On December 20, 2002, the agency announced its intention to extend *Pearson* to health claims for conventional foods (67 FR 78002). Recognizing the need for an approach for scientific evaluations for qualified health claims, the task force on ''Consumer Health Information for Better Nutrition'' was formed. As part of the task force's final report,[1] FDA developed an interim evidence-based review system that the agency intended to use to evaluate the substance/disease relationships that are subjects of qualified health claims.

In reviewing both the December 22, 1999, guidance document and the 2003 task force report, it became apparent to the agency that the components of the scientific review process for an SSA health claim and qualified health claim are very similar. Because of the similarity between the scientific reviews for SSA and qualified health claims, FDA intends to generally use the approach set out in this draft guidance for evaluating the scientific evidence in petitions that are submitted for an SSA health claim or qualified health claim.

The primary purpose of this document is to set out FDA's current thinking on the process for evaluating the scientific evidence for a health claim, the meaning of the SSA standard in section 403(r)(3) of the act and § 101.14(c), and credible scientific evidence to support a qualified health claim.

This draft guidance is being issued consistent with FDA's good guidance practice regulations (21 CFR 10.115). The draft guidance, when finalized, will represent the agency's current thinking on the scientific review process for SSA and qualified health claims. 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 statutes and regulations.

II. 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This draft guidance refers to previously approved collections of information found in FDA regulations.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 §§ 101.14 and 101.70 have been approved under OMB control number 0910–0381.

III. Comments

Interested persons may submit to the Division of Dockets Management (see **ADDRESSES**) written or electronic comments regarding the draft guidance document. 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. The draft guidance and received comments are available for public examination in the Division of Dockets Management between 9 a.m. and 4 p.m., Monday through Friday.

IV. Electronic Access

Persons with access to the Internet may obtain the draft guidance at *http://www.cfsan.fda.gov/guidance.html*.

Dated: June 28, 2007.

Jeffrey Shuren,

Assistant Commissioner for Policy.

[FR Doc. E7–13274 Filed 7–6–07; 8:45 am]

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[1]See guidance entitled ''Interim Evidence-based Ranking System for Scientific Data,'' July 10, 2003 (*http://www.cfsan.fda.gov/~dms/hclmgui4.html*).

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 the Office of Management and Budget (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 at (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 estimated 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: Office of Health Information Technology, Health Center Controlled Networks Progress Reports—New

The Office of Health Information Technology (OHIT), Division of State and Community Assistance (DSCA) plans to collect network outcome measures, conduct evaluation of those measures, and create an electronic reporting system for the following new 2007 grant opportunities: Health Information Technology Planning Grants, Electronic Health Record Implementation Health Center Controlled Networks, Health Information Technology Innovations for Health Center Controlled Networks, and High Impact Electronic Health Records Implementation for Health Center Controlled Networks and Large Multi Site Health Centers.

In order to help carry out its mission, DSCA has created a set of performance measures that grantees will use to evaluate the effectiveness of their service programs and monitor their progress through the use of performance reporting data.

OHIT will develop an electronic performance measurement reporting instrument with HRSA's Office of Information Technology. The instrument will be developed to accomplish the following goals: To monitor improved access to needed services, to evaluate the productivity and efficiency of the networks, and to monitor patient outcome measures. Grantees will submit their Progress Reports in a mid-year report and an accumulative annual progress report each fiscal year of the grant.

The estimates of burden are as follows:

Application	Number of respondents	Responses per respondent	Total responses	Hours per response	Total burden hours
Planning	12	2	24	18	432
Electronic Health Records Implementation	8	2	16	18	288
Innovations Category 1	7	2	14	18	252
Innovations Category 2	5	2	10	18	180
High Impact	8	2	16	18	288
Totals	40		80		1,440

Send comments to Susan G. Queen, Ph.D., HRSA Reports Clearance Officer, Room 10–33, Parklawn Building, 5600 Fishers Lane, Rockville, MD 20857. Written comments should be received within 60 days of this notice.

Dated: June 28, 2007.

Caroline Lewis,

Associate Administrator for Management.

[FR Doc. E7–13167 Filed 7–6–07; 8:45 am]

BILLING CODE 4165–15–P

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: Reporting Form for the MCHB National Hemophilia Program Grantees and Hemophilia Treatment Center (HTC) Affiliates Having Factor Replacement Product (FRP) Programs

The Maternal and Child Health Bureau (MCHB) of the Health Resources and Services Administration (HRSA) is planning to implement an annual reporting form required of grantees of the MCHB National Hemophilia Program and their HTC affiliates having a factor replacement product (FRP) program. The purpose of the form is to provide systematic information and data comprising a financial overview of the FRP programs of the HTCs receiving funding through grantees of the MCHB National Hemophilia Program. The proposed form will constitute a reporting requirement for the MCHB National Hemophilia Program grantees and their affiliate HTCs having FRP programs.

Data from the form will provide quantitative information on the financial and services provision aspects of each of the HTC FRP programs under each of the MCHB National Hemophilia Program grantees, specifically: (a) Patient FRP program participation, (b) FRP program revenue, (c) FRP program costs, (d) FRP program net income, and (e) use of FRP program net income. This form will provide data useful to grantees and their affiliate HTCs having FRP programs as well as to the MCHB National Hemophilia Program. The data will be used to assess FRP program performance including FRP program operational costs appropriateness, FRP program cost efficiency, and FRP program services benefits–information that is essential to evaluating HTCs having FRP programs, grantees, and the MCHB National Hemophilia Program.

Each HTC having an FRP program is to submit its report to the grantee and each grantee is to submit the individual reports of each of their affiliate HTCs having an FRP program to the MCHB National Hemophilia Program as a part of their annual grant application.

The estimated response burden for grantees is as follows:

Form	Number of respondents	Average number of responses per respondent	Total responses	Hours per response	Total burden hours
Factor Replacement Product (FRP) Data Sheet	68	1	68	30	2,040

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: June 28, 2007.

Caroline Lewis,

Associate Administrator for Management.

[FR Doc. E7–13168 Filed 7–6–07; 8:45 am]

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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 (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: ''Health Care and Other Facilities'' Project Status Update Form: NEW

The Health Resources and Services Administration's Health Care and Other Facilities (HCOF) program provides earmarked funds to health-related