the agency. Where an agency regulation implements an information collection requirement in the act or the FPLA, only any additional burden attributable to the regulation has been included in FDA's burden estimate.

No burden has been estimated for those requirements where the information to be disclosed is information that has been supplied by FDA. Also, no burden has been estimated for information that is disclosed to third parties as a usual and customary part of a food producer's normal business activities. Under 5 CFR 1320.3(c)(2), the public disclosure of information originally supplied by the Federal Government to the recipient for the purpose of disclosure to the public is not a collection of information. Under 5 CFR 1320.3(b)(2), the time, effort, and financial resources necessary to comply with a collection of information are excluded from the burden estimate if the reporting, recordkeeping, or disclosure activities needed to comply are usual and customary because they would occur in the normal course of activities.

Dated: October 2, 2000.

Margaret M. Dotzel,

Associate Commissioner for Policy.

[FR Doc. 00–25810 Filed 10–6–00; 8:45 am]

BILLING CODE 4160–01–F

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: **Regulatory Requirements—(OMB No. 0915–0108)—Revision**

This clearance request is for revision of approval for the notification, reporting and recordkeeping requirements in the HEAL program to insure that the lenders, holders and schools participating in the HEAL program follow sound management procedures in the administration of federally-insured student loans. While the regulatory requirements are approved under this OMB number, some of the burden associated with the regulations is cleared under the OMB numbers for the HEAL forms used to report required information (listed below). The table listed at the end of this notice contains the estimate of burden for the remaining regulations.

Annual Response Burden for the following regulations is cleared by OMB when the reporting forms are cleared:

OMB Approval No. 0915–0034, Lender's Application, Borrower Status, Loan Transfer, Contract for Loan Insurance

Reporting

42 CFR 60.31(a), Lender annual application.

42 CFR 60.38(a), Loan Reassignment.

Notification

42 CFR 60.12(c)(1), Borrower deferment.

OMB Approval No. 0915–0036, Lender's Application for Insurance Claim

Reporting

42 CFR 60.35(a)(2), Lender skip-tracing activities.

42 CFR 60.40(a), Lender documentation to litigate a default.

42 CFR 60.40(c)(i), (ii), and (iii), Lender default claim.

42 CFR 60.40(c)(2), Lender death claim.

42 CFR 60.40(c)(3), Lender disability claim.

42 CFR 60.40(c)(4), Lender report of student bankruptcy.

OMB Approval No. 0915–0043, Repayment Schedule, Call Report

Notification

42 CFR 60.11(e), Establishment of repayment terms-borrower.

42 CFR 60.11(f)(5), Borrower notice of supplemental repayment agreement.

42 CFR 60.34(b)(1), Establishment of repayment terms-lender.

OMB Approval No. 0915–0204, Physicians Certification of Permanent and Total Disability

Reporting

42 CFR 60.39(b)(2), Holder request to Secretary to determine borrower disability.

OMB Approval No. 0915–227, Refinancing Application/Promissory Note

42 CFR 60.33(e), Executed application and note to borrower.

The estimate of burden for the regulatory requirements of this clearance are as follows:

REPORTING REQUIREMENTS

Number of respondents	Number of transactions per respondent	Total transactions	Time per response (hours)	Total burden hours
22 Lenders	7	161	0.7	116
200 Schools	7	139	0.2	23
Total Reporting	.....	.....	.....	139

NOTIFICATION REQUIREMENTS

Number of respondents	Number of transactions per respondent	Total transactions	Time per response (hours)	Total burden hours
22 Lenders	11,271	247,958	0.2	46,293
200 Schools	30	5,956	0.3	1,988

NOTIFICATION REQUIREMENTS—Continued

Number of respondents	Number of transactions per respondent	Total transactions	Time per response (hours)	Total burden hours
20,639 Borrowers	1	20,639	0.2	3,440
Total Notification				51,721

RECORDKEEPING REQUIREMENTS

Number of respondents	Number of transactions per respondent	Total transactions	Time per response (hours)	Total burden hours
22 Lenders	4,929	128,169	0.2	28,993
200 Schools	768	101,639	0.1	14,437
Total Recordkeeping				43,430

Total Annual Burden: 95,290 Hrs.

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: October 2, 2000.

Jane Harrison,

Director, Division of Policy Review and Coordination.

[FR Doc. 00–25812 Filed 10–6–00; 8:45 am]

BILLING CODE 4160–15–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

Availability for Licensing: Chromatin Insulator Protecting Expressed Genes of Interest for Human Gene Therapy or Other Mammalian Transgenic Systems

AGENCY: National Institutes of Health, Public Health Service, DHHS.

ACTION: Notice.

SUMMARY: The National Institutes of Health (NIH), Department of Health and Human Services (DHHS), seeks licensee(s) who can effectively pursue the preclinical, clinical and commercial development of the technology embodied in U.S. Patent 5,610,053 entitled ''DNA Sequence Which Acts as a Chromatin Insulator Element to Protect Expressed Genes from Cis-acting Regulatory Sequences in Mammalian Cells,'' issued on March 11, 1997. The invention describes the isolation, identification, and characterization of a DNA element residing in higher eukaryotic chromatin structural domains. All fields of use are available for licensing. The patent rights in this technology have been assigned to the United States of America.

ADDRESSES: Requests for copies of the issued patent, inquiries, comments and other materials relating to the contemplated licenses should be directed to: Girish C. Barua, Office of Technology Transfer, National Institutes of Health, 6011 Executive Boulevard, Suite 325, Rockville, Maryland 20852–3804; telephone: 301/496–7735 ext. 266; Facsimile: 301/402–0220; E-mail: baruag@od.nih.gov.

SUPPLEMENTARY INFORMATION: The technology provides the isolation of a functional DNA sequence comprising a chromatin insulating element from a vertebrate system and provides the first employment of the pure insulator element as a functional insulator in mammalian cells. The technology further relates to a method for insulating the expression of a gene from the activity of cis-acting regulatory sequences in eukaryotic chromatin.

This technology could be of major importance in providing a mechanism and a tool to restrict the action of cis-acting regulatory elements on genes whose activities or encoded products are needed or desired to be expressed in mammalian transgenic systems. This technology provides the first pure insulator element to function solely as an insulator element in human cells. Accordingly, this technology could have tremendous practical implications for transgenic technology and human gene therapies, either in vitro or in vivo.

The technology further provides a method and constructs for insulating the expression of a gene or genes in transgenic animals such that the transfected genes will be protected and stably expressed in the tissues of the transgenic animal or its offspring. For example, even if the DNA of the construct integrates into areas of silent chromatin in the genomic DNA of the host animal, the gene will continue to be expressed. The invention could provide a means of improving the stable integration and expression of any transgenic construct of interest, with efficiencies higher than are achieved presently. Use of this invention may represent a large potential savings for licensee's constructing transgenic cell lines or animals.

The NIH seeks licensee(s), who in accordance with requirements and regulations governing the licensing of government-owned inventions (37 CFR part 404), have meritorious plan(s) for the development of the DNA Chromatin Insulator technology to a marketable status to meet the needs of the public.

Dated: September 29, 2000.

Jack Spiegel,

Director, Division of Technology Development and Transfer, Office of Technology Transfer.

[FR Doc. 00–25893 Filed 10–6–00; 8:45 am]

BILLING CODE 4140–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

Office of the Director, National Institutes of Health; Notice of Meeting

Pursuant to section 10(a) of the Federal Advisory Committee Act, as amended (5 U.S.C. Appendix 2), notice is hereby given of a meeting of the Director's Council of Public Representatives.

The meeting will be open to the public, with attendance limited to space available. Individuals who plan to attend and need special assistance, such