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 See the **SUPPLEMENTARY INFORMATION** section for electronic access to the draft guidance document.

Submit written comments on the draft guidance document to the Dockets Management Branch (HFA–305), Food and Drug Administration, 5630 Fishers Lane, rm. 1061, Rockville, MD 20852.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FDA is announcing the availability of a draft guidance document entitled ''Guidance for Industry: Supplemental Guidance on Testing for Replication Competent Retrovirus in Retroviral Vector Based Gene Therapy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.'' The draft guidance document applies to the manufacture of gene therapy retroviral vector products intended for in vivo or ex vivo use and to followup monitoring of patients who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 draft document provides guidance for replication competent retrovirus (RCR) testing during manufacture, including timing, amount of material to be tested, and general testing methods. The draft document also provides guidance on monitoring patients for evidence of retroviral infection. When finalized, the draft guidance document is intended to supplement the guidance and recommendations pertaining to RCR testing given in the following documents: (1) ''Guidance for Industry: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 IND Using Retroviral Vectors, dated September 20, 1993.

The new recommendations are based on data and analyses generated by CBER and members of the gene therapy community. Public discussion and development of these recommendations have taken place during the retroviral breakout sessions at the ''1996 Gene Therapy Conference: Development and Evaluation of Phase I Products and Workshop on Vector Development'' (61 FR 18749, April 29, 1996), and the ''Forum 1997 Gene Therapy Conference.''

The draft guidance document represents the agency's current thinking regarding testing for RCR in retroviral vector based gene therapy products.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

The draft guidance document is being distributed for comment purposes only, and is not intended for implementation at this time. Interested persons may submit to the Dockets Management Branch (address above) written comments regarding this draft guidance document. Written comments may be submitted at any time, however, comments should be submitted by February 1, 2000, to ensure adequate consideration in preparation of the final 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 draft 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 draft guidance document using the World Wide Web (WWW). For WWW access, connect to CBER at ''http://www.fda.gov/cber/guidelines.htm''.

Dated: October 19, 1999.

Margaret M. Dotzel,

Acting Associate Commissioner for Policy.

[FR Doc. 99–28560 Filed 11–2–99; 8:45 am]

BILLING CODE 4160–01–F

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Health Resources And Services Administration

Agency Information Collection Activities: Proposed Collection: Comment Request

In compliance with the requirement for opportunity for public comment on proposed data collection projects (section 3506(c)(2)(A) of Title 44, United States Code, as amended by the Paperwork Reduction Act of 1995, Pub. L. 104–13), the Health Resources and Services Administration (HRSA) publishes periodic summaries of proposed projects being developed for submission to OMB under the Paperwork Reduction Act of 1995. To request more information on the proposed project or to obtain a copy of the data collection plans and draft instruments, call the HRSA Reports Clearance Officer on (301) 443–1891.

Comments are invited on: (a) Whether the proposed collection of information is necessary for the proper performance of the functions of the agency, including whether the information shall have practical utility; (b) the accuracy of the agency's estimate of the burden of the proposed collection of information; (c) ways to enhance the quality, utility, and clarity of the information to be collected; and (d) ways to minimize the burden of the collection of information on respondents, including through the use of automated collection techniques or other forms of information technology.

Proposed Project

Querying the National Practitioner Data Bank—New.

Under the Health Resources and Services Administration (HRSA), Bureau of Health Professions (BHPr), the Division of Quality Assurance (DQA) is planning to conduct a survey to obtain information on the degree of user satisfaction with the National Practitioner Data Bank's (NPDB) reporting and querying processes, how users believe these processes can be improved, and how users perceive the usefulness of information they obtained from the NPDB for licensing and credentialing of health care entities, *e.g.* managed care organizations, State licensing boards for physicians and dentists, and professional societies. The study will also identify and survey non-user entities. The information obtained in this study will be interpreted in relation to similar information from previous studies conducted by DQA and the Office of the Inspector General.

The estimated response burden is as follows:

Questionnaire version	Number of respondents	Responses per respondent	Total responses	Hours per response	Total burden hours
Reporting:					
Hospital	1,031	1	1,031	.2	206.2
Group Practice	210	1	210	.2	42.0
HMOs	161	1	161	.2	32.2
State boards	81	1	81	.2	16.2
Malpractice Payers	188	1	188	.2	37.6
Professional Societies	67	1	67	.2	13.4
Other	209	1	209	.2	41.8
Querying:					
Hospital	770	1	770	.4	308
Group Practice	173	1	173	.4	69.2
HMOs	153	1	153	.4	61.2
State boards	74	1	74	.4	29.6
Malpractice Payers	(*)	.....	.....	.....	.....
Professional Societies	66	1	66	.4	26.4
Other	184	1	184	.4	73.6
Match Response:					
Hospital	770	3	2,310	1	2,310
Group Practice	173	3	519	1	519
HMOs	153	3	459	1	459
State boards	74	3	222	1	2,222
Malpractice Payers	(*)	.....	.....	.....	.....
Professional Societies	66	3	198	1	198
Other	184	3	552	1	552
Total	.....	.....	.....	.....	5,217.4

*Cannot query the NPDB; thus these entities do not receive query or match response questionnaires.

Send comments to Susan G. Queen, Ph.D., HRSA Reports Clearance Officer, Room 14–33, Parklawn Building, 5600 Fishers Lane, Rockville, Maryland 20857. Written comments should be received within 60 days of this notice.

Dated: October 28, 1999.

Claude Earl Fox,

Administrator.

[FR Doc. 99–28705 Filed 11–2–99; 8:45 am]

BILLING CODE 4160–15–P

DEPARTMENT OF HOUSING AND URBAN DEVELOPMENT

[Docket No. FR–4445–N–26]

Notice of Proposed Information Collection: Comment Request; Computation of Surplus Cash Distributions and Residual Receipts and Fund Authorizations

AGENCY: Office of the Assistant Secretary for Housing, HUD.

ACTION: Notice.

SUMMARY: The proposed information collection requirement described below will be submitted to the Office of Management and Budget (OMB) for review, as required by the Paperwork Reduction Act. The Department is soliciting public comments on the subject proposal.

DATES: *Comments Due Date:* January 3, 2000.

ADDRESSES: Interested persons are invited to submit comments regarding this proposal. Comments should refer to the proposal by name and/or OMB Control Number and should be sent to: Wayne Eddins, Reports Management Officer, Department of Housing and Urban Development, 451 7th Street, SW., L'Enfant Building, Room 8202, Washington, DC 20410.

FOR FURTHER INFORMATION CONTACT: Willie Spearmon, Office of Business Products, Office of Multifamily Housing Programs, Department of Housing and Urban Development, 451 7th Street SW., Washington, DC 20410, telephone (202) 708–3000 for copies of the proposed forms and other available information.

SUPPLEMENTARY INFORMATION: The Department is submitting the proposed information collection to OMB for review, as required by the Paperwork Reduction Act of 1995 (44 U.S.C. Chapter 35, as amended).

This Notice is soliciting comments from members of the public and affected agencies concerning the proposed collection of information to: (1) Evaluate whether the proposed collection is necessary for the proper performance of the functions of the agency, including whether the information will have practical utility; (2) Evaluate the accuracy of the agency's estimate of the burden of the proposed collection of information; (3) Enhance the quality, utility, and clarity of the information to be collected; and (4) Minimize the burden of the collection of information on those who are to respond; including the use of appropriate automated collection techniques or other forms of information technology, *e.g.,* permitting electronic submission of responses.

This Notice also lists the following information:

Title of Proposal: Computation of Surplus Cash Distributions and Residual Receipts and Funds Authorizations.

OMB Control Number, if applicable: 2502–0314.

Description of the need for the information and proposed use: Handbook 4350.1, Rev. 1, Chapter 25, Multifamily Asset Management and Project Servicing, applies to all non-profit and limited dividend multifamily projects with HUD-insured and HUD-held mortgages, including the Section 202 Program projects. Generally, all projects owned by non-profit mortgagors and all Section 236 and 221(d)(3) projects owned by limited distribution (LD) mortgagors as well, as Section 8 New Construction/Substantial Rehabilitation projects subject to the 1979/80 revised Section 8 regulations, are required to establish a Residual Receipts Account. The requirement for a Residual Receipts Account is