DEPARTMENT OF TRANSPORTATION

Federal Aviation Administration

14 CFR Part 71

[Airspace Docket No. 98–ACE–4]

Amendment to Class D and Class E Airspace; Joplin, MO; Correction

AGENCY: Federal Aviation Administration, DOT.

ACTION: Direct final rule; confirmation of effective date and correction.

SUMMARY: This notice confirms the effective date of a direct final rule which revises Class D and Class E airspace at Joplin Regional Airport, MO, and corrects the Airport Reference Point, as published in the direct final rule.

DATES: The direct final rule published at 63 FR 8093 is effective on 0901 UTC, June 18, 1998. This correction is effective on June 18, 1998.

FOR FURTHER INFORMATION CONTACT: Kathy Randolph, Air Traffic Division, Airspace Branch, ACE–520C, Federal Aviation Administration, 601 East 12th Street, Kansas City, Missouri 64106; telephone: (816) 426–3408.

SUPPLEMENTARY INFORMATION: On February 18, 1998, the FAA published in the **Federal Register** a direct final rule; request for comments which modified the Class D and Class E airspace at Joplin Regional Airport, MO (FR Document 98–3964, 63 FR 8093, Airspace Docket No. 98–ACE–4). An error was subsequently discovered in the Airport Reference Point for Class D and Class E airspace designations. After careful review of all available information related to the subject presented above, the FAA has determined that air safety and the public interest required adoption of the rule. The FAA has determined that this correction will not change the meaning of the action nor add any additional burden on the public beyond that already published. This action corrects the error and confirms the effective date of the direct final rule.

The FAA uses the direct final rulemaking procedure for a non-controversial rule where the FAA believes that there will be no adverse public comment. This direct final rule advised the public that no adverse comments were anticipated, and that unless a written adverse comment, or a written notice of intent to submit such an adverse comment, were received within the comment period, the regulation would become effective on June 18, 1998. No adverse comments were received, and thus this notice confirms that this direct final rule will become effective on that date.

Correction

In rule FR Doc. 98–3964 published in the **Federal Register** on February 18, 1998, 63 FR 8093, make the following correction to the Joplin Regional Airport, MO, Class D and Class E airspace designation incorporated by reference in 14 CFR 71.1:

§ 71.1 [Corrected]

ACE MO D Joplin, MO [Corrected]

On page 8095, in the first column, under Joplin Regional Airport, MO, change (lat. 37°09′05″ N., long. 94°29′54″ W.) to read (lat. 37°09′07″ N., long. 94°29′54″ W.)

ACE MO E2 Joplin, MO [Corrected]

On page 8095, in the first column, under Joplin Regional Airport, MO, change (lat. 37°09′05″ N., long. 94°29′54″ W.) to read (lat. 37°09′07″ N., long. 94°29′54″ W.)

ACE MO E5 Joplin, MO [Corrected]

On page 8095, in the first column, under Joplin Regional Airport, MO, change (lat. 37°09′05″ N., long. 94°29′54″ W.) to read (lat. 37°09′07″ N., long. 94°29′54″ W.)

Issued in Kansas City, MO on March 31, 1998.

Christopher R. Blum,

Acting Manager, Air Traffic Division, Central Region.

[FR Doc. 98–11127 Filed 4–24–98; 8:45 am]

BILLING CODE 4910–13–M

DEPARTMENT OF TRANSPORTATION

Federal Aviation Administration

14 CFR Part 71

[Airspace Docket No. 98–ACE–3]

Amendment to Class E Airspace; Columbia, MO

AGENCY: Federal Aviation Administration, DOT.

ACTION: Direct final rule; confirmation of effective date.

SUMMARY: This notice confirms the effective date of a direct final rule which revises Class E airspace at Columbia, MO.

DATES: The direct final rule published at 63 FR 8097 is effective on 0901 UTC, June 18, 1998.

FOR FURTHER INFORMATION CONTACT: Kathy Randolph, Air Traffic Division, Airspace Branch, ACE–520C, Federal Aviation Administration, 601 East 12th Street, Kansas City, Missouri 64106; telephone: (816) 426–3408.

SUPPLEMENTARY INFORMATION: The FAA published this direct final rule with a request for comments in the **Federal Register** on February 18, 1998 (63 FR 8097). The FAA uses the direct final rulemaking procedure for a non-controversial rule where the FAA believes that there will be no adverse public comment. This direct final rule advised the public that no adverse comments were anticipated, and that unless a written adverse comment, or a written notice of intent to submit such an adverse comment, were received within the comment period, the regulation would become effective on June 18, 1998. No adverse comments were received, and thus this notice confirms that this direct final rule will become effective on that date.

Issued in Kansas City, MO on March 31, 1998.

Christopher R. Blum,

Acting Manager, Air Traffic Division, Central Region.

[FR Doc. 98–11128 Filed 4–24–98; 8:45 am]

BILLING CODE 4910–13–M

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

AGENCY: Food and Drug Administration, HHS.

ACTION: Direct final rule.

SUMMARY: The Food and Drug Administration (FDA) is amending 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). FDA is publishing these amendments in accordance with its direct final rule procedures. Elsewhere in this issue of the **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 the direct final rule.

DATES: The direct final rule is effective September 9, 1998. Submit written comments on or before July 13, 1998. Submit written comments on the information collection requirements on or before June 26, 1998. If FDA receives no significant adverse comment within the specified comment period, the agency intends to publish a document confirming the effective date of the final rule in the **Federal Register** within 30 days after the comment period on this direct final rule ends.

ADDRESSES: Submit written comments 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.

On November 21, 1997, the President signed FDAMA (Pub. L. 105–115) 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. Rulemaking Action

In the **Federal Register** of November 21, 1997 (62 FR 62466), FDA described when and how it will employ direct final rulemaking. FDA believes that this rule is appropriate for direct final rulemaking because FDA views this rule as making noncontroversial amendments to an existing rule, incorporating amendments to section 515 of the act made by FDAMA. FDA anticipates no significant adverse comment on this rule. Consistent with FDA's procedures on direct final rulemaking, FDA is publishing elsewhere in this issue of the **Federal Register** a companion proposed rule to amend 21 CFR part 814. This direct final rule is substantively identical to the companion proposed 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 a significant adverse comment. The comment period for the direct final rule runs concurrently with that for the companion proposed rule. Any comments received on the companion proposed rule will be treated as comments on the direct final rule.

FDA is providing a comment period on the direct final rule of 75 days after April 27, 1998. If the agency receives a significant adverse comment, FDA intends to withdraw this final rule by publication of a notice in the **Federal Register** within 30 days after the comment period ends. A significant 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 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. For example, a comment recommending an additional change to the rule may be considered a significant adverse comment if the comment demonstrates 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. Comments that are frivolous, insubstantial, or outside the scope of the rule will not be considered significant or adverse under this procedure.

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 agency's usual notice and comment procedures. If FDA receives no significant adverse comment during the specified comment period, FDA intends to 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.

III. Environmental Impact

The agency has determined under 21 CFR 25.30(h) that this action is of a type that does not 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 this final 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 final rule is consistent with the regulatory philosophy and principles identified in the Executive Order. In addition, this direct final 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 direct final 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.

V. 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 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 the agency'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 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 this section, 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 incorporates 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.

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

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 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.

VI. Comments

Interested persons may by July 13, 1998, submit to the Dockets Management Branch (address above) written comments regarding this rule. 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 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 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 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 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 the introductory text of paragraph (a) 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 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 in writing 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. 98–11086 Filed 4–24–98; 8:45 am]

BILLING CODE 4160–01–F

DEPARTMENT OF JUSTICE

Office of the Attorney General

28 CFR Part 0

[Order No. 2147–98]

Delegation of Power of the Attorney General Respecting Transfer of Offenders To or From Foreign Countries

AGENCY: Department of Justice.

ACTION: Final rule.

SUMMARY: Section 0.64–2 of Title 28, Code of Federal Regulations, delegates to the Assistant Attorney General in charge of the Criminal Division all of the powers conferred on the Attorney General under 18 U.S.C. 4102 that have not been delegated to the Director of the Bureau of Prisons, including the authority to find appropriate or inappropriate the transfer of offenders to or from a foreign country under a treaty as referred to in Pub. L. 95–144. The section also authorizes the Assistant Attorney General in charge of the Criminal Division to redelegate this authority to the Deputy Assistant Attorneys General of the Criminal Division, the Senior Associate Director of the Office of Enforcement Operations in the Criminal Division, and, in the Senior Associate Director's absence, to the Director of the Office of Enforcement Operations. This final rule amends 28 CFR 0.64–2 by authorizing the Assistant Attorney General in charge of the Criminal Division to additionally redelegate this authority to the Director of the Office of Enforcement Operations and the Associate Directors of the Office of Enforcement Operations, and eliminating the requirement that the Senior Associate Director of the Office of Enforcement Operations be absent for this further redelegation to be effective. This rule is intended to provide greater flexibility within the Office of Enforcement Operations with respect to the management of the prisoner transfer program, reflecting an increase in both the number and complexity of our treaty relationships, and the related workload handled by the Office of Enforcement Operations.

EFFECTIVE DATE: April 15, 1998.

FOR FURTHER INFORMATION CONTACT: Frederick D. Hess, Director, Office of Enforcement Operations, Criminal Division, Department of Justice, Washington, DC 20530; 202–514–6809.

SUPPLEMENTARY INFORMATION: The Assistant Attorney General currently is authorized under 28 CFR 0.65–02 to redelegate his authority to find appropriate or inappropriate the transfer of offenders to or from a foreign country under certain treaties to his Deputy Assistant Attorneys General, the Senior Associate Director, Office of Enforcement Operations, and, in the absence of the Senior Associate Director, the Director of the Office of Enforcement Operations. This final rule permits redelegation of this authority to the Director and Associate Directors of the Office of Enforcement Operations, regardless of whether the Senior Associate Director is absent.

This rule is a matter of internal Department management.

It has been drafted and reviewed in accordance with section 1(b) of Executive Order 12866. It has been determined that this rule is not a ''significant regulatory action'' under section 3(f) of Executive Order 12866 and, accordingly, this rule has not been reviewed by the Office of Management and Budget, and no regulatory impact analysis has been prepared.

In accordance with the Regulatory Flexibility Act (5 U.S.C. 601–612; specifically at section 605(b)), the Attorney General has reviewed this rule and, by approving it, certifies that it will not have a significant economic impact on a substantial number of small entities.

This rule will not have a substantial direct impact upon the states, on the relationship between the national government and the states, or on the distribution of power and responsibilities among the various