fluoride excimer laser and is indicated for PRK treatments: (1) For the reduction or elimination of mild to moderate myopia (nearsightedness) of between -1.0 to -6.0 diopters spherical equivalent at the corneal plane, in patients with less than or equal to 1.0 diopters of astigmatism; (2) in patients with documented evidence of a change in manifest refraction of less than or equal to 0.50 diopters (in both cylinder and sphere components) per year for at least 1 year prior to the date of preoperative examination; and (3) in patients who are 18 years of age or older.

On October 20, 1995, the Ophthalmic Devices Panel of the Medical Devices Advisory Committee, an FDA advisory committee, reviewed and recommended conditional approval of the application. On March 27, 1996, 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 notice of its decision in the **Federal Register**. If FDA grants the petition, the notice will state the issue to be reviewed, the form of review to be used, the persons who may participate in the review, the time and place where the review will occur, and other details.

Petitioners may, at any time on or before April 24, 1997, file with the Dockets Management Branch (address above) two copies of each petition and supporting data and information, identified with the name of the device and the docket number found in brackets in the heading of this document. Received petitions may be seen in the office above between 9 a.m. and 4 p.m., Monday through Friday.

This notice is issued under the Federal Food, Drug, and Cosmetic Act (secs. 515(d), 520(h) (21 U.S.C. 360e(d), 360j(h))) and under authority delegated to the Commissioner of Food and Drugs (21 CFR 5.10) and redelegated to the Director, Center for Devices and Radiological Health (21 CFR 5.53).

Dated: February 20, 1997.

Joseph A. Levitt,

Deputy Director for Regulations Policy, Center for Devices and Radiological Health.

[FR Doc. 97–7478 Filed 3–24–97; 8:45 am]

BILLING CODE 4160–01–F

Health Care Financing Administration

[Document Identifier: HCFA–R–183]

Agency Information Collection Activities: Proposed Collection; Comment Request

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 the 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 currently approved collection; *Title of Information Collection:* Voluntary Customer Surveys to Implement Executive Order 12862 within HCFA; *Form No.:* HCFA–R–183; *Use:* These voluntary customer surveys will be used to implement E.O. 12862 to ascertain customer satisfaction with HCFA programs in terms of service quality. Surveys will involve individuals that are in direct or indirect beneficiaries of HCFA service and/or assistance, not partners. *Frequency:* Annually; *Affected Public:* Individuals or households; *Number of Respondents:* 1; *Total Annual Responses:* 1; *Total Annual Hours:* 1.

To obtain copies of the supporting statement for the proposed paperwork collections referenced above, access HCFA's WEB SITE ADDRESS at http://www.hcfa.gov/regs/prdact95.htm, or to obtain the supporting statement and any related forms, E-mail your request, including your address and phone number, to 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 Financial and Human Resources, Management Analysis and Planning Staff, Attention: John Burke, Room C2–26–17, 7500 Security Boulevard, Baltimore, Maryland 21244–1850.

Dated: March 18, 1997.

Edwin J. Glatzel,

Director, Management Analysis and Planning Staff, Office of Financial and Human Resources.

[FR Doc. 97–7402 Filed 3–24–97; 8:45 am]

BILLING CODE 4120–03–P

Agency Information Collection Activities: Proposed Collection: Comment Request

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, has submitted to the Office of Management and Budget (OMB) the following proposals for the collection of information. 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.

1. *Type of Request:* Revision of a currently approved collection; *Title of Information Collection:* Drug Utilization Review (DUR) (Medicaid); *Form No.:* HCFA–R–153 and HCFA–R–153a; *Use:* This is a revision of a currently approved collection of the OMB approved requirements on DUR programs that will expire on 9/30/97. The program and requirements are the same, but HCFA intends to add survey/instructions for the annual report. This framework in form HCFA–R153a would allow for reports to be more easily prepared by the states while also enhancing the usefulness of these reports for analysis and comparison by HCFA. Submission of reports has been required by Section 1927(g) of the Social Security Act; *Frequency:* Annually; *Affected Public:* State, local, or tribal government; Business or other for profit; and Not-for-profit institutions; *Number of Respondents:* 50; *Total Annual Responses:* 50; *Total Annual Hours:* 608,400.

2. *Type of Request:* Extension of a currently approved collection; *Title of Information Collection:* Systems Performance Review (SPR); *Form No.:* HCFA–R–86; *Use:* The System Performance Review (SPR) is a vehicle used to evaluate State Medicaid Management Information Systems (MMIS) to determine whether or not a State system satisfies the functional requirements and statistical levels of output relating to accuracy and timeliness. This review necessitates the documentation or maintenance of specific records; *Frequency:* Annually; *Affected Public:* State, local, or tribal government; Business or other for profit; and Federal Government; *Number of Respondents:* 17; *Total Annual Responses:* 17; *Total Annual Hours:* 22,100.

3. *Type of Request:* Revision of a currently approved collection; *Title of Information Collection:* Medicaid Posteligibility Preprint; *Form No.:* HCFA–SP0001; *Use:* To standardize the display of information on the posteligibility process in the State's Medicaid plan. The State plan is issued as a basis for Federal financial participation in the State program; *Frequency:* Annually; *Affected Public:* State, local, or tribal government; and Federal Government; *Number of Respondents:* 56; *Total Annual Responses:* 896; *Total Annual Hours:* 529.

To request copies of the proposed paperwork collection referenced above, E-mail your request, including your address, to Paperwork@hcfa.gov, or call the Reports Clearance Office on (410) 786–1326. Written comments and recommendations for the proposed information collections should be sent within 60 days of this notice directly to the HCFA Paperwork Clearance Officer designated at the following address: HCFA, Office of Financial and Human Resources, Management Analysis and Planning Staff, Attention: Linda Mansfield, Room C2–26–17, 7500 Security Boulevard, Baltimore, Maryland 21244–1850.

Dated: March 17, 1997

Edwin J. Glatzel

Director, Management Analysis and Planning Staff, Office of Financial and Human Resources, Health Care Financing Administration.

[FR Doc. 97–7466 Filed 3–24–97; 8:45 am]

BILLING CODE 4120–03–P

Submitted for Collection of Public Comment: Submission for OMB Review

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, has submitted to the Office of Management and Budget (OMB) the following proposals for the collection of information. 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.

1. *Type of Request:* Revision of a currently approved collection; *Title of Information Collection:* Statistical Report on Medical Care: Eligibles, Recipients, Payments and Services; *Form No.:* HCFA–2082; *Use:* The data reported in the HCFA–2082 are the basis of actuarial forecasts for Medicaid service utilization and costs; of analysis and cost savings estimates required for legislative initiatives relating to Medicaid and for responding to requests for information from HCFA components, the Department, Congress and other customers; *Frequency:* Annually; *Affected Public:* State, local, or tribal government; *Number of Respondents:* 54; *Total Annual Responses:* 54; *Total Annual Hours:* 17,214.

To request copies of the proposed paperwork collection referenced above, E-mail your request, including your address, to Paperwork@hcfa.gov, or call the Reports Clearance Office on (410) 786–1326. Written comments and recommendations for the proposed information collections should be sent within 30 days of this notice directly to the OMB Desk Officer designated at the following address: OMB Human Resources and Housing Branch, Attention: Allison Eydt, New Executive Office Building, Room 10235, Washington, D.C. 20503.

Dated: March 17, 1997.

Edwin J. Glatzel,

Director, Management Analysis and Planning Staff, Office of Financial and Human Resources, Health Care Financing Administration.

[FR Doc. 97–7467 Filed 3–24–97; 8:45 am]

BILLING CODE 4120–03–P

[HCFA–1957]

Agency Information Collection Activities: Submission for OMB Review; Comment Request

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, has submitted to the Office of Management and Budget (OMB) the following proposal for the collection of information. Interested persons are invited to send comments regarding the 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:* SSO Report of State Buy In Problems, 42 CFR 407.40; *Form No.:* HCFA–1957; *Use:* The HCFA–1957 is issued to assist with communications between the Social Security District Offices, Medicaid State Agencies and HCFA Central Offices in the resolution of beneficiary complaints, regarding entitlement under state buy-ins. It is used when a problem arises which cannot be resolved thru normal