Proposed Rules

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This section of the FEDERAL REGISTER contains notices to the public of the proposed issuance of rules and regulations. The purpose of these notices is to give interested persons an opportunity to participate in the rule making prior to the adoption of the final rules.

DEPARTMENT OF JUSTICE

Immigration and Naturalization Service

8 CFR Part 286

[INS Order No. 2180A–01]

RIN 1115–AG47

Establishment of a $3 Immigration User Fee for Certain Commercial Vessel Passengers Previously Exempt

AGENCY: Immigration and Naturalization Service, Department of Justice.

ACTION: Proposed rule; reopening of comment period.

SUMMARY: On April 3, 2002, at 67 FR 15753, the Immigration and Naturalization Service (Service) published a proposed rule in the **Federal Register** proposing to require certain commercial vessel operators and/or their ticketing agents to charge a $3 user fee from every commercial vessel passenger whose journey originated in the U.S., Canada, Mexico, a territory or possession of the United States, or an adjacent island except those exempted under section 286(e) of the Immigration and Nationality Act (Act) or 8 CFR part 286. The original comment period for the proposed rule closed on May 3, 2002. To ensure that the public has ample opportunity to fully review and comment on the proposed rule, this document reopens the comment period to May 28, 2002.

DATES: Written comments must be submitted on or before May 28, 2002.

ADDRESSES: Please submit written comments to the Director, Regulations and Forms Services Division, Immigration and Naturalization Service, 425 I Street, NW., Room 4034, Washington, DC 20536. To ensure proper handling, please reference INS No. 2180A–01 on your correspondence. You may also submit comments to the Service electronically at *insregs@usdoj.gov.* When submitting comments electronically please include INS No. 2180A–01 in the subject box. Comments are available for public inspection at the above address by calling (202) 514–3048 to arrange for an appointment.

FOR FURTHER INFORMATION CONTACT: Georgia Mayers, Chief of Cash Management, Office of Finance, Immigration and Naturalization, 425 I Street, NW., Washington, DC 20536, 202–305–1200.

SUPPLEMENTARY INFORMATION:

Where can the public view the April 3, 2002, proposed rule?

The April 3, 2002, proposed rule can be viewed on the Government Printing Office Web site at: *http://frwebgate.access.gpo.gov/cgi-bin/getdoc.cgi?dbname=2002—register&docid=02–8011-filed*

Dated: May 9, 2002.

James W. Ziglar,

Commissioner, Immigration, and Naturalization Service.

[FR Doc. 02–12045 Filed 5–9–02; 3:51 pm]

BILLING CODE 4410–10–P

DEPARTMENT OF TRANSPORTATION

Federal Aviation Administration

14 CFR Part 25

[Docket No. NM206; Special Conditions No. 25–02–06]

Special Conditions: Fairchild Dornier GmbH, Model 728–100; Operation Without Normal Electrical Power

AGENCY: Federal Aviation Administration (FAA), DOT.

ACTION: Notice of proposed special conditions.

SUMMARY: This action proposes special conditions for the Fairchild Dornier GmbH Model 728–100 airplane. This airplane will have a novel or unusual design feature when compared to the state of technology envisioned in the airworthiness standards for transport category airplanes. The airplane design will include an electronic flight control system. The applicable airworthiness regulations do not contain adequate or appropriate safety standards for this design feature. These special conditions, in part, contain the additional safety standards that the Administrator considers necessary to establish a level of safety equivalent to that established by the existing airworthiness standards. Additional special conditions may also be defined.

DATES: Comments must be received on or before June 28, 2002.

ADDRESSES: Comments on this proposal may be mailed in duplicate to: Federal Aviation Administration, Transport Airplane Directorate, Attention: Rules Docket (ANM–113), Docket No. NM206, 1601 Lind Avenue SW., Renton, Washington 98055–4056; or delivered in duplicate to the Transport Airplane Directorate at the above address. All comments must be marked: *Docket No. NM206*. Comments may be inspected in the Rules Docket weekdays, except Federal holidays, between 7:30 a.m. and 4 p.m.

FOR FURTHER INFORMATION CONTACT: Tom Groves, FAA, International Branch, ANM–116, Transport Airplane Directorate, Aircraft Certification Service, 1601 Lind Avenue SW., Renton, Washington 98055–4056; telephone (425) 227–1503; facsimile (425) 227–1149.

SUPPLEMENTARY INFORMATION:

Comments Invited

The FAA invites interested persons to participate in this rulemaking by submitting written comments, data, or views. The most helpful comments reference a specific portion of the proposal, explain the reason for any recommended change, and include supporting data. We ask that you send us two copies of written comments.

We will file in the docket all comments we receive, as well as a report summarizing each substantive public contact with FAA personnel concerning these proposed special conditions. The docket is available for public inspection before and after the comment closing date. If you wish to review the docket in person, go to the address in the **ADDRESSES** section of this action between 7:30 a.m. and 4 p.m., Monday through Friday, except Federal holidays. We will consider all comments we receive on or before the closing date for comments. We will consider comments filed late if it is possible to do so without incurring expense or delay. We may change the proposed special conditions in light of the comments we receive.

If you want the FAA to acknowledge receipt of your comments on this proposal, include with your comments a pre-addressed, stamped postcard on

which the docket number appears. We will stamp the date on the postcard and mail it back to you.

Background

On May 5, 1998, Fairchild Dornier GmbH applied for a type certificate for their new Model 728–100 airplane. The Model 728–100 is a 70–85 passenger twin-engine regional jet with a maximum takeoff weight of 77,600 pounds.

Type Certification Basis

Under the provisions of 14 CFR 21.17, Fairchild Dornier GmbH must show that the Model 728–100 airplane meets the applicable provisions of part 25, as amended by Amendments 25–1 through 25–96. Fairchild Dornier GmbH has also applied to extend the certification basis to include Amendments 25–97, 25–98, and 25–104.

If the Administrator finds that the applicable airworthiness regulations (*i.e.*, 14 CFR part 25) do not contain adequate or appropriate safety standards for the Model 728–100 airplane because of a novel or unusual design feature, special conditions are prescribed under the provisions of § 21.16.

In addition to the applicable airworthiness regulations and special conditions, the Model 728–100 airplane must comply with the fuel vent and exhaust emission requirements of 14 CFR part 34 and the noise certification requirements of 14 CFR part 36, and the FAA must issue a finding of regulatory adequacy pursuant to Section 611 of Public Law 92–574, the ''Noise Control Act of 1972.''

Special conditions, as defined in § 11.19, are issued in accordance with § 11.38 and become part of the type certification basis in accordance with § 21.17(a)(2).

Special conditions are initially applicable to the model for which they are issued. Should the type certificate for that model be amended later to include any other model that incorporates the same novel or unusual design feature, the special conditions would also apply to the other model under the provisions of § 21.101(a)(1).

Novel or Unusual Design Features

As noted earlier, the Fairchild Dornier GmbH Model 728–100 airplane will include an electronic flight control system. The current airworthiness standards of part 25 do not contain adequate or appropriate standards for the protection of this equipment from the adverse effects of operations without normal electrical power. Accordingly, this system is considered to be a novel or unusual design feature. Since the loss of all electrical power may be catastrophic to the airplane, special conditions are proposed to retain the level of safety envisioned by § 25.1351(d).

Discussion

The Fairchild Dornier GmbH Model 728–100 airplane will require a continuous source of electrical power for the electronic flight control system. Section 25.1351(d), ''Operation without normal electrical power,'' requires safe operation in visual flight rule (VFR) conditions for a period of not less than five minutes with inoperative normal power. This rule was structured around a traditional design utilizing mechanical connections between the flight control surfaces and the pilot controls. The Fairchild Dornier GmbH Model 728 will utilize an electronic flight control system. With an electronic flight control system, there is no mechanical linkage between the pilot controls and the flight control surfaces. Pilot control inputs are converted to electrical signals which are processed and then transmitted via wires to the control surface actuators. At the control surface actuators the electrical signals are converted to an actuator command, which moves the control surface. Uninterrupted electrical power is necessary to ensure the electronic flight control system function.

Service experience has shown that the loss of all electrical power generated by the airplane's engine generators or auxiliary power unit (APU) is not extremely improbable. Thus, it must be demonstrated that the airplane can continue safe flight and landing after total loss of the normal electrical power with only the use of its emergency electrical power systems. These emergency electrical power systems must be able to power loads that are essential for continued safe flight and landing. The emergency electrical power system must be designed to supply:

1. Electrical power required for immediate safety, without the need for crew action, following the loss of the normal engine generator electrical power system (which includes APU power).

2. Electrical power required for continued safe flight and landing.

3. Electrical power required to restart the engines.

For compliance purposes, a test of the loss of normal engine generator power must be conducted to demonstrate that when the failure condition occurs during night instrument meteorological conditions (IMC), at the most critical phase of the flight relative to the electrical power system design and distribution of equipment loads on the system, the following conditions are met:

1 Engine restart capability is provided.

2. Capability for continued operation in IMC is provided.

3. The airplane is demonstrated to be capable of continued safe flight and landing. The length of time must be computed based on the maximum diversion time capability for which the airplane is being certified. Consideration for speed reductions resulting from the associated failure must be made.

4. The availability of APU operation should not be considered in establishing emergency power system adequacy.

Applicability

As discussed above, these special conditions are applicable to the Fairchild Dornier GmbH Model 728–100. Should Fairchild Dornier GmbH apply at a later date for a change to the type certificate to include another model incorporating the same novel or unusual design feature, these special conditions would apply to that model as well under the provisions of section 21.101(a)(1). Fairchild Dornier has submitted applications for certification of both increased and reduced passenger capacity derivatives of the Model 728–100 airplane. These derivative models are designated the Model 928–100 airplane and the Model 528–100 airplane, respectively. As currently proposed, these derivative models share the same design feature of an electronic flight control system as the Model 728–100 airplane, and it is anticipated that they will be included in the applicability of these proposed special conditions.

Conclusion

This action affects only certain novel or unusual design features on Fairchild Dornier GmbH Model 728–100 airplanes. It is not a rule of general applicability, and it affects only the applicant who applied to the FAA for approval of these features on the airplane.

List of Subjects in 14 CFR Part 25

Aircraft, Aviation safety, Reporting and recordkeeping requirements.

The authority citation for these special conditions is as follows:

Authority: 49 U.S.C. 106(g), 40113, 44701, 44702, 44704.

The Proposed Special Conditions

Accordingly, the Federal Aviation Administration (FAA) proposes the

following special conditions as part of the type certification basis for Fairchild Dornier GmbH Model 728–100 airplanes.

Operation Without Normal Electrical Power. In lieu of compliance with § 25.1351(d), it must be demonstrated by test, or combination of test and analysis, that the airplane can continue safe flight and landing with inoperative normal engine and APU generator electrical power (in other words, without electrical power from any source except for the battery and any other standby electrical sources). The airplane operation should be considered at the critical phase of flight and include the ability to restart the engines and maintain flight for the maximum diversion time capability being certified.

Issued in Renton, Washington, on April 23, 2002.

Ali Bahrami,

Acting Manager, Transport Airplane Directorate, Aircraft Certification Service.

[FR Doc. 02–12023 Filed 5–13–02; 8:45 am]

BILLING CODE 4910–13–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

21 CFR Part 872

[Docket No. 02N–0114]

Dental Devices; Reclassification of Root-Form Endosseous Dental Implants and Endosseous Dental Implant Abutments

AGENCY: Food and Drug Administration, HHS.

ACTION: Proposed rule.

SUMMARY: The Food and Drug Administration (FDA) is proposing to reclassify from class III to class II root-form endosseous dental implants intended to be surgically placed in the bone of the upper or lower arches to provide support for prosthetic devices, such as artificial teeth, in order to restore the patient's chewing function. FDA is also proposing to reclassify endosseous dental implant abutments, which are separate components that are attached to the implant and intended to aid in prosthetic rehabilitation from class III to class II. This reclassification is being proposed on the Secretary of Health and Human Services (the Secretary's) own initiative based on new information. The agency is taking this action under the Federal Food, Drug, and Cosmetic Act (the act), as amended by the Medical Device Amendments of 1976 (the 1976 amendments), the Safe Medical Devices Act of 1990 (the SMDA), and the Food and Drug Administration Modernization Act of 1997 (FDAMA). Elsewhere in this issue of the **Federal Register**, FDA is publishing a notice of availability of a draft guidance document that would serve as the special control if this proposal becomes final.

DATES: Submit written or electronic comments by August 12, 2002. See section XIII of this document for the proposed effective date of a final rule based on this document.

ADDRESSES: Submit written comments to the Dockets Management Branch (HFA–305), Food and Drug Administration, 5630 Fishers Lane, rm. 1061, Rockville, MD 20852. Submit electronic comments to http://www.fda.gov/dockets/ecomments.

FOR FURTHER INFORMATION CONTACT: Angela E. Blackwell, Center for Devices and Radiological Health (HFZ–480), Food and Drug Administration, 9200 Corporate Blvd., Rockville, MD 20850, 301–827–8879.

SUPPLEMENTARY INFORMATION:

I. Background (Regulatory Authorities)

The act (21 U.S.C. 301 *et seq.*), as amended by the 1976 amendments (Public Law 94–295), the SMDA (Public Law 101–629) and FDAMA (Public Law 105–115), established a comprehensive system for the regulation of medical devices intended for human use. Section 513 of the act (21 U.S.C. 360c) established three categories (classes) of devices, depending on 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).

Under section 513 of the act, devices that were in commercial distribution before May 28, 1976 (the date of enactment of the 1976 amendments), generally referred to as 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, generally referred to as postamendments devices, are classified automatically by statute (section 513(f) of the act) into class III without any FDA rulemaking process. Those devices remain in class III and require premarket approval, unless and until: (1) The device is reclassified into class I or II; (2) FDA issues an order classifying the device into class I or II in accordance with new section 513(f)(2) of the act, as amended by FDAMA; or (3) FDA issues an order finding the device to be substantially equivalent, under section 513(i) of the act, to a predicate device that does not require premarket approval. The agency determines whether new devices are substantially equivalent to previously offered devices by means of premarket notification procedures in section 510(k) of the act (21 U.S.C. 360(k)) and 21 CFR part 807 of the regulations.

A preamendments device that has been classified into class III may be marketed, by means of premarket notification procedures, without submission of a premarket approval application (PMA) until FDA issues a final regulation under section 515(b) of the act (21 U.S.C. 360e(b)) requiring premarket approval.

Reclassification of classified preamendments devices is governed by section 513(e) of the act. This section provides that FDA may, by rulemaking, reclassify a device (in a proceeding that parallels the initial classification proceeding) based upon ''new information.'' The reclassification can be initiated by FDA or by the petition of an interested person. The term ''new information,'' as used in section 513(e) of the 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* v. *United States Department of Health, Education, and Welfare*, 587 F.2d at 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 regulatory action where the reevaluation is made in light of newly available regulatory authority (see *Bell* v. *Goddard*, supra, 366 F.2d at 181; *Ethicon , Inc.* v. *FDA*, 762 F. Supp. 382, 389-91 (D.D.C. 1991)), or in light of changes in ''medical science.'' (See *Upjohn* v. *Finch*, supra, 422 F.2d at 951.) Regardless of whether data before the agency are past or new data, the ''new information'' to support reclassification under section 513(e) of the act must be ''valid scientific evidence,'' as defined in section 513(a)(3) of the act and 21 CFR 860.7(c)(2). (*See, e.g., General Medical*