above, pursuant to 5 U.S.C. 553(b)(B), notice and public procedure are unnecessary. Since this document is not subject to the notice and public procedure requirements of 5 U.S.C. 553, it is not subject to the provisions of the Regulatory Flexibility Act (5 U.S.C. 601 *et seq.*). Further, this document does not meet the criteria for a ''significant regulatory action'' as specified in Executive Order 12866.

List of Subjects in 19 CFR Part 133

Copyrights, Counterfeit goods, Customs duties and inspection, Imports, Penalties, Prohibited merchandise, Reporting and recordkeeping requirements, Restricted merchandise, Seizures and forfeitures, Trademarks, Trade names, Unfair competition.

Amendment to the Regulations

For the reasons stated above, part 133 of the Customs Regulations (19 CFR part 133) is amended as set forth below:

PART 133—TRADEMARKS, TRADE NAMES, AND COPYRIGHTS

1. The general authority citation for part 133 continues to read as follows:

Authority: 17 U.S.C. 101, 601, 602, 603; 19 U.S.C. 66, 1624; 31 U.S.C. 9701.

* * * * *

§ 133.42 [Amended]

2. In § 133.42, the third sentence of paragraph (c) is amended by removing the words '', unless the article may be returned to the country of export as provided in § 133.47''.

§ 133.44 [Amended]

3. In § 133.44, the first sentence of paragraph (a) is amended by removing the word ''either'' and the words ''or, if the conditions prescribed by § 133.47 are met, permit the importer to return the article to the country of export''. In the last sentence, the words ''In either event, the'' are removed and the word ''The'' is added in their place.

§ 133.47 [Removed]

4. Section 133.47 is removed.

Samuel H. Banks,

Acting Commissioner of Customs.

Approved: March 24, 1997.

John P. Simpson,

Deputy Assistant Secretary of the Treasury.

[FR Doc. 97–10272 Filed 4–21–97; 8:45 am]

BILLING CODE 4820–02–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

21 CFR Part 5

Delegations of Authority and Organization

AGENCY: Food and Drug Administration, HHS.

ACTION: Final rule.

SUMMARY: The Food and Drug Administration (FDA) is amending regulations for delegations of authority to allow the Director of the Center for Drug Evaluation and Research (CDER) and the Director of the Office of Compliance, CDER, to grant or deny a request, submitted in the form of a citizen petition under its pertinent regulations, for an exception or alternative to applicable current good manufacturing practice (CGMP) requirements for positron emission tomography (PET) drug products. This action is necessary to allow CDER to be able to grant an exception or alternative to applicable CGMP requirements for PET drug products when the request is made in a citizen petition.

EFFECTIVE DATE: April 28, 1997.

FOR FURTHER INFORMATION CONTACT:

Robert K. Leedham, Center for Drug Evaluation and Research (HFD–343), Food and Drug Administration, 7500 Standish Pl., Rockville, MD 20855, 301–594–1026, or

Donna G. Page, Division of Management Systems and Policy (HFA–340), Food and Drug Administration, 5600 Fishers Lane, Rockville MD 20857, 301–827–4816.

SUPPLEMENTARY INFORMATION: A final rule providing the Director and the Director of the Office of Compliance, CDER, with the authority to grant requested exceptions and alternatives to requirements in 21 CFR part 211 pertaining to CGMP's for PET radiopharmaceutical drug products is published elsewhere in this issue of the **Federal Register**. This delegation allows these two agency officials to grant or deny such requests when submitted in the form of a citizen petition under 21 CFR 10.30.

Further redelegation of the authorities delegated is authorized. Authority delegated to a position by title may be exercised by a person officially designated to serve in such position in an acting capacity or on a temporary basis.

List of Subjects in 21 CFR Part 5

Authority delegations (Government agencies), Imports, Organization and functions (Government agencies).

Therefore, under the Federal Food, Drug, and Cosmetic Act and under authority of the Commissioner of Food and Drugs, 21 CFR part 5 is amended as follows:

PART 5—DELEGATIONS OF AUTHORITY AND ORGANIZATION

1. The authority citation for 21 CFR part 5 continues to read as follows:

Authority: 5 U.S.C. 504, 552, App. 2; 7 U.S.C. 138a, 2271; 15 U.S.C. 638, 1261–1282, 3701–3711a; secs. 2–12 of the Fair Packaging and Labeling Act (15 U.S.C. 1451–1461); 21 U.S.C. 41–50, 61–63, 141–149, 467f, 679(b), 801–886, 1031–1309; secs. 201–903 of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 321–394); 35 U.S.C. 156; secs. 301, 302, 303, 307, 310, 311, 351, 352, 361, 362, 1701–1706, 2101 of the Public Health Service Act (42 U.S.C. 241, 242, 242a, 242l, 242n, 243, 262, 263, 264, 265, 300u–300u–5, 300aa–1); 42 U.S.C. 1395y, 3246b, 4332, 4831(a), 10007–10008; E.O. 11490, 11921, and 12591.

2. Section 5.31 is amended by adding new paragraph (h) to read as follows:

§ 5.31 Petitions under part 10.

* * * * *

(h) The Director and the Director of the Office of Compliance, CDER, are each authorized to grant or deny citizen petitions submitted under § 10.30 of this chapter requesting an exception or alternative to any requirement in part 211 of this chapter pertaining to current good manufacturing practice for positron emission tomography radiopharmaceutical drug products.

Dated: April 15, 1997.

William B. Schultz,

Deputy Commissioner for Policy.

[FR Doc. 97–10340 Filed 4–21–97; 8:45 am]

BILLING CODE 4160–01–F

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

21 CFR Part 211

[Docket No. 94N–0421]

RIN 0910–AA45

Current Good Manufacturing Practice for Finished Pharmaceuticals; Positron Emission Tomography

AGENCY: Food and Drug Administration, HHS.

ACTION: Final rule.

SUMMARY: The Food and Drug Administration (FDA) is amending its regulations to permit FDA to approve requests from manufacturers of positron emission tomography (PET) radiopharmaceutical drug products for exceptions or alternatives to provisions of the current good manufacturing practice (CGMP) regulations. This action is intended to relieve manufacturers of PET radiopharmaceutical drug products from regulations that might result in unsafe handling of these products or that are inapplicable or inappropriate, and that do not enhance safety or quality in the manufacture of PET radiopharmaceutical drug products. Elsewhere in this issue of the **Federal Register**, FDA is amending its regulations to authorize the Director, Center for Drug Evaluation and Research (CDER) and CDER's Director of the Office of Compliance to grant or deny citizen petitions under FDA regulations requesting an exception or alternative to any requirement pertaining to CGMP.

EFFECTIVE DATE: April 28, 1997.

ADDRESSES: Decisions on the petitions may be seen in the Dockets Management Branch (HFA–305), Food and Drug Administration, 12420 Parklawn Dr., rm. 1–23, Rockville, MD 20857.

FOR FURTHER INFORMATION CONTACT: Robert K. Leedham, Center for Drug Evaluation and Research (HFD–343), Food and Drug Administration, 7500 Standish Pl., Rockville, MD 20855, 301–594–1026.

SUPPLEMENTARY INFORMATION:

I. Background

PET is a medical imaging modality used to assess the body's biochemical processes. Radionuclides are manufactured into PET radiopharmaceutical drug products that are then administered to patients for medical imaging. The medical images of the body's biochemical processes are then evaluated, generally for diagnostic purposes.

PET radiopharmaceutical drug product manufacturing differs in a number of important ways from the manufacture of conventional drug products:

1. Because of the short physical half-lives of PET radiopharmaceutical drug products, PET facilities generally manufacture the products in response to daily demand for a relatively small number of patients.

2. Manufacturing may be limited and only a few lots are produced each day.

3. PET radiopharmaceutical drug products must be administered to patients within a short period of time after manufacturing because of the short physical half-lives of the products.

In the **Federal Register** of February 27, 1995 (60 FR 10517), FDA proposed to permit manufacturers of PET radiopharmaceutical drug products to apply to the agency for approval of exceptions or alternatives to the requirements of the CGMP regulations in part 211 (21 CFR part 211). The agency noted in the proposal that there are fundamental principles of the CGMP regulations that must be applied to drug manufacturing processes, including those for PET radiopharmaceutical drug products, to ensure the safety and efficacy of the finished products. However, part 211 is primarily directed to regulating the manufacture of conventional, nonradioactive drug products, and there are certain aspects of the manufacture of PET radiopharmaceutical drug products that are unique. Therefore, regulations in part 211 may contain requirements that could result in unsafe handling or that are inapplicable or inappropriate to the manufacture of PET radiopharmaceutical drug products and do not otherwise enhance drug product quality.

The proposal specified that a request for an exception would be required to contain an explanation of why compliance with a particular CGMP provision is unnecessary or cannot be achieved. It also specified that a request for an alternative would be required to contain an explanation of how a proposed alternative procedure would satisfy the purpose of the CGMP requirement. The proposal stated that either the Director of CDER or CDER's Director of the Office of Compliance could approve an exception or alternative if it is determined that: (1) The requestor's compliance with the requirement is unnecessary to protect the radiopharmaceutical drug product's quality or safety; (2) the proposed alternative procedures satisfy the purpose of the CGMP requirement; or (3) the requestor's submission otherwise justified an exception or alternative. In addition, the proposal would allow either CDER's Director or CDER's Director of the Office of Compliance to withdraw the approval of an exception or alternative by issuing a written notice to the requestor who had obtained approval for the exception or alternative.

The proposed rule was one of three documents dealing with PET radiopharmaceutical drug products that FDA published in the **Federal Register** of February 27, 1995. Another document announced the availability of a draft guideline on the manufacture of PET radiopharmaceutical drug products (60 FR 10593). The third document announced a March 21, 1995, public workshop and explained the applicable statutory and regulatory requirements for these products (60 FR 10594). This final rule pertains only to the exceptions and alternatives to CGMP regulations for PET radiopharmaceutical drug products and addresses only those comments received on this issue.

This final rule will become effective 5 days after the date of publication in the **Federal Register**. This final rule is a substantive rule which, in the discretion of the agency, grants or recognizes an exemption or relieves a restriction. (See 5 U.S.C. 553(d)(1) and § 10.40(c)(4)(i) (21 CFR 10.40(c)(4)(i).) In addition, the Commissioner of Food and Drugs finds good cause for making a final rule, based on the proposal, effective 5 days after the date of publication in the **Federal Register**. (See 5 U.S.C. 553(d)(3) and § 10.40(c)(4)(ii).) The manufacturing process for PET radiopharmaceutical drug products is sufficiently different from that of other regulated products that application of certain CGMP requirements to the PET manufacturing process may be impractical. Because PET radiopharmaceutical drug products are already in use, a later effective date may delay FDA approval of exceptions or alternatives or hinder appropriate application of the CGMP regulations necessary to protect the integrity of the PET radiopharmaceutical manufacturing process.

II. Comments on the Proposed Rule

FDA gave interested persons until March 29, 1995, to comment on the proposed rule. The agency received comments from pharmaceutical manufacturers, health professionals, professional organizations, and State regulatory agencies. A summary of these comments and FDA's responses follows.

A. Application of CGMP Regulations to PET Radiopharmaceutical Drug Products

Several comments questioned the need to apply CGMP regulations to PET radiopharmaceutical drug products. One comment stated that there had not been an adequate explanation of why PET radiopharmaceutical drug products needed to be governed by CGMP regulations. Several comments suggested alternative standards for the regulation of PET radiopharmaceutical drug products such as the United States Pharmacopeia, the American Pharmaceutical Association Practice Standards for PET Nuclear Pharmacists, or standards set by State boards of pharmacy. Another comment suggested that FDA, in conjunction with the PET

radiopharmaceutical community, develop a regulation specifically for PET radiopharmaceutical drug products.

This rule does not trigger the applicability of CGMP regulations. CGMP regulations apply to PET radiopharmaceutical drug products by virtue of the fact that, under section 201(g) of the Federal Food, Drug, and Cosmetic Act (the act) (21 U.S.C. 321(g)), these products are drugs and are, therefore, subject to the drug provisions of the act. In a notice published in the **Federal Register** of February 27, 1995 (60 FR 10594 at 10595), FDA reiterated this fact concerning the regulation of PET radiopharmaceutical drug products. Under section 501(a)(2)(B) of the act (21 U.S.C. 351(a)(2)(B)), drugs are deemed adulterated unless manufactured in conformity with CGMP requirements. PET radiopharmaceutical drug products are subject to each of the adulteration provisions of the act, including CGMP requirements, even if they are prepared in pharmacies or by pharmacists. (See *Professionals & Patients for Customized Care* v. *Shalala*, 847 F. Supp. 1359, 1364 (S.D. Tex. 1994), *aff'd*, 56 F.3d 592 (5th Cir. 1995).) Therefore, all PET radiopharmaceutical drug products must be manufactured in compliance with CGMP regulations. The regulations in part 211 contain minimum manufacturing practices to be followed by manufacturers of all drug products. Thus, in the absence of this rule, all CGMP requirements would apply to the manufacturing of PET drug products.

FDA's experience has shown that the CGMP regulations are flexible enough to accommodate most drug products and that it is generally unnecessary to create specific CGMP regulations for particular classes of drug products. Such regulations would necessarily contain a large number of provisions identical to, and redundant with, those already present in part 211. Where a CGMP regulation has been shown to be unnecessary or does not enhance the safety or quality of the manufacturing process for certain drug classes, FDA has revised the application of that regulation for that class. For example, in the **Federal Register** of November 28, 1980 (45 FR 79089), FDA amended § 211.170 to reduce the time that manufacturers are required to retain reserve samples of radioactive drugs and to exempt such drugs from the requirement for annual visual examination of reserve samples.

Although the fundamental principles embodied in the CGMP regulations are applicable to the PET radiopharmaceutical drug product manufacturing process, there are certain provisions that may not apply because of unique manufacturing characteristics. As a result, this final rule permits FDA to allow exceptions or alternatives to the CGMP regulations for PET radiopharmaceutical drug products. In addition, FDA is considering making further revisions to part 211, through rulemaking including adding a new subpart to the CGMP regulations to deal with exceptions or alternatives applicable to all PET radiopharmaceutical drug products.

B. Exceptions and Alternatives to CGMP Regulations

Several comments criticized FDA's proposed procedures to receive and evaluate requests for exceptions or alternatives to the CGMP regulations for PET radiopharmaceutical drug products. The comments objected to the proposed requirement that each manufacturer must separately describe and justify each proposed specific exception or alternative. One comment stated that FDA should identify those specific CGMP provisions from which all PET manufacturers could generally be excepted. Another comment stated that excepting some PET radiopharmaceutical drug manufacturers and not others might cause problems. A third comment stated that it is important that any alternatives and exceptions be made public and that the CGMP regulations be applied consistently and equally to all PET radiopharmaceutical drug manufacturing centers.

At this time, FDA believes that it is necessary to review individualized requests to determine whether exceptions or alternatives to CGMP regulations requested for PET radiopharmaceutical drug product manufacturing are consistent with the basic principles of the CGMP regulations and whether differences in existing PET manufacturing techniques, or the volume of product produced, may have an impact on product quality. Any procedure used in the manufacture of PET radiopharmaceutical drug products must provide a reasonable degree of certainty that products will be manufactured with consistent quality. The agency will periodically provide guidance to industry on the application of the CGMP regulations to PET radiopharmaceutical drug products.

FDA agrees that it is important that exceptions and alternatives be applied consistently to all PET radiopharmaceutical drug product manufacturers. To promote such consistency, FDA has withdrawn the provision in proposed § 211.1(d) that would have, under certain circumstances, expressly allowed oral requests for exceptions and alternatives and also would have allowed FDA to issue oral decisions on such requests. The agency believes that it is important to keep written records to maintain consistency, to adequately evaluate requests for exceptions and alternatives, and to prevent misunderstandings.

FDA also agrees that information on exceptions and alternatives should be publicly available. To maintain a publicly available record of requests for exceptions and alternatives, and agency action on such requests, FDA believes that exceptions and alternatives should be submitted in the form of a citizen petition under § 10.30 (21 CFR 10.30). A request for an exception or alternative should be clearly identified as a ''PET Request for Exception or Alternative to the CGMP Regulations.'' Decisions with respect to such petitions will be maintained for public review in the Dockets Management Branch (address above) between 9 a.m. and 4 p.m., Monday through Friday.

Elsewhere in this issue of the **Federal Register**, FDA is amending 21 CFR 5.31 to authorize the Director of CDER and CDER's Director of the Office of Compliance to grant or deny citizen petitions under § 10.30 requesting an exception or alternative to any requirement in part 211 pertaining to CGMP for PET radiopharmaceutical drug products.

The proposed rule specifically listed elements that would be required to be included in a request for exception or alternative and also specifically listed the factors pertaining to FDA's decision whether to grant such a request. In response to comments that the procedure in the proposed rule was too burdensome, the final rule provides greater flexibility in that it does not require that any particular element be included in a request for exception or alternative, and does not narrowly constrain FDA's discretion to grant such a request.

Although the codified language of the regulation no longer contains specific required elements, the agency expects that a citizen petition requesting an exception or alternative would be approved if the agency determined, based upon a request, including supporting data as necessary, that: (1) The requestor's compliance with the CGMP requirement is unnecessary to provide suitable assurance that the drug meets the requirements of the act as to safety and has the identity and strength and meets the quality and purity characteristics that it purports or is represented to possess, or compliance with the requirement is not possible to

achieve; (2) alternative procedures or controls suggested and sufficiently described by the requestor satisfy the purpose of the requirement; or (3) the requestor's submission otherwise justifies an exception or alternative. Although no longer specified in the regulation, these factors, pertaining to FDA's decisions on requests for exceptions and alternatives, provide guidance both to assist PET manufacturers in preparing requests and to assist FDA in consistently evaluating those requests. As further guidance, citizen petitions for an exception or alternative may be submitted by manufacturers or trade associations individually or as a group, as long as the facts presented are sufficiently individualized for each manufacturer seeking the exception or alternative.

C. Usefulness of the Rule

Several comments objected to the proposed provision for requesting an exception or alternative to the CGMP regulations, arguing that it would not likely achieve its goal of reducing the burden on PET radiopharmaceutical drug products and would not be cost-effective.

FDA disagrees with these comments. As explained above, the purpose of the rule is to relieve PET radiopharmaceutical drug product manufacturers from regulatory provisions that might result in unsafe handling of PET radiopharmaceutical drug products, that are inapplicable or inappropriate, or that do not enhance the safety or quality of PET radiopharmaceutical drug products. The agency believes that, with the added flexibility provided by this final rule, the CGMP regulations can be applied to PET radiopharmaceutical drug products in a way that accommodates their unique manufacturing aspects while still protecting the integrity of the manufacturing process. The agency will continue to work with these manufacturers in an effort to apply CGMP requirements to PET radiopharmaceutical drug products in ways that are practical and achievable.

III. Environmental Impact

The agency has determined under 21 CFR 25.24(a)(10) that this action is of a type that does not individually or cumulatively have a significant effect on the human environment. Therefore, neither an environmental assessment nor an environmental impact statement is required.

IV. Analysis of Impacts

FDA has examined the impacts of the final rule under Executive Order 12866, under the Regulatory Flexibility Act (5 U.S.C. 601–612), and under the Unfunded Mandates Reform Act (Pub. L. 104–4). Executive Order 12866 directs agencies to assess all costs and benefits of available regulatory approaches that maximize net benefits (including potential economic, environmental, public health and safety, and other advantages; distributive impacts; and equity). Under the Regulatory Flexibility Act, if a rule is expected to have a significant economic impact on a substantial number of small entities, the agency must analyze regulatory options that would minimize any significant economic impact of the rule on small entities. The Unfunded Mandates Reform Act requires that agencies prepare an assessment of anticipated costs and benefits before proposing any rule that may result in an annual expenditure by State, local, and tribal governments, in the aggregate, or by the private sector, of $100 million or more (annually adjusted for inflation).

The agency has reviewed this final rule and has determined that the rule is consistent with the principles set forth in the Executive Order. FDA finds that the rule is not a significant regulatory action under the Executive Order. In addition, the agency finds that the rule does not impose any mandates on State, local, or tribal governments, or the private sector that will result in an annual expenditure of $100 million or more.

The fact that PET radiopharmaceuticals are drugs requires compliance with the CGMP requirements under section 501(a)(2)(B) of the act, and all finished pharmaceuticals are subject to the requirements imposed by the CGMP regulations set forth in this part. This rule will allow FDA to approve requests from manufacturers of PET radiopharmaceutical drug products for exceptions or alternatives to the CGMP requirements as they apply to the unique characteristics of PET radiopharmaceutical drug product manufacturing, without compromising CGMP standards that are necessary to meet the CGMP requirements.

FDA estimates that there are approximately 70 facilities that manufacture PET radiopharmaceutical drug products, and the agency assumes for the purposes of this analysis that each facility is a small entity within the meaning of the Regulatory Flexibility Act. The only costs associated with this rule are the possible costs associated with requesting an exception or alternative.

FDA estimates that it will take approximately 20 hours, or less, for each facility to develop its request for exceptions or alternatives. Assuming that each of the 70 facilities submits one request, the burden would total 1,400 hours. Using the 1995 median weekly earnings of $524[1] for clinical laboratory technologists and technicians, and adding 40 percent for fringe benefits, the average hourly earnings would be $18.34. Thus, the combined costs for all facilities would total less than $26,000. FDA concludes that these incidental one time costs of approximately $367 per facility would constitute an insignificant percentage of gross revenue, even for a small entity.

In addition, it is expected that some facilities will collaborate with each other, or with trade associations, to submit bundled requests, as long as the facts presented are sufficiently individualized for each manufacturer seeking the exception or alternative. Moreover, because the filing of a request for an exception or alternative is voluntary, it is unlikely that a facility will file such a request unless it expects the benefit derived to exceed the cost of preparing and filing the request. Consequently, FDA believes that the rule will, in fact, provide a net economic savings for each facility that chooses to request an exception or alternative to a CGMP requirement. Therefore, under the Regulatory Flexibility Act, 5 U.S.C. 605(b), the Commissioner of Food and Drugs certifies that this final rule will not have a significant economic impact on a substantial number of small entities.

List of Subjects in 21 CFR Part 211

Drugs, Labeling, Laboratories, Packaging and containers, Prescription drugs, Reporting and recordkeeping requirements, Warehouses.

Therefore, under the Federal Food, Drug, and Cosmetic Act and under authority delegated to the Commissioner of Food and Drugs, 21 CFR part 211 is amended as follows:

PART 211—CURRENT GOOD MANUFACTURING PRACTICE FOR FINISHED PHARMACEUTICALS

1. The authority citation for 21 CFR part 211 continues to read as follows:

Authority: Secs. 201, 501, 502, 505, 506, 507, 512, 701, 704 of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 321, 351, 352, 355, 356, 357, 360b, 371, 374).

2. Section 211.1 is amended by adding new paragraph (d) to read as follows:

[1] Employment and Earnings, U.S. Department of Labor, Bureau of Labor Statistics, vol. 43, No. 1, p. 206, January 1996.

§ 211.1 Scope.

* * * * *

(d)(1) The Director of the Center for Drug Evaluation and Research (CDER) and the CDER Director of the Office of Compliance each may approve a request from a manufacturer of positron emission tomography (PET) drug products for an exception or alternative to any requirement of this part pertaining to current good manufacturing practice for PET drug products.

(2) An approval under paragraph (d)(1) of this section may be withdrawn if either Director finds that such exception or alternative is no longer justified. Withdrawal of such approval shall be accomplished by providing written notice of such withdrawal, and the reasons for the withdrawal, to the original requestor.

Dated: April 15, 1997.

William B. Schultz,

Deputy Commissioner for Policy.

[FR Doc. 97–10341 Filed 4–21–97; 8:45 am]

BILLING CODE 4160–01–F

DEPARTMENT OF THE INTERIOR

Minerals Management Service

30 CFR Part 218

RIN 1010–AC01

Amendments to Regulations Governing Collection of Royalties, Rentals, Bonuses, and Other Monies Due the Federal Government

AGENCY: Minerals Management Service (MMS), Interior.

ACTION: Final rulemaking.

SUMMARY: MMS is amending its regulations that specify how payments are made for mineral lease royalties, rentals, and bonuses. The changes are needed to incorporate revised U.S. Treasury requirements. Also, MMS has clarified language for other parts of this regulation.

DATES: Effective date May 22, 1997.

FOR FURTHER INFORMATION CONTACT: David S. Guzy, Chief, Rules and Procedures Staff, phone (303) 231–3432, FAX (303) 231–3194, e-Mail David__Guzy@smtp.mms.gov.

SUPPLEMENTARY INFORMATION: The principal authors of this rule are David J. Menard of the Reports and Financial Division, Financial Branch, Jim McNamee of the Office of Policy and Management Improvement, and David S. Guzy of the Rules and Procedures Staff, Lakewood, Colorado.

I. Background

The purpose of this final rule is to comply with the U.S. Treasury's final rule amending 31 CFR Part 206, Management of Federal Agency Receipts, Disbursements, and Operation of the Cash Management Improvement Fund (59 FR 4536, 1/31/94). That rule requires executive agencies to use effective, efficient disbursement mechanics, principally Electronic Funds Transfer (EFT), in making their payments. That rule also requires executive agencies to use EFT for collecting funds.

MMS has written this rule in plain English.

II. Comments on Proposed Rule

MMS published a proposed rule on April 19, 1996, at 61 FR 17267. The proposed rulemaking provided for a 60-day comment period, which ended June 18, 1996, and was extended to July 19, 1996, by a **Federal Register** Notice (61 FR 28829, June 6, 1996).

General Comments

Commenters believe writing the rule in plain English improves clarity and makes the rule easier to understand. Commenters stated they will continue to work with MMS to identify the most efficient and practical way to make payments to MMS.

Response. We appreciate these comments and will continue the plain English concept in all future rulemakings.

Specific Comments

Comment on § 218.51(a). One commenter did not think it is necessary to define person or payment when used in their common or ordinary meaning.

Response. MMS has determined that these definitions lend clarity and conform with other MMS rules. No change will be made in the final rule.

Comment on § 218.51(b). The same commenter pointed out that the word *general* was misspelled.

Response. We will correct the spelling in the final rule.

Comment on § 218.51(b)(1). Five commenters responded as follows:

(1) The section is vague and arbitrary. Sentence is circular and describes a discretionary standard. As written, the payer must use EFT anytime MMS requires EFT regardless of the reasoning or criteria or basis for the decision. They suggested alternative language.

(2) The requirement is in conflict with the preamble. Their opinion is that making all payments by EFT is neither cost effective nor practicable. They said many Indian payments cost more to process than the invoice they are paying and adding the cost of making these payments by EFT would not be cost effective. They recommend a threshold of $10,000.

(3) They feel there is a conflict with § 218.51(b) which says ''to the extent it is cost effective and practicable,'' and this section which says if instructed you must pay by EFT. They recommend a threshold of $10,000.

(4) They feel the statement of ''If MMS instructs you to use * * *.'' conflicts with the general spirit of the preamble. They feel the additional cost of making EFT payments is not justifiable from the company standpoint. They recommend the $10,000 limit be maintained.

(5) They do not believe the additional cost of making EFT payments is justifiable from the company standpoint. They recommend retaining the current $10,000 threshold.

Response. MMS does not intend to be arbitrary in implementing the Treasury EFT requirement. The Treasury rule does not allow for any type of stated threshold. Our elimination of the threshold is based on Treasury's requirement that we increase our efficiency in collecting Government monies. We feel the new rule is consistent with the Treasury rule.

We are aware of the cost and technical issues associated with making EFT payments. The U.S. Treasury is working with the banking industry to broaden the use of EFT. MMS believes our record of working with payors in implementing EFT has not been arbitrary or burdensome. It has not been our policy nor will it be our policy to unduly burden industry with EFT payment requirements. As EFT becomes more widespread, the cost should decrease; therefore, EFT will be more beneficial to industry and the Government.

Comment on § 218.51(b)(3). One commenter stated that the paragraph is confusing and should be rewritten to clearly define intent. The commenter asked two questions: (1) ''Does this statement mean that separate reports or report lines are required? (2) Are separate checks or separate lines on the check stub or other payment document needed?''

Response. The intent of this paragraph is to emphasize the fact that you must not mix Federal and Indian lease payments on a payment document. In other words, you must not include any Indian lease payments in your Federal payment documents or any Federal lease payments in your Indian payment documents. This proposed rule deals only with payments and does not change any reporting requirements.