

needs for which they are designed, it is essential that they be evaluated and revised periodically. This information collection will be used to evaluate the items on the 1989 revisions of the standard certificates and to determine if there is other information that should be

included on the standards that is needed for relevant public health research. Respondents will include individuals and organizations who are involved in the completion of vital records or who utilize vital statistics data and have an interest in the content

of the standard certificates. The information collected will be used by a group of consultants to determine what changes may be needed in the 1989 standard certificates. The total cost to respondents is estimated at \$90,000.

Respondents	Number of respondents	Number of responses/re-sponses	Average burden/response (in hrs.)	Total burden (in hrs.)
Live Birth Questionnaire	2000	1	0.5	1000
Fetal Death Questionnaire	2000	1	0.5	1000
Death Questionnaire	2000	1	0.5	1000
Total				3000

Dated: December 4, 1996.

Wilma G. Johnson,

Acting Associate Director for Policy Planning and Evaluation, Centers for Disease Control and Prevention (CDC).

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[30DAY-24]

Agency Forms Undergoing Paperwork Reduction Act Review

The Centers for Disease Control and Prevention (CDC) publishes a list of information collection requests under review by the Office of Management and Budget (OMB) in compliance with the Paperwork Reduction Act (44 U.S.C. Chapter 35). To request a copy of these requests, call the CDC Reports Clearance Office on (404) 639-7090. Send written comments to CDC, Desk Officer; Human Resources and Housing Branch, New

Executive Office Building, Room 10235; Washington, DC 20503. Written comments should be received within 30 days of this notice.

The following requests have been submitted for review since the last publication date on November 27, 1996.

Proposed Project

1. Chronic Fatigue Syndrome Surveillance and Related Studies—Prevalence and Incidence of Fatiguing Illness in Sedgewick County, Kansas—New—In 1994, OMB approved the information collection "Epidemiology of Fatiguing Illness in Wichita: A Population-Based Study" under OMB Number (0920-0336). Data from this cross-sectional, point prevalence, random-digit-dial survey of prolonged fatiguing illness in San Francisco, CA concluded that CFS continues to exist and that prolonged fatigue occurs in

over five percent of the population in San Francisco.

The proposed study replicates the San Francisco study using identical methodology and data collection instruments. Beginning with a random-digit-dial telephone survey to identify fatigued individuals, followed by a case-control study where surveillance interview instruments will be used to obtain comparative data on fatigued individuals and matched health (non-fatigued) controls. Study objectives remain to refine estimates of CFS in Wichita, identify similarities and differences among cases and controls, and to evaluate the merits of a physician-based surveillance conducted by the Wichita department of health. The total annual burden is 7646. Send comments to CDC Desk Officer, Human Resources and Housing Branch, New Executive Office Building, Room 10235; Washington, DC 20503.

Respondents	Number of respondents	Number of responses/respondent	Avg. burden/response (in hrs.)
Household Screener	26,000	1	0.083
*Cross-sectional interview	6,864	1
*Follow-up interview	5,148	1
Adolescent Questionnaire	5,532	1	0.027

*These respondents are a subset of the 26,000 respondents to household.

Dated: December 4, 1996.

Wilma G. Johnson,

Acting Associate Director for Policy Planning and Evaluation, Centers for Disease Control and Prevention (CDC).

[FR Doc. 96-31416 Filed 12-10-96; 8:45 am]

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Administration for Children and Families

Proposed Information Collection Activity; Comment Request

Proposed Projects

Title: Child Support Enforcement Technical Assistance Survey and Best Practices Report.

OMB No.: New Collection.

Description: The new welfare reform law requires the Federal Office of Child Support Enforcement (OCSE) to provide technical assistance to States and localities. This information collection is designed to help OCSE learn what type of technical assistance is needed, and what child support practices have been successful. We plan to collect the first type of information through voluntary needs assessment and technical

assistance reporting documents, and the second through a voluntary best practices reporting form.

Respondents: States, District of Columbia, Guam, Puerto Rico and Virgin Islands.

Annual Burden Estimates:

Instrument	Number of respondents	Number of responses per respondent	Average burden hours per response	Total burden hours
Needs Assessment	54	1	16	864
Technical Assistance Request/Report	54	1	3	162
Best Practices Report	54	1	3	162

Estimated Total Annual Burden Hours: 1,188.

In compliance with the requirements of Section 3506(c)(2)(A) of the Paperwork Reduction Act of 1995, the Administration for Children and Families is soliciting public comment on the specific aspects of the information collection described above. Copies of the proposed collection of information can be obtained and comments may be forwarded by writing to the Administration for Children and Families, Office of Information Services, Division of Information Resource Management Services, 370 L'Enfant Promenade SW., Washington, DC 20447, Attn: ACF Reports Clearance Officer. All requests should be identified by the title of the information collection.

The Department specifically requests comments 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) 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. Consideration will be given to comments and suggestions submitted within 60 days of this publication.

Dated: December 5, 1996.

Douglas J. Godesky,

Reports Clearance Officer.

[FR Doc. 96-31377 Filed 12-10-96; 8:45 am]

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Food and Drug Administration

[Docket No. 96M-0472]

Neuromedical Systems, Inc.; Premarket Approval of the PAPNET® Testing System

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is announcing its approval of the application by Neuromedical Systems, Inc., Suffern, NY, for premarket approval, under the Federal Food, Drug, and Cosmetic Act (the act), of the PAPNET® Testing System. After reviewing the recommendation of the Hematology and Pathology Devices Panel, FDA's Center for Devices and Radiological Health (CDRH) notified the applicant, by letter of November 8, 1995, of the approval of the application.

DATES: Petitions for administrative review by January 10, 1997.

ADDRESSES: Written requests for copies of the summary of safety and effectiveness data and petitions for administrative review to the Dockets Management Branch (HFA-305), Food and Drug Administration, 12420 Parklawn Dr., rm. 1-23, Rockville, MD 20857.

FOR FURTHER INFORMATION CONTACT: Peter E. Maxim, Center for Devices and Radiological Health (HFZ-440), Food and Drug Administration, 2098 Gaither Rd., Rockville, MD 20850, 301-594-1293.

SUPPLEMENTARY INFORMATION: On September 21, 1994, Neuromedical Systems, Inc., Suffern, NY 10901-4164, submitted to CDRH an application for premarket approval of the PAPNET® Testing System. The device is a semi-automated test indicated to aid in the rescreening of cervical Papanicolaou (Pap) smears previously reported as negative. The PAPNET® Testing System is intended to detect evidence of cervical epithelial abnormalities including the following categories of the Bethesda System for classification of cervical cytology results: (1) Primary squamous cell carcinoma of the cervix and its possible precursor lesions, i.e., low grade squamous intra epithelial lesions (LGSIL), high grade intra epithelial (HGSIL), and atypical squamous cells of undetermined significance (ASCUS); and (2) primary

endocervical adenocarcinoma and its possible precursor lesion, atypical glandular cells of undetermined significance (AGUS). The PAPNET® testing is intended as an adjunct to all standard laboratory quality control and mandated re-screening procedures.

On August 7, 1995, the Hematology and Pathology Devices Panel of the Medical Devices Advisory Committee, an FDA advisory committee, reviewed and recommended approval of the application. On November 8, 1995, CDRH approved the application by a letter to the applicant from the Director of the Office of Device Evaluation, CDRH.

A summary of the safety and effectiveness data on which CDRH based its approval is on file in the Dockets Management Branch (address above) and is available from that office upon written request. Requests should be identified with the name of the device and the docket number found in brackets in the heading of this document.

Opportunity for Administrative Review

Section 515(d)(3) of the act (21 U.S.C. 360e(d)(3)) authorizes any interested person to petition, under section 515(g) of the act, for administrative review of CDRH's decision to approve this application. A petitioner may request either a formal hearing under 21 CFR part 12 of FDA's administrative practices and procedures regulations or a review of the application and CDRH's action by an independent advisory committee of experts. A petition is to be in the form of a petition for reconsideration under 21 CFR 10.33(b). A petitioner shall identify the form of review requested (hearing or independent advisory committee) and shall submit with the petition supporting data and information showing that there is a genuine and substantial issue of material fact for resolution through administrative review. After reviewing the petition, FDA will decide whether to grant or deny the petition and will publish a