The Proposed Amendment

Accordingly, pursuant to the authority delegated to me by the Administrator, the Federal Aviation Administration proposes to amend part 39 of the Federal Aviation Regulations (14 CFR part 39) as follows:

PART 39—AIRWORTHINESS DIRECTIVES

1. The authority citation for part 39 continues to read as follows:

Authority: 49 U.S.C. 106(g), 40113, 44701.

§ 39.13 [Amended]

2. Section 39.13 is amended by adding the following new airworthiness directive:

Gulfstream Aerospace Corporation (Formerly Grumman): Docket 97–NM–302–AD.

Applicability: All Model G–159 (G–I) airplanes, certificated in any category.

Note 1: This AD applies to each airplane identified in the preceding applicability provision, regardless of whether it has been modified, altered, or repaired in the area subject to the requirements of this AD. For airplanes that have been modified, altered, or repaired so that the performance of the requirements of this AD is affected, the owner/operator must request approval for an alternative method of compliance in accordance with paragraph (b) of this AD. The request should include an assessment of the effect of the modification, alteration, or repair on the unsafe condition addressed by this AD; and, if the unsafe condition has not been eliminated, the request should include specific proposed actions to address it.

Compliance: Required as indicated, unless accomplished previously.

To prevent loss of airplane controllability, or engine overspeed and consequent loss of engine power, caused by the power levers being positioned below the flight idle stop while the airplane is in flight, accomplish the following:

(a) For turbopropeller-powered Gulfstream Model G–159 (G–1) airplanes: Within 30 days after the effective date of this AD, revise the Limitations Section of the FAA-approved Airplane Flight Manual (AFM) to include the following statements. This action may be accomplished by inserting a copy of this AD into the AFM.

''Positioning of the propeller flight fine pitch lock selector to the ground interlock position in flight is PROHIBITED. Such positioning may lead to loss of airplane control.''

(b) An alternative method of compliance or adjustment of the compliance time that provides an acceptable level of safety may be used if approved by the Manager, FAA, Small Airplane Directorate, Atlanta Aircraft Certification Office (ACO). Operators shall submit their requests through an appropriate FAA Principal Operations Inspector, who may add comments and then send it to the Manager, Atlanta ACO.

Note 2: Information concerning the existence of approved alternative methods of compliance with this AD, if any, may be obtained from the Atlanta ACO.

(c) Special flight permits may be issued in accordance with §§ 21.197 and 21.199 of the Federal Aviation Regulations (14 CFR 21.197 and 21.199) to operate the airplane to a location where the requirements of this AD can be accomplished.

Issued in Renton, Washington, on April 21, 1998.

Darrell M. Pederson,

Acting Manager, Transport Airplane Directorate, Aircraft Certification Service.

[FR Doc. 98–11102 Filed 4–24–98; 8:45 am]

BILLING CODE 4910–13–U

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

21 CFR Part 814

[Docket No. 98N–0168]

Medical Devices; 30–Day Notices and 135–Day PMA Supplement Review; Companion Document to Direct Final Rule

AGENCY: Food and Drug Administration, HHS.

ACTION: Proposed rule.

SUMMARY: The Food and Drug Administration (FDA) is proposing to amend its regulations governing the submission and review of premarket approval application (PMA) supplements to allow for the submission of a 30-day notice for modifications to manufacturing procedures or methods of manufacture. Amendments are being made to implement revisions to the Federal Food, Drug, and Cosmetic Act (the act) as amended by the Food and Drug Administration Modernization Act of 1997 (FDAMA). This proposed rule is a companion document to the direct final rule published elsewhere in this issue of the **Federal Register**.

DATES: Submit written comments on or before July 13, 1998. Submit written comments on the information collection requirements on or before June 26, 1998.

ADDRESSES: Submit written comments on the proposed 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: Kathy M. Poneleit, Center for Devices and Radiological Health (HFZ–402), Food and Drug Administration, 9200 Corporate Blvd., Rockville, MD 20850, 301–594–2186.

SUPPLEMENTARY INFORMATION:

I. Background

This proposed rule is a companion document to the direct final rule published elsewhere in this issue of the **Federal Register**. This proposed rule is substantively identical to its companion direct final rule. The proposed rule will provide the procedural framework to finalize the rule in the event the companion direct final rule receives any significant adverse comment and is withdrawn. The comment period for this companion proposed rule runs concurrently with that for the direct final rule. All comments on this proposed rule will also be considered as comments on the companion direct final rule. FDA is publishing the direct final rule because the rule contains noncontroversial changes, and FDA anticipates that it will receive no significant adverse comments. If no significant comment is received in response to the direct final rule, no further action will be taken related to this proposed rule. Instead, FDA will publish a confirmation notice within 30 days after the comment period ends confirming that the direct final rule will go into effect on September 9, 1998. Because this rule makes noncontroversial changes to an existing regulation in order to implement changes required by FDAMA, FDA believes that publication of a direct final rule is appropriate. Additional information about FDA's direct final rulemaking procedures is set forth in a guidance published in the **Federal Register** of November 21, 1997 (62 FR 62466).

If FDA receives a significant adverse comment regarding this rule, FDA will publish a document withdrawing the direct final rule within 30 days after the comment period ends and will proceed to respond to all of the comments received under this companion rule using usual notice-and-comment procedures. The comment period for this companion proposed rule runs concurrently with the direct final rule's comment period. Any comments received under this companion proposed rule will also be considered comments regarding the direct final rule.

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 adverse under this procedure. For example, a comment recommending a rule change in addition to the rule will not be considered a significant adverse comment, unless the comment states why the rule would be ineffective without the additional change. In addition, if a significant adverse comment applies to part of a rule and that part can be severed from the remainder of the rule, FDA may adopt as final those parts of the rule that are not the subject of a significant adverse comment.

This action 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 medical devices, without diminishing the protection of public health.

On November 21, 1997, the President signed FDAMA into law. As one of its provisions, FDAMA added section 515(d)(6) to the act (21 U.S.C. 360e(d)(6)). This new section provides that PMA supplements are required for all changes that affect safety and effectiveness, unless such changes involve modifications to manufacturing procedures or method of manufacture. Those types of manufacturing changes will require a 30-day notice or, where FDA finds such notice inadequate, a 135-day PMA supplement. Examples of changes that potentially qualify for a 30-day notice are those intended by the PMA holder to reduce manufacturing and/or labor cost, reduce manufacturing time, reduce waste, or compensate for a change in suppliers of raw material or components.

Manufacturers who believe that the change they intend to make qualifies for this review will be required to submit a 30-day notice to FDA that describes in detail the change the manufacturer intends to make, summarizes the data or information supporting the change, and states that the change has been made in accordance with the requirements of part 820 (21 CFR part 820). The manufacturer may distribute the device 30 days after FDA receives the notice, unless FDA notifies the applicant within that 30-day period that the notice is not adequate. If the notice is not adequate, FDA will inform the applicant in writing that a 135-day supplement is needed and will describe what further action or information is required for FDA to approve the change. The time FDA uses to review the 30-day notice will be deducted from the 135-day supplement review period if the notice contains the appropriate information that is required for review of PMA supplements.

This rule incorporates the provisions for a 30-day notice and 135-day PMA supplements into FDA's regulations at § 814.39 (21 CFR 814.39).

The agency has developed guidance on this issue, entitled ''CDRH Guidance for 30-Day Notices and 135-Day PMA Supplements for Manufacturing Method or Process Changes for Use by OC, ODE, and Industry,'' and it has announced the availability of the guidance in the **Federal Register** of February 25, 1998 (63 FR 9570).

II. Environmental Impact

The agency has determined under 21 CFR 25.30(h) 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.

III. Analysis of Impacts

FDA has examined the impacts of this proposed rule under Executive Order 12866 and the Regulatory Flexibility Act (5 U.S.C. 601–612) (as amended by subtitle D of the Small Business Regulatory Fairness Act of 1996 (Pub. L. 104–121)), and the Unfunded Mandates Reform Act of 1995 (Pub. L. 104–4). Executive Order 12866 directs agencies to assess all costs of available regulatory alternatives and, when regulatory action is necessary, to select regulatory approaches that maximize net benefits (including potential economic, environmental, public health and safety, and other advantages; distributive impacts; and equity). The agency believes that this proposed rule is consistent with the regulatory philosophy and principles identified in the Executive Order. In addition, this proposed rule is not a significant regulatory action as defined by the Executive Order and so is not subject to review under the Executive Order.

The Regulatory Flexibility Act requires agencies to analyze regulatory options that would minimize any significant impact of a rule on small entities. The rule merely codifies applicable statutory requirements imposed by the FDAMA. 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. This proposed 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, or tribal governments in the aggregate, or by the private sector, in any 1 year.

IV. Paperwork Reduction Act of 1995

This proposed rule contains information collection provisions which are subject to review by the Office of Management and Budget (OMB) under the Paperwork Reduction Act of 1995 (the PRA) (44 U.S.C. 3501–3520). The title, description, and respondent description of the information collection provisions are shown below along with an estimate of the annual reporting burden. Included in the estimate is the time for reviewing 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: Supplements to Premarket Approval Applications for Medical Devices

Description: FDAMA (Pub. L. 105–115) added section 515(d)(6) to the act, modifying FDA's statutory authority regarding premarket approval of medical devices. This new section provides for an alternate form of notice to the agency for certain types of changes to a device for which the manufacturer has an approved PMA. Under section 515(d)(6) of the act, PMA supplements are required for all changes that affect safety and effectiveness unless such changes involve modifications to manufacturing procedures or the method of manufacture. For those types of manufacturing changes, the manufacturer may submit to the agency an alternate form of notice in the form of a 30-day notice or, where FDA finds such notice inadequate, a 135-day PMA supplement. The 30-day notice must describe the change the manufacturer

intends to make, summarize the data or information supporting the change, and state that the change has been made in accordance with the requirements of part 820.

The manufacturer may distribute the device 30 days after FDA receives the notice, unless FDA notifies the applicant, within that 30-day period, that the notice is inadequate. If the notice is not adequate, FDA will inform the manufacturer that a 135-day supplement is required and will describe what additional information or action is necessary for FDA to approve the change.

This rule would incorporate the provisions for a 30-day notice and 135-day supplements into FDA's regulations at § 814.39 to reflect the changes made by FDAMA.

Description of Respondents: Businesses or other for profit organizations.

The information collection for § 814.39 has been approved by OMB until September 30, 1998, under Premarket Approval of Medical Devices, OMB Control Number 0910–0231, for a total of 36,063 hours. FDA believes that the submission of 30-day notices in lieu of PMA supplements will result in approximately a 10 percent reduction in total number of hours needed to comply with § 814.39. As a result, FDA estimates that the new total number of hours needed to comply with the information collection requirements in § 814.39 is 32,612 for a reduction of 3,451 hours.

FDA estimates the burden for this collection of information as follows:

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
814.39	493	1	493	66.15	32,612

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

FDA believes that the proposed amendments to § 814.39 permitting the submission of 30-day notices in lieu of PMA supplements would result in approximately a 10-percent reduction in the total number of hours needed to comply as compared to § 814.39 prior to these proposed amendments. As a result, FDA estimates that the new total number of hours that would be needed to comply with the information collection requirements in § 814.39 is 32,612, for a reduction of 3,451 hours.

For consistency with the direct final rule to which this proposed rule is a companion, FDA is following the PRA comment procedures for direct final rules in this proposed rule. As provided in 5 CFR 1320.5(c)(1), collections of information in a direct final rule is 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 proposed rule by June 26, 1998 to the Dockets Management Branch (address above).

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.

V. Comments

Interested persons may, by July 13, 1998, submit to the Dockets Management Branch (address above) written comments regarding this proposal. This comment period runs concurrently with the comment period for the direct final 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 the 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 as comments regarding the direct final rule and this proposed rule. In the event the direct final rule is withdrawn, all comments received will be considered comments on this proposed rule.

List of Subjects in 21 CFR Part 814

Administrative practice and procedure, Confidential business information, Medical devices, Medical research, Reporting and recordkeeping requirements.

Therefore, under the Federal Food, Drug, and Cosmetic Act, and under the authority delegated to the Commissioner of the Food and Drugs, 21 CFR part 814 is amended as follows:

PART 814—PREMARKET APPROVAL OF MEDICAL DEVICES

1. The authority citation for 21 CFR part 814 continues to read as follows:

Authority: 21 U.S.C. 351, 352, 353, 360, 360c-360j, 371, 372, 373, 374, 375, 379, 379e, 381.

2. Section 814.39 is amended by revising paragraph (a) introductory text and paragraph (a)(4) and by adding paragraph (f) to read as follows:

§ 814.39 PMA supplements.

(a) After FDA's approval of a PMA, an applicant shall submit a PMA supplement for review and approval by FDA before making a change affecting the safety or effectiveness of the device for which the applicant has an approved PMA, unless the change is of a type for which FDA, under paragraph (e) of this section, has advised that an alternate submission is permitted or is of a type which, under section 515(d)(6)(A) of the act and paragraph (f) of this section, does not require a PMA supplement under this paragraph. While the burden for determining whether a supplement is required is primarily on the PMA holder, changes for which an applicant shall submit a PMA supplement include, but are not limited to, the following types of changes if they affect the safety or effectiveness of the device:

* * * * *

(4) Changes in manufacturing facilities, methods, or quality control procedures that do not meet the requirements for a submission under paragraph (e) or (f) of this section.

* * * * *

(f) Under section 515(d) of the act, modifications to manufacturing procedures or methods of manufacture that affect the safety and effectiveness of a device subject to an approved PMA do not require submission of a PMA supplement under paragraph (a) of this

section and are eligible to be the subject of a a 30-day notice. A 30-day notice shall describe in detail the change, summarize the data or information supporting the change, and state that the change has been made in accordance with the requirements of 21 CFR part 820. The manufacturer may distribute the device 30 days after the date on which FDA receives the 30-day notice, unless FDA notifies the applicant within 30 days from receipt of the notice that the notice is not adequate. If the notice is not adequate, FDA shall inform the applicant that a 135-day PMA supplement is needed and shall describe what further information or action is required for acceptance of such change. The number of days under review as a 30-day notice shall be deducted from the 135-day PMA supplement review period if the notice meets appropriate content requirements for a PMA supplement.

Dated: March 24, 1998.

William B. Schultz,

Deputy Commissioner for Policy.

[FR Doc. 98–11085 Filed 4–24–98; 8:45 am]

BILLING CODE 4160–01–F

DEPARTMENT OF THE INTERIOR

Office of Surface Mining Reclamation and Enforcement

30 CFR Part 917

[KY–217–FOR]

Kentucky Regulatory Program; Reopening of Public Comment Period

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

ACTION: Proposed rule; reopening of public comment period.

SUMMARY: OSM is reopening the public comment period on a proposed amendment to the Kentucky regulatory program (hereinafter the ''Kentucky program'') under the Surface Mining Control and Reclamation Act of 1977 (SMCRA). Kentucky submitted a letter requesting the removal of an amendment at 30 CFR 917.17(a) which required that it maintain a staffing level of 156 field inspectors and, in the same letter, provided justification for its request. The amendment is intended to revise the Kentucky program to be consistent with the corresponding Federal regulations.

DATES: Written comments must be received by 4:00 p.m., [E.D.T.], May 12, 1998.

ADDRESSES: Written comments and requests to speak at the hearing should be mailed or hand delivered to William J. Kovacic, Director, at the address listed below.

Copies of the Kentucky program, the proposed amendment, a listing of any scheduled public hearings, and all written comments received in response to this document will be available for public review at the addresses listed below during normal business hours, Monday through Friday, excluding holidays. Each requester may receive one free copy of the proposed amendment by contacting OSM's Lexington Field Office.

William J. Kovacic, Director, Lexington Field Office, Office of Surface Mining Reclamation and Enforcement, 2675 Regency Road, Lexington, Kentucky 40503, Telephone: (606) 233–2494

Department of Surface Mining Reclamation and Enforcement, 2 Hudson Hollow Complex, Frankfort, Kentucky 40601, Telephone: (502) 564–6940.

FOR FURTHER INFORMATION CONTACT: William J. Kovacic, Director, Lexington Field Office, Telephone: (606) 233–2494.

SUPPLEMENTARY INFORMATION:

I. Background on the Kentucky Program

On May 18, 1982, the Secretary of the Interior conditionally approved the Kentucky program. Background information on the Kentucky program, including the Secretary's findings, the disposition of comments, and the conditions of approval can be found in the May 18, 1982, **Federal Register** (47 FR 21404). Subsequent actions concerning the conditions of approval and program amendments can be found at 30 CFR 917.11, 917.13, 917.15, 917.16, and 917.17.

II. Description of the Proposed Amendment

By letter dated November 3, 1997 (Administrative Record No. KY–1418), Kentucky submitted a proposed amendment to its program requesting the removal of an amendment at 30 CFR 917.17(a) requiring that Kentucky maintain a staffing level of 156 field inspectors. In the same letter, Kentucky provided the following justification for its request:

1. Field inspector staffing levels are no longer based on 1984 inspection numbers and budgetary needs.

2. A study performed during the National Wildlife Federation Settlement Agreement determined that a cap of 24 inspectable units per field inspector should be established.

3. OSM has accepted the limits set by the study in determining inspection staff levels as indicated by the approval of Title V administrative and enforcement grants.

4. OSM's annual reports indicate that Kentucky's Title V regulatory program consistently meets high inspection frequency levels.

Kentucky also maintains that using a fixed number of field inspectors fails to provide the latitude necessary to adapt its inspection force to changing conditions in the coal industry. Further, the number of inspectors Kentucky maintains is based on the current and ever-changing number of inspectable units.

The proposed amendment was announced in the December 10, 1997, **Federal Register** (62 FR 65044). The notice did not clarify that Kentucky submitted documents that provide evidence that it has sufficient inspection and enforcement staffing levels to regulate mining in accordance with SMCRA. Those documents are: ''Historical Information on Kentucky's Surface Mining Primacy Program,'' complied by Kentucky, July 1997 (Administrative Record No. KY–1418); ''Review of Current Staffing and Funding Levels,'' prepared by the OSM Lexington Field Office, December 1997 (Administrative Record No. KY–1420); and ''Inspection Resources Study,'' prepared by OSM and Kentucky, August 1989 (Administrative Record No. KY–1418).

III. Public Comment Procedures

In accordance with the provisions of 30 CFR 732.17(h), OSM is seeking comments on whether the proposed amendment satisfies the applicable program approval criteria of 30 CFR 732.15. If the amendment is deemed adequate, it will become part of the Kentucky program.

Written Comments

Written comments should be specific, pertain only to the issues proposed in this rulemaking, and include explanations in support of the commenter's recommendations. Comments received after the time indicated under **DATES** or at locations other than the Lexington Field Office will not necessarily be considered in the final rulemaking or included in the Administrative Record.

IV. Procedural Determinations

Executive Order 12866

This rule is exempted from review by the Office of Management and Budget (OMB) under Executive Order 12866 (Regulatory Planning and Review).