

of the act. February 21, 1997. FDA has verified the applicant's claim that the new drug application (NDA) for Singulair® (NDA 20-829) was initially submitted on February 21, 1997.

3. *The date the application was approved:* February 20, 1998. FDA has verified the applicant's claim that NDA 20-829 was approved on February 20, 1998.

This determination of the regulatory review period establishes the maximum potential length of a patent extension. However, the U.S. Patent and Trademark Office applies several statutory limitations in its calculations of the actual period for patent extension. In its application for patent extension, this applicant seeks 428 days of patent term extension.

Anyone with knowledge that any of the dates as published is incorrect may, on or before May 3, 1999, 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 August 30, 1999 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: February 16, 1999.

**Thomas J. McGinnis,**

*Deputy Associate Commissioner for Health Affairs.*

[FR Doc. 99-5132 Filed 3-2-99; 8:45 am]

BILLING CODE 4160-01-F

## DEPARTMENT OF HEALTH AND HUMAN SERVICES

### Health Care Financing Administration

[Document Identifier: HCFA-484]

#### Agency Information Collection Activities: Proposed Collection; Comment Request

AGENCY: Health Care Financing Administration.

In compliance with the requirement of section 3506(c)(2)(A) of the Paperwork Reduction Act of 1995, the Health Care Financing Administration (HCFA), Department of Health and Human Services, is publishing the following summary of proposed collections for public comment. Interested persons are invited to send comments regarding this burden estimate or any other aspect of this collection of information, including any of the following subjects: (1) The necessity and utility of the proposed information collection for the proper performance of the agency's functions; (2) the accuracy of the estimated burden; (3) ways to enhance the quality, utility, and clarity of the information to be collected; and (4) the use of automated collection techniques or other forms of information technology to minimize the information collection burden.

#### *Type of Information Collection*

*Request:* Extension of a currently approved collection;

#### *Title of Information Collection:*

Attending Physician's Certification of Medical Necessity for Home Oxygen Therapy and Supporting Regulations in 42 CFR 410.38 and 424.5;

*Form No.:* HCFA-484 (OMB# 0938-0534);

*Use:* To determine if oxygen is reasonable and necessary pursuant to Medicare Statute, Medicare claims for home oxygen therapy must be supported by the treating physician's statement and other information including estimate length of need (# of months), diagnosis codes (ICD-9) and:

1. Results and date of the most recent arterial blood gas PO<sub>2</sub> and/or oxygen saturation tests.

2. The most recent arterial blood gas PO<sub>2</sub> and/or oxygen saturation test performed EITHER with the patient in a chronic stable state as an outpatient, OR within two days prior to discharge from an inpatient facility to home.

3. The most recent arterial blood gas PO<sub>2</sub> and/or oxygen saturation test performed at rest, during exercise, or during sleep.

4. Name and address of the physician/provider performing the most recent arterial blood gas PO<sub>2</sub> and/or oxygen saturation test.

5. If ordering portable oxygen, information regarding the patient's mobility within the home.

6. Identification of the highest oxygen flow rate (in liters per minute) prescribed.

7. If the prescribed liters per minute (LPM), as identified in item 6, are greater than 4 LPM, provide the results and date of the most recent arterial

blood gas PO<sub>2</sub> and/or oxygen saturation test taken on 4 LPM.

If the PO<sub>2</sub> = 56-59, or the oxygen saturation = 89%, then evidence of the beneficiary meeting at least one of the following criteria must be provided.

8. The patient having dependent edema due to congestive heart failure.

9. The patient having cor pulmonale or pulmonary hypertension, as documented by pulmonale on an EKG or by an echocardiogram, gated blood pool scan or direct pulmonary artery pressure measurement.

10. The patient having a hematocrit greater than 56%.

Form HCFA-484 obtains all pertinent information and promotes national consistency in coverage determinations;

*Frequency:* Other (as needed);

*Affected Public:* Business or other for-profit, and Federal Government;

*Number of Respondents:* 500,000;

*Total Annual Responses:* 500,000;

*Total Annual Hours:* 50,000.

To obtain copies of the supporting statement and any related forms for the proposed paperwork collections referenced above, access HCFA's Web Site address at <http://www.hcfa.gov/regs/prdact95.htm>, or E-mail your request, including your address, phone number, OMB number, and HCFA document identifier, to [Paperwork@hcfa.gov](mailto:Paperwork@hcfa.gov), or call the Reports Clearance Office on (410) 786-1326.

Written comments and recommendations for the proposed information collections must be mailed within 60 days of this notice directly to the HCFA Paperwork Clearance Officer designated at the following address: HCFA, Office of Information Services, Security and Standards Group, Division of HCFA Enterprise Standards, Attention: Dawn Willingham, Room N2-14-26, 7500 Security Boulevard, Baltimore, Maryland 21244-1850.

Dated: February 23, 1999.

**John P. Burke III,**

*HCFA Reports Clearance Officer, HCFA Office of Information Services, Security and Standards Group, Division of HCFA Enterprise Standards.*

[FR Doc. 99-5220 Filed 3-2-99; 8:45 am]

BILLING CODE 4120-03-P