- A copy of the labeling claims of specific clinical advantages approved by the FDA for the IOL.
- A copy of the IOL's original FDA approval notification.
- Reports of modifications made after the original FDA approval.
- Other information that supports the requestor's claim (that is, clinical trials, case studies, journal articles, *etc.*).

Privileged or Confidential Information

To the extent that information received from an IOL manufacturer can reasonably be characterized as a trade secret or as privileged or confidential commercial or financial information, we maintain the confidentiality of the information and protect it from disclosure not otherwise authorized or required by Federal law as allowed under Exemption 4 of the Freedom of Information Act (5 U.S.C. 552(b)(4)) and, for trade secrets, the Trade Secrets Act (18 U.S.C. 1905). We recommend that the requestor clearly identify all information that is to be characterized as confidential. Under the Freedom of Information Act, we may not withhold publication of information based on the type of information contained, but rather on an identifiable harm that release of that information would present.

Application of the Payment Adjustment

We recognize the IOL(s) that define a new technology subset for purposes of subpart F of part 416 as belonging to the class of NTIOLs for a period of 5 years effective from the date that we recognize the first new technology IOL within the subset for a payment adjustment. Any IOL that we subsequently recognize as belonging to a new technology subset receives the new technology payment adjustment for the remainder of the 5-year period established with our recognition of the first NTIOL in the subset.

II. Provisions of This Notice

Under our rules at 42 CFR part 416, subpart F, we are soliciting requests for review of the appropriateness of the payment amount for intraocular lenses furnished by an ASC. Requests for review must comply with our regulations at § 416.195 and be received at the address provided by the date specified in the DATES section of this notice. We will announce timely requests for review in a subsequent notice that will allow for public comment. Currently, if we determine a lens as an NTIOL, the lens will be eligible for a payment adjustment of $50 or a different amount implemented through proposed and final rules.

III. Collection of Information Requirements

Because the requirements referenced in this notice will not affect 10 or more persons on an annual basis, this notice does not impose any information collection and record keeping requirements that are subject to review by the Office of Management and Budget (OMB) under the Paperwork Reduction Act of 1995 (44 U.S.C. 3501 *et seq.*).

IV. Regulatory Impact Statement

We have examined the impacts of this rule as required by Executive Order 12866 (September 1993, Regulatory Planning and Review), the Regulatory Flexibility Act (RFA) (September 16, 1980, Pub. L. 96–354), section 1102(b) of the Social Security Act, the Unfunded Mandates Reform Act of 1995 (Pub. L. 104–4), and Executive Order 13132.

Executive Order 12866 directs agencies to assess all costs and benefits of available regulatory alternatives and, if regulation is necessary, to select regulatory approaches that maximize net benefits (including potential economic, environmental, public health and safety effects, distributive impacts, and equity). A regulatory impact analysis (RIA) must be prepared for major rules with economically significant effects ($100 million or more annually). We have determined that this notice is not a major rule because it is merely soliciting interested parties to submit requests for review of the appropriateness of the payment amount with regard to a particular intraocular lens furnished by an ambulatory surgical center.

The RFA requires agencies to analyze options for regulatory relief of small businesses. For purposes of the RFA, small entities include small businesses, nonprofit organizations, and government agencies. Most hospitals and most other providers and suppliers are small entities, either by nonprofit status or by having revenues of $26 to $29 million or less in any 1 year. We have determined that this notice will not affect small businesses.

In addition, section 1102(b) of the Act requires us to prepare a regulatory impact analysis if a rule may have a significant impact on the operations of a substantial number of small rural hospitals. This analysis must conform to the provisions of section 604 of the RFA. For purposes of section 1102(b) of the Act, we define a small rural hospital as a hospital that is located outside of a Metropolitan Statistical Area and has fewer than 100 beds. We have determined that this notice does not have a significant impact on the operations of a substantial number of small rural hospitals.

Section 202 of the Unfunded Mandates Reform Act of 1995 also requires that agencies assess anticipated costs and benefits before issuing any rule that may result in an expenditure in any one year by State, local, or tribal governments, in the aggregate, or by the private sector, of $110 million. We have determined that this notice will not have a consequential effect on the governments mentioned or on the private sector.

Executive Order 13132 establishes certain requirements that an agency must meet when it promulgates a proposed rule (and subsequent final rule) that imposes substantial direct requirement costs on State, local, or tribal governments, preempts State law, or otherwise has Federalism implications. We have determined that this notice does not have an economic impact on State, local, or tribal governments.

In accordance with the provisions of Executive Order 12866, this notice was not reviewed by the Office of Management and Budget.

Authority: Section 1832(a)(2)(F)(i) and 1833(i)(2)(a) of the Social Security Act (42 U.S.C. 1395k(a)(2)(F)(i) and 1395l(i)(2)(A)).

(Catalog of Federal Domestic Assistance Program No.93.773 Medicare—Hospital Insurance Program; and No. 93.774, Medicare—Supplementary Medical Insurance Program)

Dated: February 24, 2003.

Thomas A. Scully,

Administrator, Centers for Medicare & Medicaid Services.

[FR Doc. 03–4734 Filed 2–27–03; 8:45 am]

BILLING CODE 4120–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Centers for Medicare & Medicaid Services

[CMS–1225–GNC]

RIN 0938–ZA22

Medicare Program; Criteria and Standards for Evaluating Intermediary, Carrier, and Durable Medical Equipment, Prosthetics, Orthotics, and Supplies (DMEPOS) Regional Carrier Performance During Fiscal Year 2003

AGENCY: Centers for Medicare & Medicaid Services (CMS), Health and Human Services (HHS).

ACTION: General notice with comment period.

SUMMARY: This notice describes the criteria and standards to be used for evaluating the performance of fiscal intermediaries, carriers, and Durable Medical Equipment, Prosthetics, Orthotics, and Supplies (DMEPOS) regional carriers in the administration of the Medicare program beginning on the first day of the first month following publication of this notice in the **Federal Register**. The results of these evaluations are considered whenever we enter into, renew, or terminate an intermediary agreement, carrier contract, or DMEPOS regional carrier contract or take other contract actions, for example, assigning or reassigning providers or services to an intermediary or designating regional or national intermediaries. We are requesting public comment on these criteria and standards.

EFFECTIVE DATE: The criteria and standards are effective the March 3, 2003.

Comment Period: Comments will be considered if we receive them at the appropriate address as provided below no later than 5 p.m. (EDT) on March 31, 2003.

ADDRESSES: In commenting, please refer to file code CMS–1225–GNC. Because of staff and resource limitations, we cannot accept comments by facsimile (fax) transmission. Mail written comments (one original and two copies) to the following address:

Centers for Medicare & Medicaid Services, Department of Health and Human Services, Attention: CMS–1225–GNC, P.O. Box 8016, Baltimore, MD 21244–8016.

If you prefer, you may deliver (by hand or courier) your written comments (one original and two copies) to one of the following addresses:

Room 443–G, Hubert H. Humphrey Building, 200 Independence Avenue, SW., Washington, DC, 20201 or Room C5–14–03, 7500 Security Boulevard, Baltimore, Maryland 21244–1850.

(Because access to the interior of the HHH Building is not readily available to persons without Federal Government identification, commenters are encouraged to leave their comments in the CMS drop slots located in the main lobby of the building. A stamp-in clock is available for persons wishing to retain a proof of the comments being filed.)

Comments mailed to the addresses indicated as appropriate for hand or courier delivery may be delayed and could be considered late.

For information on viewing public comments, see the **SUPPLEMENTARY INFORMATION** section.

FOR FURTHER INFORMATION CONTACT: Sue Lathroum, (410) 786–7409.

SUPPLEMENTARY INFORMATION: In several instances, we identify a Medicare manual as a source of more detailed requirements. Medicare fee-for-service contractors have copies of the various Medicare manuals referenced in this notice. Members of the public also have access to our manual instructions.

Medicare manuals are available for review at local Federal Depository Libraries (FDLs). Under the FDL Program, government publications are sent to approximately 1,400 designated public libraries throughout the United States. To locate the nearest FDL, individuals should contact any public library.

In addition, individuals may contact regional depository libraries that receive and retain at least one copy of nearly every Federal government publication, either in printed or microfilm form, for use by the general public. These libraries provide reference services and interlibrary loans; however, they are not sales outlets. Individuals may obtain information about the location of the nearest regional depository library from any library. Information may also be obtained from the following Web site: *http://www.hcfa.gov/pubforms/progman.htm.* Some manuals may be obtained from the following Web site: *http://www.cms.gov/pubforms/p2192toc.htm.*

Finally, all of our Regional Offices (ROs) maintain all Medicare manuals for public inspection. To find the location of our nearest available RO, you may call the individual listed at the beginning of this notice. That individual can also provide information about purchasing or subscribing to the various Medicare manuals.

Response to Public Comments: Because of the large number of items of correspondence we normally receive on **Federal Register** documents published for comment, we are unable to acknowledge or respond to them individually. We will consider all comments we receive by the date and time specified in the *Comment Period* section of this preamble, and, if we proceed with a subsequent document, we will respond to the comments in the preamble of that document.

Inspection of Public Comments: Comments received timely are available for public inspection beginning approximately 2 weeks after the close of the comment period, at the headquarters of the Centers for Medicare & Medicaid Services, 7500 Security Boulevard, Baltimore, Maryland 21244, Monday through Friday of each week from 8:30 a.m. to 4 p.m.

To schedule an appointment to view public comments, phone (410) 786–7197.

I. Background

A. Part A—Hospital Insurance

Under section 1816 of the Social Security Act (the Act), public or private organizations and agencies participate in the administration of Part A (Hospital Insurance) of the Medicare program under agreements with us. These agencies or organizations, known as fiscal intermediaries, determine whether medical services are covered under Medicare, determine correct payment amounts and then make payments to the health care providers (for example, hospitals, skilled nursing facilities (SNFs), community mental health centers, etc.) on behalf of the beneficiaries. Section 1816(f) of the Act requires us to develop criteria, standards, and procedures to evaluate an intermediary's performance of its functions under its agreement.

Section 1816(e)(4) of the Act requires us to designate regional agencies or organizations, which are already Medicare intermediaries under section 1816 of the Act, to perform claim processing functions with respect to freestanding Home Health Agency (HHA) claims. We refer to such organizations as Regional Home Health Intermediaries (RHHIs). *See* 42 CFR 421.117 and the final rule published in the **Federal Register** on May 19, 1988 at 53 FR 17936 for more details about the RHHIs.

Evaluations of Medicare fee-for-service contractor performance need not be limited to the current fiscal year (FY), other fixed term basis, or agreement term. We may evaluate performance using a time frame that does not mirror the FY or other fixed term. The evaluation of intermediary performance is part of our contract management process.

B. Part B Medical Insurance

Under section 1842 of the Act, we are authorized to enter into contracts with carriers to fulfill various functions in the administration of Part B (Supplementary Medical Insurance) of the Medicare program. Beneficiaries, physicians, and suppliers of services submit claims to these carriers. The carriers determine whether the services are covered under Medicare and the amount payable for the services or supplies, and then make payment to the appropriate party.

Under section 1842(b)(2) of the Act, we are required to develop criteria, standards, and procedures to evaluate a

carrier's performance of its functions under its contract. Evaluations of Medicare fee-for-service contractor performance need not be limited to the current FY, other fixed term basis, or contract term. We may evaluate performance using a timeframe that does not mirror the FY. The evaluation of carrier performance is part of our contract management process.

C. Durable Medical Equipment, Prosthetics, Orthotics, and Supplies (DMEPOS) Regional Carriers

In accordance with section 1834(a)(12) of the Act, we have entered into contracts with four DMEPOS regional carriers to perform all of the duties associated with the processing of claims for DMEPOS, under Part B of the Medicare program. These DMEPOS regional carriers process claims based on a Medicare beneficiary's principal residence by State. Section 1842(a) of the Act authorizes contracts with carriers for the payment of Part B claims for Medicare covered services and items. Section 1842(b)(2) of the Act requires us to publish in the **Federal Register** criteria and standards for the efficient and effective performance of carrier contract obligations. Evaluation of Medicare fee-for-service contractor performance need not be limited to the current FY, other fixed term basis, or contract term. We may evaluate performance using a timeframe that does not mirror the FY. The evaluation of DMEPOS regional carrier performance is part of our contract management process.

D. Development and Publication of Criteria and Standards

In addition to the statutory requirements, § 421.120 and § 421.122 provide for publication of a **Federal Register** notice to announce criteria and standards for intermediaries before implementation. Section 421.201 provides for publication of a **Federal Register** notice to announce criteria and standards for carriers before implementation. The current criteria and standards for intermediaries, carriers, and DMEPOS regional carriers were published in the **Federal Register** on December 28, 2001 at 66 FR 67257.

To the extent possible, we make every effort to publish the criteria and standards before the beginning of the Federal FY, which is October 1. If we do not publish a **Federal Register** notice before the new FY begins, readers may presume that until and unless notified otherwise, the criteria and standards that were in effect for the previous FY remain in effect.

In those instances in which we are unable to meet our goal of publishing the subject **Federal Register** notice before the beginning of the FY, we may publish the criteria and standards notice at any subsequent time during the year. If we publish a notice in this manner, the evaluation period for the criteria and standards that are the subject of the notice will be effective on the first day of the first month following publication. Any revised criteria and standards will measure performance prospectively; that is, we will not apply new measurements to assess performance on a retroactive basis.

It is not our intention to revise the criteria and standards that will be used during the evaluation period once this information has been published in a **Federal Register** notice. However, on occasion, either because of administrative action or congressional mandate, there may be a need for changes that have a direct impact on the criteria and standards previously published, or that require the addition of new criteria or standards, or that cause the deletion of previously published criteria and standards. If we must make these changes, we will publish an amended **Federal Register** notice before implementation of the changes. In all instances, necessary manual issuances will be published to ensure that the criteria and standards are applied uniformly and accurately. Also, as in previous years, this **Federal Register** notice will be republished and the effective date revised if changes are warranted as a result of the public comments received on the criteria and standards.

II. Analysis of and Response to Public Comments Received on FY 2001 Criteria and Standards

In response to the December 28, 2001 **Federal Register** general notice with comment, we received comments from five entities. We reviewed all comments, but none necessitated our reissuance of the FY 2002 criteria and standards. Not all comments submitted pertained specifically to the FY 2002 criteria and standards. We advised Medicare program components of the concerns as appropriate. When warranted, we have incorporated revisions in this **Federal Register** notice. We are responding to the following performance evaluation comments:

Comment: A commenter advised that we have established an ''acceptable reversal rate'' of intermediary reconsideration determinations by Administrative Law Judges (ALJs), but that we have not developed an acceptable reversal rate for DMEPOS regional carriers.

Response: Section 1816(f)(2) of the Act requires that we develop a standard to evaluate the extent to which intermediary determinations are reversed on appeal. This section of the Act applies only to intermediaries. The statute does not include a similar requirement for carriers and DMEPOS regional carriers, who by law employ a different process in reviewing Part B claims, including an additional level of contractor appeal known as the fair hearing. While there is no similar mandate under the Part B program for carriers or DMEPOS regional carriers, our reviewers routinely evaluate the accuracy of appeals decisions when they conduct a CPE review of a contractor's appeals operation. This review includes an evaluation of reversals both at the fair hearing and the ALJ level. We believe that this process adequately identifies problems with the accuracy of carrier and DMERC appeals decisions.

Comment: A commenter advised that intermediaries must be given specific customer service performance objectives, and providers must be allowed to influence those objectives and to participate directly in the evaluations of contractor performance. The commenter considers provider input more critical if the Administration continues to support contractor reform.

Response: Both intermediaries and carriers are required to have Provider Communications Advisory Groups which are comprised of representatives from the various Medicare provider types, such as hospitals, home health agencies, skilled nursing facilities, and physicians. These groups are to have meetings on a quarterly basis during which the provider representatives give contractors feedback about education and customer service needs and how well these needs are being met. The contractors report the minutes of these meetings to CMS's headquarters in quarterly update reports. We factor in this feedback when setting customer service standards for the contractor. We notify contractors of specific customer service performance standards by means of administrative directives. However, because such standards are not mandated by law or court decision, we do not specify them in this notice.

Currently we evaluate contractor customer service by verifying implementation and execution of administrative directives, reviewing responses to correspondence, monitoring telephone responses, and reviewing educational materials distributed to providers. As we prepare

for the anticipated passage of contracting reform we will be doing even more to seek provider input into customer service performance objectives.

Comment: A commenter requested that we publish the annual evaluations of all of the contractors so that the affected public will know whether contractors meet performance requirements. The commenter advised that currently, the evaluations are available only through a Freedom of Information Act (FOIA) request. Many providers, particularly smaller providers, are not aware of the procedures for making a FOIA request.

Response: The current evaluation reports for Medicare fee-for-service contractors are lengthy narratives, which are not conducive to publication. They are, however, available to the public upon written request. The policy that governs releasing these reports is explained at §§ 401.133(c), 401.135, 401.136, and 401.140. There is no requirement that reports be requested under the FOIA. Written requests for reports may be addressed to: Centers for Medicare & Medicaid Services, ATTN: Center for Medicare Management, Mailstop S2–21–28, 7500 Security Boulevard, Baltimore, Maryland 21244–1850.

Comment: A commenter remarked that the Contractor Performance Evaluation (CPE) Rebuttal Process introduced in FY 2001 which gives contractors an opportunity to submit a written rebuttal within 7 calendar days from the CPE exit conference, needs to be clarified as to how it applies to the review of provider audit workpapers under our Audit Quality Review Program (AQRP). The commenter believes we should have a consistent policy for responding to all CPE findings. The commenter further suggests that CMS needs to clarify its policies with respect to AQRP findings and how they relate to the summarized annual CPE for Provider audit.

Response: The AQRP has an established procedure allowing contractors 30 days to review and respond to draft findings prepared as a result of the AQRP review. We review the contractor's responses for each individual AQRP review, delete or modify the findings as appropriate, prepare a rebuttal for those findings that are not modified, and issue a Management Letter. We then prepare and send to the contractor an Executive Summary of the results of all the individual AQRP reviews. This Executive Summary is then used as a basis for the preparation of a CPE report. Because the contractor has already been given a formal review and rebuttal type process under AQRP that exceeds the 7 calendar day CPE rebuttal process, and because the CPE report adopts the final AQRP findings, we have determined the CPE rebuttal process is unnecessary for AQRP reviews.

III. Criteria and Standards—General

Basic principles of the Medicare program are to pay claims promptly and accurately and to foster good beneficiary and provider relations. Contractors must administer the Medicare program efficiently and economically. The goal of performance evaluation is to ensure that contractors meet their contractual obligations. We measure contractor performance to ensure that contractors do what is required of them by law, regulation, contract, and our directives.

We have developed a contractor oversight program for FY 2003 that outlines expectations of the contractor; measures the performance of the contractor; evaluates the performance against the expectations; and provides for appropriate contract action based upon the evaluation of the contractor's performance.

Several times throughout this notice, we refer to the ''readability'' of letters, decisions, or correspondence that are going to Medicare beneficiaries from intermediaries or carriers. In those instances, ''readability'' is defined as being below the 8th grade reading level unless it is obvious that an incoming request from the beneficiary contains language written at a higher level. In such cases, the readability level is tailored to the capacities and circumstances of the intended recipient.

In addition to evaluating performance based upon expectations for FY 2003, we may also conduct follow-up evaluations throughout FY 2003 of areas in which contractor performance was out of compliance with laws, regulations, and our performance expectations during prior review years and thus required the contractor to submit a Performance Improvement Plan (PIP).

In FY 2001, we established the Contractor Rebuttal Process as a commitment to continual improvement of CPE. We will continue the use of this process in FY 2003. The Contractor Rebuttal Process provides the contractors an opportunity to submit a written rebuttal of CPE findings of fact. Whenever we conduct an evaluation of contractor operations, contractors have 7 calendar days from the date of the CPE review exit conference to submit a written rebuttal. The CPE review team or, if appropriate, the individual reviewer will consider the contents of the rebuttal before the issuance of the final CPE report to the contractor.

The FY 2003 CPE for intermediaries and carriers is structured into five criteria designed to meet the stated objectives. The first criterion is ''Claims Processing'' which measures contractual performance against claims processing accuracy and timeliness requirements as well as activities in handling appeals. Within the Claims Processing Criterion, we have identified those performance standards that are mandated by legislation, regulation, or judicial decision. These standards include claims processing timeliness, the accuracy of Explanations of Medicare Benefits (EOMBs) and Medicare Summary Notices (MSNs), the appropriateness of determinations reversed by ALJs, the timeliness of intermediary reconsideration cases, the timeliness of carrier reviews and hearings, and the readability of carrier reviews. Further evaluation in the Claims Processing Criterion may include, but is not limited to, the accuracy of claims processing, the percent of claims paid with interest, and the accuracy of reconsiderations, reviews, and hearings.

The second criterion is ''Customer Service'' which assesses the adequacy of the service provided to customers by the contractor in its administration of the Medicare program. The mandated standard in the Customer Service Criterion is the need to provide beneficiaries with written replies that are responsive, that is, provide in detail the reasons for a determination when a beneficiary requests such information, have a customer-friendly tone and clarity, and are at the appropriate reading level. Further evaluation of services under this criterion may include, but is not limited to, the timeliness and accuracy of all correspondence both to beneficiaries and providers; monitoring of the quality of replies provided by the contractor's customer service representatives (quality call monitoring); beneficiary and provider education, training, and outreach activities; and service by the contractor's customer service representatives to beneficiaries who come to the contractor's facility (walk-in inquiry service).

The third criterion is ''Payment Safeguards'' which evaluates whether the Medicare Trust Fund is safeguarded against inappropriate program expenditures. Intermediary and carrier performance may be evaluated in the areas of Benefit Integrity (BI), Medical Review (MR), Medicare Secondary Payer (MSP), Overpayments (OP), and Provider Enrollment (PE). In addition,

intermediary performance may be evaluated in the area of Audit and Reimbursement (A&R). Mandated performance standards for intermediaries in the Payment Safeguards criterion are the accuracy of decisions on Skilled Nursing Facility (SNF) demand bills, and the timeliness of processing Tax Equity and Fiscal Responsibility Act (TEFRA) target rate adjustments, exceptions, and exemptions. There are no mandated performance standards for carriers in the Payment Safeguards criterion. Intermediaries and carriers may also be evaluated on any Medicare Integrity Program (MIP) activities if performed under their agreement or contract.

The fourth criterion is ''Fiscal Responsibility'' which evaluates the contractor's efforts to protect the Medicare program and the public interest. Contractors must effectively manage Federal funds for both the payment of benefits and costs of administration under the Medicare program. Proper financial and budgetary controls, including internal controls, must be in place to ensure contractor compliance with its agreement with HHS and CMS.

Additional functions reviewed under this criterion may include, but are not limited to, adherence to approved budget, compliance with the Budget and Performance Requirements (BPRs), and compliance with financial reporting requirements.

The fifth and final criterion is ''Administrative Activities'' which measures a contractor's administrative management of the Medicare program. A contractor must efficiently and effectively manage its operations. Proper systems security (general and application controls), Automated Data Processing (ADP) maintenance, and disaster recovery plans must be in place. A contractor's evaluation under the Administrative Activities criterion may include, but is not limited to, establishment, application, documentation, and effectiveness of internal controls which are essential in all aspects of a contractor's operation, and the degree to which the contractor cooperates with us in complying with the Federal Managers' Financial Integrity Act of 1982 (FMFIA). Administrative Activities evaluations may also include reviews related to contractor implementation of our general instructions and data and reporting requirements.

We have developed separate measures for RHHIs in order to evaluate the distinct RHHI functions. These functions include the processing of claims from freestanding HHAs, hospital-affiliated HHAs, and hospices. Through an evaluation using these criteria and standards, we may determine whether the RHHI is effectively and efficiently administering the program benefit or whether the functions should be moved from one intermediary to another in order to gain that assurance.

Below, we list the criteria and standards to be used for evaluating the performance of intermediaries, RHHIs, carriers, and DMEPOS regional carriers.

IV. Criteria and Standards for Intermediaries

A. Claims Processing Criterion

The Claims Processing criterion contains the following four mandated standards:

Standard 1. 95.0 percent of clean electronically submitted non-Periodic Interim Payment claims are paid within statutorily specified time frames. Clean claims are defined as claims that do not require Medicare intermediaries to investigate or develop them outside of their Medicare operations on a prepayment basis. Specifically, clean, non-Periodic Interim Payment electronic claims can be paid as early as the 14th day (13 days after the date of receipt) and must be paid by the 31st day (30 days after the date of receipt). Our expectation is that contractors will meet this percentage on a monthly basis.

Standard 2. 95.0 percent of clean paper non-Periodic Interim Payment claims are paid within specified time frames. Specifically, clean, non-Periodic Interim Payment paper claims can be paid as early as the 27th day (26 days after the date of receipt) and must be paid by the 31st day (30 days after the date of receipt). Our expectation is that contractors will meet this percentage on a monthly basis.

Standard 3. The percentage of reconsideration determinations reversed by ALJs is acceptable. We have defined an acceptable reversal rate by ALJs as one that is at or below 5.0 percent.

Standard 4. 75.0 percent of reconsiderations are processed within 60 days, and 90.0 percent are processed within 90 days. Our expectation is that contractors will meet this percentage on a monthly basis.

Standard 5. 95.0 percent of Part B review determinations are completed within 45 days. Our expectation is that contractors will meet this percentage on a monthly basis.

Standard 6. 90.0 percent of Part B hearing decisions are completed within 120 days. Our expectation is that contractors will meet this percentage on a monthly basis.

Additional functions that may be evaluated under this criterion include, but are not limited to, the following:

- Claims processing accuracy.
- Establishment and maintenance of relationship with Common Working File (CWF) Host.
- Accuracy of processing reconsideration cases with determination letters that are clear and have appropriate customer-friendly tone.

Because intermediaries process many claims for benefits under the Part B Medical Insurance portion of the Medicare Program, we also may evaluate how well an intermediary follows the procedures for processing appeals of any Part B claims. This includes accuracy of reviews and hearings, as well as the appropriateness of the reading level of any review determination letters. (See Claims Process Criterion for carriers under section VI.)

B. Customer Service Criterion

Functions that may be evaluated under this criterion include, but are not limited to, the following:

- Providing timely and accurate replies to beneficiary and provider telephone inquiries.
- Quality Call Monitoring.
- Training of Customer Service Representatives.
- Ensuring the validity of the call center performance data that are being reported in the Customer Service Assessment and Management System.
- Providing timely and accurate replies to beneficiaries and providers that address the concerns raised and are written with appropriate customer-friendly tone and clarity and that those written to beneficiaries are at the appropriate reading level.
- Walk-in inquiry service.
- Conducting beneficiary and provider education, training and outreach activities.
- Effectively maintaining an Internet Website dedicated to furnishing providers and physicians timely, accurate, and useful Medicare program information.

C. Payment Safeguards Criterion

The Payment Safeguard criterion contains the following two mandated standards:

Standard 1. Decisions on SNF demand bills are accurate.

Standard 2. TEFRA target rate adjustments, exceptions, and exemptions are processed within mandated time frames. Specifically, applications must be processed to completion within 75 days after receipt

by the contractor or returned to the hospitals as incomplete within 60 days of receipt.

Intermediaries may also be evaluated on any MIP activities if performed under their Part A agreement. These functions and activities include, but are not limited to the following:

- Audit and Reimbursement
+ Performing the activities specified in our general instructions for conducting audit and settlement of Medicare cost reports.
+ Establishing accurate interim payments.
- Benefit Integrity
+ Identifying potential fraud cases that exist within the intermediary's service area and taking appropriate actions to resolve these cases.
+ Investigating allegations of potential fraud that are made by beneficiaries, providers, CMS, Office of Inspector General (OIG), and other sources.
+ Putting in place effective detection and deterrence programs for potential fraud.
- Medical Review
+ Increasing the effectiveness of medical review activities.
+ Exercising accurate and defensible decision making on medical reviews.
+ Effectively educating and communicating with the provider community.
+ Collaborating with other internal components and external entities to ensure correct claims payment, and to address situations of fraud, waste, and abuse.
- Medicare Secondary Payer
+ Accurately reporting MSP savings.
+ Accurately following MSP claim development and edit procedures.
+ Auditing hospital files and claims to determine that claims are being filed to Medicare appropriately.
+ Supporting the Coordination of Benefits Contractor's efforts to identify responsible payers primary to Medicare.
+ Identifying, recovering, and referring mistaken Medicare payments in accordance with appropriate Medicare Intermediary Manual instructions and our other pertinent general instructions, in the specified order of priority.
- Overpayments
+ Collecting and referring Medicare debts timely.
+ Accurately reporting overpayments to us.
+ Adhering to our instructions for management of Medicare Trust Fund debts.
- Provider Enrollment
+ Complying with assignment of staff to the provider enrollment function and training the staff in procedures and verification techniques.
+ Complying with the operational standards relevant to the process for enrolling providers.

D. Fiscal Responsibility Criterion

We may review the intermediary's efforts to establish and maintain appropriate financial and budgetary internal controls over benefit payments and administrative costs. Proper internal controls must be in place to ensure that contractors comply with their agreements with us.

Additional functions that may be reviewed under the Fiscal Responsibility criterion include, but are not limited to, the following:

- Adherence to approved program management and MIP budgets.
- Compliance with the BPRs.
- Compliance with financial reporting requirements.
- Control of administrative cost and benefit payments.

E. Administrative Activities Criterion

We may measure an intermediary's administrative ability to manage the Medicare program. We may evaluate the efficiency and effectiveness of its operations, its system of internal controls, and its compliance with our directives and initiatives.

We may measure an intermediary's efficiency and effectiveness in managing its operations. Proper systems security (general and application controls), ADP maintenance, and disaster recovery plans must be in place. An intermediary must also test system changes to ensure the accurate implementation of our instructions.

Our evaluation of an intermediary under the Administrative Activities criterion may include, but is not limited to, reviews of the following:

- Systems security.
- ADP maintenance (configuration management, testing, change management, security, etc).
- Disaster recovery plan.
- Implementation of our general instructions.
- Data and reporting requirements implementation.
- Internal controls establishment and use, including the degree to which the contractor cooperates with the Secretary in complying with the FMFIA.

V. Criteria and Standards for Regional Home Health Intermediaries (RHHIs)

The following three standards are mandated for the RHHI criterion:

Standard 1. 95.0 percent of clean electronically submitted non-Periodic Interim Payment HHA and hospice claims are paid within statutorily specified time frames. Clean claims are defined as claims that do not require Medicare intermediaries to investigate or develop them outside of their Medicare operations on a prepayment basis. Specifically, clean, non-Periodic Interim Payment electronic claims can be paid as early as the 14th day (13 days after the date of receipt) and must be paid by the 31st day (30 days after the date of receipt). Our expectation is that contractors will meet this percentage on a monthly basis.

Standard 2. 95.0 percent of clean paper non-Periodic Interim Payment HHA and hospice claims are paid within specified time frames. Specifically, clean, non-Periodic Interim Payment paper claims can be paid as early as the 27th day (26 days after the date of receipt) and must be paid by the 31st day (30 days after the date of receipt). Our expectation is that contractors will meet this percentage on a monthly basis.

Standard 3. 75.0 percent of HHA and hospice reconsiderations are processed within 60 days and 90.0 percent are processed within 90 days. Our expectation is that contractors will meet this percentage on a monthly basis.

Standard 4. 95.0 percent of HHA and Hospice Part B review determinations are completed within 45 days. Our expectation is that contractors will meet this percentage on a monthly basis.

Standard 5. 90.0 percent of HHA and Hospice Part B hearing decisions are completed within 120 days. Our expectation is that contractors will meet this percentage on a monthly basis.

We may use this criterion to review an RHHI's performance with respect to handling the HHA and hospice workload. This includes processing HHA and hospice claims timely and accurately; properly paying and settling HHA cost reports; and timely and accurately processing reconsiderations from beneficiaries, HHAs, and hospices.

VI. Criteria and Standards for Carriers

A. Claims Processing Criterion

The Claims Processing criterion contains the following six mandated standards:

Standard 1. 95.0 percent of clean electronically submitted claims are processed within statutorily specified time frames. Clean claims are defined as claims that do not require Medicare carriers to investigate or develop them outside of their Medicare operations on a prepayment basis. Specifically, clean electronic claims can be paid as early as the 14th day (13 days after the date of receipt) and must be paid by the 31st

day (30 days after the date of receipt). Our expectation is that contractors will meet this percentage on a monthly basis.

Standard 2. 95.0 percent of clean paper claims are processed within specified time frames. Specifically, clean paper claims can be paid as early as the 27th day (26 days after the date of receipt) and must be paid by the 31st day (30 days after the date of receipt). Our expectation is that contractors will meet this percentage on a monthly basis.

Standard 3. 98.0 percent of EOMBs and MSNs are properly generated. Our expectation is that EOMB and MSN messages are accurately reflecting the services provided.

Standard 4. 95.0 percent of review determinations are completed within 45 days. Our expectation is that contractors will meet this percentage on a monthly basis.

Standard 5. 90.0 percent of carrier hearing decisions are completed within 120 days. Our expectation is that contractors will meet this percentage on a monthly basis.

Standard 6. Review determination letters prepared in response to beneficiary initiated appeal requests are written at an appropriate reading level.

Additional functions that may be evaluated under this criterion include, but are not limited to, the following:

- Claims Processing accuracy.
- Establishment and maintenance of relationship with the CWF Host.
- Accuracy of processing review determination cases.
- Accuracy of processing hearing cases with decision letters that are clear and have appropriate customer-friendly tone.

B. Customer Service Criterion

The Customer Service criterion contains the following mandated standard:

Standard. Replies to beneficiary correspondence address the beneficiary's concerns, are written with appropriate customer-friendly tone and clarity, and are at the appropriate reading level.

Contractors must meet our performance expectations that beneficiaries and providers are served by prompt and accurate administration of the program in accordance with all applicable laws, regulations, and our general instructions.

Additional functions that may be evaluated under this criterion include, but are not limited to, the following:

- Providing timely and accurate replies to beneficiary and provider telephone inquiries.
- Quality Call Monitoring.
- Training of Customer Service Representatives.
- Ensuring the validity of the call center performance data that are being reported in the Customer Service Assessment and Management System.
- Walk-in inquiry service.
- Conducting beneficiary and provider education, training, and outreach activities.
- Effectively maintaining an Internet Website dedicated to furnishing providers timely, accurate, and useful Medicare program information.

C. Payment Safeguards Criterion

Carriers may be evaluated on any MIP activities if performed under their contracts. In addition, other carrier functions and activities that may be reviewed under this criterion include, but are not limited to the following:

- Benefit Integrity

+ Identifying potential fraud cases that exist within the carrier's service area and taking appropriate actions to resolve these cases.
+ Investigating allegations of potential fraud that are made by beneficiaries, providers, CMS, OIG, and other sources.
+ Putting in place effective detection and deterrence programs for potential fraud.

- Medical Review

+ Increasing the effectiveness of medical review activities.
+ Exercising accurate and defensible decision making on medical reviews.
+ Effectively educating and communicating with the provider community.
+ Collaborating with other internal components and external entities to ensure correct claims payment, and to address situations of fraud, waste, and abuse.

- Medicare Secondary Payer

+ Accurately reporting MSP savings.
+ Accurately following MSP claim development/edit procedures.
+ Supporting the Coordination of Benefits Contractor's efforts to identify responsible payers primary to Medicare.
+ Identifying, recovering, and referring mistaken Medicare payments in accordance with the appropriate Medicare Carriers Manual instructions, and our other pertinent general instructions.

- Overpayments

+ Collecting and referring Medicare debts timely.
+ Accurately reporting overpayments to us.
+ Compliance with our instructions for management of Medicare Trust Fund debts.

- Provider Enrollment

+ Complying with assignment of staff to the provider enrollment function and training staff in procedures and verification techniques.
+ Complying with the operational standards relevant to the process for enrolling suppliers.

D. Fiscal Responsibility Criterion

We may review the carrier's efforts to establish and maintain appropriate financial and budgetary internal controls over benefit payments and administrative costs. Proper internal controls must be in place to ensure that contractors comply with their contracts.

Additional functions that may be reviewed under the Fiscal Responsibility criterion include, but are not limited to, the following:

- Adherence to approved program management and MIP budgets.
- Compliance with the BPRs.
- Compliance with financial reporting requirements.
- Control of administrative cost and benefit payments.

E. Administrative Activities Criterion

We may measure a carrier's administrative ability to manage the Medicare program. We may evaluate the efficiency and effectiveness of its operations, its system of internal controls, and its compliance with our directives and initiatives.

We may measure a carrier's efficiency and effectiveness in managing its operations. Proper systems security (general and application controls), Automatic Data Processing (ADP) maintenance, and disaster recovery plans must be in place. Also, a carrier must test system changes to ensure accurate implementation of our instructions.

Our evaluation of a carrier under this criterion may include, but is not limited to, reviews of the following:

- Systems security.
- ADP maintenance (configuration management, testing, change management, security, etc.).
- Disaster recovery plan.
- Implementation of our general instructions.
- Data and reporting requirements implementation.
- Internal controls establishment and use, including the degree to which the contractor cooperates with the Secretary in complying with the FMFIA.

VII. Criteria and Standards for Durable Medical Equipment, Prosthetics, Orthotics, and Supplies (DMEPOS) Regional Carriers

For FY 2003 Contractor Performance Evaluation for DMEPOS regional

carriers has been structured into five criteria, which are the same criteria used for intermediaries and carriers: Claims Processing; Customer Service; Payment Safeguards; Fiscal Responsibility; and Administrative Activities. These criteria for DMEPOS regional carriers were referred to in prior **Federal Register** notices as Quality, Efficiency, Service, and Benefit Integrity.

In these five criteria there are a total of seven mandated standards against which all DMEPOS regional carriers must be evaluated. There also are examples of other activities for which the DMEPOS regional carriers may be evaluated. The mandated standards are in the Claims Processing and Customer Service Criteria. In addition to being described in these criteria, the mandated standards are also described in Attachment J–37 to the DMEPOS regional carrier statement of work (SOW).

A. Claims Processing Criterion

The Claims Processing criterion contains the following six mandated standards:

Standard 1. 95.0 percent of clean electronically submitted claims are processed within statutorily specified time frames. Clean claims are defined as claims that do not require Medicare DMEPOS regional carriers to investigate or develop them outside of their Medicare operations on a prepayment basis. Specifically, clean electronic claims can be paid as early as the 14th day (13 days after the date of receipt) and must be paid by the 31st day (30 days after the date of receipt). Our expectation is that contractors will meet this percentage on a monthly basis.

Standard 2. 95.0 percent of clean paper claims are processed within specified time frames. Specifically, clean paper claims can be paid as early as the 27th day (26 days after the date of receipt) and must be paid by the 31st day (30 days after the date of receipt). Our expectation is that contractors will meet this percentage on a monthly basis.

Standard 3. Properly generated 98.0 percent of MSNs. Our expectation is that MSN messages are accurately reflecting the services provided.

Standard 4. 95.0 percent of review determinations are completed within 45 days. Our expectation is that contractors will meet this percentage on a monthly basis.

Standard 5. 90.0 percent of DMEPOS regional carrier hearing decisions are completed within 120 days. CMS's expectation is that contractors will meet this percentage on a monthly basis.

Standard 6. Review determination letters prepared in response to beneficiary initiated requests are written at an appropriate reading level and state in detail the reasons for the determination.

Additional functions that may be evaluated under this criterion include, but are not limited to, the following:

- Claims processing accuracy.
- Review determinations and hearing decisions are written accurately and clearly.
- Telephone reviews are appropriately documented and adjudicated timely.
- Requests for ALJ hearings are processed timely.

B. Customer Service Criterion

The Customer Service Criterion contains the following mandated standard:

Standard 1. Replies to beneficiary correspondence address concerns raised, are written with appropriate customer-friendly tone and clarity, and are at the appropriate reading level.

Contractors must meet our performance expectations that beneficiaries and suppliers are served by prompt and accurate administration of the program in accordance with all applicable laws, regulations, the DMEPOS regional carrier SOW, and our general instructions.

Additional functions that may be evaluated under this criterion include, but are not limited to, the following:

- Providing timely and accurate replies to beneficiary and supplier telephone inquiries.
- Quality Call Monitoring.
- Training of Customer Service Representatives.
- Ensuring the validity of the call center performance data that are being reported in the Customer Service Assessment and Management System.
- Providing timely and accurate replies to beneficiaries, providers, and suppliers that address their concerns and are written with appropriate customer-friendly tone and clarity.
- Walk-in inquiry service.
- Conducting beneficiary and supplier education, training, and outreach activities.
- Effectively maintaining an Internet Website dedicated to furnishing suppliers timely, accurate, and useful Medicare program information.
- Ensuring that communications are made to interested supplier organizations for the purpose of developing and maintaining collaborative supplier education and training activities and programs.

C. Payment Safeguards Criterion

DMEPOS regional carriers may be evaluated on any MIP activities if performed under their contracts. The DMEPOS regional carriers must undertake actions to promote an effective program administration with respect to DMEPOS regional carrier claims. These functions and activities include, but are not limited to the following:

- Benefit Integrity

+ Identifying potential fraud cases that exist within the DMEPOS regional carrier's service area and taking appropriate actions to resolve these cases.
+ Investigating allegations of potential fraud made by beneficiaries, suppliers, CMS, OIG, and other sources.
+ Putting in place effective detection and deterrence programs for potential fraud.

- Medical Review

+ Reducing the error rate by identifying patterns of in appropriate billing.
+ Educating suppliers concerning Medicare coverage and coding requirements.

- Medicare Secondary Payer

+ Accurately reporting MSP savings.
+ Accurately following MSP claim development/edit procedures.
+ Supporting the Coordination of Benefits Contractor's efforts to identify responsible payers primary to Medicare.
+ Identifying, recovering, and referring mistaken Medicare payments in accordance with the appropriate program instructions in the specified order of priority.

- Overpayments

+ Determining that the DMEPOS regional carrier completely, accurately, timely, and aggressively pursued all outstanding overpayments in adherence with the Medicare Carriers Manual and CMS Program Memoranda resulting from the Debt Collection Improvement Act (DCIA).
+ Verify that all overpayments were timely and accurately recorded.

D. Fiscal Responsibility Criterion

We may review the DMEPOS regional carrier's efforts to establish and maintain appropriate financial and budgetary internal controls over benefit payments and administrative costs. Proper internal controls must be in place to ensure that contractors comply with their contracts. Additional matters that may be reviewed under this criterion include, but are not limited to the following:

- Compliance with financial reporting requirements.

• Adherence to approved program management and MIP budgets.
• Control of administrative cost and benefit payments.

E. Administrative Activities

We may measure a DMEPOS regional carrier's administrative ability to manage the Medicare program. We may evaluate the efficiency and effectiveness of its operations, its system of internal controls, and its compliance with our directives and initiatives. Our evaluation of a DMEPOS regional carrier under this criterion may include, but is not limited to review of the following:
• Systems Security.
• Disaster recovery plan.
• Internal controls establishment and use, including the degree to which the contractor cooperates with the Secretary in complying with the FMFIA.

VIII. Action Based on Performance Evaluations

We evaluate a contractor's performance against applicable program requirements for each criterion. Each contractor must certify that all information submitted to us relating to the contract management process, including, without limitation, all files, records, documents and data, whether in written, electronic, or other form, is accurate and complete to the best of the contractor's knowledge and belief. A contractor will also be required to certify that its files, records, documents, and data have not been manipulated or falsified in an effort to receive a more favorable performance evaluation. A contractor must further certify that, to the best of its knowledge and belief, the contractor has submitted, without withholding any relevant information, all information required to be submitted with respect to the contract management process under the authority of applicable law(s), regulation(s), contract(s), or our manual provision(s). Any contractor that makes a false, fictitious, or fraudulent certification may be subject to criminal and/or civil prosecution, as well as appropriate administrative action. This administrative action may include debarment or suspension of the contractor, as well as the termination or nonrenewal of a contract.

If a contractor meets the level of performance required by operational instructions, it meets the requirements of that criterion. When we determine a contractor is not meeting performance requirements, we will use the terms ''major nonconformance'' or ''minor nonconformance'' to classify our findings. A major nonconformance is a nonconformance that is likely to result in failure of the supplies or services, or to materially reduce the usability of the supplies or services for their intended purpose. A minor nonconformance is a nonconformance that is not likely to materially reduce the usability of the supplies or services for their intended purpose, or is a departure from established standards having little bearing on the effective use or operation of the supplies or services. The contractor will be required to develop and implement a PIP for findings determined to be either a major or minor nonconformance. The contractor will be monitored to ensure effective and efficient compliance with the PIP, and to ensure improved performance when requirements are not met.

The results of performance evaluations and assessments under all criteria applying to intermediaries, carriers, RHHIs, and DMEPOS regional carriers will be used for contract management activities and will be published in the contractor's annual Report of Contractor Performance (RCP). We may initiate administrative actions as a result of the evaluation of contractor performance based on these performance criteria. Under sections 1816 and 1842 of the Act, we consider the results of the evaluation in our determinations when—

• Entering into, renewing, or terminating agreements or contracts with contractors, and

• Deciding other contract actions for intermediaries and carriers (such as deletion of an automatic renewal clause). These decisions are made on a case-by-case basis and depend primarily on the nature and degree of performance. More specifically, these decisions depend on the following:

• Relative overall performance compared to other contractors.
• Number of criteria in which nonconformance occurs.
• Extent of each nonconformance.
• Relative significance of the requirement for which nonconformance occurs within the overall evaluation program.
• Efforts to improve program quality, service, and efficiency.
• Deciding the assignment or reassignment of providers and designation of regional or national intermediaries for classes of providers.

We make individual contract action decisions after considering these factors in terms of their relative significance and impact on the effective and efficient administration of the Medicare program.

In addition, if the cost incurred by the intermediary, RHHI, carrier, or DMEPOS regional carrier to meet its contractual requirements exceeds the amount that we find to be reasonable and adequate to meet the cost that must be incurred by an efficiently and economically operated intermediary or carrier, these high costs may also be grounds for adverse action.

IX. Regulatory Impact Statement

We have examined the impacts of this notice as required by Executive Order 12866 (September 1993, Regulatory Planning and Review), the Regulatory Flexibility Act (RFA) (September 16, 1980, Pub. L. 96–354), section 1102(b) of the Social Security Act, the Unfunded Mandates Reform Act of 1995 (Pub. L. 104–4), and Executive Order 13132.

Executive Order 12866 directs agencies to assess all costs and benefits of available regulatory alternatives and, if regulation is necessary, to select regulatory approaches that maximize net benefits (including potential economic, environmental, public health and safety effects, distributive impacts, and equity). A regulatory impact analysis (RIA) must be prepared for major rules with economically significant effects ($100 million in any one year). Since this notice only describes criteria and standards for evaluating FIs (including RHHIs), carriers, and DMEPOS regional carriers and has no significant economic impact on the program, its beneficiaries, providers or suppliers, this is not a major notice.

The RFA requires agencies to analyze options for regulatory relief of small businesses. This notice does not affect small businesses; individuals and States are not included in the definition of small business entities.

In addition, section 1102(b) of the Act requires us to prepare a regulatory impact analysis if a rule may have a significant impact on the operations of a substantial number of small rural hospitals. This notice does not affect small rural hospitals.

Section 202 of the Unfunded Mandates Reform Act of 1995 also requires that agencies assess anticipated costs and benefits before issuing any rule that may result in expenditure in any 1 year by State, local, or tribal governments, in the aggregate, or by the private sector, of $110 million. In accordance with Section 202, we have determined that the notice does not impose any unfunded mandates on State, local or tribal governments, or on the private sector.

Executive Order 13132 establishes certain requirements that an agency must meet when it promulgates a notice that imposes substantial direct

requirement costs on State and local governments, preempts State law, or otherwise has Federalism implications. We have determined that the notice does not significantly affect the rights, roles, and responsibilities of States.

We have not prepared a Regulatory Impact Analysis for this notice, in accordance with Executive Order 12866, because it will not have a significant economic impact, nor does it impose any unfunded mandates on State, local, or tribal governments or the private sector. Furthermore, we certify that the notice will not have a significant impact on a substantial number of small entities or small rural hospitals.

In accordance with the provisions of Executive Order 12866, this notice was reviewed by the Office of Management and Budget.

X. Collection of Information Requirements

This document does not impose information collection and recordkeeping requirements. Consequently it need not be reviewed by the Office of Management and Budget under the authority of the Paperwork Reduction Act of 1995 (44 U.S.C. 3501 *et seq.*).

Authority: Sections 1816(f), 1834(a)(12), and 1842(b) of the Social Security Act (42 U.S.C. 1395h(f), 1395m(a)(12), and 1395u(b)).

(Catalog of Federal Domestic Assistance Program No. 93.773, Medicare—Hospital Insurance, and Program No. 93.774, Medicare—Supplementary Medical Insurance Program)

Dated: August 6, 2002.

Thomas A. Scully,

Administrator, Centers for Medicare & Medicaid Services.

[FR Doc. 03–4087 Filed 2–27–03; 8:45 am]

BILLING CODE 4120–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. 02E–0020]

Determination of Regulatory Review Period for Purposes of Patent Extension; ZOMETA

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) has determined the regulatory review period for ZOMETA and is publishing this notice of that determination as required by law. FDA has made the determination because of the submission of an application to the Director of Patents and Trademarks, Department of Commerce, for the extension of a patent that claims that human drug product.

ADDRESSES: Submit written comments and petitions to the Dockets Management Branch (HFA–305), Food and Drug Administration, 5630 Fishers Lane, rm. 1061, Rockville, MD 20852. Submit electronic comments to http://www.fda.gov/dockets/ecomments.

FOR FURTHER INFORMATION CONTACT: Claudia Grillo, Office of Regulatory Policy (HFD–013), Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857, 301–827–3460.

SUPPLEMENTARY INFORMATION: The Drug Price Competition and Patent Term Restoration Act of 1984 (Public Law 98–417) and the Generic Animal Drug and Patent Term Restoration Act (Public Law 100–670) generally provide that a patent may be extended for a period of up to 5 years so long as the patented item (human drug product, animal drug product, medical device, food additive, or color additive) was subject to regulatory review by FDA before the item was marketed. Under these acts, a product's regulatory review period forms the basis for determining the amount of extension an applicant may receive.

A regulatory review period consists of two periods of time: A testing phase and an approval phase. For human drug products, the testing phase begins when the exemption to permit the clinical investigations of the drug becomes effective and runs until the approval phase begins. The approval phase starts with the initial submission of an application to market the human drug product and continues until FDA grants permission to market the drug product. Although only a portion of a regulatory review period may count toward the actual amount of extension that the Director of Patents and Trademarks may award (for example, half the testing phase must be subtracted as well as any time that may have occurred before the patent was issued), FDA's determination of the length of a regulatory review period for a human drug product will include all of the testing phase and approval phase as specified in 35 U.S.C. 156(g)(1)(B).

FDA recently approved for marketing the human drug product ZOMETA (zoledronic acid). ZOMETA is indicated for the treatment of hypercalcemia of malignancy. Subsequent to this approval, the Patent and Trademark Office received a patent term restoration application for ZOMETA (U.S. Patent No. 4,939,130) from Novartis Corp., and the Patent and Trademark Office requested FDA's assistance in determining this patent's eligibility for patent term restoration. In a letter dated February 14, 2002, FDA advised the Patent and Trademark Office that this human drug product had undergone a regulatory review period and that the approval of ZOMETA represented the first permitted commercial marketing or use of the product. Shortly thereafter, the Patent and Trademark Office requested that FDA determine the product's regulatory review period.

FDA has determined that the applicable regulatory review period for ZOMETA is 2,810 days. Of this time, 2,201 days occurred during the testing phase of the regulatory review period, while 609 days occurred during the approval phase. These periods of time were derived from the following dates:

1. *The date an exemption under section 505 of the Federal Food, Drug, and Cosmetic Act (the act) (21 U.S.C. 355) became effective*: December 12, 1993. The applicant claims September 18, 1993, as the date the investigational new drug application (IND) became effective. However, FDA records indicate that the IND effective date was December 12, 1993, which was 30 days after FDA receipt of the IND.

2. *The date the application was initially submitted with respect to the human drug product under section 505 of the act*: December 21, 1999. FDA has verified the applicant's claim that the new drug application (NDA) for ZOMETA (NDA 21–223) was initially submitted on December 21, 1999.

3. *The date the application was approved*: August 20, 2001. FDA has verified the applicant's claim that NDA 21–223 was approved on August 20, 2001.

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 1,752 days of patent term extension.

Anyone with knowledge that any of the dates as published are incorrect may submit to the Dockets Management Branch (see **ADDRESSES**) written or electronic comments and ask for a redetermination by April 29, 2003. Furthermore, any interested person may petition FDA for a determination regarding whether the applicant for extension acted with due diligence during the regulatory review period by August 27, 2003. To meet its burden, the petition must contain sufficient facts to merit an FDA investigation. (See H.