

the agency unit(s) that are prepared to receive electronic submissions and the specific types of records and submissions that can be accepted in electronic format (62 FR 13467, March 20, 1997).

In the **Federal Register** of January 28, 1999 (64 FR 4433), CDER and CBER jointly published a guidance entitled "Providing Regulatory Submissions in Electronic Format--General Considerations." Since that time, CDER and CBER have included NDA's and BLA's on the docket as submission types that we are able to accept in electronic format.

This draft guidance is being issued consistent with FDA's good guidance practices regulation (21 CFR 10.115; 65 FR 56468, September 19, 2001). This draft guidance represents the agency's current thinking on providing promotional materials in electronic format to CDER and CBER. 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, regulations, or both.

Interested persons may submit to the Dockets Management Branch (address above) written comments on the draft guidance. Two copies of any comments are to be submitted, except that individuals may submit one copy. Comments and requests 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 The draft guidance and received comments are available for public examination in the Dockets Management Branch between 9 a.m. and 4 p.m., Monday through Friday. As in the past, applicants planning to make submissions in electronic format should consult public Docket No. 92S-0251 to determine which agency units are prepared to receive electronic

submissions and the specific types of documents that can be submitted in electronic format.

Dated: January 24, 2001.

**Ann M. Witt,**

*Acting 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 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: The Health Education Assistance Loan (HEAL) Program: Physician's Certification of Borrower's Total and Permanent Disability Form (OMB No. 0915-0204)—Revision**

The Health Education Assistance (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, make new refinanced HEAL loans which are insured by the Federal Government against loss due to borrower's death, disability, bankruptcy, and default. 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 refinances previous HEAL loans, 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 determinable 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	Total responses	Minutes per responses	Total burden hours
Borrower* .....	117	1	117	5	10
Physician .....	117	1	117	30	58.5
Loan Holder .....	20	5.85	117	10	19.5
<b>Total .....</b>	<b>254</b>	<b>.....</b>	<b>351</b>	<b>.....</b>	<b>88</b>

\*Includes 2 categories of borrowers requesting disability waivers: (1) whose loans have previously defaulted and (2) whose loans have not defaulted.

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, DC 20503.

Dated: January 26, 2001.

**Jane M. Harrison,**

*Director, Division of Policy Review and Coordination.*

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