20852.

**FOR FURTHER INFORMATION CONTACT:**

Randy Levin, Food and Drug Administration, CDER (HFD–140), 5600 Fishers Lane, Rockville, MD 20857, 301–594–5411, *levinr@cder.fda.gov*, or

Michael Fauntleroy, Food and Drug Administration CBER (HFM–025), 1401 Rockville Pike, Rockville, MD 20852, 301–827–5132, or

Stuart Carlow, Food and Drug Administration, CDRH (HFZ–040), 2098 Gaither Rd., Rockville, MD 20850, 301–594–4550, or

JoAnn Ziyad, Food and Drug Administration CFSAN (HFS–206), 5100 Paint Branch Pkwy., College Park, MD 20740, 202–418–3116, or

Elizabeth Parbuoni, Food and Drug Administration, CVM (HFV–16), 7519 Standish Pl., Rockville, MD 20835, 301–827–4621.

**SUPPLEMENTARY INFORMATION:** FDA is announcing the availability of a draft guidance for industry entitled ''Providing Regulatory Submissions in Electronic Format—General Considerations.'' The draft guidance discusses general issues common to all types of electronic regulatory submissions and updates the guidance of the same name, which was issued in January of 1999. The update now includes information for CDRH, CFSAN, and CVM and reflects advances in technology as well as lessons learned from experience with electronic submissions received over the past several years. Changes from the 1999 version of the draft guidance include a new section describing the relationship of electronic submissions to 21 CFR part 11. There are updates on the recommendations for creating portable document format documents including specific guidance for the use of fonts. New file formats for data, specifically extensible markup language and standardized markup language are introduced. The electronic transmission of files is discussed.

This draft guidance is being issued as a level 1 guidance, consistent with FDA's regulation on good guidance practices regulation (21 CFR 10.115). It represents the agency's current thinking on ''Providing Regulatory Submissions in Electronic Format—General Considerations.'' It does not create or confer any rights for or on any person and does not operate to bind FDA or the public. An alternative approach may be used if such approach satisfies the requirements of the applicable statute and regulations.

Interested persons may submit to the Division of Dockets Management (see **ADDRESSES**) written or electronic comments on the draft guidance. Two copies of mailed comments are to be submitted, except that individuals may submit one copy. Comments are to be identified with the docket number found in brackets in the heading of this document. The draft guidance and received comments are available for public examination in the Division of Dockets Management between 9 a.m. and 4 p.m., Monday through Friday.

Copies of this draft guidance for industry are available on the Internet at *http://www.fda.gov/cder/guidance/index.htm*, *http://www.fda.gov/cber/guidelines.htm*, and *http://www.fda.gov/cvm/guidance/guidance.html*.

Dated: October 14, 2003.

**Jeffrey Shuren,**

*Assistant Commissioner for Policy.*

[FR Doc. 03–26571 Filed 10–21–03; 8:45 am]

**BILLING CODE 4160–01–S**