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

and Drug Administration, 5630 Fishers Lane, Rm. 1061, Rockville, MD 20852.

• For written/paper comments submitted to the Division of Dockets Management, FDA will post your comment, as well as any attachments, except for information submitted, marked and identified, as confidential, if submitted as detailed in ''Instructions.''

Instructions: All submissions received must include the Docket No. FDA–2016–N–0436 for ''Refurbishing, Reconditioning, Rebuilding, Remarketing, Remanufacturing, and Servicing of Medical Devices Performed by Third-Party Entities and Original Equipment Manufacturers; Request for Comments.'' Received comments will be placed in the docket and, except for those submitted as ''Confidential Submissions,'' publicly viewable at *http://www.regulations.gov* or at the Division of Dockets Management between 9 a.m. and 4 p.m., Monday through Friday.

• *Confidential Submissions*—To submit a comment with confidential information that you do not wish to be made publicly available, submit your comments only as a written/paper submission. You should submit two copies total. One copy will include the information you claim to be confidential with a heading or cover note that states ''THIS DOCUMENT CONTAINS CONFIDENTIAL INFORMATION.'' The Agency will review this copy, including the claimed confidential information, in its consideration of comments. The second copy, which will have the claimed confidential information redacted/blacked out, will be available for public viewing and posted on *http://www.regulations.gov.* Submit both copies to the Division of Dockets Management. If you do not wish your name and contact information to be made publicly available, you can provide this information on the cover sheet and not in the body of your comments and you must identify this information as ''confidential.'' Any information marked as ''confidential'' will not be disclosed except in accordance with 21 CFR 10.20 and other applicable disclosure law. For more information about FDA's posting of comments to public dockets, see 80 FR 56469, September 18, 2015, or access the information at: *http://www.fda.gov/regulatoryinformation/dockets/default.htm.*

Docket: For access to the docket to read background documents or the electronic and written/paper comments received, go to *http://www.regulations.gov* and insert the docket number, found in brackets in the heading of this document, into the ''Search'' box and follow the prompts and/or go to the Division of Dockets Management, 5630 Fishers Lane, Rm. 1061, Rockville, MD 20852.

FOR FURTHER INFORMATION CONTACT: Valerie Flournoy, Center for Devices and Radiological Health, Food and Drug Administration, 10903 New Hampshire Ave., Silver Spring, MD 20993–0002, 301–796–5495.

SUPPLEMENTARY INFORMATION:

I. Background

Over the past 20 years, the Center for Devices and Radiological Health has sought to clarify our regulatory requirements and expectations, under part 820 (21 CFR part 820), to entities servicing, refurbishing, rebuilding, reconditioning, remarketing, and remanufacturing medical devices. In addition, FDA medical device regulations include requirements that device manufacturers establish and maintain instructions and procedures for servicing. However, in the **Federal Register** on December 4, 1998 (63 FR 67076), refurbishers and servicers of medical devices were excluded from the requirement to comply with the 1997 Quality System Regulation under part 820.

Moreover, EPRC requirements of the FD&C Act (Pub. L. 90–602, amended by Pub. L. 103–80), include provisions specific to manufacturers and assemblers of certified x-ray components. Under § 1020.30(c) (21 CFR 1020.30(c)), manufacturers of diagnostic x-ray systems are responsible for providing assembly instructions adequate to assure compliance of their components with the applicable performance standards when installed properly. Furthermore, under § 1020.30(d), assemblers are then required to assemble, install, adjust, and test the certified components according to the instructions of their respective manufacturers.

FDA has previously issued guidance on these topics, including an Assembler's Guide to Diagnostic X-ray Equipment (Ref. 1) and Information Disclosure by Manufacturers to Assemblers for Diagnostic X-ray Systems (Ref. 2). Under the EPRC provision in 21 CFR 1040.10(h)(1)(i), manufacturers of laser products are required to provide instructions for assembly, operation, and maintenance, including warnings and precautions on how to avoid exposure, and maintenance schedules to ensure product complies with requirements in the standard.

Stakeholders have expressed concerns that some third-party entities who refurbish, recondition, rebuild, remarket, remanufacture, service, and repair medical devices may use unqualified personnel to perform service, maintenance, refurbishment, and device alterations on their equipment and that the work performed may not be adequately documented. Possible public health issues arising from these activities include ineffective recalls, disabled device safety features, and improper or unexpected device operation. OEMs have also requested clarification of their responsibilities when their devices have been altered by a third-party entity. Federal Agencies other than FDA address service and maintenance activities as well.

FDA is interested in comments concerning the service, maintenance, refurbishment, and alteration of medical devices, including endoscopes (Ref. 3), by third-party entities. In addition, we want to know more about the challenges third-party entities face in maintaining or restoring devices to their original or current specifications. This docket is not intended to address the reprocessing of single-use or reusable medical devices.

FDA intends to hold a public meeting later in 2016 to further engage this segment of the device industry and healthcare community. The comments submitted to this docket will help inform the content of the public meeting.

II. Issues for Consideration

A. Proposed Definitions of Third-Party and OEM Activities

FDA is asking for assistance in defining the following terms specific to this document. These terms, while not an exhaustive list, should capture and encompass most of the activities performed on medical devices. While we suggest language for each term, we are inviting interested persons to suggest revisions and any additional terms that may help define third-party and OEM activities including additional activities that are not encompassed by the following suggested terms and all-encompassing terms that can include some or all of the activities discussed in this section II.A.

1. *Recondition:* Restores and/or refurbishes a medical device to the OEM's original specifications. Under limited circumstances the medical device may be restored and/or refurbished to current specifications.

2. *Service:* Maintenance or repair of a finished device after distribution for purposes of returning it to the safety and performance specifications established by the OEM and to meet its original

intended use. Servicing *cannot* change the intended use(s) of the device from its original purpose(s).

3. *Repair:* Return the device or component to original specifications including replacing non-working components or parts outside of routine or periodic upkeep for the current owner of the device.

4. *Refurbish:* Restore device to a condition of safety and effectiveness that is comparable to when new. This includes reconditioning, repair, installation of certain software/hardware updates that do not change the intended use of the original device, and replacement of worn parts.

5. *Remanufacture:* Process, condition, renovate, repackage, restore, or any other act done to a finished device that significantly changes the finished device's performance, safety specifications, or intended use.

6. *Remarket:* The act of facilitating the transfer of a previously owned device from one party to another by sale, donation, gift, or lease.

B. Evaluation of Risk Associated With These Third-Party and OEM Activities

In addition to obtaining comments that define the key terms applicable to this issue, FDA believes that a need exists for interested persons to comment on the benefits and risks related to the previously defined activities. We invite interested persons to comment on the following questions:

1. Who are the different stakeholders involved with the medical device activities listed previously? What are their respective roles?

2. What evidence exists regarding actual problems with the safety and/or performance of devices that result from these activities? Specific examples should be submitted.

3. What are the potential risks (patients/users) and failure modes (devices) introduced as a result of performing the previously defined activities on medical devices? Please speak to issues common to all devices as well as specific risks with specific devices.

4. These activities are performed by OEMs and various third-party entities, including hospitals and humanitarian organizations. Are the risks different depending on who performs the previously mentioned activities?

5. We are interested in knowing if these activities are more difficult or riskier to perform on certain devices versus others. Please cite specific examples in your response, along with an explanation of the source of this particular complexity.

6. What information do third-party entities need in order to perform these activities in a way that results in safe and effective operation of the medical device? Please provide specific examples.

7. What additional challenges do stakeholders encounter with devices that result from these activities?

III. Paperwork Reduction Act of 1995

This document refers to previously approved collections of information found in FDA regulations. These collections of information 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 collections of information in 21 CFR part 820 have been approved under OMB control number 0910–0073; the collections of information in 21 CFR parts 1020 and 1040 have been approved under OMB control number 0910–0025.

IV. References

The following references are on display in the Division of Dockets Management (see **ADDRESSES**) and are available for viewing by interested persons between 9 a.m. and 4 p.m., Monday through Friday; they are also available electronically at *http://www.regulations.gov.* FDA has verified the Web site addresses, as of the date this document publishes in the **Federal Register**, but Web sites are subject to change over time.

1. Guidance for Industry and Food and Drug Administration Staff on Assembler's Guide to Diagnostic X-Ray Equipment. Available at *http://www.fda.gov/downloads/MedicalDevices/.../UCM257783.pdf.*
2. Guidance for Industry and FDA Staff on Information Disclosure by Manufacturers to Assemblers for Diagnostic X-ray Systems. Available at *http://www.fda.gov/downloads/Radiation-EmittingProducts/ElectronicProductRadiationControlProgram/IndustryGuidance/UCM136731.pdf.*
3. *FDA Executive Summary: Effective Reprocessing of Endoscopes Used in Endoscopic Retrograde Cholangiopancreatography (ERCP) Procedures,* FDA. Available at *http://www.fda.gov/downloads/AdvisoryCommittees/CommitteesMeetingMaterials/MedicalDevices/MedicalDevicesAdvisoryCommittee/Gastroenterology-UrologyDevicesPanel/UCM445592.pdf.*

Dated: February 26, 2016.

Leslie Kux,

Associate Commissioner for Policy.

[FR Doc. 2016–04700 Filed 3–3–16; 8:45 am]

BILLING CODE 4164–01–P

DEPARTMENT OF JUSTICE

Drug Enforcement Administration

21 CFR Part 1308

[Docket No. DEA–436]

Schedules of Controlled Substances: Placement of 10 Synthetic Cathinones Into Schedule I

AGENCY: Drug Enforcement Administration, Department of Justice.

ACTION: Notice of proposed rulemaking.

SUMMARY: The Drug Enforcement Administration proposes placing 10 synthetic cathinones: 4-methyl-*N*-ethylcathinone (4-MEC); 4-methyl-*alpha*-pyrrolidinopropiophenone (4-MePPP); alpha-pyrrolidinopentiophenone (α-PVP); 1-(1,3-benzodioxol-5-yl)-2-(methylamino)butan-1-one (butylone); 2-(methylamino)-1-phenylpentan-1-one (pentedrone); 1-(1,3-benzodioxol-5-yl)-2-(methylamino)pentan-1-one (pentylone); 4-fluoro-*N*-methylcathinone (4-FMC); 3-fluoro-*N*-methylcathinone (3-FMC); 1-(naphthalen-2-yl)-2-(pyrrolidin-1-yl)pentan-1-one (naphyrone); alpha-pyrrolidinobutiophenone (α-PBP) and their optical, positional, and geometric isomers, salts and salts of isomers into schedule I of the Controlled Substances Act. This proposed scheduling action is pursuant to the Controlled Substances Act which requires that such actions be made on the record after opportunity for a hearing through formal rulemaking. If finalized, this action would impose the regulatory controls and administrative, civil, and criminal sanctions applicable to schedule I controlled substances on persons who handle (manufacture, distribute, import, export, engage in research, conduct instructional activities or chemical analysis, or possess), or propose to handle 4-MEC, 4-MePPP, α-PVP, butylone, pentedrone, pentylone, 4-FMC, 3-FMC, naphyrone, or α-PBP.

DATES: Interested persons may file written comments on this proposal in accordance with 21 CFR 1308.43(g). Comments must be submitted electronically or postmarked on or before April 4, 2016. Commenters should be aware that the electronic Federal Docket Management System will not accept comments after 11:59 p.m. Eastern Time on the last day of the comment period.

Interested persons, defined at 21 CFR 1300.01 as those ''adversely affected or aggrieved by any rule or proposed rule issuable pursuant to section 201 of the Act (21 U.S.C. 811),'' may file a request