(4) 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.

List of Subjects in 14 CFR Part 39

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

The Proposed Amendment

Accordingly, under the authority delegated to me by the Administrator, the FAA proposes to amend 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. The FAA amends § 39.13 by removing Amendment 39–11320 (64 FR 50440; September 17, 1999), and adding the following new AD:

Blanik Limited: Docket No. FAA–2016–4233; Directorate Identifier 2016–CE–003–AD.

(a) Comments Due Date

We must receive comments by April 18, 2016.

(b) Affected ADs

This AD replaces AD 99–19–33, Amendment 39–11320 (64 FR 50440; September 17, 1999) (''AD 99–19–33'').

(c) Applicability

This AD applies to BLANIK LIMITED Models L–13 Blanik and L–13 AC Blanik gliders (type certificate previously by LET Aeronautical Works), all serial numbers, certificated in any category.

(d) Subject

Air Transport Association of America (ATA) Code 27: Flight Controls.

(e) Reason

This AD was prompted by mandatory continuing airworthiness information (MCAI) originated by an aviation authority of another country to identify and correct an unsafe condition on an aviation product. The MCAI describes the unsafe condition as lack of distinct color marking of the elevator drive. We are issuing this AD to prevent inadvertent backward installation of the elevator drive, which could cause significant elevator deflection changes and lead to loss of control.

(f) Actions and Compliance

Unless already done, do the following actions in paragraphs (f)(1) and (f)(2) of this AD, including all subparagraphs:

(1) *Model L–13 Blanik gliders:*

(i) Within the next 3 calendar months after November 8, 1999 (the effective date retained from AD 99–19–33), paint the elevator drive mechanism using a contrasting color (such as red) following the procedures in LET Mandatory Bulletin MB No.: L13/082a, dated December 10, 1998.

(ii) As of November 8, 1999 (the effective date retained from AD 99–19–33), only install an elevator bellcrank that has been painted as specified in paragraph (f)(1)(i) of this AD and that has been properly oriented to make sure it is not being installed backward.

(2) *Model L–13 AC Blanik gliders:*

(i) Within the next 3 calendar months after the effective date of this AD, paint the elevator drive mechanism using a contrasting color (such as red) following the procedures in LET Mandatory Bulletin MB No.: L13/082a, dated December 10, 1998.

(ii) As of the effective date of this AD, only install an elevator bellcrank that has been painted as specified in paragraph (f)(2)(i) of this AD and that has been properly oriented to make sure it is not being installed backward.

(g) Other FAA AD Provisions

The following provisions also apply to this AD:

(1) *Alternative Methods of Compliance (AMOCs):* The Manager, Standards Office, FAA, has the authority to approve AMOCs for this AD, if requested using the procedures found in 14 CFR 39.19. Send information to ATTN: Jim Rutherford, Aerospace Engineer, FAA, Small Airplane Directorate, 901 Locust, Room 301, Kansas City, Missouri 64106; telephone: (816) 329–4165; fax: (816) 329–4090; email: *jim.rutherford@faa.gov.* 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.

(2) *Airworthy Product:* For any requirement in this AD to obtain corrective actions from a manufacturer or other source, use these actions if they are FAA-approved. Corrective actions are considered FAA-approved if they are approved by the State of Design Authority (or their delegated agent). You are required to assure the product is airworthy before it is returned to service.

(h) Related Information

Refer to MCAI Civil Aviation Authority AD CAA–AD–4–099/98, dated December 30, 1998, for related information. You may examine the MCAI on the Internet at *http://www.regulations.gov* by searching for and locating Docket No. FAA–2016–4233. For service information related to this AD, contact Blanik Limited, 2nd Floor Beaux Lane House, Mercer Street Lower, Dublin 2, Republic of Ireland; phone: +420 733 662 194; email: *info@blanik.aero;* Internet: *http://www.blanik.aero/%EF%BB%BFcustomer_support.* You may review this referenced service information at the FAA, Small Airplane Directorate, 901 Locust, Kansas City, Missouri 64106. For information on the availability of this material at the FAA, call (816) 329–4148.

Issued in Kansas City, Missouri, on February 24, 2016.

Robert P. Busto,

Acting Manager, Small Airplane Directorate, Aircraft Certification Service.

[FR Doc. 2016–04542 Filed 3–3–16; 8:45 am]

BILLING CODE 4910–13–P

DEPARTMENT OF TRANSPORTATION

Federal Aviation Administration

14 CFR Part 39

[Docket No. FAA–2016–4232; Directorate Identifier 2015–CE–043–AD]

RIN 2120–AA64

Airworthiness Directives; EVECTOR, spol. s.r.o. Gliders

AGENCY: Federal Aviation Administration (FAA), Department of Transportation (DOT).

ACTION: Notice of proposed rulemaking (NPRM).

SUMMARY: We propose to adopt a new airworthiness directive (AD) for EVECTOR, spol. s.r.o. Model L 13 SEH VIVAT and L 13 SDM VIVAT gliders (type certificate previously held by AEROTECHNIK s.r.o.). This proposed AD results from mandatory continuing airworthiness information (MCAI) originated by an aviation authority of another country to identify and correct an unsafe condition on an aviation product. The MCAI describes the unsafe condition as lack of distinct color marking of the elevator drive. We are issuing this proposed AD to require actions to address the unsafe condition on these products.

DATES: We must receive comments on this proposed AD by April 18, 2016.

ADDRESSES: You may send comments by any of the following methods:

- *Federal eRulemaking Portal: Go to http://www.regulations.gov.* Follow the instructions for submitting comments.
- *Fax:* (202) 493–2251.
- *Mail:* U.S. Department of Transportation, Docket Operations, M–30, West Building Ground Floor, Room W12–140, 1200 New Jersey Avenue SE., Washington, DC 20590.
- *Hand Delivery:* U.S. Department of Transportation, Docket Operations, M–30, West Building Ground Floor, Room W12–140, 1200 New Jersey Avenue SE., Washington, DC 20590, between 9 a.m. and 5 p.m., Monday through Friday, except Federal holidays.

For service information identified in this proposed AD, contact EVEKTOR, spol. s.r.o, Letecka 1008, 686 04 Kunovice, Czech Republic; phone: +420

572 537 428; email: *evektor@evektor.cz;* Internet: *http://www.evektor.cz/en/sales-and-support.* You may review this referenced service information at the FAA, Small Airplane Directorate, 901 Locust, Kansas City, Missouri 64106. For information on the availability of this material at the FAA, call (816) 329–4148.

Examining the AD Docket

You may examine the AD docket on the Internet at *http://www.regulations.gov* by searching for and locating Docket No. FAA–2016–4232; or in person at the Docket Management Facility between 9 a.m. and 5 p.m., Monday through Friday, except Federal holidays. The AD docket contains this proposed AD, the regulatory evaluation, any comments received, and other information. The street address for the Docket Office (telephone (800) 647–5527) is in the **ADDRESSES** section. Comments will be available in the AD docket shortly after receipt.

FOR FURTHER INFORMATION CONTACT: Jim Rutherford, Aerospace Engineer, FAA, Small Airplane Directorate, 901 Locust, Room 301, Kansas City, Missouri 64106; telephone: (816) 329–4165; fax: (816) 329–4090; email: *jim.rutherford@faa.gov.*

SUPPLEMENTARY INFORMATION:

Comments Invited

We invite you to send any written relevant data, views, or arguments about this proposed AD. Send your comments to an address listed under the **ADDRESSES** section. Include ''Docket No. FAA–2016–4232; Directorate Identifier 2015–CE–043–AD'' at the beginning of your comments. We specifically invite comments on the overall regulatory, economic, environmental, and energy aspects of this proposed AD. We will consider all comments received by the closing date and may amend this proposed AD because of those comments.

We will post all comments we receive, without change, to *http://regulations.gov,* including any personal information you provide. We will also post a report summarizing each substantive verbal contact we receive about this proposed AD.

Discussion

The Civil Aviation Authority, which is the aviation authority for the Czech Republic, has issued AD CAA–AD–4–099/98, dated December 30, 1998 (referred to after this as ''the MCAI''), to correct an unsafe condition for EVECTOR, spol. s.r.o. Models L 13 SEH VIVAT and L 13 SDM VIVAT gliders and BLANIK LIMITED Models L–13 Blanik and L–13 AC Blanik gliders and was based on mandatory continuing airworthiness information originated by an aviation authority of another country. The MCAI states:

> Colour marking of elevator drive is not inspected or re-painted during sailplane operation. The elevator drive is asymmetrical and improper installation causes significant elevator deflection changes.

A review of records revealed that the FAA inadvertently did not address this MCAI for the EVECTOR, spol. s.r.o. Models L 13 SEH VIVAT and L 13 SDM VIVAT gliders and the BLANIK LIMITED Model L–13 AC Blanik gliders. This proposed AD would address this MCAI for the EVECTOR, spol. s.r.o. Models L 13 SEH VIVAT and L 13 SDM VIVAT gliders and would require painting or re-painting the elevator drive mechanism a contrasting color to prevent the backward installation of the elevator drive bellcrank. You may examine the MCAI on the Internet at *http://www.regulations.gov* by searching for and locating Docket No. FAA–2016–4232.

The FAA will address the BLANIK LIMITED Model L–13 AC Blanik gliders in another AD action.

Related Service Information Under 1 CFR Part 51

AEROTECHNIK CZ s.r.o. issued Mandatory Service Bulletin SEH 13–003a, dated December 15, 1998. The service information describes procedures for painting the left arm of the elevator drive. This service information is reasonably available because the interested parties have access to it through their normal course of business or by the means identified in the **ADDRESSES** section of this NPRM.

FAA's Determination and Requirements of the Proposed AD

This product has been approved by the aviation authority of another country, and is approved for operation in the United States. Pursuant to our bilateral agreement with this State of Design Authority, they have notified us of the unsafe condition described in the MCAI and service information referenced above. We are proposing this AD because we evaluated all information and determined the unsafe condition exists and is likely to exist or develop on other products of the same type design.

Costs of Compliance

We estimate that this proposed AD will affect 9 products of U.S. registry. We also estimate that it would take about 1 work-hour per product to comply with the basic requirements of this proposed AD. The average labor rate is $85 per work-hour. Required parts would cost about $10 per product.

Based on these figures, we estimate the cost of the proposed AD on U.S. operators to be $855, or $95 per product.

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 Findings

We determined that this proposed AD would not have federalism implications under Executive Order 13132. This proposed AD 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.

For the reasons discussed above, I certify 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),

(3) Will not affect intrastate aviation in Alaska, and

(4) 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.

List of Subjects in 14 CFR Part 39

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

The Proposed Amendment

Accordingly, under the authority delegated to me by the Administrator,

the FAA proposes to amend 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. The FAA amends § 39.13 by adding the following new AD:

EVECTOR, spol. s.r.o.: Docket No. FAA–2016–4232; Directorate Identifier 2015–CE–043–AD.

(a) Comments Due Date

We must receive comments by April 18, 2016.

(b) Affected ADs

None.

(c) Applicability

This AD applies to EVECTOR, spol. s.r.o. L 13 SEH VIVAT and L 13 SDM VIVAT gliders (type certificate previously held by AEROTECHNIK s.r.o.), all serial numbers, certificated in any category.

(d) Subject

Air Transport Association of America (ATA) Code 27: Flight Controls.

(e) Reason

This AD was prompted by mandatory continuing airworthiness information (MCAI) originated by an aviation authority of another country to identify and correct an unsafe condition on an aviation product. The MCAI describes the unsafe condition as lack of distinct color marking of the elevator drive. We are issuing this AD to prevent inadvertent backward installation of the elevator drive, which could cause significant elevator deflection changes and lead to loss of control.

(f) Actions and Compliance

Unless already done, do the following actions in paragraphs (f)(1) and (f)(2) of this AD.

(1) Within the next 3 calendar months after the effective date of this AD, paint the elevator drive mechanism using a contrasting color (such as red) following the procedures in AEROTECHNIK CZ s.r.o. issued Mandatory Service Bulletin SEH 13–003a, dated December 15, 1998.

(2) As of the effective date of this AD, only install an elevator bellcrank that has been painted as specified in paragraph (f)(1) of this AD and that has been properly oriented to make sure it is not being installed backward.

(g) Other FAA AD Provisions

The following provisions also apply to this AD:

(1) *Alternative Methods of Compliance (AMOCs):* The Manager, Standards Office, FAA, has the authority to approve AMOCs for this AD, if requested using the procedures found in 14 CFR 39.19. Send information to ATTN: Jim Rutherford, Aerospace Engineer, FAA, Small Airplane Directorate, 901 Locust, Room 301, Kansas City, Missouri 64106; telephone: (816) 329–4165; fax: (816) 329–4090; email: *jim.rutherford@faa.gov.* 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.

(2) *Airworthy Product:* For any requirement in this AD to obtain corrective actions from a manufacturer or other source, use these actions if they are FAA-approved. Corrective actions are considered FAA-approved if they are approved by the State of Design Authority (or their delegated agent). You are required to assure the product is airworthy before it is returned to service.

(h) Related Information

Refer to MCAI Civil Aviation Authority AD CAA–AD–4–099/98, dated December 30, 1998, for related information. You may examine the MCAI on the Internet at *http://www.regulations.gov* by searching for and locating Docket No. FAA–2016–4232. For service information related to this AD, contact EVEKTOR, spol. s.r.o, Letecka 1008, 686 04 Kunovice, Czech Republic; phone: +420 572 537 428; email: *evektor@evektor.cz;* Internet: *http://www.evektor.cz/en/sales-and-support.* You may review this referenced service information at the FAA, Small Airplane Directorate, 901 Locust, Kansas City, Missouri 64106. For information on the availability of this material at the FAA, call (816) 329–4148.

Issued in Kansas City, Missouri, on February 24, 2016.

Robert P. Busto,

Acting Manager, Small Airplane Directorate, Aircraft Certification Service.

[FR Doc. 2016–04573 Filed 3–3–16; 8:45 am]

BILLING CODE 4910–13–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

21 CFR Part 820

[Docket No. FDA–2016–N–0436]

Refurbishing, Reconditioning, Rebuilding, Remarketing, Remanufacturing, and Servicing of Medical Devices Performed by Third-Party Entities and Original Equipment Manufacturers; Request for Comments

AGENCY: Food and Drug Administration, HHS.

ACTION: Notification; request for comments.

SUMMARY: The Food and Drug Administration (FDA or we) is announcing the establishment of a docket to receive information and comments on the medical device industry and healthcare community that refurbish, recondition, rebuild, remarket, remanufacture, service, and repair medical devices (hereafter termed ''third-party entity or entities''), including radiation-emitting devices subject to the electronic product radiation control (EPRC) provisions of the Federal Food, Drug, and Cosmetic Act (the FD&C Act). FDA is taking this action, in part, because various stakeholders have expressed concerns about the quality, safety, and continued effectiveness of medical devices that have been subject to one or more of these activities that are performed by both original equipment manufacturers (OEM) and third parties, including health care establishments. We are seeking comments from the widest range of interested persons, including those who are engaged in one or more of the activities noted previously or who utilize refurbished, reconditioned, rebuilt, remarketed, remanufactured, or third-party serviced and repaired medical devices.

DATES: Submit either electronic or written comments by May 3, 2016.

ADDRESSES: You may submit comments as follows:

Electronic Submissions

Submit electronic comments in the following way:

- *Federal eRulemaking Portal: http://www.regulations.gov.* Follow the instructions for submitting comments. Comments submitted electronically, including attachments, to *http://www.regulations.gov* will be posted to the docket unchanged. Because your comment will be made public, you are solely responsible for ensuring that your comment does not include any confidential information that you or a third party may not wish to be posted, such as medical information, your or anyone else's Social Security number, or confidential business information, such as a manufacturing process. Please note that if you include your name, contact information, or other information that identifies you in the body of your comments, that information will be posted on *http://www.regulations.gov.*
- If you want to submit a comment with confidential information that you do not wish to be made available to the public, submit the comment as a written/paper submission and in the manner detailed (see ''Written/Paper Submissions'' and ''Instructions'').

Written/Paper Submissions

Submit written/paper submissions as follows:

- *Mail/Hand delivery/Courier (for written/paper submissions):* Division of Dockets Management (HFA–305), Food