(g) Inspection of Fluid Level and Nitrogen Pressure in HR

Within the compliance time defined in table 1 to paragraph (g) of this AD, as applicable, inspect the HR fluid level and nitrogen pressure of each hydraulic circuit, in accordance with the instructions of paragraph 4.2.2.1 of Airbus Alert Operators Transmission (AOT) A29L005–16, Revision 01, dated June 28, 2016. Repeat the inspection thereafter at intervals not to exceed 1,600 flight hours.

TABLE 1 TO PARAGRAPH (g) OF THIS AD—INITIAL INSPECTION COMPLIANCE TIME

Compliance Time (A or B, whichever occurs later)	
A	Before accumulating 1,600 flight hours since first flight of the airplane.
B	Within 1,000 flight hours or 3 months, whichever occurs first after the effective date of this AD.

(h) Corrective Action

If, during any inspection required by paragraph (g) of this AD, any unacceptable pressure or fluid level is identified, before further flight, do the actions in paragraphs (h)(1) and (h)(2) of this AD, as applicable, for each unacceptable pressure or fluid level that is discovered. Accomplishment of these actions on an airplane does not constitute terminating action for the repetitive inspections as required by paragraph (g) of this AD for that airplane.

(1) Add or remove hydraulic fluid, as applicable, in accordance with the instructions of paragraph 4.2.2.2 of Airbus Alert Operators Transmission (AOT) A29L005–16, Revision 01, dated June 28, 2016.

(2) Add or remove nitrogen gas, as applicable, in accordance with the instructions of paragraph 4.2.2.2 of Airbus AOT A29L005–16, Revision 01, dated June 28, 2016.

(i) Servicing Hydraulic Reservoir

Concurrent with the initial inspection specified in paragraph (g) of this AD, revise the maintenance or inspection program, as applicable, to incorporate the hydraulic reservoir servicing actions specified in paragraph 4.2.2.2 of Airbus AOT A29L005–16, Revision 01, dated June 28, 2016.

(j) No Alternative Actions and Intervals

After accomplishing the revision required by paragraph (i) of this AD, no alternative actions (*e.g.,* inspections) and intervals may be used unless the actions and intervals are approved as an alternative method of compliance (AMOC) in accordance with the procedures specified in paragraph (l)(1) of this AD.

(k) Credit for Previous Actions

This paragraph provides credit for actions required by paragraphs (g) and (h) of this AD, if those actions were performed before the effective date of this AD using Airbus AOTA29L005–16, dated January 28, 2016.

(l) Other FAA AD Provisions

The following provisions also apply to this AD:

(1) *Alternative Methods of Compliance (AMOCs):* The Manager, International Branch, ANM–116, Transport Airplane Directorate, FAA, has the authority to approve AMOCs for this AD, if requested using the procedures found in 14 CFR 39.19. In accordance with 14 CFR 39.19, send your request to your principal inspector or local Flight Standards District Office, as appropriate. If sending information directly to the International Branch, send it to ATTN: Vladimir Ulyanov, Aerospace Engineer, International Branch, ANM–116, Transport Airplane Directorate, FAA, 1601 Lind Avenue SW., Renton, WA 98057–3356; telephone 425–227–1138; fax 425–227–1149. Information may be emailed to: *9–ANM–116–AMOC–REQUESTS@faa.gov.* Before using any approved AMOC, notify your appropriate principal inspector, or lacking a principal inspector, the manager of the local flight standards district office/certificate holding district office.

(2) *Contacting the Manufacturer:* For any requirement in this AD to obtain corrective actions from a manufacturer, the action must be accomplished using a method approved by the Manager, International Branch, ANM–116, Transport Airplane Directorate, FAA; or the European Aviation Safety Agency (EASA); or Airbus's EASA Design Organization Approval (DOA). If approved by the DOA, the approval must include the DOA-authorized signature.

(m) Related Information

(1) Refer to Mandatory Continuing Airworthiness Information (MCAI) EASA AD 2016–0107, dated June 7, 2016, for related information. This MCAI may be found in the AD docket on the Internet at *http://www.regulations.gov* by searching for and locating Docket No. FAA–2016–9117.

(2) Service information identified in this AD that is not incorporated by reference is available at the addresses specified in paragraphs (n)(3) and (n)(4) of this AD.

(n) Material Incorporated by Reference

(1) The Director of the Federal Register approved the incorporation by reference (IBR) of the service information listed in this paragraph under 5 U.S.C. 552(a) and 1 CFR part 51.

(2) You must use this service information as applicable to do the actions required by this AD, unless this AD specifies otherwise.

(i) Airbus Alert Operators Transmission (AOT) A29L005–16, Revision 01, dated June 28, 2016.

(ii) Reserved.

(3) For service information identified in this AD, contact Airbus SAS, Airworthiness Office—EAL, 1 Rond Point Maurice Bellonte, 31707 Blagnac Cedex, France; telephone: +33 5 61 93 36 96; fax: +33 5 61 93 45 80; email: *airworthiness.A330–A340@airbus.com;* Internet: *http://www.airbus.com.*

(4) You may view this service information at the FAA, Transport Airplane Directorate, 1601 Lind Avenue SW., Renton, WA. For information on the availability of this material at the FAA, call 425–227–1221.

(5) You may view this service information that is incorporated by reference at the National Archives and Records Administration (NARA). For information on the availability of this material at NARA, call 202–741–6030, or go to: *http://www.archives.gov/federal-register/cfr/ibr-locations.html.*

Issued in Renton, Washington, on December 23, 2016.

Thomas Groves,

Acting Manager, Transport Airplane Directorate, Aircraft Certification Service.

[FR Doc. 2016–31868 Filed 1–5–17; 8:45 am]

BILLING CODE 4910–13–P

DEPARTMENT OF TRANSPORTATION

Federal Aviation Administration

14 CFR Part 39

[Docket No. FAA–2016–7420; Directorate Identifier 2015–NM–017–AD; Amendment 39–18774; AD 2017–01–07]

RIN 2120–AA64

Airworthiness Directives; Dassault Aviation Airplanes

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

ACTION: Final rule.

SUMMARY: We are adopting a new airworthiness directive (AD) for all Dassault Aviation Model FAN JET FALCON airplanes; Model FAN JET FALCON SERIES C, D, E, F, and G airplanes; Model MYSTERE-FALCON 200 airplanes; Model MYSTERE-FALCON 20–C5, 20–D5, 20–E5, and 20–F5 airplanes; and MYSTERE-FALCON 50 airplanes. This AD was prompted by a report that, during approach for landing, the main entry door detached from an airplane. This AD requires a functional test or check of the main entry door closure and warning system, and applicable door closing inspections, adjustments, operational tests, and corrective actions if necessary. We are issuing this AD to address the unsafe condition on these products.

DATES: This AD is effective February 10, 2017.

The Director of the Federal Register approved the incorporation by reference of certain publications listed in this AD as of February 10, 2017.

ADDRESSES: For service information identified in this final rule, contact Dassault Falcon Jet Corporation, Teterboro Airport, P.O. Box 2000, South Hackensack, NJ 07606; telephone 201–440–6700; Internet *http://*

www.dassaultfalcon.com. You may view this referenced service information at the FAA, Transport Airplane Directorate, 1601 Lind Avenue SW., Renton, WA. For information on the availability of this material at the FAA, call 425 227–1221. It is also available on the Internet at *http://www.regulations.gov* by searching for and locating Docket No. FAA–2016–7420.

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–2016–7420; 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 AD, the regulatory evaluation, any comments received, and other information. The street address for the Docket Office (telephone 800–647–5527) is Docket Management Facility, U.S. Department of Transportation, Docket Operations, M–30, West Building Ground Floor, Room W12–140, 1200 New Jersey Avenue SE., Washington, DC 20590.

FOR FURTHER INFORMATION CONTACT: Tom Rodriguez, Aerospace Engineer, International Branch, ANM–116, Transport Airplane Directorate, FAA, 1601 Lind Avenue SW., Renton, WA 98057–3356; telephone 425–227–1137; fax 425–227–1149.

SUPPLEMENTARY INFORMATION:

Discussion

We issued a notice of proposed rulemaking (NPRM) to amend 14 CFR part 39 by adding an AD that would apply to all Dassault Aviation Model FAN JET FALCON airplanes; Model FAN JET FALCON SERIES C, D, E, F, and G airplanes; Model MYSTERE-FALCON 200 airplanes; Model MYSTERE-FALCON 20–C5, 20–D5, 20–E5, and 20–F5 airplanes; and MYSTERE–FALCON 50 airplanes. The NPRM published in the **Federal Register** on July 1, 2016 (81 FR 43120).

The European Aviation Safety Agency (EASA), which is the Technical Agent for the Member States of the European Union, has issued EASA Airworthiness Directive 2015–0007, dated January 15, 2015 (referred to after this as the Mandatory Continuing Airworthiness Information, or ''the MCAI''), to correct an unsafe condition for all Dassault Aviation Model FAN JET FALCON airplanes; Model FAN JET FALCON SERIES C, D, E, F, and G airplanes; Model MYSTERE-FALCON 200 airplanes; Model MYSTERE-FALCON 20–C5, 20–D5, 20–E5, and 20–F5 airplanes; and MYSTERE-FALCON 50 airplanes. The MCAI states:

> During approach for landing, a Mystère-Falcon 20–X5 lost the main entrance door [MED] at an altitude of 7,000 feet. The flight crew maintained control of the aeroplane to land uneventfully. The results of the preliminary technical investigations concluded that the cause of this event could be either a broken cable, or an unlocked safety catch, associated with one or two deficient micro switches.
>
> This condition, if not detected and corrected, could lead to in-flight opening and/or detachment of the Crew/Passenger door, possibly resulting in loss of control of the aeroplane, and/or injury to persons on the ground.
>
> To address this potential unsafe condition, Dassault Aviation issued Service Bulletins (SB) F20–789, F200–133 and MF50–531, providing instructions for inspection/adjustment, as well as an operational test of the Crew/Passenger door closure.
>
> For the reasons described above, this [EASA] AD requires a one-time accomplishment of a functional test/check of the MED closure/warning system. It also requires [a general visual] inspection and operational test of the Crew/Passenger door [including the control and latching mechanisms] and, depending on findings, applicable corrective actions.

Corrective actions include adjusting the telescopic rod bolts on the door until the clearance between the lower part of the door and the fuselage is within the specified tolerances. The corrective actions for the control and latching mechanisms include adjusting components and replacing damaged components (including pull latches, microswitches, pulleys, and cables). Signs of damage include cracks, corrosion, wear, and distortion. You may examine the MCAI in the AD docket on the Internet at *http://www.regulations.gov* by searching for and locating Docket No. FAA–2016–7420.

Comments

We gave the public the opportunity to participate in developing this AD. We received no comments on the NPRM or on the determination of the cost to the public.

Conclusion

We reviewed the relevant data and determined that air safety and the public interest require adopting this AD as proposed except for minor editorial changes. We have determined that these minor changes:

- Are consistent with the intent that was proposed in the NPRM for correcting the unsafe condition; and
- Do not add any additional burden upon the public than was already proposed in the NPRM.

Related Service Information Under 1 CFR Part 51

Dassault Aviation issued the following service information.

- Dassault Service Bulletin F20–789, also referred to as 789, dated December 9, 2014.
- Dassault Service Bulletin F50–531, also referred to as 531, dated December 9, 2014.
- Dassault Service Bulletin F200–133, also referred to as 133, dated December 9, 2014.

The service information describes procedures for inspections, adjustments, and operational tests of certain doors and corrective actions. These documents are distinct since they apply to different airplane models. 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.

Costs of Compliance

We estimate that this AD affects 392 airplanes of U.S. registry.

We estimate the following costs to comply with this AD:

ESTIMATED COSTS

Action	Labor cost	Parts cost	Cost per product	Cost on U.S. operators
Inspections/adjustments/operational tests.	4 work-hours × $85 per hour = $340	$0	$340	$133,280

We have received no definitive data that will enable us to provide cost estimates for the on-condition actions specified in this AD.

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 AD will not have federalism implications under Executive Order 13132. This AD 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.

For the reasons discussed above, I certify that this AD:

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.

Adoption of the Amendment

Accordingly, under the authority delegated to me by the Administrator, the FAA amends 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 airworthiness directive (AD):

2017–01–07 Dassault Aviation: Amendment 39–18774; Docket No. FAA–2016–7420; Directorate Identifier 2015–NM–017–AD.

(a) Effective Date

This AD is effective February 10, 2017.

(b) Affected ADs

None.

(c) Applicability

This AD applies to the Dassault Aviation airplanes, certificated in any category, identified in paragraphs (c)(1) through (c)(5) of this AD, all airplanes.

(1) Model FAN JET FALCON airplanes.

(2) Model FAN JET FALCON SERIES C, D, E, F, and G airplanes.

(3) Model MYSTERE–FALCON 200 airplanes.

(4) Model MYSTERE–FALCON 20–C5, 20–D5, 20–E5, and 20–F5 airplanes.

(5) Model MYSTERE–FALCON 50 airplanes.

(d) Subject

Air Transport Association (ATA) of America Code 52, Doors.

(e) Reason

This AD was prompted by a report that, during approach for landing, the main entry door detached from an airplane. We are issuing this AD to detect and correct defective crew/passenger doors. Such a condition could result in the in-flight opening or detachment of the crew/passenger door, which could result in loss of control of the airplane and injury to persons on the ground.

(f) Compliance

Comply with this AD within the compliance times specified.

(g) Main Entry/Passenger/Crew Door Check or Functional Test

Within 65 days after the effective date of this AD, unless done within 6 months before the effective date of this AD, do the applicable functional test or door lock check specified in paragraph (g)(1), (g)(2), or (g)(3) of this AD, and do all applicable corrective actions, using a method approved by the Manager, International Branch, ANM–116, Transport Airplane Directorate, FAA; or the European Aviation Safety Agency (EASA); or Dassault Aviation's EASA Design Organization Approval (DOA). Do all applicable corrective actions before further flight.

(1) For Model FAN JET FALCON airplanes; Model FAN JET FALCON SERIES C, D, E, F, and G airplanes; and Model MYSTERE-FALCON 20–C5, 20–D5, 20–E5, and 20–F5 airplanes: A functional test of the passenger/crew door warning system.

(2) For Model MYSTERE-FALCON 200 airplanes: A check of the door locking indicator system.

(3) For Model MYSTERE-FALCON 50 airplanes: A check of the door lock indication.

(h) Main Entry/Passenger/Crew Door Closing Inspections, Adjustments, and Operational Tests and Corrective Actions

Within 330 flight hours or 13 months, whichever occurs first after the effective date of this AD, unless already done: Do the applicable door closing inspections, adjustments, and operational tests, and do all applicable corrective actions, in accordance with the Accomplishment Instructions of the applicable service information identified in paragraph (h)(1), (h)(2), or (h)(3) of this AD. Do all applicable corrective actions before further flight.

(1) For Model FAN JET FALCON airplanes; Model FAN JET FALCON SERIES C, D, E, F, and G airplanes; and Model MYSTERE-FALCON 20–C5, 20–D5, 20–E5, and 20–F5 airplanes: Dassault Service Bulletin F20–789, also referred to as 789, dated December 9, 2014.

(2) For Model MYSTERE-FALCON 200 airplanes: Dassault Service Bulletin F200–133, also referred to as 133, dated December 9, 2014.

(3) For Model MYSTERE-FALCON 50 airplanes: Dassault Service Bulletin F50–531, also referred to as 531, dated December 9, 2014.

(i) Other FAA AD Provisions

The following provisions also apply to this AD:

(1) *Alternative Methods of Compliance (AMOCs):* The Manager, International Branch, ANM–116, Transport Airplane Directorate, FAA, has the authority to approve AMOCs for this AD, if requested using the procedures found in 14 CFR 39.19. In accordance with 14 CFR 39.19, send your request to your principal inspector or local Flight Standards District Office, as appropriate. If sending information directly to the International Branch, send it to ATTN: Tom Rodriguez, Aerospace Engineer, International Branch, ANM–116, Transport Airplane Directorate, FAA, 1601 Lind Avenue SW., Renton, WA 98057–3356; telephone 425–227–1137; fax 425–227–1149. Information may be emailed to: *9-ANM-116-AMOC-REQUESTS@faa.gov*. Before using any approved AMOC, notify your appropriate principal inspector, or lacking a principal inspector, the manager of the local flight standards district office/certificate holding district office.

(2) *Contacting the Manufacturer:* For any requirement in this AD to obtain corrective actions from a manufacturer, the action must be accomplished using a method approved by the Manager, International Branch, ANM–116, Transport Airplane Directorate, FAA; or the EASA; or Dassault Aviation's EASA DOA. If approved by the DOA, the approval must include the DOA-authorized signature.

(j) Related Information

Refer to Mandatory Continuing Airworthiness Information (MCAI) EASA Airworthiness Directive 2015–0007, dated January 15, 2015, for related information. This MCAI may be found in the AD docket on the Internet at *http://www.regulations.gov* by searching for and locating Docket No. FAA–2016–7420.

(k) Material Incorporated by Reference

(1) The Director of the Federal Register approved the incorporation by reference (IBR) of the service information listed in this paragraph under 5 U.S.C. 552(a) and 1 CFR part 51.

(2) You must use this service information as applicable to do the actions required by this AD, unless this AD specifies otherwise.

(i) Dassault Service Bulletin F20–789, also referred to as 789, dated December 9, 2014.

(ii) Dassault Service Bulletin F50–531, also referred to as 531, dated December 9, 2014.

(iii) Dassault Service Bulletin F200–133, also referred to as 133, dated December 9, 2014.

(3) For service information identified in this AD, contact Dassault Falcon Jet Corporation, Teterboro Airport, P.O. Box 2000, South Hackensack, NJ 07606; telephone 201–440–6700; Internet *http://www.dassaultfalcon.com.*

(4) You may view this service information at the FAA, Transport Airplane Directorate, 1601 Lind Avenue SW., Renton, WA. For information on the availability of this material at the FAA, call 425–227–1221.

(5) You may view this service information that is incorporated by reference at the National Archives and Records Administration (NARA). For information on the availability of this material at NARA, call 202–741–6030, or go to: *http://www.archives.gov/federal-register/cfr/ibr-locations.html.*

Issued in Renton, Washington, on December 23, 2016.

Thomas Groves,

Acting Manager, Transport Airplane Directorate, Aircraft Certification Service.

[FR Doc. 2016–31871 Filed 1–5–17; 8:45 am]

BILLING CODE 4910–13–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

21 CFR Part 884

[Docket No. FDA–2014–N–0297]

Obstetrical and Gynecological Devices; Reclassification of Surgical Instrumentation for Use With Urogynecologic Surgical Mesh

AGENCY: Food and Drug Administration, HHS.

ACTION: Final order.

SUMMARY: The Food and Drug Administration (FDA or the Agency) is reclassifying surgical instrumentation for use with urogynecologic surgical mesh from class I (general controls) exempt from premarket notification to class II (special controls) and subject to premarket notification, and identifying them as ''specialized surgical instrumentation for use with urogynecologic surgical mesh.'' FDA is designating special controls that are necessary to provide a reasonable assurance of safety and effectiveness of the device. FDA is reclassifying this device on its own initiative based on new information.

DATES: This order is effective January 6, 2017. See further discussion in section V, ''Implementation Strategy.''

FOR FURTHER INFORMATION CONTACT: Sharon Andrews, Center for Devices and Radiological Health, 10903 New Hampshire Ave., Bldg. 66, Rm. G110, Silver Spring, MD 20993, 301–796–6529, *Sharon.Andrews@fda.hhs.gov.*

SUPPLEMENTARY INFORMATION:

I. Background—Regulatory Authorities

The Federal Food, Drug, and Cosmetic Act (the FD&C Act) (21 U.S.C. 301 *et seq.*), as amended, established a comprehensive system for the regulation of medical devices intended for human use. Section 513 of the FD&C Act (21 U.S.C. 360c) established three categories (classes) of devices, reflecting the regulatory controls needed to provide reasonable assurance of their safety and effectiveness. The three categories of devices are class I (general controls), class II (special controls), and class III (premarket approval).

Devices that were in commercial distribution before the enactment of the 1976 amendments on May 28, 1976, are generally referred to as preamendments devices. Under section 513(d) of the FD&C Act, preamendments devices are classified after FDA has: (1) Received a recommendation from a device classification panel (an FDA advisory committee); (2) published the panel's recommendation for comment, along with a proposed regulation classifying the device; and (3) published a final regulation classifying the device. FDA has classified most preamendments devices under these procedures.

Devices that were not in commercial distribution prior to May 28, 1976, are generally referred to as postamendments devices. Postamendments devices are automatically classified into class III without any FDA rulemaking process (section 513(f) of the FD&C Act). Postamendments devices remain in class III and require premarket approval unless, and until, the device is reclassified into class I or II or FDA issues an order finding the device to be substantially equivalent, under section 513(i) of the FD&C Act, to a predicate device that does not require premarket approval. The Agency determines whether new devices are substantially equivalent to predicate devices by means of premarket notification procedures in section 510(k) of the FD&C Act (21 U.S.C. 360(k)) and 21 CFR part 807.

On July 9, 2012, the Food and Drug Administration Safety and Innovation Act (FDASIA) (Pub. L. 112–144) was enacted. Section 608(a) of FDASIA amended section 513(e) of the FD&C Act, changing the mechanism for reclassifying a device from rulemaking to an administrative order.

Section 513(e) of the FD&C Act provides that FDA may, by administrative order, reclassify a device based upon ''new information.'' FDA can initiate a reclassification under section 513(e) of the FD&C Act or an interested person may petition FDA to reclassify a device. The term ''new information,'' as used in section 513(e) of the FD&C Act, includes information developed as a result of a reevaluation of the data before the Agency when the device was originally classified, as well as information not presented, not available, or not developed at that time. (See, *e.g., Holland-Rantos Co.* v. *United States Department of Health, Education, and Welfare,* 587 F.2d 1173, 1174 n.1 (D.C. Cir. 1978); *Upjohn* v. *Finch,* 422 F.2d 944 (6th Cir. 1970); *Bell* v. *Goddard,* 366 F.2d 177 (7th Cir. 1966).)

Reevaluation of the data previously before the Agency is an appropriate basis for subsequent action where the reevaluation is made in light of newly available authority (see *Bell,* 366 F.2d at 181; *Ethicon, Inc.* v. *FDA,* 762 F.Supp. 382, 388–391 (D.D.C. 1991)), or in light of changes in ''medical science'' (*Upjohn,* 422 F.2d at 951). Whether data before the Agency are old or new data, the ''new information'' to support reclassification under section 513(e) must be ''valid scientific evidence,'' as defined in section 513(a)(3) of the FD&C Act and § 860.7(c)(2) (21 CFR 860.7(c)(2)). (See, *e.g., Gen. Medical Co.* v. *FDA,* 770 F.2d 214 (D.C. Cir. 1985); *Contact Lens Mfrs. Assoc.* v. *FDA,* 766 F.2d 592 (D.C. Cir. 1985), cert. denied, 474 U.S. 1062 (1986).) To be considered in the reclassification process, the ''valid scientific evidence'' upon which the Agency relies must be publicly available. Publicly available information excludes trade secret and/or confidential commercial information, *e.g.,* the contents of a pending premarket approval application (PMA). (See section 520(c) of the FD&C Act (21 U.S.C. 360j(c)).)

The process for issuing a final reclassification order is specified in section 513(e)(1) of the FD&C Act. Prior to the issuance of a final order reclassifying a device, the following must occur: (1) Publication of a proposed order in the **Federal Register**;