

Alternative Methods of Compliance (AMOCs)

(j)(1) The Manager, Seattle Aircraft Certification Office, FAA, ATTN: Nick Wilson, Aerospace Engineer, Cabin Safety and Environmental Systems Branch, ANM-150S, 1601 Lind Avenue, SW., Renton, Washington 98057-3356; telephone (425) 917-6476; fax (425) 917-6590; has the authority to approve AMOCs for this AD, if requested using the procedures found in 14 CFR 39.19.

(2) To request a different method of compliance or a different compliance time for this AD, follow the procedures in 14 CFR 39.19. Before using any approved AMOC on any airplane to which the AMOC applies, notify your appropriate principal inspector (PI) in the FAA Flight Standards District Office (FSDO), or lacking a PI, your local FSDO.

Issued in Renton, Washington, on January 31, 2008.

Ali Bahrami,

Manager, Transport Airplane Directorate, Aircraft Certification Service.

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DEPARTMENT OF TRANSPORTATION

Federal Aviation Administration

14 CFR Part 39

[Docket No. 2003-NM-33-AD]

RIN 2120-AA64

Airworthiness Directives; Empresa Brasileira de Aeronautica S.A. (EMBRAER) Model EMB-120, -120ER, -120FC, -120QC, and -120RT Airplanes

AGENCY: Federal Aviation Administration, DOT.

ACTION: Supplemental notice of proposed rulemaking; reopening of comment period.

SUMMARY: This document revises an earlier proposed airworthiness directive (AD), applicable to all EMBRAER Model EMB-120 series airplanes, that would have required revising the airplane flight manual to include operational limitations for use of the autopilot, and installing two placards that advise the flight crew to check the pitch trim before descent. This new action would retain the original requirements, but with revised placard language. This new action would also require modifying the elevator trim system, which would terminate the requirements of the AD. The actions specified by this new proposed AD are intended to prevent pitch trim upsets if the pitch trim actuators jam or freeze, which could result in reduced controllability of the

airplane. This action is intended to address the identified unsafe condition.

DATES: Comments must be received by March 4, 2008.

ADDRESSES: Submit comments in triplicate to the Federal Aviation Administration (FAA), Transport Airplane Directorate, ANM-114, Attention: Rules Docket No. 2003-NM-33-AD, 1601 Lind Avenue, SW., Renton, Washington 98057-3356. Comments may be inspected at this location between 9 a.m. and 3 p.m., Monday through Friday, except Federal holidays. Comments may be submitted via fax to (425) 227-1232. Comments may also be sent via the Internet using the following address: 9-anm-nprmcomment@faa.gov. Comments sent via fax or the Internet must contain "Docket No. 2003-NM-33-AD" in the subject line and need not be submitted in triplicate. Comments sent via the Internet as attached electronic files must be formatted in Microsoft Word 97 or 2000 or ASCII text.

The service information referenced in the proposed rule may be obtained from Empresa Brasileira de Aeronautica S.A. (EMBRAER), P.O. Box 343—CEP 12.225, Sao Jose dos Campos—SP, Brazil. This information may be examined at the FAA, Transport Airplane Directorate, 1601 Lind Avenue, SW., Renton, Washington.

FOR FURTHER INFORMATION CONTACT: Dan Rodina, Aerospace Engineer, International Branch, ANM-116, FAA, Transport Airplane Directorate, 1601 Lind Avenue, SW., Renton, Washington 98057-3356; telephone (425) 227-2125; fax (425) 227-1149.

SUPPLEMENTARY INFORMATION:

Comments Invited

Interested persons are invited to participate in the making of the proposed rule by submitting such written data, views, or arguments as they may desire. Communications shall identify the Rules Docket number and be submitted in triplicate to the address specified above. All communications received on or before the closing date for comments, specified above, will be considered before taking action on the proposed rule. The proposals contained in this action may be changed in light of the comments received.

Submit comments using the following format:

- Organize comments issue-by-issue. For example, discuss a request to change the compliance time and a request to change the service bulletin reference as two separate issues.

- For each issue, state what specific change to the proposed AD is being requested.

- Include justification (e.g., reasons or data) for each request.

Comments are specifically invited on the overall regulatory, economic, environmental, and energy aspects of the proposed rule. All comments submitted will be available, both before and after the closing date for comments, in the Rules Docket for examination by interested persons. A report summarizing each FAA-public contact concerned with the substance of this proposal will be filed in the Rules Docket.

Commenters wishing the FAA to acknowledge receipt of their comments submitted in response to this action must submit a self-addressed, stamped postcard on which the following statement is made: "Comments to Docket Number 2003-NM-33-AD." The postcard will be date stamped and returned to the commenter.

Availability of NPRMs

Any person may obtain a copy of this NPRM by submitting a request to the FAA, Transport Airplane Directorate, ANM-114, Attention: Rules Docket No. 2003-NM-33-AD, 1601 Lind Avenue SW., Renton, Washington 98057-3356.

Discussion

A proposal to amend part 39 of the Federal Aviation Regulations (14 CFR part 39) to add an airworthiness directive (AD), applicable to all EMBRAER Model EMB-120 series airplanes, was published as a notice of proposed rulemaking (NPRM) in the **Federal Register** on April 1, 2003 (68 FR 15684). That NPRM would have required revising the airplane flight manual to include operational limitations for use of the autopilot, and installing two placards that advise the flight crew to check the pitch trim before descent. That NPRM was prompted by pitch trim upsets during the autopilot-coupled descent phase of flight, which have been attributed to jammed or frozen pitch trim actuators. That condition, if not corrected, could result in reduced controllability of the airplane.

New Relevant Service Information

The original NPRM cited EMBRAER Service Bulletin 120-25-0262, dated October 15, 2001, and Change 01, dated September 3, 2002, as the appropriate sources of service information for installing the placards. Since we issued the original NPRM, EMBRAER revised the service bulletin. Change 02, dated October 30, 2003, recommends revised

placard language that clarifies that the pitch trim system is to be checked only before the initial descent.

EMBRAER has issued Service Bulletins 120-27-0095 and 120-27-0096, both dated February 16, 2007, which describe procedures for modifying the elevator trim system. Service Bulletin 120-27-0095 describes procedures for replacing the elevator trim tab actuators with new ones that have been developed using corrosion-resistant internal materials and other improvements, including a damper coupled to one of the two actuators. Service Bulletin 120-27-0096 describes procedures for replacing some segments of the elevator trim tab control cables. The replacement segments have a different diameter, and have been developed to contribute to the new actuator dampening function specified in Service Bulletin 120-27-0095.

Accomplishing the actions specified in the service information is intended to adequately address the unsafe condition. The Agência Nacional de Aviação Civil (ANAC), which is the airworthiness authority for Brazil, mandated the service information and issued Brazilian airworthiness directive 2001-06-01R4, effective August 23, 2007, to ensure the continued airworthiness of these airplanes in Brazil.

Comments

Due consideration has been given to the comments received in response to the original NPRM.

Support for Original NPRM

SkyWest Airlines concurs with the proposed requirement to revise the Limitations section of the Collins APS-65B Autopilot AFM Supplement. The Air Line Pilots Association (ALPA) concurs (conditionally, based on its comments as discussed below) with the proposed actions.

Request for Appropriate Solution for Mechanical Problem

ALPA asserts that the original NPRM would implement an operational fix to address a mechanical problem, and requests that we revise the original NPRM to adequately correct the unsafe condition. ALPA notes that the original NPRM addresses pitch trim actuators that freeze in position when moisture accumulates at colder temperatures. ALPA requests that the FAA and EMBRAER identify the extent of water intrusion in this area and look into a mechanical means to preclude the actuators from jamming. ALPA also notes that the original NPRM does not identify the cause of the jammed pitch

trim actuators. ALPA explains that pitch trim actuators have become mechanically jammed on other EMBRAER aircraft due to insufficient power available from the actuator. If the cause of the jamming can be mechanical, ALPA requests that the FAA and the manufacturer identify a means to preclude such a failure.

We agree. In this supplemental NPRM, we consider the AFM revisions and placards to be interim solutions, and propose to also mandate the modifications described in Service Bulletins 120-27-0095 and 120-27-0096, which would terminate the proposed requirements to revise the AFM and install the placards.

Assertion Regarding Jamming Conditions

The commenter, Thomas Kuhlman, states that the original NPRM apparently assumes that all or most of the jamming occurs during cruise flight. Mr. Kuhlman instead asserts, based on the supportive data that accompany his comment, that the pitch trim actuator jamming can and does occur when moisture is present in freezing conditions.

Although Mr. Kuhlman makes no specific request regarding the original NPRM's proposed requirements, we agree with his rationale. When actuator internal frictions are within their normal specified ranges, the system can manage normal envelope load increases attributed to events such as speed variations and cold soak environment icing, so a jam attributable solely to a cold soak environment is unlikely. If contamination is gradually occurring inside the actuators, the proposed manual checks of the pitch trim systems on initial descent on every flight will inform the flight crew of degraded system performance, and affected actuators would then be removed before they reach a condition that could lead to a complete jam. In any event, as stated previously, we have revised this supplemental NPRM to require modifications that will adequately address the commenter's concerns.

Request To Allow Autopilot Re-Engagement Under Certain Conditions

SkyWest concurs with the proposed requirement in the original NPRM to revise the elevator trim jamming procedure specified in the flight controls failure paragraph of the AFM abnormal procedures section, but requests that we allow the flight crew to re-engage the autopilot once pitch trim is recovered. The commenter asserts that SkyWest's experience suggests that, once normal elevator trim operation was

restored, continued use of the autopilot did not result in any abnormal operation.

We disagree. When free pitch trim is restored after jamming, the appropriate approach is to continue the flight manually without the autopilot and report the issue to maintenance, rather than re-engaging the autopilot, so the cause of the jam can be evaluated and corrected before further use of the autopilot. We have not changed the supplemental NPRM regarding this issue.

Request To Revise AFM Normal Procedures

SkyWest reports that its EMB-120 SOP already includes an advisory to check the pitch trim before initiating a descent if trim jamming is suspected. The commenter requests that we revise the original NPRM to include these revised procedures in the descent checklist in the AFM's normal procedures section.

We acknowledge that conducting such checks whenever a trim system jam is suspected is a reasonable practice. But conducting such manual checks of the pitch trim system at every flight before initial descent on autopilot is a more effective approach because it will detect jamming before it is suspected. We have not changed the supplemental NPRM regarding this issue.

Request To Revise Placard Language

SkyWest asserts that the placard language proposed in the original NPRM, which specifies a check before any (all) descents, will compromise the safe operation of Model EMB-120 airplanes. The commenter reports that it is not unusual to level off at intermediate altitudes four to eight times during descent from cruise altitude and approach, depending on cruise altitude, terminal area requirements, and type of approach. As a result, the proposed limitation would require the pilot to disconnect the autopilot during flight an equal number of times, including just before ILS glide slope intercept. The commenter requests that we change the proposed placard language to the following: "Perform pitch trim system check prior to initial descent and anytime elevator trim jamming is suspected." According to the commenter, limiting the checks in this way would ensure that the check is completed at least once per flight (consistent with EMBRAER's recommendations from the 2002 World Wide Operators Conference), but mandating a check before every descent would create a distraction,

unnecessarily increase pilot workload, and compromise safety.

We partially agree. EMBRAER has revised the placard language to require trim system checks only before initial descent. Manually checking the system when jamming is suspected would be a natural reaction, so it is not necessary to add the extra requested words to the placard. We have revised paragraph (c) in this supplemental NPRM to mandate Change 02 of the service bulletin.

Request To Remove Placard Requirement: Potential Pilot Distraction

The commenter, Thomas Kuhlman, feels that the proposed requirement to test the trim system before every descent could result in little effect, or even decreased safety due to pilot distraction, during arrival procedures with multiple descents. He also notes that most precision approaches have a level flight segment just before glide slope intercept. The AD as proposed would require an elevator trim test at the critical glide slope intercept.

We infer the commenter wants us to remove the proposed requirement to install the placards. We partially agree. We agree with the manufacturer's recommendation to check the system manually before initial descent only. As we stated previously, the placard language has been revised in Change 02 of Service Bulletin 120-25-0262, and in corresponding paragraph (c) of this supplemental NPRM, to clarify that such checks are necessary only before the initial descent of every flight. Limiting the number of checks in this

way would maintain the safety of the fleet and still address the commenter's concern about potential pilot distraction during critical phases of flight.

Request To Remove Placard Requirement: Inadequate Solution

The commenter, SkyWest Airlines, states that merely installing the placards as proposed in the original NPRM would not adequately address the problem of elevator trim jamming. The commenter notes that this procedure would be inconsistent with its findings: In the 18 months before the original NPRM was issued, there were ten incidents involving elevator trim jamming; of these, four occurred in the descent phase of flight, four occurred in the cruise phase of flight, and two occurred during climb to cruise altitude. The commenter concludes that advising the flight crew to perform a pitch trim check only during descent will not prevent problems associated with pitch upset.

We infer that the commenter wants us to require revised procedures during other phases of flight. We partially agree. We agree that the pitch trim can jam during any phase of flight. But while the data provided by SkyWest might reflect results for SkyWest, the fleet data suggest that most of the reported events occurred during the descent phase or during transition from cruise to descent. The possibility that a pitch trim jam can occur during any flight phase does not render the proposed approach ineffective. The

multiple system checks will assist in reducing the possibility of a pitch oscillation event due to actuator performance degradation. Since the comment was submitted, we revised this supplemental NPRM to add the modifications of the elevator trim system, which will address the identified unsafe condition and eliminate the need for the placards.

Explanation of Additional Changes to Original NPRM

We have revised the applicability identified in the original NPRM to identify model designations as published in the most recent type certificate data sheet for the affected models.

To correspond with the ANAC AD, we have revised paragraph (b) of this supplemental NPRM to specify that the revised AFM language in that paragraph also be included in the Normal Procedures section (in addition to the Limitations section) of the autopilot system supplement.

Conclusion

Since certain changes described above expand the scope of the originally proposed rule, the FAA has determined that it is necessary to reopen the comment period to provide additional opportunity for public comment.

Cost Impact

The following table provides the estimated costs for U.S. operators to comply with this supplemental NPRM.

ESTIMATED COSTS

| Action | Work hours | Average labor rate per hour | Parts | Cost per product | Number of U.S.-registered airplanes | Fleet cost |
|----------------------------|------------|-----------------------------|--------|------------------|-------------------------------------|------------|
| AFM revisions | 1 | \$80 | \$0 | \$80 | 103 | \$8,240 |
| Placard installation | 2 | 80 | 182 | 342 | 103 | 35,226 |
| Actuator replacement | 7 | 80 | 16,670 | 17,230 | 103 | 1,774,690 |
| Cable replacement | 14 | 80 | 1,050 | 2,170 | 103 | 223,510 |

The cost impact figures discussed above are based on assumptions that no operator has yet accomplished any of the proposed requirements of this AD action, and that no operator would accomplish those actions in the future if this proposed AD were not adopted. The cost impact figures discussed in AD rulemaking actions represent only the time necessary to perform the specific actions actually required by the AD. These figures typically do not include incidental costs, such as the time required to gain access and close up,

planning time, or time necessitated by other administrative actions.

Authority for This Rulemaking

Title 49 of the United States Code specifies the FAA's authority to issue rules on aviation safety. Subtitle I, Section 106, describes the authority of the FAA Administrator. Subtitle VII, Aviation Programs, describes in more detail the scope of the Agency's authority.

We are issuing this rulemaking under the authority described in Subtitle VII, Part A, Subpart III, Section 44701,

"General requirements." Under that section, Congress charges the FAA with promoting safe flight of civil aircraft in air commerce by prescribing regulations for practices, methods, and procedures the Administrator finds necessary for safety in air commerce. This regulation is within the scope of that authority because it addresses an unsafe condition that is likely to exist or develop on products identified in this rulemaking action.

Regulatory Impact

The regulations proposed herein would not have a substantial direct effect on the States, on the relationship between the national Government and the States, or on the distribution of power and responsibilities among the various levels of government. Therefore, it is determined that this proposal would not have federalism implications under Executive Order 13132.

For the reasons discussed above, I certify that this proposed regulation (1) is not a "significant regulatory action" under Executive Order 12866; (2) is not a "significant rule" under the DOT Regulatory Policies and Procedures (44 FR 11034, February 26, 1979); and (3) if promulgated, will not have a significant economic impact, positive or negative, on a substantial number of small entities under the criteria of the Regulatory Flexibility Act. A copy of the draft regulatory evaluation prepared for this action is contained in the Rules Docket. A copy of it may be obtained by

contacting the Rules Docket at the location provided under the caption **ADDRESSES**.

List of Subjects in 14 CFR Part 39

Air transportation, Aircraft, Aviation safety, Safety.

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:

Empresa Brasileira De Aeronautica S.A. (Embraer): Docket 2003–NM–33–AD.

Applicability: All Model EMB–120, –120ER, –120FC, –120QC, and –120RT airplanes, certificated in any category.

Compliance: Required as indicated, unless accomplished previously.

To prevent pitch trim upsets if the pitch trim actuators jam or freeze, which could result in reduced controllability of the airplane, accomplish the following:

Revision of Airplane Flight Manual (AFM): AFM–120/794

(a) Within 100 flight hours after the effective date of this AD, revise the FAA-approved AFM, EMBRAER AFM–120/794, as specified in paragraphs (a)(1) and (a)(2) of this AD. These actions may be accomplished by inserting a copy of this AD into the AFM.

(1) Revise the FLIGHT CONTROLS FAILURES paragraph of the Abnormal Procedures section by replacing the existing ELEVATOR TRIM JAMMING procedure with the following:

“ELEVATOR TRIM JAMMING

| | |
|---|---|
| Control Wheel | Hold Firmly. |
| Autopilot | Disengage. |
| Airspeed | Reduce. |
| NOTE: Minimum airspeed with flap 0°—160 KIAS | |
| Pitch trim command | Check all switches and elevator trim wheel. |

If pitch trim is recovered:

Re-trim the airplane and continue the flight with the autopilot disengaged, not exceeding the airspeed when the trim was recovered.

If pitch trim is not recovered:

Land at the nearest suitable airport.

Approach and landing configuration:

| | |
|--------------------|---------|
| Landing gear | Down. |
| Flaps | 25. |
| Airspeed | Vref25. |

CAUTION: DO NOT TRY TO RE-ENGAGE THE AUTOPILOT.”

(2) Revise the Normal Procedures section of the AFM, after the current checklist item for activating the FASTEN BELTS switch, by inserting the following:

“PITCH TRIM SYSTEM CHECK

| | |
|----------------------------|--------------|
| Control Wheel | Hold firmly. |
| Autopilot | Disengage. |
| Power Levers | As required. |
| Elevator Trim Wheels | As required. |

CAUTION: MANUALLY SET THE ELEVATOR TRIM WHEELS TO THE REQUIRED DESCENT ATTITUDE.

If any trim system binding (if trim wheel rotates more than one trim wheel index mark after being released), or abnormal trim operation is observed:

| | |
|---------------------------------------|----------|
| Elevator Trim Jamming Procedure | Perform. |
|---------------------------------------|----------|

CAUTION: DO NOT TRY TO RE-ENGAGE THE AUTOPILOT.

If no abnormal trim operation is observed:

| | |
|-------------------------------------|--------------|
| Flight Director Vertical Mode | As required. |
| Autopilot | Reengage.” |

AFM Revision: Collins APS–65B Autopilot AFM Supplement

(b) Concurrently with the AFM revisions required by paragraph (a) of this AD, revise

the Limitations section of the Collins APS–65B Autopilot System Supplement to include the following (this may be accomplished by

inserting a copy of this AD into the AFM Supplement):

“(1) The autopilot must not be used during descent unless a trim check has been performed successfully prior to descent, as follows:

PITCH TRIM SYSTEM CHECK

| | |
|---------------------|--------------|
| Control Wheel | Hold firmly. |
|---------------------|--------------|

| | |
|----------------------------|--------------|
| Autopilot | Disengage. |
| Power Levers | As required. |
| Elevator Trim Wheels | As required. |

CAUTION: MANUALLY SET THE ELEVATOR TRIM WHEELS TO THE REQUIRED DESCENT ATTITUDE.

If any trim system binding (if trim wheel rotates more than one trim wheel index mark after being released), or abnormal trim operation is observed:

| | |
|---------------------------------------|----------|
| Elevator Trim Jamming Procedure | Perform. |
|---------------------------------------|----------|

CAUTION: DO NOT TRY TO RE-ENGAGE THE AUTOPILOT.

If no abnormal trim operation is observed:

| | |
|-------------------------------------|--------------|
| Flight Director Vertical Mode | As required. |
| Autopilot | Reengage. |

“(2) If an elevator trim jamming is detected during flight and the pitch trim system resumes normal operation on ground, only a ferry flight using a special permit may be performed to return the aircraft to a maintenance base for replacement of the actuators. In this case, the use of autopilot is prohibited.”

Placard Installation

(c) Within 300 flight hours after the effective date of this AD, install two placards on the glareshield, advising the flight crew to check the pitch trim before initial descent, in accordance with Part II of the Accomplishment Instructions of EMBRAER Service Bulletin 120-25-0262, Change 02, dated October 30, 2003.

Elevator Trim System Modification

(d) Within 36 months after the effective date of this AD, modify the elevator trim system, in accordance with the Accomplishment Instructions of EMBRAER Service Bulletin 120-27-0095 and 120-27-0096, both dated February 16, 2007. Accomplishment of the modification terminates the requirements of paragraphs (a), (b), and (c) of this AD, and the corresponding AFM revisions and placards may be removed.

Parts Installation

(e) As of 36 months after the effective date of this AD, no person may install, on any airplane, an elevator trim tab actuator or control cable having a part number identified in Table 1 of this AD.

TABLE 1.—PROHIBITED PARTS

| Part | Part No. |
|-------------------------------|---------------|
| Elevator trim tab actuator .. | 120-19685-001 |
| | 120-19685-003 |
| | 120-19685-007 |
| | 120-38650-001 |
| | 120-39205-001 |
| Control cable | 5299 |
| | 5299-1 |
| | 120-27729-095 |
| | 120-27729-097 |
| | 120-31370-095 |
| | 120-31370-097 |

Alternative Methods of Compliance

(f)(1) The Manager, International Branch, ANM-116, Transport Airplane Directorate, FAA, has the authority to approve AMOCs for this AD, if requested in accordance with the procedures found in 14 CFR 39.19.

(2) To request a different method of compliance or a different compliance time for this AD, follow the procedures in 14 CFR 39.19. Before using any approved AMOC on any airplane to which the AMOC applies, notify your appropriate principal inspector (PI) in the FAA Flight Standards District

Office (FSDO), or lacking a PI, your local FSDO.

Note 1: The subject of this AD is addressed in Brazilian airworthiness directive 2001-06-01R4, effective August 23, 2007.

Issued in Renton, Washington, on February 1, 2008.

Ali Bahrami,

Manager, Transport Airplane Directorate, Aircraft Certification Service.

[FR Doc. E8-2356 Filed 2-7-08; 8:45 am]

BILLING CODE 4910-13-P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

21 CFR Part 880

[Docket No. 2007N-0484]

Devices: General Hospital and Personal Use Devices; Reclassification of Medical Device Data System

AGENCY: Food and Drug Administration, HHS.

ACTION: Proposed rule.

SUMMARY: The Food and Drug Administration (FDA) is proposing to reclassify, on its own initiative, the Medical Device Data System (MDDS) from class III (premarket approval) to class I (general controls). This action does not include medical device data systems with new diagnostic or alarm functions. FDA is also proposing that the MDDS be exempt from the premarket notification requirements when it is indicated for use only by a healthcare professional and does not perform irreversible data compression.

DATES: Submit written or electronic comments on the proposed rule by May 8, 2008. Submit comments regarding information collection by March 10, 2008, to the Office of Management and Budget (OMB) (see **ADDRESSES**). FDA proposes that any final regulation based on this proposal become effective 60 days after its date of publication in the

Federal Register. See section VIII of the **SUPPLEMENTARY INFORMATION** section of the preamble for further information about the effective date.

ADDRESSES: You may submit comments, identified by Docket No. 2007N-0484, by any of the following methods:

Electronic Submissions

Submit electronic comments in the following way:

- Federal eRulemaking Portal: <http://www.regulations.gov>. Follow the instructions for submitting comments.

Written Submissions

Submit written submissions in the followings ways:

- FAX: 301-827-6870.
- Mail/Hand delivery/Courier (For paper, disk, or CD-ROM submissions): Division of Dockets Management (HFA-305), Food and Drug Administration, 5630 Fishers Lane, rm. 1061, Rockville, MD 20852.

To ensure more timely processing of comments, FDA is no longer accepting comments submitted to the agency by e-mail. FDA encourages you to continue to submit electronic comments by using the Federal eRulemaking Portal or the agency Web site, as described previously, in the **ADDRESSES** portion of this document under *Electronic Submissions*.

Instructions: All submissions received must include the agency name and Docket No.(s) and Regulatory Information Number (RIN) (if a RIN number has been assigned) for this rulemaking. All comments received may be posted without change to <http://www.regulations.gov>, including any personal information provided. For additional information on submitting comments, see the “Comments” heading of the **SUPPLEMENTARY INFORMATION** section of this document.

Docket: For access to the docket to read background documents or comments received, go to <http://www.regulations.gov> and insert the docket number(s), found in brackets in the heading of this document, into the