

statutory limitations in its calculations of the actual period for patent extension. In its application for patent extension, this applicant seeks 1,761 days of patent term extension.

Anyone with knowledge that any of the dates as published is incorrect may, on or before July 14, 2000, submit to the Dockets Management Branch (address above) written comments and ask for a redetermination. Furthermore, any interested person may petition FDA, on or before November 13, 2000, for a determination on 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. Three copies of any information are to be submitted, except that individuals may submit one copy. Comments are to be 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: May 6, 2000.

Jane A. Axelrad,

Associate Director for Policy, Center for Drug Evaluation and Research.

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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: Children's Hospital Graduate Medical Education Program—New

Public Law Number 106-129 amended the Public Health Service Act to establish a new program to support graduate medical education (GME) in children's hospitals. The provision authorizes payments in FY 2000 and FY 2001 for direct and indirect expenses associated with operating approved GME programs. Section 340E(c)(1) states that the amount determined under this subsection for payments for direct medical expenses for a fiscal year is

equal to the product of (A) the updated per resident amount as determined, and (B) the average number of FTE residents in the hospital's approved graduate medical residency training programs as determined under section 1886(h)(4) of the Social Security Act during the fiscal year. The statute directs the Secretary to take into account factors identified in section 340E(b)(1)(B) and 340E(d)(2) " case mix, number of FTE residents, treatment of more severely ill patients and the additional costs related to teaching residents.

Administration of the Children's Hospital Graduate Medical Education Program relies on the reporting of the number of full-time equivalent residents in applicant children's hospital training programs to determine the amount of direct and indirect expense payments to participating children's hospitals. Indirect expense payments will also be derived from a formula that requires the reporting of case mix index information from participating children's hospitals.

Hospitals will be requested to submit such information in an annual application. The statute also requires reconciliation of the estimated numbers of residents with the actual number determined after the close of the fiscal year. Participating children's hospitals would be required to complete an adjusted report to correct such information on an annual basis.

ESTIMATES OF ANNUALIZED HOUR BURDEN

Form name	Number of respondents	Responses per respondent	Total responses	Hrs. per response	Total hour burden
Form E (Short)	42	1	42	*99.9	4,194
Form E (Long)	12	1	12	*46.7	560
Form F (Short)	42	1	42	8	336
Form F (Long)	12	1	12	8	96
IME Data *	54	1	54	14	756
Required GPRA Tables	54	1	54	28	1,512
Total	54				7,454

*The hours per response are paradoxically greater for the short form because of the relatively large number of hospitals which have been reporting residency counts to Medicare but expect considerable work in translating resident counts based on hospital cost-reporting years to counts, in part prospective, based on Federal fiscal years, including obtaining interim counts from other hospitals of incoming rotations.

HRSA is requesting from OMB an emergency review and approval of this data collection within 40 days from the date of publication of this notice, with a 180-day approval period. During this 180-day approval period, we will publish a separate **Federal Register** notice announcing the initiation of an extensive 60-day review and public

comment period on the data collection activity.

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, 725 17th St., NM, New

Executive Office Building, Room 10235, Washington, DC 20503.

Dated: May 8, 2000.

Claude Earl Fox,

Administrator.

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