Requirements for Approval of Pharmaceuticals for Human Use for several years to develop harmonized technical requirements for the approval of human pharmaceutical and biological products among the European Union, Japan, and the United States. VICH is a parallel initiative for veterinary medicinal products. VICH is concerned with developing harmonized technical requirements for the approval of veterinary medicinal products in the European Union, Japan, and the United States, and includes input from both regulatory and industry representatives.

The VICH steering committee is composed of member representatives from the European Commission; European Medicines Evaluation Agency; European Federation of Animal Health; Committee on Veterinary Medicinal Products; FDA; the U.S. Department of Agriculture; the Animal Health Institute; the Japanese Veterinary Pharmaceutical Association; the Japanese Association of Veterinary Biologics; and the Japanese Ministry of Agriculture, Forestry, and Fisheries.

Four observers are eligible to participate in the VICH steering committee: One representative from the government of Australia/New Zealand, one representative from the industry in Australia/New Zealand, one representative from the government of Canada, and one representative from the industry of Canada. The VICH Secretariat, which coordinates the preparation of documentation, is provided by the International Federation for Animal Health (IFAH). An IFAH representative also participates in the VICH steering committee meetings.

II. Draft Guidance on Target Animal Safety

The VICH steering committee held a meeting in December 2006 and agreed that the draft guidance document entitled ''Draft Guidance for Industry on Target Animal Safety for Veterinary Pharmaceutical Products,''VICH GL43 should be made available for public comment. This draft VICH guidance document has been developed as a harmonized standard to aid in development of mutually acceptable TAS studies for the relevant governmental regulatory bodies. This draft guidance document is intended to cover TAS studies for any Investigational Veterinary Pharmaceutical Product used in the following species: Bovine, ovine, caprine, feline, canine, porcine, equine, and poultry (chickens and turkeys). Minor species and minor uses may be excluded from this guidance for local registration. The guidance does not provide information for the design of TAS studies in other species including aquatic animals. For other species, TAS studies should be designed following local guidance.

FDA and the VICH Expert Working Group will consider comments about the draft guidance document.

III. Paperwork Reduction Act of 1995

This draft guidance refers to previously approved collections of information found in FDA regulations. These collections of information are subject to review by the Office of Management and Budget (OMB) under the Paperwork Reduction Act of 1995 (44 U.S.C. 3501–3520). The collections of information in section 1-5 of the draft guidance have been approved under OMB Control No. 0910–0032.

IV. Significance of Guidance

This draft document, developed under the VICH process, has been revised to conform to FDA's good guidance practices regulation (21 CFR 10.115). For example, the document has been designated ''guidance'' rather than ''guideline.'' In addition, guidance documents must not include mandatory language such as ''shall,'' ''must,'' ''require,'' or ''requirement,'' unless FDA is using these words to describe a statutory or regulatory requirement.

The draft VICH guidance (GFI #185) is consistent with the agency's current thinking on this topic. This guidance does not create or confer any rights for or on any person and will not operate to bind FDA or the public. An alternative method may be used as long as it satisfies the requirements of applicable statutes and regulations.

IV. Comments

This draft guidance document is being distributed for comment purposes only and is not intended for implementation at this time. Interested persons may submit written or electronic comments regarding this draft guidance document to the Division of Dockets Management (see **ADDRESSES**). Submit a single copy of electronic comments or two paper copies of any mailed comments, except that individuals may submit one paper 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 and received comments may be seen in the Division of Dockets Management between 9 a.m. and 4 p.m., Monday through Friday.

V. Electronic Access

Electronic comments may also be submitted electronically on the Web site at *http://www.fda.gov/dockets/ecomments*. Once on this Internet site, select Docket No. 2007D–0166 entitled ''Draft Guidance for Industry on Target Animal Safety for Veterinary Pharmaceutical Products,''VICH GL43 and follow the directions.

Copies of the draft guidance document entitled ''Draft Guidance for Industry on Target Animal Safety for Veterinary Pharmaceutical Products,''VICH GL43 may be obtained on the Web site from the Center for Veterinary Medicine home page at *http://www.fda.gov/cvm*.

Dated: May 10, 2007.

Jeffrey Shuren,

Assistant Commissioner for Policy.

[FR Doc. E7–9592 Filed 5–17–07; 8:45 am]

BILLING CODE 4160–01–S

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 (OMB), 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 on (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: OAT Telehealth Outcome Measures: NEW.

In order to help carry out its mission, the Office for the Advancement of Telehealth (OAT) created a set of performance measures that grantees can use to evaluate the effectiveness of their services programs and monitor their progress through the use of performance reporting data.

As required by the Government Performance and Review Act of 1993 (GPRA), all Federal agencies must develop strategic plans describing their overall goal and objectives. The Office for the Advancement of Telehealth (OAT) has worked with its grantees to develop performance measures to be used to evaluate and monitor the

progress of the grantees. Grantee goals are to: Improve access to needed services, reduce rural practitioner isolation, improve health system productivity and efficiency, and improve patient outcomes. In each of these categories, specific indicators were designed to be reported through a performance monitoring Web site.

The Program Assessment Response Tool (PART) is the newest instrument created for use by Federal agencies. The Office of Management and Budget (OMB) uses the PART to assess Federal programs. The PART is a series of diagnostic questions used to assess and evaluate programs across a set of performance-related criteria including program design and purpose, strategic planning, program management, and results. PART results are used to inform the budget process and improve program management. OAT's Telehealth Network Grant Program has been undergoing a PART assessment this year. Thus, in addition to responding to the GPRA initiative, OAT now has the added responsibility of responding to the PART assessment of its Telehealth Network Grant Program. The proposed performance measures will provide performance data that will address the PART assessment, monitor progress, and evaluate program effectiveness.

The estimates of burden are as follows:

Form	Number of respondents	Responses per respondent	Total responses	Hour burden	Total burden hours
Performance Measurement Tool	667	2	1,334	7	9,338

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

Dated: May 11, 2007.

Caroline Lewis,

Associate Administrator for Management.

[FR Doc. E7–9536 Filed 5–17–07; 8:45 am]

BILLING CODE 4165–15–P

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 (44 U.S.C. 3506(c)(2)(A)), 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) 443–1129.

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: Data System for Organ Procurement and Transplantation Network (42 CFR Part 121, OMB No. 0915–0184): Extension

The operation of the Organ Procurement and Transplantation Network (OPTN) necessitates certain recordkeeping and reporting requirements in order to perform the functions related to organ transplantation under contract to HHS. This is a request for an extension of the current recordkeeping and reporting requirements associated with the OPTN. These data will be used by HRSA in monitoring the contracts for the OPTN and the Scientific Registry of Transplant Recipients (SRTR) and in carrying out other statutory responsibilities. Information is needed to match donor organs with recipients, to monitor compliance of member organizations with OPTN rules and requirements, to ensure that all qualified entities are accepted for membership in the OPTN, and to ensure patient safety.

ESTIMATED ANNUAL REPORTING AND RECORDKEEPING BURDEN

Section and Activity	Number of respondents	Responses per respondents	Total responses	Hours per response	Total burden hours
121.3(b)(2).					
OPTN membership and application requirements for OPOs, hospitals, and histocompatibility laboratories	40	3	120	15	1, 800
121.3(b)(4)					
Appeal for OPTN membership	2	1	2	3	6
121.6(c) (Reporting)					
Submitting criteria for organ acceptance	900	1	900	0.5	450
121.6(c) (Disclosure)					
Sending criteria to OPOs	900	1	900	0.5	450
121.7(b)(4)					
Reasons for Refusal	900	38	34,200	0.5	17,100
121.7(e)					
Transplant to prevent organ wastage	260	1.5	390	0.5	195
121.9(b)					
Designated Transplant Program Requirements	10	1	10	5.0	50
121.9(d)					