

any interested person may petition FDA, on or before June 5, 1996, for a determination regarding whether the applicant for extension acted with due diligence during the regulatory review period. To meet its burden, the petition must contain sufficient facts to merit an FDA investigation. (See H. Rept. 857, part 1, 98th Cong., 2d sess., pp. 41–42, 1984.) Petitions should be in the format specified in 21 CFR 10.30.

Comments and petitions should be submitted to the Dockets Management Branch (address above) in three copies (except that individuals may submit single copies) and identified with the docket number found in brackets in the heading of this document. Comments and petitions may be seen in the Dockets Management Branch between 9 a.m. and 4 p.m., Monday through Friday.

Dated: November 30, 1995.
Stuart L. Nightingale,
Associate Commissioner for Health Affairs.
[FR Doc. 95–29808 Filed 12–6–95; 8:45 am]
BILLING CODE 4160–01–F

Health Resources and Services Administration

Agency Forms Undergoing Paperwork Reduction Act Review

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:

Health Education Assistance Loan (HEAL) Program Physician's Certification of Borrower's Total and Permanent Disability Form—New—This form, completed by the HEAL borrower, the borrower's physician, and the holder of the loan, is used to certify that the

HEAL borrower meets the total and permanent disability provisions. The PHS will use this form to obtain precise information about the disability claim 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 a disability claim not being honored.

Type of respondent	Number of respondents	Responses per respondent	Average burden per response	Total burden (hours)
Borrower	42	1.0	0.08	3
Physician	42	1.0	2.75	116
Lender	35	1.2	0.17	7

Estimated Total Annual Burden: 126 hours.

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

Dated: December 1, 1995.
J. Henry Montes,
Associate Administrator for Policy Coordination
[FR Doc. 95–29810 Filed 12–6–95; 8:45 am]
BILLING CODE 4160–15–P

National Institutes of Health

Government-Owned Inventions; Availability for Licensing

AGENCY: National Institutes of Health, HHS.

ACTION: Notice.

SUMMARY: The inventions listed below are owned by an agency of the U.S. Government and are available for licensing in the U.S. in accordance with 36 U.S.C. 207 or pursuant to 42 U.S.C.

241 to achieve expeditious commercialization of results of federally-funded research and development.

ADDRESSES: Licensing information for the technologies referenced below may be obtained by contacting Stephen Finley, Ph.D., at the Office of Technology Transfer, National Institutes of Health, 6011 Executive Boulevard, Suite 325, Rockville, Maryland 20852–3804 (telephone 301/496–7056 ext 215; fax 301/402–0220).

cDNA Sequence of a Clone Encoding Arylalkylamine N-acetyltransferase

Klein et al. (NICHHD)

[DHHS Reference No. E–161–95/0]

and

Human Gene Encoding Serotonin N-acetyltransferase

Klein et al. (NICHHD)

[DHHS Reference No. E–222–95/0]

The identification of an arylalkylamine N-acetyltransferase (AA-NAT) mRNA in the brain and the cloning of ovine and human cDNAs encoding for the pineal enzyme

serotonin N-acetyltransferase. These findings open a new area of research—the importance of AA-NAT in the regulation of brain serotonin and the development of drugs which raise serotonin levels by inhibiting this enzyme. This enzyme is the rate-controlling step in the conversion of serotonin to melatonin. The hormone melatonin has been linked to controlling circadian rhythms. Development of regulators of the synthesis of the hormone melatonin may be the preferred route to controlling seasonal reproduction cycles or sleep cycles of vertebrates. Activators of the serotonin N-acetyltransferase may be beneficial to induce or enhance the quality of sleep at night. Inhibitors of serotonin N-acetyltransferase may lead to drugs that stimulate the levels of alertness and physical activity or delay the onset of fatigue. Licenses for the cDNAs encoding for this enzyme or the production of the enzyme are available.