**ACTION:** Notice.

**SUMMARY:** The Food and Drug Administration (FDA) is announcing that the proposed collection of information listed below has been submitted to the Office of Management and Budget (OMB) for review and clearance under the Paperwork Reduction Act of 1995.

**DATES:** Submit written comments on the collection of information by August 4, 2000.

**ADDRESSES:** Submit written comments on the collection of information to the Office of Information and Regulatory Affairs, OMB, New Executive Office Bldg., 725 17th St. NW., rm. 10235, Washington, DC 20503, Attn: Wendy Taylor, Desk Officer for FDA.

**FOR FURTHER INFORMATION CONTACT:** Karen L. Nelson, Office of Information Resources Management (HFA–250), Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857, 301–827–1482.

**SUPPLEMENTARY INFORMATION:** In compliance with 44 U.S.C. 3507, FDA has submitted the following proposed collection of information to OMB for review and clearance.

### Guidance for Industry: Submitting and Reviewing Complete Responses to Clinical Holds

On November 21, 1997, the President signed into law the Food and Drug Administration Modernization Act (the Modernization Act) (Public Law 105–115). Section 117 of the Modernization Act provides that a written request to FDA from the applicant of an investigation that a clinical hold be removed shall receive a decision in writing, specifying the reasons for that decision, within 30 days after receipt of such request. A clinical hold is an order issued by FDA to the applicant to delay a proposed clinical investigation or to suspend an ongoing investigation for a drug or biologic. An applicant may respond to a clinical hold.

Section 505(i)(3)(C) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 355(i)(3)(C)) requires that any written request to FDA from the sponsor of an investigation that a clinical hold be removed must receive a decision, in writing and specifying the reasons, within 30 days after receipt of the request. The request must include sufficient information to support the removal of the clinical hold.

In the **Federal Register** of May 14, 1998 (63 FR 26809), FDA published a notice of availability of a guidance that described how applicants should submit responses to clinical holds so that they may be identified as complete responses, and the agency can track the time to respond. FDA is now issuing a revised guidance.

The revised guidance states that FDA will respond in writing within 30 calendar days of receipt of a sponsor's request to release a clinical hold and a complete response to the issue(s) that led to the clinical hold. An applicant's complete response to an investigational new drug application (IND) clinical hold is a response in which all clinical hold issues identified in the clinical hold letter have been addressed.

The guidance requests that applicants type in large, bold letters at the top of the cover letter of the complete response ''Clinical Hold Complete Response'' to expedite review of the response. The guidance also requests that applicants submit the complete response letter in triplicate to the IND, and that they fax a copy of the cover letter to FDA's contact, listed in the clinical hold letter, who is responsible for the IND. The guidance requests more than an original and two copies, i.e., three copies, of the cover letter in order to ensure that the submission is received and handled in a timely manner.

Based on data concerning the number of complete responses to clinical holds received by the Center for Drug Evaluation and Research (CDER) from July 1, 1998, to June 30, 1999, CDER estimates that approximately 48 responses are submitted annually from approximately 43 applicants, and that it takes approximately 284 hours to prepare and submit to CDER each response.

Based on data concerning the number of complete responses to clinical holds received by the Center for Biologics Evaluation and Research (CBER) in fiscal year 1999, CBER estimates that approximately 134 responses are submitted annually from approximately 110 applicants, and that it takes approximately 284 hours to prepare and submit to CBER each response.

FDA estimates the burden of this collection of information as follows:

TABLE 1.—ESTIMATED ANNUAL REPORTING BURDEN[1]

| Complete responses to clinical holds | No. of respondents | No. of responses per respondent | Total annual responses | Hours per response | Total hours |
|---|---|---|---|---|---|
| CDER | 43 | approx. 1 | 48 | 284 | 13,632 |
| CBER | 110 | approx. 1 | 134 | 284 | 38,056 |
| Total | | | | | 51,688 |

[1]There are no capital costs or operating and maintenance costs associated with this collection of information.

In the **Federal Register** of April 13, 2000 (65 FR 19911), the agency requested comments on the proposed collections of information. No significant comments were received.

Dated: June 27, 2000.

**William K. Hubbard,**

*Senior Associate Commissioner for Policy, Planning, and Legislation.*

[FR Doc. 00–16813 Filed 7–3–00; 8:45 am]

**BILLING CODE 4160–01–F**

## DEPARTMENT OF HEALTH AND HUMAN SERVICES

### 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 biothreat 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: June 26, 2000.

**Linda A. Suydam,**

*Senior Associate Commissioner.*

[FR Doc. 00–16809 Filed 7–3–00; 8:45 am]

BILLING CODE 4160–01–F

## DEPARTMENT OF HEALTH AND HUMAN SERVICES

### Food and Drug Administration

### Ear, Nose, and Throat 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:* Ear, Nose, and Throat 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 20, 2000, 9:45 a.m. to 5 p.m., and July 21, 2000, 8:30 a.m. to 5 p.m.

*Location:* Holiday Inn, Goshen Room, Two Montgomery Village Ave., Gaithersburg, MD.

*Contact Person:* Sara M. Thornton, Center for Devices and Radiological Health (HFZ–460), Food and Drug Administration, 9200 Corporate Blvd., Rockville, MD 20850, SMT@CDRH.FDA.GOV, or FDA Advisory Committee Information Line, 1–800–741–8138 (301–443–0572 in the Washington, DC area), code 12522. Please call the Information Line for up-to-date information on this meeting.

*Agenda:* On July 20, 2000, the committee will discuss, make recommendations, and vote on a premarket approval application (PMA) for a direct-drive implantable middle ear hearing device intended to provide a useful level of sound perception via mechanical stimulation of the ossicles. On July 21, 2000, the committee will discuss, make recommendations and vote on a PMA for an implant intended to restore useful hearing to individuals with Neurofibromatosis Type II who have become deaf as a result of surgery to remove bilateral auditory nerve tumors.

*Procedure:* On July 20, 2000, from 9:45 a.m. to 5 p.m., and on July 21, 2000, from 9:15 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 13, 2000. Oral presentations from the public will be