

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.

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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
TIIR 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]

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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.