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:

2001–17–04 Empresa Brasileira de Aeronautica S.A. (EMBRAER): Amendment 39–12395. Docket 2001–NM–249–AD.

Applicability: Model EMB–135ER and –135LR series airplanes, and Model EMB–145, –145ER, –145MR, and –145LR series airplanes, as listed in EMBRAER Alert Service Bulletin 145–55–A025, dated June 5, 2001; 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 (e) 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 severing of the bonding jumpers that connect the vertical stabilizer to the horizontal stabilizer, which could result in reduced elevator control capability, and consequent reduced controllability of the airplane; accomplish the following:

Inspection of the Bonding Jumpers

(a) Within the next 100 flight hours after the effective date of this AD, perform a detailed visual inspection to determine if the two bonding jumpers that connect the horizontal to the vertical stabilizers are properly installed, per EMBRAER Alert Service Bulletin 145–55–A025, dated June 5, 2001.

Note 2: For the purposes of this AD, a detailed visual inspection is defined as: ''An intensive visual examination of a specific structural area, system, installation, or assembly to detect damage, failure, or irregularity. Available lighting is normally supplemented with a direct source of good lighting at intensity deemed appropriate by the inspector. Inspection aids such as mirror, magnifying lenses, etc., may be used. Surface cleaning and elaborate access procedures may be required.''

Follow-on Action

(b) If both bonding jumpers are installed properly, before further flight, determine if the jumpers are mechanically tensioned to a slack distance of 5 millimeters (mm) or less between the reference line and the jumper as specified in View E of EMBRAER Alert Service Bulletin 145–55–A025, dated June 5, 2001.

(1) If any slack distance is 5 mm or less, before further flight, replace the bonding jumper with a new jumper having part number (P/N) LN926416X165, per the alert service bulletin.

(2) If any slack distance is 6 mm or more, at the time specified in paragraph (d) of this AD, accomplish those actions specified in paragraph (d) of this AD.

Corrective Actions

(c) If either bonding jumper is not installed properly (e.g., misaligned, signs of previous elongation, or damage), before further flight, replace the bonding jumper with a new jumper having P/N LN926416X165, in accordance with EMBRAER Alert Service Bulletin 145–55–A025, dated June 5, 2001.

Inspection of the Connecting Supports

(d) Within the next 100 flight hours after the effective date of this AD, perform a detailed visual inspection to determine if the supports that connect the bonding jumpers to the horizontal stabilizers are deformed, cracked, or ruptured, per EMBRAER Alert Service Bulletin 145–55–A025, dated June 5, 2001.

(1) If no deformation is detected, no further action is required by this paragraph.

(2) If any connecting support having deformation of 30 degrees or less has any sign of a painting discrepancy, before further flight, repaint the support per the alert service bulletin. The support must remain in the position it was found, as specified in the alert service bulletin.

(3) If any connecting support is deformed above 30 degrees or any signs of cracking or ruptures are detected, before further flight, replace the connecting support with a new support per the alert service bulletin.

Alternative Methods of Compliance

(e) 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, Atlanta Aircraft Certification Office (ACO), FAA. Operators shall submit their requests through an appropriate FAA Principal Maintenance Inspector, who may add comments and then send it to the Manager, Atlanta ACO.

Note 3: Information concerning the existence of approved alternative methods of compliance with this AD, if any, may be obtained from the Atlanta ACO.

Special Flight Permits

(f) Special flight permits may be issued in accordance with sections 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.

Incorporation by Reference

(g) The actions shall be done in accordance with EMBRAER Alert Service Bulletin 145–55–A025, dated June 5, 2001. This incorporation by reference was approved by the Director of the Federal Register in accordance with 5 U.S.C. 552(a) and 1 CFR part 51. Copies may be obtained from Empresa Brasileira de Aeronautica S.A. (EMBRAER), P.O. Box 343—CEP 12.225, Sao Jose dos Campos—SP, Brazil. Copies may be inspected at the FAA, Transport Airplane Directorate, 1601 Lind Avenue, SW., Renton, Washington; or at the FAA, Atlanta Aircraft Certification Office, One Crown Center, 1895 Phoenix Boulevard, suite 450, Atlanta, Georgia; or at the Office of the Federal Register, 800 North Capitol Street, NW., suite 700, Washington, DC.

Note 4: The subject of this AD is addressed in Brazilian airworthiness directive 2001–06–03, dated June 13, 2001.

Effective Date

(h) This amendment becomes effective on September 5, 2001.

Issued in Renton, Washington, on August 13, 2001.

Vi L. Lipski,

Manager, Transport Airplane Directorate, Aircraft Certification Service.

[FR Doc. 01–20806 Filed 8–20–01; 8:45 am]

BILLING CODE 4910–13–U

DEPARTMENT OF TRANSPORTATION

Federal Aviation Administration

14 CFR Part 39

[Docket No. 2000–NM–410–AD; Amendment 39–12381; AD 2001–16–12]

RIN 2120–AA64

Airworthiness Directives; McDonnell Douglas Model DC–10–10, –15, –30, and –30F (KC–10A Military) Series Airplanes, and Model MD–10–10F and –30F Series Airplanes

AGENCY: Federal Aviation Administration, DOT.

ACTION: Final rule.

SUMMARY: This amendment supersedes an existing airworthiness directive (AD), applicable to certain McDonnell Douglas Model DC–10–10, –15, –30, and –30F (KC–10A military) series airplanes, and Model MD–10–10F and –30F series airplanes, that currently requires repetitive inspections to determine the condition of the lockwires on the forward engine mount bolts and correction of any discrepancies found. That AD also provides for optional terminating actions for the repetitive inspections. This amendment requires accomplishment of the previously optional terminating actions. This amendment is prompted by a report of discrepant forward engine mount bolts at the number 3 engine. The actions specified by this AD are intended to

prevent broken lockwires, which could result in loosening of the engine mount bolts, and consequent separation of the engine from the airplane.

DATES: Effective September 25, 2001.

The incorporation by reference of McDonnell Douglas DC–10 Service Bulletin 71–133, Revision 6, dated June 30, 1992; McDonnell Douglas Service Bulletin DC10–71–159, dated September 6, 1995; and McDonnell Douglas Service Bulletin DC10–71–159, Revision 01, dated July 28, 1997; as listed in the regulations, is approved by the Director of the Federal Register as of September 25, 2001.

The incorporation by reference of McDonnell Douglas Alert Service Bulletin DC10–71A159, Revision 1, dated January 31, 1995; as listed in the regulations, was approved previously by the Director of the Federal Register as of November 10, 1999 (64 FR 54202, October 6, 1999).

ADDRESSES: The service information referenced in this AD may be obtained from Boeing Commercial Aircraft Group, Long Beach Division, 3855 Lakewood Boulevard, Long Beach, California 90846, Attention: Data and Service Management, Dept. C1–L5A (D800–0024). This information may be examined at the Federal Aviation Administration (FAA), Transport Airplane Directorate, Rules Docket, 1601 Lind Avenue, SW., Renton, Washington; or at the FAA, Los Angeles Aircraft Certification Office, 3960 Paramount Boulevard, Lakewood, California; or at the Office of the Federal Register, 800 North Capitol Street, NW., suite 700, Washington, DC.

FOR FURTHER INFORMATION CONTACT: Ron Atmur, Aerospace Engineer, Airframe Branch, ANM–120L, FAA, Los Angeles Aircraft Certification Office, 3960 Paramount Boulevard, Lakewood, California 90712–4137; telephone (562) 627–5224; fax (562) 627–5210.

SUPPLEMENTARY INFORMATION: A proposal to amend part 39 of the Federal Aviation Regulations (14 CFR part 39) by superseding AD 95–04–07 R2, amendment 39–11354 (64 FR 54202, October 6, 1999), which is applicable to certain McDonnell Douglas Model DC–10–10, –15, –30, and –30F (KC–10A military) series airplanes, and Model MD–10–10F and –30F series airplanes, was published in the **Federal Register** on March 21, 2001 (66 FR 15817). The action proposed to continue to require repetitive inspections to determine the condition of the lockwires on the forward engine mount bolts and correction of any discrepancies found. The action also proposed to require accomplishment of the previously optional terminating actions.

Comments Received

Interested persons have been afforded an opportunity to participate in the making of this amendment. Due consideration has been given to the comments received.

Support for the Proposed Rule

Two commenters express support for the proposed rule.

Request To Revise Applicability and Clarify Terminating Actions

One commenter requests that the ''Applicability'' of the proposed rule be revised to specify that it would not apply to certain airplanes on which, not only McDonnell Douglas DC–10 Service Bulletin 71–133, Revision 6, dated June 30, 1992, has been accomplished (as specified in the applicability of the proposed rule); but also would not apply to certain airplanes on which McDonnell Douglas Service Bulletin DC10–71–159, dated September 6, 1995, or Revision 01, dated July 28, 1997, has been accomplished. The commenter also requests that paragraph (b) of the proposed rule be clarified to specify that, for certain models, the terminating action may be accomplished in accordance with either McDonnell Douglas Service Bulletin 71–133, or McDonnell Douglas Service Bulletin DC10–71–159. The commenter states that the proposed rule, as written, implies that both service bulletins must be accomplished for the terminating action.

The FAA agrees with the commenter, and has determined that clarification is needed. It is the intent of the FAA to permit terminating action to be completed in accordance with either of the referenced service bulletins. We have revised the ''Applicability'' and paragraph (b) of the final rule to specify that, for certain models, compliance with the terminating action may be accomplished by either of the service bulletins noted above. Since the terminating actions for Model DC–10–30 and –30F (KC–10A military) series airplanes are now completely addressed in paragraph (b) of the final rule, we have revised paragraph (c) of the final rule to remove reference to those models and specify that the applicability of paragraph (c) of the final rule applies only to McDonnell Douglas Model DC–10–10 and –15 series airplanes, and Model MD–10–10F series airplanes.

Conclusion

After careful review of the available data, including the comments noted above, the FAA has determined that air safety and the public interest require the adoption of the rule with the changes previously described. The FAA has determined that these changes will neither increase the economic burden on any operator nor increase the scope of the AD.

Cost Impact

There are approximately 389 Model DC–10–10, –15, –30, and –30F (KC–10A military) series airplanes, and Model MD–10–10F and –30F series airplanes, of the affected design in the worldwide fleet. The FAA estimates that 229 airplanes of U.S. registry will be affected by this AD.

The actions that are currently required by AD 95–04–07 R2, and retained in this AD, take approximately 2 work hours per airplane to accomplish, at an average labor rate of $60 per work hour. Based on these figures, the cost impact of the currently required actions on U.S. operators is estimated to be $27,480, or $120 per airplane, per inspection cycle.

Should an operator be required to accomplish the terminating installation specified in McDonnell Douglas DC–10 Service Bulletin 71–133, it will take approximately 4 work hours per airplane to accomplish, at an average labor rate of $60 per hour. Required parts will cost between $2,744 and $2,822 per airplane. Based on these figures, the cost impact of the terminating installation required by this AD on U.S. operators is estimated to be between $2,984 and $3,062 per airplane.

Should an operator be required to accomplish the terminating modification specified in McDonnell Douglas Service Bulletin DC10–71–159, it will take approximately 16 work hours per airplane to accomplish, at an average labor rate of $60 per work hour. Required parts will cost between $2,744 and $2,822 per airplane. Based on these figures, the cost impact of the terminating modification required by this AD on U.S. operators is estimated to be between $3,704 and $3,782 per airplane.

The cost impact figures discussed above are based on assumptions that no operator has yet accomplished any of the requirements of this AD action, and that no operator would accomplish those actions in the future if this 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.

Regulatory Impact

The regulations adopted herein will 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 final rule does not have federalism implications under Executive Order 13132.

For the reasons discussed above, I certify that this action (1) is not a ''significant regulatory action'' under Executive Order 12866; (2) is not a ''significant rule'' under DOT Regulatory Policies and Procedures (44 FR 11034, February 26, 1979); and (3) 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 final evaluation has been prepared for this action and it is contained in the Rules Docket. A copy of it may be obtained from the Rules Docket at the location provided under the caption **ADDRESSES**.

List of Subjects in 14 CFR Part 39

Air transportation, Aircraft, Aviation safety, Incorporation by reference, Safety.

Adoption of the Amendment

Accordingly, pursuant to the authority delegated to me by the Administrator, the Federal Aviation Administration amends 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 removing amendment 39–11354 (64 FR 54202, October 6, 1999), and by adding a new airworthiness directive (AD), amendment 39–12381, to read as follows:

2001–16–12 McDonnell Douglas: Amendment 39–12381. Docket 2000–NM–410–AD. Supersedes AD 95–04–07 R2, Amendment 39–11354.

Applicability: The following airplanes, certificated in any category:

Model	Excluding airplanes
1. DC–10–30 and –30F (KC–10A military) series airplanes, and MD–10–30F series airplanes.	On which bolt retainers have been installed on the engine mount per McDonnell Douglas DC–10 Service Bulletin 71–133, Revision 6, dated June 30, 1992, or on which the modification specified in McDonnell Douglas Service Bulletin DC10–71–159, dated September 6, 1995, or Revision 01, dated July 28, 1997, has been performed.
2. DC–10–10 and –15 series airplanes, and Model MD–10–10F series airplanes.	On which the modification specified in McDonnell Douglas Service Bulletin DC10–71–159, dated September 6, 1995, or Revision 01, dated July 28, 1997, has been done.

Note 1: This AD applies to each airplane identified in the preceding applicability provision, regardless of whether it has been otherwise 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 (d)(1) 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 broken lockwires, which could result in loosening of the engine mount bolts, and consequent separation of the engine from the airplane, accomplish the following:

Restatement of Requirements of AD 95–04–07 R2, Amendment 39–11354

(a) Within 120 days after March 17, 1995 (the effective date of AD 95–04–07 R1, amendment 39–9317), unless accomplished previously within the last 750 flight hours prior to March 17, 1995, perform a visual inspection to detect broken lockwires on the forward engine mount bolts on engines 1, 2, and 3, in accordance with McDonnell Douglas Alert Service Bulletin DC10–71A159, Revision 1, dated January 31, 1995.

(1) If no lockwire is found broken, repeat the inspection thereafter at intervals not to exceed 750 flight hours.

(2) If any lockwire is found broken, prior to further flight: Check the torque of the bolt, install a new lockwire, and install a torque stripe on the bolt, in accordance with the alert service bulletin. Thereafter at intervals not to exceed 750 flight hours, perform a visual inspection to detect misalignment of the torque stripes, and repeat the inspection to detect broken lockwires, in accordance with the alert service bulletin.

Terminating Actions

(b) For Model DC–10–30 and –30F (KC–10A military) series airplanes, and Model MD–10–30F series airplanes: Within 18 months after the effective date of this AD, install retainers on the engine mount bolts of engine 1, 2, or 3 per the procedures depicted in Figure 6 of Revision 6 of McDonnell Douglas DC–10 Service Bulletin 71–133, dated June 30, 1992; or modify the forward engine mount bolts for engine 1, 2, or 3, per McDonnell Douglas Service Bullletin DC10–71–159, dated September 6, 1995, or Revision 01, dated July 28, 1997. Accomplishment of the installation constitutes terminating action for the requirements of this AD for that engine.

(c) For Model DC–10–10 and –15 series airplanes, and Model MD–10–10F series airplanes: Within 18 months after the effective date of this AD, modify the forward engine mount bolts for engine 1, 2, or 3, per McDonnell Douglas Service Bulletin DC10–71–159, dated September 6, 1995; or Revision 01, dated July 28, 1997. Accomplishment of the modification constitutes terminating action for the requirements of this AD for that engine.

Alternative Methods of Compliance

(d)(1) 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, Los Angeles Aircraft Certification Office (ACO), FAA. Operators shall submit their requests through an appropriate FAA Principal Maintenance Inspector, who may add comments and then send it to the Manager, Los Angeles ACO.

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

(2) Alternative methods of compliance, approved previously in accordance with AD 95–04–07 R2, amendment 39–11354, are approved as alternative methods of compliance with this AD.

Special Flight Permits

(e) Special flight permits may be issued in accordance with sections 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.

Incorporation by Reference

(f) The actions shall be done in accordance with McDonnell Douglas DC–10 Service Bulletin 71–133, Revision 6, dated June 30, 1992; McDonnell Douglas Service Bulletin DC10–71–159, dated September 6, 1995, or McDonnell Douglas Service Bulletin DC10–71–159 RO1, Revision 01, dated July 28, 1997; and McDonnell Douglas Alert Service Bulletin DC10–71A159, Revision 1, dated January 31, 1995; as applicable.

(1) The incorporation by reference of McDonnell Douglas DC–10 Service Bulletin 71–133, Revision 6, dated June 30, 1992; McDonnell Douglas Service Bulletin DC10–71–159, dated September 6, 1995; and McDonnell Douglas Service Bulletin DC10–71–159 R01, Revision 01, dated July 28, 1997;

is approved by the Director of the Federal Register in accordance with 5 U.S.C. 552(a) and 1 CFR part 51.

(2) The incorporation by reference of McDonnell Douglas Alert Service Bulletin DC10–71A159, Revision 1, dated January 31, 1995, was approved previously by the Director of the Federal Register as of November 10, 1999 (64 FR 54202, October 6, 1999).

(3) Copies may be obtained from Boeing Commercial Aircraft Group, Long Beach Division, 3855 Lakewood Boulevard, Long Beach, California 90846, Attention: Data and Service Management, Dept. C1–L5A (D800–0024). Copies may be inspected at the FAA, Transport Airplane Directorate, 1601 Lind Avenue, SW., Renton, Washington; or at the FAA, Los Angeles Aircraft Certification Office, 3960 Paramount Boulevard, Lakewood, California; or at the Office of the Federal Register, 800 North Capitol Street, NW., suite 700, Washington, DC.

Effective Date

(g) This amendment becomes effective on September 25, 2001.

Issued in Renton, Washington, on August 13, 2001.

Vi L. Lipski,

Manager, Transport Airplane Directorate, Aircraft Certification Service.

[FR Doc. 01–20804 Filed 8–20–01; 8:45 am]

BILLING CODE 4910–13–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

21 CFR Part 510

New Animal Drugs; Change of Sponsor's Name and Address

AGENCY: Food and Drug Administration, HHS.

ACTION: Final rule.

SUMMARY: The Food and Drug Administration (FDA) is amending the animal drug regulations to reflect a change of sponsor's name and address for Orion Corp. ORION-FARMOS.

DATES: This rule is effective August 21, 2001.

FOR FURTHER INFORMATION CONTACT: Lonnie W. Luther, Center for Veterinary Medicine (HFV–102), Food and Drug Administration, 7500 Standish Pl., Rockville, MD 20855, 301–827–0209.

SUPPLEMENTARY INFORMATION: Orion Corp. ORION-FARMOS, P.O. Box 425, SF–20101 Turku, Finland, has informed FDA of a change of sponsor's name and address to Orion Corp., Orionintie 1, 02200 Espoo, Finland. Accordingly, the agency is amending the regulations in 21 CFR 510.600(c)(1) and (c)(2) to reflect the change of sponsor's name and address.

This rule does not meet the definition of ''rule'' in 5 U.S.C. 804(3)(A) because it is a rule of ''particular applicability.'' Therefore, it is not subject to the congressional review requirements in 5 U.S.C. 801–808.

List of Subjects in 21 CFR Part 510

Administrative practice and procedure, Animal drugs, 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 and redelegated to the Center for Veterinary Medicine, 21 CFR part 510 is amended as follows:

PART 510—NEW ANIMAL DRUGS

1. The authority citation for 21 CFR part 510 continues to read as follows:

Authority: 21 U.S.C. 321, 331, 351, 352, 353, 360b, 371, 379e.

2. Section 510.600 is amended in the table in paragraph (c)(1) by revising the entry for ''Orion Corp. ORION-FARMOS'' and in the table in paragraph (c)(2) by revising the entry for ''052483'' to read as follows:

§ 510.600 Names, addresses, and drug labeler codes of sponsors of approved applications.

* * * * *

(c) * * *

(1) * * *

Firm name and address	Drug labeler code
* * * * * * *	
Orion Corp., Orionintie 1, 02200 Espoo, Finland	052483
* * * * * * *	

(2) * * *

Drug labeler code	Firm name and address
* * * * * * *	
052483	Orion Corp., Orionintie 1, 02200 Espoo, Finland
* * * * * * *	

Dated: July 31, 2001.

Claire M. Lathers,

Director, Office of New Animal Drug Evaluation, Center for Veterinary Medicine.

[FR Doc. 01–20982 Filed 8–20–01; 8:45 am]

BILLING CODE 4160–01–S

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

21 CFR Part 520

Oral Dosage Form New Animal Drugs; Ponazuril

AGENCY: Food and Drug Administration, HHS.

ACTION: Final rule.

SUMMARY: The Food and Drug Administration (FDA) is amending the animal drug regulations to reflect approval of a new animal drug application (NADA) filed by Bayer Corp., Agriculture Division, Animal Health. The NADA provides for veterinary prescription use of ponazuril