List of Subjects in 16 CFR Part 305

Advertising, Energy conservation, Household appliances, Labeling, Reporting and recordkeeping requirements.

Accordingly, 16 CFR Part 305 is amended as follows:

PART 305—[AMENDED]

1. The authority citation for Part 305 continues to read as follows:

Authority: 42 U.S.C. 6294.

2. Appendix F to Part 305 is revised to read as follows:

Appendix F to Part 305—Clothes Washers

Range Information:

''Compact'' includes all household clothes washers with a tub capacity of less than 1.6 cu. ft. or 13 gallons of water.

''Standard'' includes all household clothes washers with a tub capacity of 1.6 cu. ft. or 13 gallons of water or more.

Capacity	Range of estimated annual energy consumption (kWh/yr.)	
	Low	High
Compact:		
Top Loading	592	607
Front Loading	(*)	(*)
Standard:		
Top Loading	294	1231
Front Loading	241	318

(*) No data submitted.

By direction of the Commission.

Donald S. Clark,

Secretary.

[FR Doc. 98–10391 Filed 4–17–98; 8:45 am]

BILLING CODE 6750–01–M

DEPARTMENT OF THE TREASURY

Customs Service

19 CFR Part 142

[T.D. 98–34]

Technical Correction Regarding Time Limit for Filing Documentation After Release

AGENCY: United States Customs Service, Department of the Treasury.

ACTION: Final rule.

SUMMARY: This document makes a technical correction to the regulation regarding time limit for filing documentation after release, in accordance with Customs policy of periodically reviewing its regulations to ensure that they are current and accurate.

EFFECTIVE DATE: April 20, 1998.

FOR FURTHER INFORMATION CONTACT: Harold Singer, Chief, Regulations Branch, (202) 927–2268.

SUPPLEMENTARY INFORMATION:

Background

In accordance with Customs policy of periodically reviewing its regulations to ensure that they are current and accurate, Customs has discovered that there is a typographical error in § 142.23, Customs Regulations (19 CFR 142.23). Section 142.23 was amended by Treasury Decision 80–26, which was published in the **Federal Register** (45 FR 3901) on January 21, 1980. When that amendment was codified in Title 19 in 1980, the word ''period'' was inadvertently omitted. The error has been carried forward in each volume of Title 19 since that publication. This document corrects the error.

Inapplicability of Public Notice and Comment and Delayed Effective Date Requirements, the Regulatory Flexibility Act, and Executive Order 12866

Inasmuch as this amendment merely corrects a typographical error, pursuant to 5 U.S.C. 553(b)(B), notice and public procedure thereon are unnecessary, and pursuant to 5 U.S.C. (d)(3), a delayed effective date is not required. 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.*). This amendment does not meet the criteria for a ''significant regulatory action'' as defined in Executive Order 12866.

Drafting Information

The principal author of this document was Janet L. Johnson, Regulations Branch, U.S. Customs Service. However, personnel from other offices participated in its development.

List of Subjects in 19 CFR Part 142

Customs duties and inspection.

Amendment to the Regulations

Part 142, Customs Regulations (19 CFR part 142), is amended as set forth below.

PART 142—ENTRY PROCESS

1. The general authority citation for part 142 continues to read as follows:

Authority: 19 U.S.C. 66, 1448, 1484, 1624.

§ 142.23 [Amended]

2. Section 142.23 is amended by removing the words ''for quota class merchandise within the quota'' and adding in their place ''for quota class merchandise within the quota period''.

Dated: April 15, 1998.

Harold M. Singer,

Chief, Regulations Branch.

[FR Doc. 98–10316 Filed 4–17–98; 8:45 am]

BILLING CODE 4820–02–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

21 CFR Part 610

[Docket No. 97N–0449]

RIN 0910–ZA08

Revisions to the General Safety Requirements for Biological Products

AGENCY: Food and Drug Administration, HHS.

ACTION: Direct final rule.

SUMMARY: The Food and Drug Administration (FDA) is amending the biologics regulations by adding ''cellular therapy products'' to the list of products excepted from the general safety test (GST) and by adding an administrative procedure for obtaining exemptions from the GST requirements for other biological products. FDA is taking this

action because the GST may not be relevant or necessary for biological products, including cellular therapy products, currently in various stages of development. This direct final rule is part of FDA's continuing effort to achieve the objectives of the President's ''Reinventing Government'' initiative, and is intended to reduce the burden of unnecessary regulations on biological products without diminishing the protection of the public health. Elsewhere in this **Federal Register**, FDA is publishing a companion proposed rule under FDA's usual procedures for notice and comment to provide a procedural framework to finalize the rule in the event the agency receives any significant adverse comment and withdraws this direct final rule.

DATES: This regulation is effective September 2, 1998. Submit written comments on this direct final rule on or before July 6, 1998. Submit written comments on the information collection provisions by June 19, 1998.

ADDRESSES: Submit written comments on the direct final rule to the Dockets Management Branch (HFA–305), Food and Drug Administration, 12420 Parklawn Dr., rm. 1–23, Rockville, MD 20857.

FOR FURTHER INFORMATION CONTACT: Dano B. Murphy, Center for Biologics Evaluation and Research (HFM–630), Food and Drug Administration, 1401 Rockville Pike, suite 200N, Rockville, MD 20852–1448, 301–594–3074.

SUPPLEMENTARY INFORMATION:

I. Background

Under § 610.11 (21 CFR 610.11), a test for general safety shall be performed on biological products intended for administration to humans. A GST is one of several tests in part 610, General Biological Product Standards (21 CFR part 610), that are intended to help ensure the safety, purity, and potency of biological products administered to humans. The test is used to detect extraneous toxic contaminants that may be present in a particular biological product. As outlined in § 610.11, an amount of the final container product is injected into the peritoneum of guinea pigs and mice. The GST is satisfactory when: The criteria in § 610.11(d) are met, i.e., injected animals survive the test period, they do not exhibit an unexpected or nonspecific response that may indicate a difference in quality of the product, and they weigh no less at the end of the test period than they did at the time of injection. Section 610.11(g) identifies the biological products for which the GST is not required.

The requirement for a GST test was originally intended as a means by which harmful extraneous toxins could be detected (41 FR 10888, March 15, 1976). The source of such toxins may be bacterial toxins that persist even after the bacteria producing the toxins had been removed by filtration or killed by sterilization, or formulation errors that result in harmful levels of certain substances, e.g., preservatives. The test continues to serve as a safety net to detect harmful contaminants that may enter or be introduced into the final container through undetected failures in the manufacture of biological products.

In the last 15 years, technological advances have increased the ability of manufacturers to control and analyze the manufacture of many biotechnology derived biological products. After more than a decade of experience with these products, FDA found that it could evaluate many aspects of a biological product's safety, purity, or potency with tests other than those prescribed in part 610. In response to these developments, FDA published in the **Federal Register** on May 14, 1996 (61 FR 24227), a final rule exempting certain biotechnology and synthetic biological products from, among other things, specified regulations applicable to biological products, including the GST (§ 601.2 (21 CFR 601.2)).

Recent scientific advances have dramatically increased the diversity of biological products regulated under section 351 of the Public Health Service Act. In particular, cellular-based therapies intended for the diagnosis, cure, mitigation, treatment, or prevention of disease in man have been the subject of much biomedical research and are used with increasing frequency. Typically, cellular therapies use autologous or allogeneic cells, often lymphocyte subpopulations, but other cell types may be used, obtained from a donor and manipulated ex vivo to varying degrees before use in the recipient patient. The ex vivo manipulation may consist of, for example, growing a small number of cells to increase their number (cellular expansion), selective enrichment of a specific cell subpopulation, or the addition of specific cell factors or genetic sequences. A common characteristic of cellular therapies is the need for a relatively short turn-around time between first obtaining the cells and their final infusion as a cellular therapy product into the patient. In many cases, cells used in the final cellular therapeutic are obtained only hours before they must be used and turn-around times of several days or less are presently typical. A test, such as the GST, that requires 7 days to complete is not compatible with such products and such a requirement would make it impossible to use many of these products. Furthermore, because the procedures and materials used to produce cellular therapy products are stringently controlled and monitored, the likelihood of an extraneous toxic component contaminating a final product is greatly reduced.

In the **Federal Register** of June 3, 1994 (59 FR 28821 at 28822), FDA announced that the Center for Biologics Evaluation and Research (CBER) would review certain biologics regulations to identify regulations that are outdated, burdensome, inefficient, duplicative, or otherwise unsuitable or unnecessary. FDA included § 610.11 in the review. On January 26, 1995, FDA held a public meeting to discuss the retrospective review of regulations applicable to biological products and to provide a forum for the public to voice its comments regarding the retrospective review. At the meeting, only one comment addressed whether § 610.11 should be retained unchanged, modified, or deleted. The comment acknowledged the utility of the GST for products that have a high degree of intrinsic variability. However, despite its recognized value in some specific cases, the comment questioned the rationale for requiring the GST for all biological products intended for administration to humans. The comment noted that the amount of final container product administered to animals for the GST may not have any correlation with the human dose, that some biological products possess extensive documented histories of no GST failure, and that each run of the test requires the use of at least four animals. The comment suggested that FDA revise § 610.11 to grant exemptions from the GST when the test is unnecessary to evaluate the safety of a specific product.

FDA received several comments from the public regarding issues raised at the January 26, 1995, meeting. Two comments agreed with the suggestion made at the public meeting that § 610.11 be amended to include a provision that would allow certain products to be exempted from the GST upon approval of the Director, CBER. Another comment suggested that exemptions be permitted for appropriate biological products by the Director, CBER, after a suitable qualification period was met without any failure of the GST, such as 1 year of production or after 10 consecutive production lots pass the GST. The comment suggested that a demonstrated record of GST compliance also be supported by well-documented in-

process safety controls, long-term compliance with current good manufacturing practices regulations (21 CFR parts 210 and 211), and the use of sophisticated analytical techniques capable of adequately characterizing the final product and validating its safety.

On March 17, 1997, FDA held a public meeting to discuss the agency's proposed approach to the regulation of human cellular and tissue-based products. The meeting was attended by FDA, members of industry, representatives from accrediting organizations, and interested members of the public. During the meeting, two attendees addressed the use of the GST with cellular therapy products. The comments regarded the 7-day incubation time of the test as an unworkable requirement for many cellular therapy products and suggested that such products be exempted from the test, including allogeneic and autologous cell therapy products.

II. Highlights of the Direct Final Rule

FDA agrees with the comments received that cellular therapy products should be exempt from the GST requirement. FDA is issuing this direct final rule to expand the exceptions in § 610.11(g) to include ''cellular therapy products.'' In addition, FDA is adding an administrative procedure for manufacturers of other biological products to request and obtain exemptions from the GST. Many biological products are currently manufactured, or will be manufactured in the future, under highly controlled and rigorously monitored conditions. Therefore, under the amended rule, manufacturers of biological products that employ appropriate production controls and quality assurance safeguards would be permitted to apply for an exemption from the GST requirement. Such manufacturers will be required to provide supporting documentation to the Director, CBER, as to why a product should not be subject to the GST requirement. The request shall include an explanation of why the GST is unnecessary or cannot be performed due to the mode of administration, the method of preparation, or the special nature of the product and shall describe alternate procedures, if any, to be employed. The Director, CBER, may grant an exemption if she finds that the manufacturer's submission justifies an exemption.

The value of the GST as a final assay for the presence of extraneous toxins may be diminished for certain biological products, such as vaccines containing recombinant or purified protein antigens. Recombinant protein antigens are not produced from infectious bacteria or virus and antigens derived from infectious pathogens may undergo many production steps that kill or neutralize the pathogen or inactivate toxic materials. Therefore, for these kinds of products, the risk is extremely low that viable pathogenic or toxic materials will persist through production to the final filling. The effectiveness of such steps can be validated by specific in-process tests and controls which can be used to alert manufacturers to potential problems. To further reduce the possibility that an undetected extraneous toxin could contaminate the product just before or during the final fill stage, a manufacturer may use production facilities and final fill equipment that can detect or enable the detection of any loss in the integrity of the production and fill processes. In addition, a method of production and detailed product characterization able to meet requirements similar to those set out in § 601.2(c) could be used to demonstrate the safety, purity, and potency of a biological product without the use of the GST. Each manufacturer will be responsible for identifying the product or products that are produced in such a manner that makes the GST unnecessary to ensure the safety, purity, and potency of the biological product. Manufacturers wishing to obtain an exemption to the GST for a particular product would contact the appropriate product division of CBER for specific information regarding how to apply and what information should be included in the application or supplemental application.

III. Rulemaking Action

In the **Federal Register** of November 21, 1997 (62 FR 62466), FDA described its procedures on when and how FDA will employ direct final rulemaking. FDA believes that this rule is appropriate for direct final rulemaking because FDA views this rule as a noncontroversial amendment and anticipates no significant adverse comments. Consistent with FDA's procedures on direct final rulemaking, FDA is publishing elsewhere in this **Federal Register** issue, a companion proposed rule to amend the existing GST rule. The companion proposed rule provides a procedural framework within which the rule may be finalized in the event the direct final rule is withdrawn because of any significant adverse comment. The comment period for the direct final rule runs concurrently with the companion proposed rule. Any comments received under the companion proposed rule will be considered as comments regarding the direct final rule.

FDA has provided a comment period on the direct final rule of 75 days after April 20, 1998. If the agency receives any significant adverse comment, FDA intends to withdraw this direct final rule action by publication in the **Federal Register** within 30 days after the comment period ends. A significant adverse comment is defined as a comment that explains why the rule would be inappropriate, including challenges to the rule's underlying premise or approach, or would be ineffective or unacceptable without a change. In determining whether a significant adverse comment is sufficient to terminate a direct final rulemaking, FDA will consider whether the comment raises an issue serious enough to warrant a substantive response in a notice-and-comment process. Comments that are frivolous, insubstantial, or outside the scope of the rule will not be considered significant or adverse under this procedure. For example, a comment requesting inclusion of additional product classes in the exceptions paragraph of the GST (§ 610.11(g)) will not be considered a significant adverse comment because it is outside the scope of this rule. A comment recommending a rule change in addition to the rule would not be considered a significant adverse comment, unless the comment states why the rule would be ineffective without additional change. In addition, if a significant adverse comment applies to part of a rule and that part can be severed form the remainder of the rule, FDA may adopt as final those parts of the rule that are not subject of a significant adverse comment.

If any significant adverse comment is received during the comment period, FDA will publish, within 30 days after the comment period ends, a document withdrawing the direct final rule. If FDA withdraws the direct final rule, all comments received will be applied to the proposed rule and will be considered in developing a final rule using the usual Administrative Procedure Act notice-and-comment procedures.

If FDA receives no significant adverse comments during the specified comment period, FDA intends to publish a confirmation document within 30 days after the comment period ends confirming that the direct final rule will go into effect on September 2, 1998.

IV. Analysis of Impacts

A. Review Under Executive Order 12866 and the Regulatory Flexibility Act

FDA has examined the impact of the direct final rule under Executive Order 12866, the Regulatory Flexibility Act (5 U.S.C. 601–612), and the Unfunded Mandates Reform Act of 1995 (Pub. L. 104–4). Executive Order 12866 directs agencies to assess all costs and benefits of available regulatory alternatives and, when regulation is necessary, to select regulatory approaches that maximize net benefits (including potential economic, environmental, public health and safety, and other advantages; distributive impact; and equity). The agency believes that this direct final rule is consistent with the regulatory philosophy and principles identified in the Executive Order. The direct final rule is a significant regulatory action as defined by the Executive Order and is subject to review under the Executive Order because it deals with a novel policy issue.

In accordance with the principles of Executive Order 12866, the result of the direct final rule will be a substantial reduction in burdens on applicants filing for approval of certain biological products

The Regulatory Flexibility Act requires agencies to analyze regulatory options that would minimize any significant impact of a rule on small business entities. Because, as stated previously, the overall result of the direct final rule will be a substantial reduction of the regulatory and reporting burdens, the agency certifies that the direct final rule will not have a significant negative economic impact on a substantial number of small entities. Therefore, under the Regulatory Flexibility Act, no further analysis is required. This rule also does not trigger the requirement for a written statement under section 202(a) of the Unfunded Mandates Reform Act because it does not impose a mandate that results in an expenditure of $100 million or more by State, local, and tribal governments in the aggregate, or by the private sector in any one year.

B. Environmental Impact

The agency has determined under 21 CFR 25.31(j) 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.

V. The Paperwork Reduction Act of 1995

This direct final rule contains information collection provisions that are subject to review by the Office of Management and Budget (OMB) under the Paperwork Reduction Act of 1995 (44 U.S.C. 3501–3520). The title, description, and respondent description of the information collection provisions are shown below with an estimate of the annual reporting burden. Included in the estimate is the time for reviewing the instructions, searching existing data sources, gathering and maintaining the data needed, and completing and reviewing each collection of information.

FDA invites comments on: (1) Whether the proposed collection of information is necessary for the proper performance of FDA's functions, including whether the information will have practical utility; (2) the accuracy of FDA's estimate of the burden of the proposed collection of information, including the validity of the methodology and assumptions used; (3) ways to enhance the quality, utility, and clarity of the information to be collected; and (4) ways to minimize the burden of the collection of information on respondents, including through the use of automated collection techniques, when appropriate, and other forms of information technology.

Title: Requests for Exemptions from the General Safety Testing Requirements for Biological Products.

Description: FDA is revising the requirements for general safety testing (GST) set forth in § 610.11. The test serves as a safety net to detect harmful contaminants that may enter or be introduced into the final container through undetected failures in the manufacture of biological products. The revision would add ''cellular therapy products'' to the list of products excepted from the GST, and add an administrative procedure for obtaining exemptions from the GST requirements for other biological products. FDA is proposing the new administrative procedure because the GST may not be feasible or appropriate for some biological products. FDA anticipates that manufacturers requesting exemptions would have a demonstrated record of GST compliance supported by long-term compliance with CGMP's, well-documented in-process safety controls, and use sophisticated analytical techniques to adequately characterize the final product and validate its safety. Manufacturers would submit their request and documentation to the Director, CBER, who may grant the exemption if it is determined that the manufacturer's submission justifies an exemption.

Description of Respondents: Manufacturers of biological products.

The direct final rule would require only those manufacturers requesting an exemption from the GST under § 610.11(g)(2) to submit additional information as part of a license application or supplement to an approved license application. Manufacturers of ''cellular therapy products'' would be excepted from the GST under § 610.11(g)(1) and thus, not have to submit an exemption request. In fact, manufacturers of cellular therapy products would be relieved of significant burdens because they would no longer be required to perform the GST and report the results to FDA. FDA estimates that annually it will receive approximately 10 requests for administrative exemption from the GST under § 610.11(g)(2). FDA estimates that 40 hours will be required for an applicant to complete and submit the appropriate information for the exemption request. Since that information is ordinarily compiled and organized by the manufacturer while performing the GST, FDA anticipates that the additional time needed to submit an exemption request will be minimal.

TABLE 1.—ESTIMATED ANNUAL REPORTING BURDEN[1]

21 CFR Section	No. of Respondents	Annual Frequency per Response	Total Annual Responses	Hours per Response	Total Hours
610.11(g)(2)	10	1	10	40	400
Total	10		10	40	400

[1] There are no capital costs or operating and maintenance costs associated with this collection of information.

As provided in 5 CFR 1320.5(c)(1), collections of information in a direct final rule are subject to the procedures set forth in 5 CFR 1320.10. Interested persons and organizations may submit comments on the information collection requirements of this direct final rule by June 19, 1998, to the Dockets Management Branch (HFA–305), Food and Drug Administration, 12420 Parklawn Dr., rm. 1–23, Rockville, MD 20857.

At the close of the 60-day comment period, FDA will review the comments received, revise the information collection provisions as necessary, and submit these provisions to OMB for review. FDA will publish a notice in the **Federal Register** when the information collection provisions are submitted to OMB, and an opportunity for public comment to OMB will be provided at that time. Prior to the effective date of the direct final rule, FDA will publish a notice in the **Federal Register** of OMB's decision to approve, modify, or disapprove the information collection provisions. An agency may not conduct or sponsor, and a person is not required to respond to, a collection of information unless it displays a currently valid OMB control number.

VI. Request for Comments

Interested persons may, on or before July 6, 1998, submit to the Docket Management Branch (address above) written comments regarding this proposal. This comment period runs concurrently with the comment period for the companion proposed rule. Two copies of any comments are to be submitted, except that individuals may submit one copy. Comments are to be identified with the docket number found in brackets in the heading of this document. Received comments may be seen in the office above between 9 a.m. and 4 p.m., Monday through Friday. All comments received will be considered comments regarding the proposed rule and this direct final rule. In the event the direct final rule is withdrawn, all comments received regarding the companion proposed rule and the direct final rule will be considered comments on the proposed rule.

List of Subjects in 21 CFR Part 610

Biologics, Labeling, Reporting and recordkeeping requirements.

Therefore under the Federal Food, Drug, and Cosmetic Act, and under authority delegated to the Commissioner of Food and Drugs, 21 CFR part 610 is amended as follows:

PART 610—GENERAL BIOLOGICAL PRODUCTS STANDARDS

1. The authority citation for 21 CFR part 610 continues to read as follows:

Authority: 21 U.S.C. 321, 351, 352, 353, 355, 360, 371; 42 U.S.C. 216, 262, 263, 263a, 264.

2. Section 610.11 is amended by revising paragraph (g) to read as follows:

§ 610.11 General safety.

* * * * *

(g) *Exceptions*—(1) The test prescribed in this section need not be performed for Whole Blood, Red Blood Cells, Cryoprecipitated AHF, Platelets, Plasma, or Cellular Therapy Products.

(2) For products other than those identified in paragraph (g)(1) of this section, a manufacturer may request from the Director, Center for Biologics Evaluation and Research, an exemption from the general safety test. The manufacturer shall submit information as part of a license application submission or supplement to an approved license application establishing that because of the mode of administration, the method of preparation, or the special nature of the product a test of general safety is unnecessary to assure the safety, purity, and potency of the product or cannot be performed. The request shall include any alternate procedures, if any, to be performed. The Director, Center for Biologics Evaluation and Research, upon finding that the manufacturer's request justifies an exemption, may exempt the product from the general safety test subject to any condition necessary to assure the safety, purity, and potency of the product.

Dated: April 10, 1998.

William B. Schultz,

Deputy Commissioner for Policy.

[FR Doc. 98–10314 Filed 4–17–98; 8:45 am]

BILLING CODE 4160–01–F

DEPARTMENT OF THE INTERIOR

Office of Surface Mining Reclamation and Enforcement

30 CFR Part 920

[MD–042–FOR]

Maryland Regulatory Program

AGENCY: Office of Surface Mining Reclamation and Enforcement (OSM), Interior.

ACTION: Final rule; approval of amendment.

SUMMARY: OSM is approving a proposed amendment to the Maryland regulatory program (hereinafter referred to as the ''Maryland program'') under the Surface Mining Control and Reclamation Act of 1977 (SMCRA). Maryland proposed revisions to the Maryland regulations regarding a reduced bond liability period for lands remined. The amendments are intended to revise the Maryland program to be consistent with the corresponding Federal regulations and SMCRA.

EFFECTIVE DATE: April 20, 1998.

FOR FURTHER INFORMATION CONTACT: George Rieger, Program Manager, OSM, Appalachian Regional Coordinating Center, 3 Parkway Center, Pittsburgh, PA 15220. Telephone: (412) 937–2153.

SUPPLEMENTARY INFORMATION:

I. Background on the Maryland Program

On December 1, 1980, the Secretary of the Interior conditionally approved the Maryland program. Background information on the Maryland program, including the Secretary's findings, the disposition of comments, and the conditions of approval can be found in the December 1, 1980, **Federal Register** (45 FR 79449). Subsequent actions concerning conditions of approval and program amendments can be found at 30 CFR 920.12, 920.15, and 920.16.

II. Submission of the Proposed Amendment

Maryland provided an informal amendment to OSM regarding a reduced bond liability period for lands remined in a letter dated August 21, 1996. OSM completed its review of the informal amendment and submitted comments to Maryland in a letter dated August 4, 1997. By letter dated October 9, 1997 (Administrative Record No. MD–579–00), Maryland submitted its response to OSM's comments in the form of a proposed amendment to its program pursuant to SMCRA. OSM's review of the proposed amendment resulted in additional questions for Maryland, to which they responded in a fax dated February 26, 1998 (Administrative Record No. 579–04).

OSM announced receipt of the proposed amendment in the November 21, 1997 **Federal Register** (62 FR 62273), and in the same document opened the public comment period and provided an opportunity for a public hearing on the adequacy of the proposed amendment. The public comment period closed on December 22, 1997.