Contact Person: Sara M. Thornton, Center for Devices and Radiological Health (HFZ 460), Food and Drug Administration, 9200 Corporate Blvd., Rockville, MD 20850, 301–594–2053, e-mail: SMT@CDRH.FDA.GOV, or FDA Advisory Committee Information Line, 1–800–741–8138 (301–443–0572 in the Washington, DC area), code 12396. Please call the Information Line for up-to-date information on this meeting.

Agenda: The committee will discuss, make recommendations, and vote on a premarket approval application (PMA) for a collagen glaucoma drainage device for the reduction of intraocular pressure in patients with open-angle glaucoma uncontrolled on maximum tolerated medical therapy. The committee will also discuss issues related to the development of guidance for the postapproval study of extended wear contact lenses used beyond 7 days. Study design topics will include the type of study, definition of endpoints, and selection of participating study sites.

Procedure: 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 November 1, 2000. Oral presentations from the public will be scheduled between approximately 8:45 a.m. and 9:15 a.m. Near the end of the committee deliberations on the PMA, an additional 30-minute open public session will be conducted for interested persons to address issues specific to the submission before the committee. Time allotted for each presentation may be limited. Those desiring to make formal oral presentations should notify the contact person before November 1, 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.

Notice of this meeting is given under the Federal Advisory Committee Act (5 U.S.C. app. 2).

Dated: October 11, 2000.

Linda A. Suydam,

Senior Associate Commissioner.

[FR Doc. 00–26741 Filed 10–17–00; 8:45 am]

BILLING CODE 4160–01–F

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. 99D–4114]

''Guidance for Industry: Supplemental Guidance on Testing for Replication Competent Retrovirus in Retroviral Vector Based Gene Therapy Products and During Follow-up of Patients in Clinical Trials Using Retroviral Vectors;'' Availability

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is announcing the availability of a guidance document entitled ''Guidance for Industry: Supplemental Guidance on Testing for Replication Competent Retrovirus in Retroviral Vector Based Gene Therapy Products and During Follow-up of Patients in Clinical Trials Using Retroviral Vectors'' dated October 2000. The guidance document applies to the manufacture of gene therapy retroviral vector products intended for in vivo or ex vivo use and to followup monitoring of patients who have received retroviral vector products. The guidance document announced in this notice finalizes the draft guidance document entitled ''Guidance for Industry: Supplemental Guidance on Testing for Replication Competent Retrovirus in Retroviral Vector Based Gene Therapy Products and During Follow-up of Patients in Clinical Trials Using Retroviral Vectors,'' announced in the **Federal Register** of November 3, 1999. The guidance document also supplements the guidance document entitled ''Guidance for Industry: Guidance for Human Somatic Cell Therapy and Gene Therapy,'' dated March 1998; and a letter to sponsors of an investigational new drug using retroviral vectors, dated September 20, 1993.

DATES: Submit written comments at any time.

ADDRESSES: Submit written requests for single copies of the guidance document entitled ''Guidance for Industry: Supplemental Guidance on Testing for Replication Competent Retrovirus in Retroviral Vector Based Gene Therapy Products and During Follow-up of Patients in Clinical Trials Using Retroviral Vectors,'' dated October 2000 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. Send one self-addressed adhesive label to assist that office in processing your requests. The guidance document may also be obtained by mail by calling the CBER Voice Information System at 1–800–835–4709 or 301–827–1800, or by fax by calling the FAX Information System at 1–888–CBER–FAX or 301–827–3844. See the **SUPPLEMENTARY INFORMATION** section for electronic access to the guidance document.

Submit written comments on the guidance document to the Dockets Management Branch (HFA–305), Food and Drug Administration, 5630 Fishers Lane, rm. 1061, Rockville, MD 20852.

FOR FURTHER INFORMATION CONTACT: Valerie A. Butler, Center for Biologics Evaluation and Research (HFM–17), Food and Drug Administration, 1401 Rockville Pike, Rockville, MD 20852–1448, 301–827–6210.

SUPPLEMENTARY INFORMATION:

I. Background

FDA is announcing the availability of a guidance document entitled ''Guidance for Industry: Supplemental Guidance on Testing for Replication Competent Retrovirus in Retroviral Vector Based Gene Therapy Products and During Follow-up of Patients in Clinical Trials Using Retroviral Vectors'' dated October 2000. The guidance document applies to the manufacture of gene therapy retroviral vector products intended for in vivo or ex vivo use and to followup monitoring of patients who have received retroviral vector products. The document provides guidance for replication competent retrovirus (RCR) testing during manufacture, including timing, amount of material to be tested, and general testing methods. The document also provides guidance on monitoring patients for evidence of retroviral infection. The recommendations are based on data and analyses generated by CBER and members of the gene therapy community. The guidance document finalizes the draft document entitled ''Guidance for Industry: Supplemental Guidance on Testing for Replication Competent Retrovirus in Retroviral Vector Based Gene Therapy Products and During Follow-up of Patients in Clinical Trials Using Retroviral Vectors,'' announced in the **Federal Register** of November 3, 1999 (64 FR 59783). The guidance document also supplements the guidance and recommendations pertaining to RCR testing given in the following documents: (1) ''Guidance for Industry: Guidance for Human Somatic Cell

Therapy and Gene Therapy'' dated March 1998 (issued on the Internet); and (2) letter to sponsors of an investigational new drug using retroviral vectors, dated September 20, 1993.

The guidance document represents the agency's current thinking regarding testing for RCR in retroviral vector based gene therapy products. 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, regulations, or both. As with other guidance documents, FDA does not intend this document to be all-inclusive and cautions that not all information may be applicable to all situations. The document is intended to provide information and does not set forth requirements.

II. Comments

Interested persons may, at any time submit written comments to the Dockets Management Branch (address above) regarding this guidance document. Two copies of any 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. A copy of the guidance document and received comments are available for public examination in the Dockets Management Branch between 9 a.m. and 4 p.m., Monday through Friday.

III. Electronic Access

Persons with access to the Internet may obtain the guidance document at http://www.fda.gov/cber/guidelines.htm.

Dated: October 5, 2000.

Margaret M. Dotzel,

Associate Commissioner for Policy.

[FR Doc. 00–26670 Filed 10–17–00; 8:45 am]

BILLING CODE 4160–01–F

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Health Resources and Services Administration

Agency Information Collection Activities: Submission for OMB Review; Comment Request

Periodically, the Health Resources and Services Administration (HRSA) publishes abstracts of information collection requests under review by the Office of Management and Budget, in compliance with the Paperwork Reduction Act of 1995 (44 U.S.C. Chapter 35). To request a copy of the clearance requests submitted to OMB for review, call the HRSA Reports Clearance Office at (301) 443–1129.

The following request has been submitted to the Office of Management and Budget for review under the Paperwork Reduction Act of 1995:

Proposed Project: Grantee Reporting Requirements for the Ryan White Comprehensive AIDS Resources Emergency (CARE) Act of 1990—Title III (OMB 0915–0158)—Revision.

Section 2651 of the Public Health Service (PHS) Act (commonly known as Title III of the Ryan White Comprehensive AIDS Resource Emergency (CARE) Act of 1990), provides categorical funding to increase the capacity and capability of organizations that provide primary health care to HIV-related early intervention services to medically underserved persons who have, or are at high risk for, HIV infection. These services are provided as part of a continuum of HIV prevention and health care services.

The bulk of the information being collected describes the epidemiologic and demographic characteristics of the populations receiving early intervention services from grant recipients, and provides the basis for the annual report to the Secretary, which is legislatively mandated. It is also used to monitor the delivery of services, guide Federal policy, and assist in program development and evaluation.

The estimated response burden is as follows:

Form name	No. of respondents	Responses per respondent	Total responses	Average time per response	Total burden hours
TIII PDR	278	1	278	80	22,240

Written comments and recommendations concerning the proposed information collection should be sent within 30 days of this notice to: John Morrall, Human Resources and Housing Branch, Office of Management and Budget, New Executive Office Building, Room 10235, Washington, D.C. 20503.

Dated: October 12, 2000.

Jane M. Harrison,

Director, Division of Policy Review and Coordination.

[FR Doc. 00–26742 Filed 10–17–00; 8:45 am]

BILLING CODE 4160–15–U

DEPARTMENT OF THE INTERIOR

Office of the Secretary

Invasive Species Advisory Committee

AGENCY: Office of the Secretary, Interior.

ACTION: Notice of meeting of the Invasive Species Advisory Committee.

SUMMARY: Pursuant to the provisions of the Federal Advisory Committee Act, notice is hereby given of meeting of the Invasive Species Advisory Committee. The purpose of the Advisory Committee is to provide advice to the Council, as authorized by Executive Order 13112, on a broad array of issues related to preventing the introduction of invasive species and providing for their control and minimizing the economic, ecological, and human health impacts that invasive species cause. The meeting on October 24 will be a joint meeting of the Advisory Committee and various Federal Agency Officials. The meeting on October 25 will consist of the Advisory Committee only. Both meetings will be open to the public. Attendance will be limited to space available.

DATES: Meeting of Invasive Species Advisory Committee and Federal Agencies: 8:00 a.m.–4:15 p.m., Tuesday October 24, 2000; Meeting of Advisory Committee only: 8:30 a.m.–3:00 p.m., Wednesday, October 25, 2000.

ADDRESSES: U.S. Fish and Wildlife Service, National Conservation Training Center, Shepherdstown, WV. The October 24th meeting will be held in the Auditorium. The October 25th meeting will be held in the Instructional West Building, Room 170.

FOR FURTHER INFORMATION CONTACT: Kelsey Passe, National Invasive Species Council Program Analyst; E-mail: kelsey_passe@ios.doi.gov; Phone: (202) 208–6336; Fax: (202) 208–1526.