

Administration, 5630 Fishers Lane, rm. 1061, Rockville, MD 20852. Submit electronic comments to <http://www.fda.gov/dockets/ecomments>.

**FOR FURTHER INFORMATION CONTACT:**

David J. Cummings, Center for Drug Evaluation and Research, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 21, rm. 3525, Rockville, MD 20993-0002, 301-796-2400, e-mail:

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**SUPPLEMENTARY INFORMATION:**

**I. Background**

On February 7, 2007, FDA held a public meeting to solicit comments on issues that FDA should consider if it decides to propose revisions to § 314.70 (21 CFR 314.70) regarding CMC supplements and other changes to approved marketing applications for human drugs. In the notice announcing the public meeting (72 FR 574), FDA stated that current § 314.70 categorizes postapproval CMC changes and their associated reporting requirements without consideration of the applicant's risk management activities or internal quality systems and practices; therefore, § 314.70 reflects a rules-based, or prescriptive, approach to regulating postapproval manufacturing changes. Current § 314.70 may create regulatory burdens and costs that discourage beneficial manufacturing changes and may not support a desirable level of innovation, modernization, and flexibility for the industry as described in FDA's pharmaceutical current good manufacturing practices for the 21st century initiative (CGMP Initiative). Consistent with the agency's risk-based approach to regulating pharmaceutical manufacturing described in the CGMP Initiative, FDA is considering possible revisions to § 314.70 to allow for more manufacturing changes to be made without prior FDA approval using a firm's internal change control system and to allow for consideration of risk-based approaches based on manufacturing process understanding, including prior knowledge of similar products, and overall quality systems to provide an enhanced risk-based approach to the CMC regulatory process.

Interested persons were given until March 7, 2007, to submit written or

electronic comments to the agency related to the focus of the public meeting. As a result of continued public interest, FDA is reopening the comment period until May 18, 2007, to allow interested persons additional time to submit comments.

**II. Request for Comments**

Interested persons may submit to the Division of Dockets Management (see **ADDRESSES**) written or electronic comments related to this topic (see **DATES**). All relevant data and information should be submitted with the written comments. Submit a single copy of electronic comments or two paper copies of any mailed comments, except that individuals may submit one copy. Comments are to be identified with Docket No. 2006N-0525. Received comments may be seen in the Division of Dockets Management between 9 a.m. and 4 p.m., Monday through Friday.

Dated: April 5, 2007.

**Jeffrey Shuren,**

*Assistant Commissioner for Policy.*

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**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 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: Bureau of Primary Health Care (BPHC) Uniform Data System (OMB No. 0915-0193) Revision for 2008**

The Uniform Data System (UDS) contains the annual reporting requirements for the cluster of primary care grantees funded by the Health Resources and Services Administration (HRSA). The UDS includes reporting requirements for grantees of the following primary care programs: Community Health Centers, Migrant Health Centers, Health Care for the Homeless, Public Housing Primary Care, and other grantees under Section 330. The authorizing statute is section 330 of the Public Health Service Act, as amended.

HRSA collects data in the UDS which is used to ensure compliance with legislative mandates and to report to Congress and policymakers on program accomplishments. To meet these objectives, BPHC requires a core set of data collected annually that is appropriate for monitoring and evaluating performance and reporting on annual trends. The 2008 calendar year UDS will be revised in several ways. Certain UDS tables are being proposed for elimination or modification to streamline data collection and reporting. A limited number of clinical measures will be added for reporting quality of care, health outcomes, and disparities data. In addition, the tool used to report calendar year UDS data will be changed to a Web-based tool.

Estimates of Annualized Reporting Burden are as Follows:

Type of report	Number of respondents	Responses per respondent	Hours per response	Total burden hours
Universal report .....	1076	1	30	32,280
Grant report .....	240	1	18	4,320
Total .....	1076	.....	.....	36,600

Send comments to Susan G. Queen, PhD, 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: April 6, 2007.

**Caroline Lewis,**

*Acting Associate Administrator for Administration and Financial Management.*  
[FR Doc. E7-6991 Filed 4-12-07; 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 OMB for review under the Paperwork Reduction Act of 1995:

#### **Proposed Project: The Health Education Assistance Loan Program: Physician's Certification of Borrower's Total and Permanent Disability Form (OMB No. 0915-0204 Extension)**

The Health Education Assistance Loan (HEAL) program provided federally-insured loans to students in schools of allopathic medicine, osteopathic medicine, dentistry, veterinary medicine, optometry, podiatric medicine, pharmacy, public health, allied health or chiropractic, and graduate students in health administration or clinical psychology through September 30, 1998. Eligible lenders, such as banks, savings and loan associations, credit unions, pension funds, State agencies, HEAL schools, and insurance companies, were permitted to refinance HEAL loans which were insured by the Federal Government against loss due to borrower's death, disability, bankruptcy, and default until the authority to refinance HEAL loans expired on September 30, 2004. The basic purpose of the program was to assure the

availability of funds for loans to eligible students who needed to borrow money to pay for their educational loans.

Currently, the program monitors the Federal liability and assists in default prevention activities. The HEAL borrower, the borrower's physician, and the holder of the loan completes the Physician's Certification form to certify that the HEAL borrower meets the total and permanent disability provisions.

The Department uses this form to obtain detailed information about disability claims which includes the following: (1) The borrower's consent to release medical records to the Department of Health and Human Services and to the holder of the borrower's HEAL loans, (2) pertinent information supplied by the certifying physician, (3) the Physician's Certification that the borrower is unable to engage in any substantial gainful activity because of a medically determined impairment that is expected to continue for a long and indefinite period of time or to result in death, and (4) information from the lender on the unpaid balance. Failure to submit the required documentation will result in disapproval of a disability claim.

The estimate of burden for the Physician's Certification form is as follows:

Type of respondent	Number of respondents	Responses per respondent	Number of responses	Minutes per response	Total burden hours
Borrower .....	80	1	80	5	7
Physician .....	80	1	80	30	40
Loan Holder .....	17	5	85	10	14
Total .....	177	.....	245	.....	61

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

Dated: April 6, 2007.

**Caroline Lewis,**

*Acting Associate Administrator for Administration and Financial Management.*  
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**BILLING CODE 4165-15-P**

## DEPARTMENT OF HEALTH AND HUMAN SERVICES

### Health Resources and Services Administration

#### **National Vaccine Injury Compensation Program; List of Petitions Received**

**AGENCY:** Health Resources and Services Administration, HHS.

**ACTION:** Notice.

**SUMMARY:** The Health Resources and Services Administration (HRSA) is publishing this notice of petitions received under the National Vaccine Injury Compensation Program ("the Program"), as required by Section 2112(b)(2) of the Public Health Service (PHS) Act, as amended. While the Secretary of Health and Human Services is named as the respondent in all proceedings brought by the filing of petitions for compensation under the

Program, the United States Court of Federal Claims is charged by statute with responsibility for considering and acting upon the petitions.

**FOR FURTHER INFORMATION CONTACT:** For information about requirements for filing petitions, and the Program is general, contact the Clerk, United States Court of Federal Claims, 717 Madison Place, NW., Washington, DC 20005, (202) 357-6400. For information on HRSA's role in the Program, contact the Director, National Vaccine Injury Compensation Program, 5600 Fishers Lane, Room 11C-26, Rockville, MD 20857; (301) 443-6593.

**SUPPLEMENTARY INFORMATION:** The Program provides a system of no-fault compensation for certain individuals who have been injured by specified childhood vaccines. Subtitle 2 of Title XXI of the PHS Act, 42 U.S.C. 300aa-10 *et seq.*, provides that those seeking