

DEPARTMENT OF HEALTH AND HUMAN SERVICES

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Food and Drug Administration

Microbiology Devices Panel of the Medical Devices Advisory Committee; Notice of Meeting

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

This notice announces a forthcoming meeting of a public advisory committee of the Food and Drug Administration (FDA). At least one portion of the meeting will be closed to the public.

*Name of Committee:* Microbiology Devices Panel of the Medical Devices Advisory Committee.

*General Function of the Committee:* To provide advice and recommendations to the agency on FDA's regulatory issues.

*Date and Time:* The meeting will be held on July 27, 2000, 10:30 a.m. to 5:30 p.m. and July 28, 2000, 8 a.m. to 5 p.m.

*Location:* Holiday Inn, Walker/Whetstone Rooms, Two Montgomery Village Ave., Gaithersburg, MD.

*Contact Person:* Freddie M. Poole, Center for Devices and Radiological Health (HFZ-440), Food and Drug Administration, 2098 Gaither Rd., Rockville, MD 20850, 301-594-2096, or FDA Advisory Committee Information Line, 1-800-741-8138 (301-443-0572 in the Washington, DC area), code 12517. Please call the Information Line for up-to-date information on this meeting.

*Agenda:* On July 27, 2000, the committee will discuss and make recommendations on issues concerning the appropriate types of data and information required to assess the safety and effectiveness of diagnostic tests intended to identify biotreat agents, or to provide evidence of

exposure to biothreat agents, when used on different specimen types and under different conditions for use.

The following draft questions are proposed for discussion and may be subject to changes prior to the committee meeting:

1. What types of data and information would be recommended to evaluate effectiveness when the assay is used:

(a) To definitively identify or rule-out identification of isolates;

(b) to identify biothreat agents directly in specimens from individuals suspected (clinically or using other diagnostic procedures) to have been infected with the agent of interest; and

(c) to identify/detect the biothreat agent directly in specimens from individuals without clinical or other diagnostic evidence of infection, who may have been exposed to the biothreat agent.

2. For each of these potential uses what is the level of inaccuracy that can be tolerated, or would the same criteria apply to all?

3. To determine or infer effectiveness for these devices, can specimens from naturally- or experimentally-infected animals be used when appropriate specimens from humans cannot be obtained? What are the constraints/limitations for use of animal data as evidence for effectiveness?

4. Are there any other issues not addressed in the previous questions that would affect the reliable use of these assays for human diagnosis?

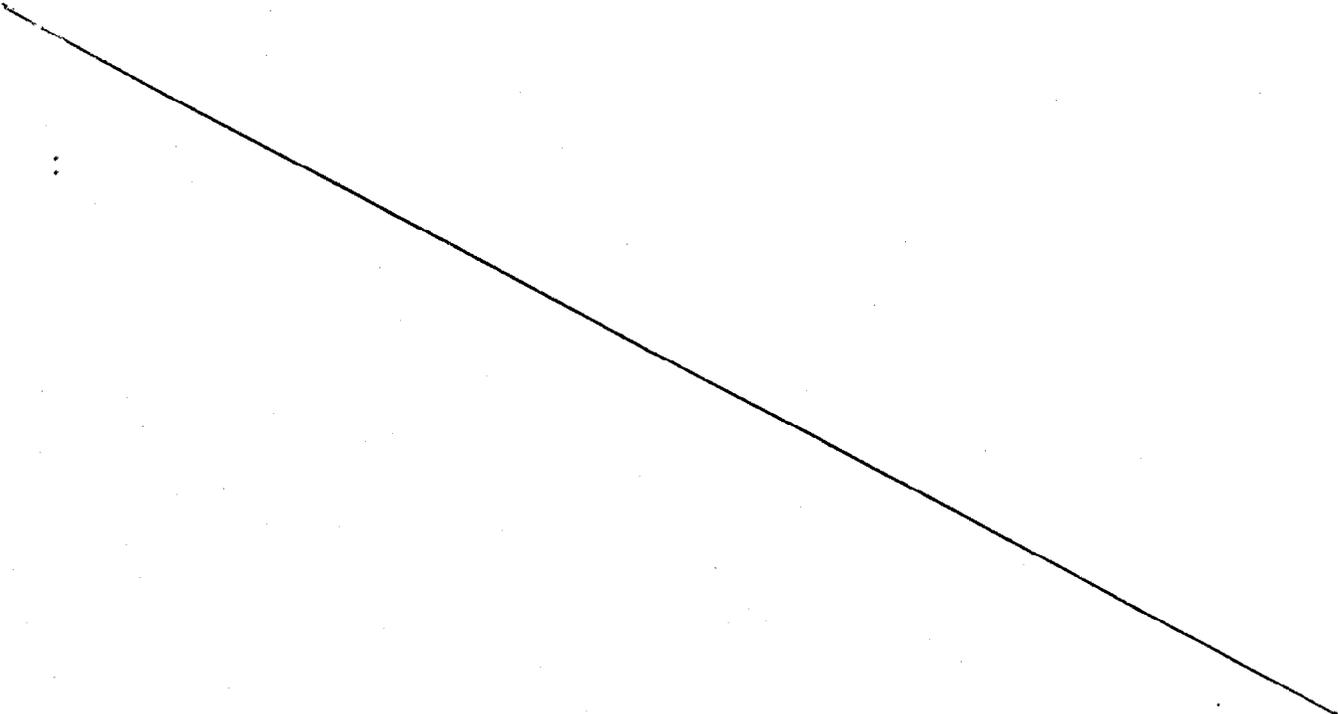
FDA will consider these recommendations in the future development of review criteria for *in vitro* diagnostic devices, developed in response to the threat of bioterrorism, for the identification of biothreat agents, as valid scientific evidence to determine whether there is reasonable assurance that these devices are safe and effective.

On July 28, 2000, the committee will discuss, make recommendations, and vote on a premarket approval application (PMA) for an *in vitro* diagnostic nucleic acid amplification test for the qualitative detection of hepatitis C virus (HCV) ribonucleic acid (RNA) in human serum or plasma. On the same day the committee will discuss, make recommendations, and vote on a PMA for an automated *in vitro* diagnostic nucleic acid amplification test for the qualitative detection of

HCV RNA in human serum or plasma. These devices are not intended for use in blood or plasma donor screening.

*Procedure:* On July 27, 2000, from 10:30 a.m. to 5:30 p.m. and on July 28, 2000, from 9 a.m. to 5 p.m., the meeting is open to the public. Interested persons may present data, information, or views, orally or in writing, on issues pending before the committee. Written submissions may be made to the contact person by July 12, 2000. Oral presentations from the public will be scheduled between approximately 11:45 a.m. and 12:30 p.m. on July 27, 2000, and between approximately 11:30 a.m. and 12:15 p.m., and 3 p.m. and 3:30 p.m. on July 28, 2000. Time allotted for each presentation may be limited. Those desiring to make formal oral presentations should notify the contact person before July 12, 2000, and submit a brief statement of the general nature of the evidence or arguments they wish to present, the names and addresses of proposed participants, and an indication of the approximate time requested to make their presentation.

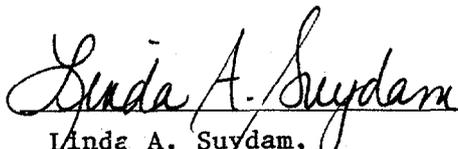
*Closed Committee Deliberations:* On July 28, 2000, from 8 a.m. to 9 a.m., the meeting will be closed to permit FDA staff to present to the committee trade secret and/or confidential commercial information regarding pending and future device submissions. This portion of the meeting will be closed to permit discussion of this information (5 U.S.C. 552b(c)(4)).



Notice of this meeting is given under the Federal Advisory Committee Act (5 U.S.C. app.

2).

Dated: 6/26/00

  
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Linda A. Suydam,  
Senior Associate Commissioner.

[FR Doc. 00-???? Filed ??-??-00; 8:45 am]

**BILLING CODE 4160-01-F**

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COPY OF THE ORIGINAL**

  
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Suzette N. Reese