

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 Quality Report, and the National Healthcare Disparities Report. The official agenda will be available on AHRQ's Web site at <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.*

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## 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#### Draft Guidance for Industry on Providing Regulatory Submissions in Electronic Format—General Considerations; Availability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**SUMMARY:** The Food and Drug Administration (FDA) is announcing the availability of a draft guidance for industry entitled "Providing Regulatory Submissions in Electronic Format—General Considerations." The draft guidance discusses general issues common to all types of electronic regulatory submissions and updates the guidance of the same name, issued in January 1999.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**DATES:** Submit written or electronic comments on the draft guidance by December 22, 2003.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**ADDRESSES:** Submit written requests for single copies of the draft guidance to the Office of Training and Communications, Division of Communications Management, Division of Drug Information (HFD-240), Center for Drug Evaluation and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](mailto: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.*

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