Dated: March 31, 2004.

Ann C. Agnew,

Executive Secretary to the Department.

[FR Doc. 04–7716 Filed 4–1–04; 11:57 am]

BILLING CODE 4120–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Centers for Medicare & Medicaid Services

42 CFR Part 414

[CMS–1380–IFC]

RIN 0938–AN05

Medicare Program; Manufacturer Submission of Manufacturer's Average Sales Price (ASP) Data for Medicare Part B Drugs and Biologicals

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

ACTION: Interim final rule with comment period.

SUMMARY: This interim final rule with comment period will implement the provisions of the Medicare Prescription Drug, Improvement, and Modernization Act of 2003 (MMA) related to the calculation and submission of manufacturer's average sales price (ASP) data on certain Medicare Part B drugs and biologicals to CMS by manufacturers.

DATES: Effective date: These regulations are effective on April 30, 2004.

Comment date: Comments will be considered if we receive them at the appropriate address, as provided below, no later than 5 p.m. on June 7, 2004.

ADDRESSES: In commenting, please refer to file code CMS–1380–IFC. Because of staff and resource limitations, we cannot accept comments by facsimile (FAX) transmission.

Submit electronic comments to *http://www.cms.hhs.gov/regulations/ecomments* or to *http://www.regulations.gov.* Mail written comments (one original and three copies) to the following address ONLY: Centers for Medicare & Medicaid Services, Department of Health and Human Services, Attention: CMS–1380–IFC, P.O. Box 8010, Baltimore, MD 21244–1850.

Please allow sufficient time for mailed comments to be timely received in the event of delivery delays.

If you prefer, you may deliver (by hand or courier) your written comments (one original and three copies) to one of the following addresses: Room 445–G, Hubert H. Humphrey Building, 200 Independence Avenue, SW., Washington, DC 20201, or Room C4–26–05, 7500 Security Boulevard, Baltimore, MD 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 commenters wishing to retain a proof of filing by stamping in and retaining an extra copy 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.

All comments received before the close of the comment period are available for viewing by the public, including any personally identifiable or confidential business information that is included in a comment. After the close of the comment period, CMS posts all electronic comments received before the close of the comment period on its public website.

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

FOR FURTHER INFORMATION CONTACT: Marjorie Baldo, (410) 786–0548.

SUPPLEMENTARY INFORMATION:

Submitting Comments: We welcome comments from the public on all issues set forth in this rule to assist us in fully considering issues and developing policies. You can assist us by referencing the file code CMS–1380–IFC and the specific "issue identifier'' that precedes the section on which you choose to comment.

Inspection of Public Comments: Comments received timely will be available for public inspection as they are received, generally beginning approximately 3 weeks after publication of a document, 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, call telephone number: (410) 786–7197.

I. Background

[If you choose to comment on issues in this section, please include the caption "BACKGROUND'' at the beginning of your comments.]

Section 303(c) of the MMA amends Title XVIII of the Social Security Act (the Act) by adding new section 1847A. This new section establishes the use of the ASP methodology for payment for drugs and biologicals described in section 1842(o)(1)(C) of the Act furnished on or after January 1, 2005. For calendar quarters beginning on or after January 1, 2004, the statute requires manufacturers to report manufacturer's ASP data to CMS for Medicare Part B drugs and biologicals paid under sections 1842(o)(1)(D), 1847A, or 1881(b)(13)(A)(ii) of the Act. Manufacturers are required to submit their initial quarterly ASP data to us beginning April 30, 2004. Subsequent reports are due not later than 30 days after the last day of each calendar quarter. The types of Medicare Part B covered drugs and biologicals paid under sections 1842(o)(1)(D), 1847A, or 1881(b)(13)(A)(ii) of the Act include drugs furnished incident to a physician's service, drugs furnished under the durable medical equipment (DME) benefit, certain oral anti-cancer drugs, and oral immunosuppressive drugs.

All Medicare Part B covered drugs and biologicals paid under sections 1842(o)(1)(D), 1847A, or 1881(b)(13)(A)(ii) of the Act are subject to the ASP reporting requirements. Certain drugs and biologicals, for example, radiopharmaceuticals, are not paid under these sections of the Act and will not be subject to the ASP reporting requirements.

We are issuing this interim final rule with comment period in order to allow us to implement the manufacturer ASP reporting requirement of section 303(i)(4) of the MMA within the time frames established by the MMA. Therefore, effective April 30, 2004, this interim final rule with comment period will provide implementation guidelines for manufacturers to submit their ASP data to us. We expect to publish a proposed rule on the 2005 ASP based payment system later this year.

II. Provisions of the Interim Final Rule

[If you choose to comment on issues in this section, please include the caption "Provisions of the Interim Final Rule'' at the beginning of your comments.]

In this interim final rule with comment period, we are adding a new subpart J (Submission of Manufacturer's Average Sales Price Data) to Part 414 that implements section 1927(b)(3)(A)(iii) of the Act by specifying the requirements for submission of a manufacturer's ASP data for certain drugs and biologicals covered under Part B of Title XVIII of the Act that are paid under sections 1847A, 1842(o)(1)(D), or 1881(b)(13)(A)(ii) of the Act.

A. Calculation of ASP Data

New section 1847A(c)(1) of the Act defines the manufacturer's ASP for a National Drug Code (NDC) associated with a drug or biological to be the manufacturer's sales to all purchasers in the United States (excluding units associated with sales exempted below) for the NDC for a quarter divided by the total number of units of that NDC sold by the manufacturer in that quarter (excluding units associated with sales exempted below). Section 1847A(c)(6)(A) of the Act adopts the definition of "manufacturer'' set forth in section 1927(k)(5) of the Act. In that section, the term "manufacturer'' means any entity that is engaged in the following (This term does not include a wholesale distributor of drugs or a retail pharmacy licensed under State law):

- Production, preparation, propagation, compounding, conversion or processing of prescription drug product, either directly or indirectly by extraction from substances of natural origin, or independently by means of chemical synthesis, or by a combination of extraction and chemical synthesis.
- Packaging, repackaging, labeling, relabeling, or distribution of prescription drug products. (Manufacturers that also engage in wholesaler activities are required to report ASP data for those drugs that they manufacture.)

In performing this calculation, manufacturers must use the NDC at the standardized 11-digit level. For the purposes of the ASP calculation, the "unit'' is the product represented by the 11-digit NDC as defined in section 1847A(b)(2)(B) of the Act. In other words, the denominator is the total number of the ASP applicable sales of that NDC.

B. Sales Exempted From ASP Calculation Other Than Nominal Sales

Section 1847A(c)(2)(A) of the Act requires that in calculating the manufacturer's ASP, a manufacturer must exclude sales that are exempt from the Medicaid best price calculation under sections 1927(c)(1)(C)(i) and 1927(c)(1)(C)(ii)(III) of the Act.

C. Sales to an Entity That Are Nominal in Amount Are Exempted From the ASP Calculation

Section 1847A(c)(2)(B) of the Act requires that sales to an entity that are nominal in amount are to be exempted from the ASP calculation. Sales to an entity that are nominal in amount are defined for purposes of section 1927(c)(1)(C)(ii)(III) of the Act for the Medicaid drug rebate program in the Medicaid drug rebate agreement.

D. Inclusion of Rebates and Other Price Concessions in the ASP Calculation

1. General Rule

Section 1847A(c)(3) of the Act requires that in calculating the manufacturer's ASP, a manufacturer must include volume discounts, prompt pay discounts, cash discounts, free goods that are contingent on any purchase requirement, chargebacks, and rebates (other than rebates under the Medicaid drug rebate program).

2. Estimation Methodology

a. Use of the Most Recent 12-Month Period Available

Section 1847A(c)(5)(A) of the Act states that the ASP is to be calculated by the manufacturer on a quarterly basis. To the extent that data on volume discounts, prompt pay discounts, cash discounts, free goods that are contingent on any purchase requirement, chargebacks, and rebates are available on a lagged basis, the manufacturer is required to apply a methodology based on the most recent 12-month period available to estimate costs attributable to these price concessions. Specifically, a manufacturer should add the volume discounts, prompt pay discounts, cash discounts, free goods that are contingent on any purchase requirement, chargebacks, and rebates for the most recent 12-month period available and divide by 4 to determine the estimate to apply in calculating the manufacturer's ASP for the quarter being submitted.

b. Allocation to Individual NDCs

For situations in which a manufacturer is unable to associate volume discounts, prompt pay discounts, cash discounts, free goods that are contingent on any purchase requirement, chargebacks and rebates, with a specific NDC, the manufacturer will allocate those discounts, rebates, free goods, and chargebacks to associated NDCs. This association will be based on the percentage of sales (in dollars) attributable to each particular NDC within the group of NDCs for which the manufacturer can associate discounts, rebates, free goods, and chargebacks.

c. Future Changes to the Methodology

As we gain more experience with the ASP system, we may seek to change the methodology to estimate costs attributable to rebates and chargebacks and the scope of price concessions for years after 2004. Pursuant to section 1847A(c)(5)(A) of the Act, the Secretary may establish a uniform methodology to estimate and apply those costs. For years after 2004, the Secretary may include in the calculation of the ASP, other price concessions which may be based upon recommendations of the Inspector General that would result in a reduction of the cost to the purchaser.

E. Reporting of ASP Data to CMS

1. Format

Manufacturers must report the ASP data to us in Microsoft Excel using the template provided in Addendum A. Manufacturers are required to calculate and report the ASP information to us at the 11-digit NDC level, along with the associated units used in the calculation of the ASP. As we gain more experience with the ASP system, we may seek to modify these requirements in the future.

2. Contacts

As indicated in Addendum B, manufacturers must submit the names of one or more individuals that we may contact if we have questions or issues with respect to the data submission.

3. Certification by the Chief Executive Officer or Chief Financial Officer

Due to the consequences of failing to submit accurate and timely ASP data, each quarterly ASP data submission must be certified by one of the following: the manufacturer's Chief Executive Officer (CEO), the manufacturer's Chief Financial Officer (CFO), or an individual who has delegated authority to sign for, and who reports directly to, the manufacturer's CEO or CFO.

F. Penalties Associated With the Failure To Submit Timely and Accurate ASP Data

Section 1847A(d)(4) of the Act specifies the penalties for misrepresentations associated with ASP data. If the Secretary determines that a manufacturer has made a misrepresentation in the reporting of ASP data, a civil money penalty in an amount of up to $10,000 may be applied for each price misrepresentation and for each day in which the price misrepresentation was applied. Section 1927 of the Act, as amended by section 303(i)(4) of the MMA, specifies the penalties associated with a manufacturer's failure to submit timely information or the submission of false information.

III. Response to Comments

Because of the large number of public comments we normally receive on **Federal Register** documents, we are not able to acknowledge or respond to them individually. We will consider all comments we receive by the date and time specified in the **DATES** section of this preamble, and, when we proceed with a subsequent document, we will

respond to the comments in the preamble to that document.

IV. Waiver of Proposed Rulemaking

We ordinarily publish a notice of proposed rulemaking in the **Federal Register** and invite public comment on the proposed rule. The notice of proposed rulemaking includes a reference to the legal authority under which the rule is proposed, and the terms and substances of the proposed rule or a description of the subjects and issues involved. This procedure can be waived, however, if an agency finds good cause that a notice-and-commentprocedure is impracticable, unnecessary, or contrary to the public interest and incorporates a statement of the finding and its reasons in the rule issued. In addition, the Administrative Procedure Act normally requires a 30-day delay in the effective date of a final rule. Furthermore, the Congressional Review Act generally requires an agency to delay the effective date of a major rule by 60-days in order to allow for congressional review of the agency action. Section 1871 of the Act provides for publication of a notice of proposed rulemaking and opportunity for public comment before CMS issues a final rule. However, section 1871(b)(2)(B) of the Act provides an exception when a law establishes a specific deadline for implementation of a provision and the deadline is less than 150 days after the law's date of enactment. The MMA was enacted by Congress on November 25, 2003, and signed into law by the President on December 8, 2003. The provisions of this interim final rule with comment period are required to be implemented by April 30, 2004. Therefore, these provisions are subject to waiver of proposed rulemaking and public comment in accordance with section 1871(b)(2)(B) of the Act.

Even if section 1871(b)(2)(B) of the Act were not directly applicable here, we would find good cause to waive the requirement for publication of a notice of proposed rulemaking and public comment on the grounds that it is impracticable, unnecessary, and contrary to the public interest. This interim final rule with comment period sets forth non-discretionary provisions of MMA with respect to the calculation and submission of ASP data for certain Medicare Part B drugs and biologicals. Because the rule is generally ministerial, we believe that pursuing notice and comment is unnecessary. Moreover, because that process would delay the implementation of congressionally-mandated submissions of drug payment-related data, we find that pursuing that process would be both impracticable and contrary to the public interest.

With respect to the requirement of a 60-day delay in the effective date of any final rule pursuant to the Congressional Review Act (CRA), see 5 U.S.C. section 801, the CRA provides that the 60-day delayed effective date shall not apply to any rule "which an agency for good cause finds * * * that notice and public procedure thereon are impracticable, unnecessary, or contrary to the public interest.'' (5 U.S.C. section 808(2)). For the reasons set forth above, we believe that additional notice and comment rulemaking on this subject would be impracticable, unnecessary, or contrary to the public interest. Therefore, we do not believe that the CRA requires a 60-day delay in the effective date of this interim final rule with comment period.

V. Collection of Information Requirements

Under the Paperwork Reduction Act of 1995, we are required to provide notice in the **Federal Register** and solicit public comment before a collection of information requirement is submitted to the Office of Management and Budget (OMB) for review and approval. In order to fairly evaluate whether an information collection should be approved by OMB, section 3506(c)(2)(A) of the Paperwork Reduction Act of 1995 requires that we solicit comment on the following issues:

- The need for the information collection and its usefulness in carrying out the proper functions of our agency.
- The accuracy of our estimate of the information collection burden.
- The quality, utility, and clarity of the information to be collected.
- Recommendations to minimize the information collection burden on the affected public, including automated collection techniques.

We are, however, requesting an emergency review of the information collection referenced below. In compliance with the requirement of section 3506(c)(2)(A) of the Paperwork Reduction Act of 1995, we have submitted to the Office of Management and Budget (OMB) the following requirements for emergency review. We are requesting an emergency review because the collection of this information is needed before the expiration of the normal time limits under OMB's regulations at 5 CFR Part 1320. This is necessary to ensure compliance with a statutory deadline. We cannot reasonably comply with the normal clearance procedures because of an unanticipated event.

CMS is requesting OMB review and approval of this collection by April 23, 2004, with a 180-day approval period. Written comments and recommendations will be accepted from the public if received by the individuals designated below by April 16, 2004. During this 180-day period, we will publish a separate **Federal Register** notice announcing the initiation of an extensive 60-day agency review and public comment period on these requirements.

We are soliciting public comment on each of these issues for the following sections of this document that contain information collection requirements:

In summary, this interim final rule with comment period requires manufacturers of Medicare Part B covered drugs and biologicals paid under sections 1847A, 1842(o)(1)(D), or 1881(b)(13)(A)(ii) of the Act to submit manufacturer's quarterly ASP data to CMS beginning April 30, 2004. This interim final rule with comment period lays out the requirements and provides the template manufacturers should use to report their ASP data to CMS.

The burden associated with the requirements in this rule is the time and effort required by manufacturers of Medicare Part B drugs and biologicals to prepare and submit the required data to CMS. We estimate that it will take approximately 4 hours for each submission. We also estimate that this requirement will affect approximately 120 manufacturers. Therefore, we estimate the total reporting burden to be approximately 480 hours per quarter for a total of 1920 hours annually.

As required by section 3504(h) of the Paperwork Reduction Act of 1995, we have submitted a copy of this document to OMB for its review of these information collection requirements.

If you comment on these information collection and recordkeeping requirements, please mail copies directly to the following: Centers for Medicare & Medicaid Services, Office of Strategic Operations and Regulatory Affairs, Regulations Development and Issuances Group, Attn: Dawn Willinghan, CMS–1380–IFC, Room C5–14–03, 7500 Security Boulevard, Baltimore, MD 21244–1850; and Office of Information and Regulatory Affairs, Office of Management and Budget, Room 10235, New Executive Office Building, Washington, DC 20503, Attn: Brenda Aguilar, CMS Desk Officer, *baguilar@omb.eop.gov.* Fax (202) 395–6974.

VI. Regulatory Impact

We have examined the impact 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 in any 1 year). This rule does not reach the economic threshold and thus is not considered a major rule.

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 $6 million to $29 million in any 1 year. Individuals and States are not included in the definition of a small entity. We are not preparing an analysis for the RFA because we have determined that this rule will not have a significant economic impact on a substantial number of small 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 analysis must conform to the provisions of section 604 for final rules 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 are not preparing an analysis for section 1102(b) of the Act because we have determined that this rule will 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 expenditure in any 1 year by State, local, or tribal governments, in the aggregate, or by the private sector, of $110 million. While this interim final rule with comment period does implement a new statutory data reporting requirement for drug manufacturers, the costs associated with this requirement are expected to be below the $110 million annual threshold established by section 202 of the Unfunded Mandates Reform Act.

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 and local governments, preempts State law, or otherwise has Federalism implications. Since this regulation does not impose any costs on State or local governments, the requirements of E.O. 13132 are not applicable.

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

List of Subjects in 42 CFR Part 414

Administrative practice and procedure, Health facilities, Health professions, Kidney diseases, Medicare, Reporting and recordkeeping requirements.

■ For the reasons set forth in the preamble, the Centers for Medicare & Medicaid Services amends 42 CFR Chapter IV, as set forth below:

PART 414—PAYMENT FOR PART B MEDICAL AND OTHER HEALTH SERVICES

■ 1. The authority citation for part 414 continues to read as follows:

Authority: Secs. 1102, 1871, and 1881(b)(1) of the Social Security Act (42 U.S.C. 1302, 1395hh, and 1395rr(b)(1)).

■ 2. Part 414 is amended by adding a new subpart J to read as follows:

Subpart J—Submission of Manufacturer's Average Sales Price Data

Sec.

§ 414.800 Purpose.

This subpart implements section 1847A of the Act by specifying the requirements for submission of a manufacturer's average sales price data for certain drugs and biologicals covered under Part B of Title XVIII of the Act that are paid under sections 1842(o)(1)(D), 1847A, and 1881(b)(13)(A)(ii) of the Act.

§ 414.802 Definitions.

As used in this subpart, unless the context indicates otherwise—

Drug means both drugs and biologicals.

Manufacturer means any entity that is engaged in the following (This term does not include a wholesale distributor of drugs or a retail pharmacy licensed under State law):

(1) Production, preparation, propagation, compounding, conversion or processing of prescription drug products, either directly or indirectly by extraction from substances of natural origin, or independently by means of chemical synthesis, or by a combination of extraction and chemical synthesis.

(2) The packaging, repackaging, labeling, relabeling, or distribution of prescription drug products.

Unit means the product represented by the 11-digit National Drug code.

§ 414.804 Basis of payment.

(a) *Calculation of manufacturer's average sales price.*

(1) The manufacturer's average sales price for a quarter for a drug or biological represented by a particular 11-digit National Drug Code must be calculated as the manufacturer's sales to all purchasers in the United States for that particular 11-digit National Drug Code (after deducting the types of items and transactions listed in paragraph (a)(2) of this section and excluding sales referenced in paragraph (a)(4) of this section) divided by the total number of units sold by the manufacturer in that quarter (after excluding units associated with sales referenced in paragraph (a)(4) of this section).

(2) In calculating the manufacturer's average sales price, a manufacturer must deduct the following types of transactions and items:

(i) Volume discounts.

(ii) Prompt pay discounts.

(iii) Cash discounts.

(iv) Free goods that are contingent on any purchase requirement.

(v) Chargebacks and rebates (other than rebates under the Medicaid drug rebate program).

(3) To the extent that data on volume discounts, prompt pay discounts, cash discounts, free goods that are contingent on any purchase requirement, chargebacks and rebates (other than rebates under the Medicaid drug rebate program) are available on a lagged basis, the manufacturer should add the data for the most recent 12-month period available and divide by 4 to determine the estimate to apply in calculating the manufacturer's average sales price for the quarter being submitted.

(4) In calculating the manufacturer's average sales price, a manufacturer must exclude sales that are exempt from the Medicaid best price calculation under sections 1927(c)(1)(C)(i) and 1927(c)(1)(C)(ii)(III) of the Act.

(5) The manufacturer's average sales price must be calculated by the manufacturer every calendar quarter and submitted to CMS within 30 days of the close of the quarter. The first quarter submission must be submitted by April 30, 2004. Subsequent reports are due not later than 30 days after the last day of each calendar quarter.

(6) Each report must be certified by one of the following:

(i) The manufacturer's Chief Executive Officer (CEO).

(ii) The manufacturer's Chief Financial Officer (CFO).

(iii) An individual who has delegated authority to sign for, and who reports directly to, the manufacturer's CEO or CFO.

§ 414.806 Penalties associated with the failure to submit timely and accurate ASP data.

Section 1847A(d)(4) specifies the penalties associated with misrepresentations associated with ASP data. If the Secretary determines that a manufacturer has made a misrepresentation in the reporting of ASP data, a civil money penalty in an amount of up to $10,000 may be applied for each price misrepresentation and for each day in which the price misrepresentation was applied. Section 1927(b)(3)(C) of the Act, as amended by section 303(i)(4) of the MMA, specifies the penalties associated with a manufacturer's failure to submit timely information or the submission of false information.

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

Dated: March 4, 2004.

Dennis G. Smith,

Acting Administrator, Centers for Medicare & Medicaid Services.

Approved: March 23, 2004.

Tommy G. Thompson,

Secretary.

BILLING CODE 4120–01–P

Addendum A

Manufacturer's Name	National Drug Code	Manufacturer's Average Sales Price	Number of Units

Addendum B

The Centers for Medicare & Medicaid Services
Average Sales Price Data

Name of Drug or Biological Manufacturer (as "manufacturer" is defined in section 1927(k)(5) of the Social Security Act):

Legal Address:

Manufacturer Contact(s):
Name: Email:

Title: Fax:

Address: Telephone No.:

Name: Email:

Title: Fax:

Address: Telephone No.:

I certify that the reported Average Sales Prices were calculated accurately and that all information and statements made in this submission are true, complete, and current to the best of my knowledge and belief and are made in good faith. I understand that information contained in this submission may be used for Medicare reimbursement purposes.

Name of CEO, CFO or Authorizing Official:
Title:

_____ _____
Signature Date

According to the Paperwork Reduction Act of 1995, no persons are required to respond to a collection of information unless it displays a valid OMB control number. The valid OMB control number for this information collection is 0938-0921. The time required to complete this information collection is estimated to average 1 hour per response, including the time to review instructions, search existing data resources, gather the data needed, and complete and review the information collection. If you have comments concerning the accuracy of the time estimate(s) or suggestions for improving this form, please write to: CMS, 7500 Security Boulevard, Attn: PRA Reports Clearance Officer, Baltimore, Maryland 21244-1850.

[FR Doc. 04–7715 Filed 4–1–04; 11:24 am]
BILLING CODE 4120–01–C

FEDERAL MARITIME COMMISSION

46 CFR Part 515

[Docket No. 04–02]

Optional Rider for Proof of Additional NVOCC Financial Responsibility

AGENCY: Federal Maritime Commission.

ACTION: Final rule.

SUMMARY: The Federal Maritime Commission amends its regulations governing proof of financial responsibility for ocean transportation intermediaries to allow an optional rider to be filed with a licensed non-vessel-operating common carrier's proof of financial responsibility to provide additional proof of financial responsibility for such carriers serving the U.S. oceanborne trade with the People's Republic of China.

EFFECTIVE DATE: April 6, 2004.

FOR FURTHER INFORMATION CONTACT: Amy W. Larson, General Counsel, Federal Maritime Commission, 800 North Capitol Street, NW., Room 1018, Washington, DC 20573–0001, (202) 523–5740, E-mail: *GeneralCounsel@fmc.gov.*

Sandra A. Kusumoto, Director, Bureau of Consumer Complaints and Licensing, Federal Maritime Commission, 800 North Capitol Street, NW., Room 970, Washington, DC 20573–0001, (202) 523–5787, E-mail: *otibonds@fmc.gov.*

SUPPLEMENTARY INFORMATION:

I. Background

This rulemaking proceeding was initiated on January 23, 2004, with the issuance by the Federal Maritime Commission ("FMC" or "Commission") of a Notice of Proposed Rulemaking ("NPR"). 69 FR 4271 (January 29, 2004). Comments on the NPR were to be due on February 20, 2004, but requests for