

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. 2006D-0347]

DMB

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Certifier Roone

**In Vitro Diagnostic Multivariate Index Assays; Public Meeting**

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

**ACTION:** Notice of public meeting.

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**SUMMARY:** The Food and Drug Administration (FDA) is announcing a public meeting on In Vitro Diagnostic Multivariate Index Assays. The meeting is intended to provide a public forum during which FDA will hear presentations and comments from interested stakeholders regarding the draft guidance entitled "Draft Guidance for Industry, Clinical Laboratories, and FDA Staff on In Vitro Diagnostic Multivariate Index Assays." This draft guidance is intended to provide clarification on FDA's approach to regulation of in vitro diagnostic multivariate index assays. FDA is seeking comments on this draft guidance.

**DATES:** The public meeting will be held on February 8, 2007, from 8 a.m. to 5 p.m. Online registration is available until 5 p.m. on February 5, 2007; however, if space permits onsite registration will be permitted on February 8, 2007 (see the **Registration** section of this notice for details).

**ADDRESSES:** The public meeting will be held at the Grand Ballroom of the Hilton Washington DC/Gaithersburg Hotel located at 620 Perry Pkwy., Gaithersburg, MD 20877. Additional information about and directions to the facility are available by calling the hotel at 1-301-977-8900 or on the Internet at: <http://www.hilton.com> (under Find a Hotel, type in Gaithersburg, MD under city and State). (FDA has verified the Web site address, but FDA is not

responsible for any subsequent changes to the Web site after this document publishes in the **Federal Register**.)

The comment period on this draft guidance closes on March 5, 2007. Submit written comments to the Division of Dockets Management (HFA-305), Food and Drug Administration, 5630 Fishers Lane, rm. 1061, Rockville, MD 20852. Submit electronic comments on the draft guidance to <http://www.fda.gov/dockets/ecomments>. Identify comments with the docket number found in brackets in the heading of this document.

**FOR FURTHER INFORMATION CONTACT:** Sousan Altaie, Center for Devices and Radiological Health (HFZ-440), Food and Drug Administration, 2098 Gaither Rd., Rockville, MD 20850, 240-276-0450, ext. 106, e-mail: [Sousan.Aaltaie@fda.hhs.gov](mailto:Sousan.Aaltaie@fda.hhs.gov).

**SUPPLEMENTARY INFORMATION:**

**I. Background**

FDA announced the availability of a draft guidance entitled "Draft Guidance for Industry, Clinical Laboratories, and FDA Staff on In Vitro Diagnostic Multivariate Index Assays," on September 7, 2006 (71 FR 52800). This draft guidance addresses the definition and regulatory status of a class of in vitro diagnostic devices referred to as In Vitro Diagnostic Multivariate Index Assays (IVDMIA). The draft guidance also addresses premarket and postmarket requirements with respect to IVDMIA. An IVDMIA employs clinical data, which may be derived in part from one or more in vitro assays, and an algorithm to integrate the variables, and reports a result that cannot be interpreted by the well-trained health care practitioner using prior knowledge of medicine without information from the test developer regarding its clinical performance and effectiveness.

FDA is seeking comments on this draft guidance and has extended the comment period to March 5, 2007 (71 FR 68822). FDA is announcing in this notice a public meeting on this draft guidance.

## **II. Agenda**

FDA will start the meeting with a brief presentation on the draft guidance entitled "Draft Guidance for Industry, Clinical Laboratories, and FDA Staff on In Vitro Diagnostic Multivariate Index Assays." The purpose of this meeting is to obtain public input on this guidance. Hence, presentations by the public will make-up the remainder of the agenda. Interested persons who would like to make a presentation during the meeting will be given 10 minutes to do so if they submit their request (electronic or written) and a copy of the material to be presented by February 1, 2007, to the contact person, Sousan Altaie, at the address or the email above and to the docket for this draft guidance. Depending upon the number of presenters submitting requests to present, the allotted time may be expanded or shortened to provide appropriate representation by all interested parties. Presentations and comments are to be identified with the docket number found in brackets in the heading of this document.

This public meeting agenda will be available on the Internet on February 7, 2007, at <http://www.fda.gov/cdrh/oivd/meetings/020807agenda.html>.

## **III. Registration**

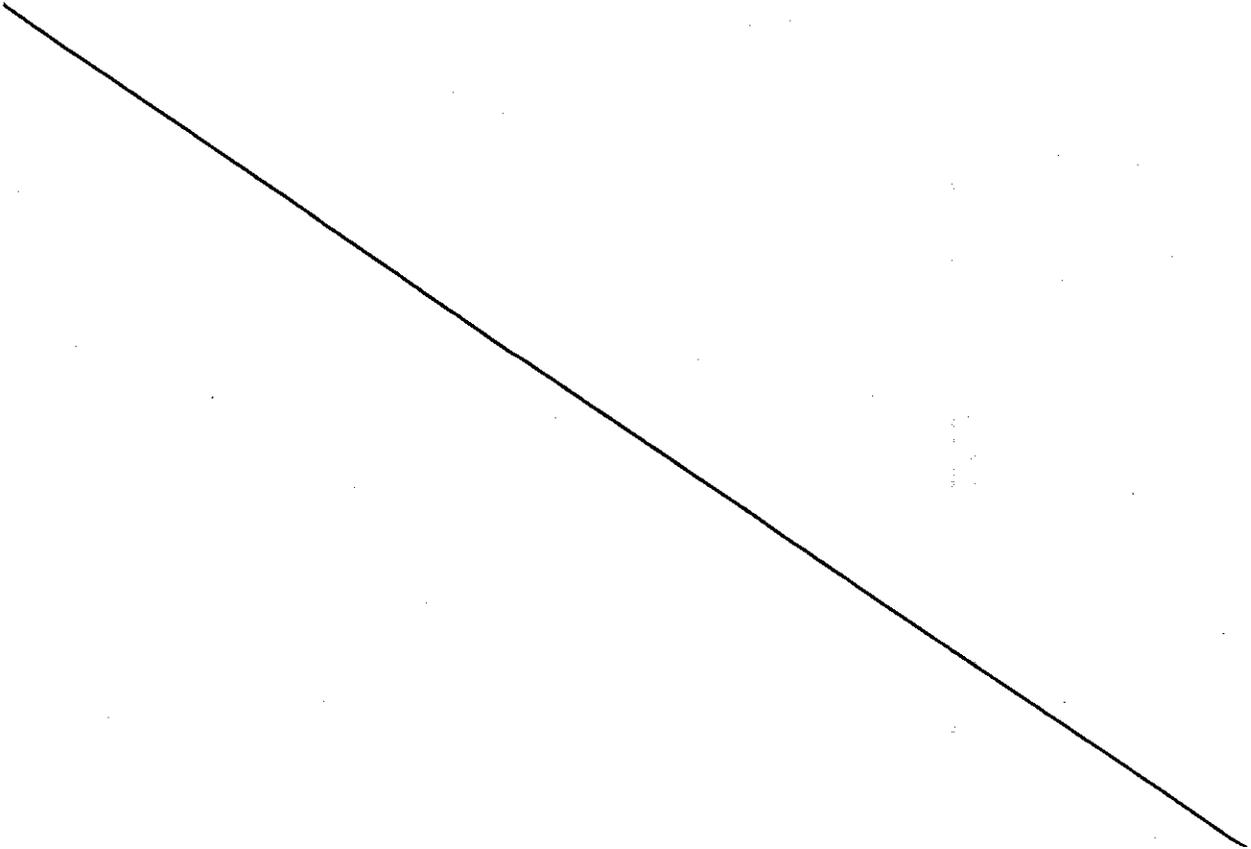
Those interested in attending may register online at [http://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfSUD/oivd\\_meeting.cfm](http://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfSUD/oivd_meeting.cfm). There is no registration fee to attend the meeting. Please submit registration early in order to reserve a space, as space is limited. You may register online until February 5, 2007; however, onsite registration will be permitted if space remains. If you require special accommodations due to a disability, please

contact the Hilton Washington DC/Gaithersburg Hotel directly at 1-301-977-8900, at least 7 days in advance.

Persons without Internet access may call Sousan Altaie at 240-276-0450 ext. 106, by February 5, 2007, to register for onsite meeting attendance.

#### **IV. Request for Input and Materials**

FDA is interested in receiving input from stakeholders on the draft guidance. Send suggestions or recommendations to the Division of Dockets Management (see **ADDRESSES**). FDA will place an additional copy of any material it receives on the docket (Docket Number 2006D-0347). Suggestions, recommendations, and materials may be seen at the Division of Dockets Management between 9 a.m. and 4 p.m., Monday through Friday.



**V. Transcripts**

Following the meeting, transcripts will be available for review at <http://www.fda.gov/cdrh/oivd/presentations.html#r>, and the Division of Dockets Management (see **ADDRESSES**) between 9 a.m. and 4 p.m., Monday through Friday.

Dated: 1/3/07  
January 3, 2007.

  
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Jeffrey Shuren,  
Assistant Commissioner for Policy.

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