

RMS

Display Date 6-23-03 @ 3:07 pm  
Publication Date 6-25-03  
Certifier G. Lynn Perry

**DEPARTMENT OF HEALTH AND HUMAN SERVICES**

**Food and Drug Administration**

[Docket No. 2003N-0281]

**Severe Acute Respiratory Syndrome Diagnostics: Scientific and Regulatory Challenges Public Workshop; Request for Comments**

**AGENCY:** Food and Drug Administration, HHS.

**ACTION:** Notice of public workshop; request for comments.

1022  
03 JUN 23 03:21

**SUMMARY:** The Food and Drug Administration (FDA) is announcing a public workshop to discuss methods for evaluating new diagnostic tests for severe acute respiratory syndrome (SARS). The purpose of this workshop is to serve as a public forum for interested stakeholders and FDA to consider resources and methods to evaluate SARS diagnostic tests. In addition, the workshop serves as an opportunity to provide mechanisms for public-private partnerships and sharing of both information and resources to facilitate evaluation and safe use of new diagnostic tests.

*Date and Time:* The public workshop will be held on July 14, 2003, from 8 a.m. to 5 p.m.

*Addresses:* The public workshop will be held at the DoubleTree Rockville Hotel and Executive Meeting Center (<http://www.doubletreerockville.com>), 1750 Rockville Pike, Rockville, MD 20852, 301-468-1100, FAX: 301-468-0163. The hotel may be reached by Metro using the Twinbrook station on the red line. Submit written or electronic comments to the Division of Dockets Management (HFA-305), Food and Drug Administration, 5630 Fishers Lane, rm. 1061, Rockville, MD 20852, e-mail: [FDADockets@oc.fda.gov](mailto:FDADockets@oc.fda.gov). Online

registration, additional information about the meeting, and directions to the facility are available on the Internet at: <http://www.fda.gov/cdrh/meetings/071403.html>.

*Contact Person:* Cynthia Benson, Center for Devices and Radiological Health (HFZ-3), Food and Drug Administration, 9200 Corporate Blvd., Rockville, MD 20850, 301-827-7989, e-mail: [cmh@cdrh.fda.gov](mailto:cmh@cdrh.fda.gov).

*Agenda:* At the workshop, FDA will receive questions and comments from stakeholders likely to be affected by FDA policies or procedures regarding SARS diagnostic tests. Stakeholders include, but are not limited to, medical device product manufacturers, members of the academic and clinical communities, and consumer and patient advocacy groups.

*Registration:* Preregistration is required by July 7, 2003, and will be accepted on a first-come, first-served basis; however, notwithstanding attendance at the workshop, interested persons are encouraged to provide comments (see the *Request for Comments* section of this document). Please register online at <http://www.fda.gov/cdrh/meetings/071403.html>. Persons without Internet access may call 1-888-203-6161 to register. To accommodate overnight attendees, a limited number of reserved rooms are available by calling the DoubleTree Rockville Hotel and Conference Center (see the *Addresses* section of this document). Please register with the hotel by June 30, 2003. FDA is pleased to provide the opportunity for interested persons to listen from a remote location to the live proceedings of the workshop. In order to ensure that a sufficient number of call-in lines are available, please register to listen to the meeting at <http://www.fda.gov/cdrh/meetings/071403.html>. Persons without Internet access may call 1-888-203-6161 to register. Please register by July 7, 2003. FDA will provide audio conference participants the

opportunity for comments and questions by fax (fax number to be provided at the workshop).

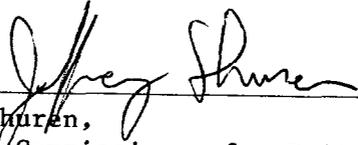
If you need special accommodations due to a disability, please contact Shirley Meeks at 301-594-1283 at least 7 days in advance.

*Request for Comments:* Regardless of attendance at the workshop, interested persons may submit written or electronic comments to the Division of Dockets Management (see the *Addresses* section of this document). Submit two paper copies of any mailed comments. Individuals may submit one paper copy. Identify comments with the docket number found in brackets in the heading of this document. The comments that FDA receives will be made available at the Division of Dockets Management between 9 a.m. and 4 p.m., Monday through Friday.

*Transcripts:* Following the workshop, transcripts will be available for review at the Division of Dockets Management (see the *Addresses* section of this document).

**SUPPLEMENTARY INFORMATION:** The objectives of the workshop are to discuss methods for evaluating new SARS assays for clinical and public health use and to develop information on availability and access to control materials, reagents, and specimens needed for development and qualification of SARS diagnostic assays. FDA hopes to address unique issues related to the evaluation of nucleic acid amplification, direct antigen, and serologic assays. FDA also wishes to promote partnerships among government, industry, health care providers, and the clinical laboratory community that would facilitate the development of new SARS diagnostic assays through sharing of information and resources.

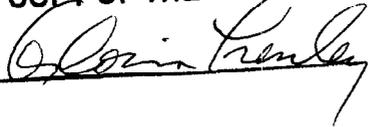
Dated: 6/20/03  
June 20, 2003.

  
\_\_\_\_\_  
Jeffrey Shuren,  
Assistant Commissioner for Policy.

[FR Doc. 03-????? Filed ??-??-03; 8:45 am]

**BILLING CODE 4160-01-S**

**CERTIFIED TO BE A TRUE  
COPY OF THE ORIGINAL**

  
\_\_\_\_\_  
Gloria Hendley