

Actions	Compliance	Procedures
(1) Inspect, using eddy current inspection, the inboard forward flap bellcrank for cracks.	Initially inspect upon the accumulation of 4,000 landings on the bellcrank or within the next 250 landings after December 31, 2002 (the effective date of this AD), whichever occurs later. Repetitively inspect thereafter at every 500 landings until 7,000 landings are accumulated.	In accordance with the Inspection Instructions of Cessna Service Bulletin No. CAB02-1, dated February 11, 2002, and the applicable maintenance manual.
(2) Replace the inboard forward flap bellcrank.	Prior to further flight when cracks are found; and upon the accumulation of 7,000 landings or within the next 75 landings after December 31, 2002 (the effective date of this AD), whichever occurs later.	In accordance with the Inspection Instructions of Cessna Service Bulletin No. CAB02-1, dated February 11, 2002, and the applicable maintenance manual.

Note 1: Inboard forward flap bellcranks with 7,000 landings or more do not have to be replaced until 75 landings after the effective date of this AD.

Note 2: The compliance times of this AD are presented in landings instead of hours. If the number of landings is unknown, hours time-in-service (TIS) may be used by multiplying the number of hours TIS by 1.25.

(e) *Can I comply with this AD in any other way?* You may use an alternative method of compliance or adjust the compliance time if:

- (1) Your alternative method of compliance provides an equivalent level of safety; and
- (2) The Manager, Wichita Aircraft Certification Office (ACO), approves your alternative. Submit your request through an FAA Principal Maintenance Inspector, who may add comments and then send it to the Manager, Wichita ACO.

Note 3: This AD applies to each airplane identified in paragraph (a) of this AD, 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 you have not eliminated the unsafe condition, specific actions you propose to address it.

(f) *Where can I get information about any already-approved alternative methods of compliance?* Contact Paul Nguyen, Aerospace Engineer, FAA, Aircraft Certification Office, 1801 Airport Road, Room 100, Wichita, Kansas 67209; telephone: 316-946-4125; facsimile: 816-946-4407.

(g) *What if I need to fly the airplane to another location to comply with this AD?* The FAA can issue a special flight permit under §§ 21.197 and 21.199 of the Federal Aviation Regulations (14 CFR 21.197 and 21.199) to operate your airplane to a location where you can accomplish the requirements of this AD.

(h) *Are any service bulletins incorporated into this AD by reference?* Actions required by this AD must be done in accordance with Cessna Service Bulletin No. CAB02-1, dated February 11, 2002. The Director of the Federal Register approved this incorporation by reference under 5 U.S.C. 552(a) and 1 CFR part 51. You may get copies from Cessna

Aircraft Company, Product Support, PO Box 7706, Wichita, Kansas 67277; telephone: (316) 517-5800; facsimile: (316) 942-9006. You may view copies at the FAA, Central Region, Office of the Regional Counsel, 901 Locust, Room 506, Kansas City, Missouri, or at the Office of the Federal Register, 800 North Capitol Street, NW, suite 700, Washington, DC.

(i) *When does this amendment become effective?* This amendment becomes effective on December 31, 2002.

Issued in Kansas City, Missouri, on October 31, 2002.

Michael Gallagher,

Manager, Small Airplane Directorate, Aircraft Certification Service.

[FR Doc. 02-28408 Filed 11-8-02; 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-0010]

Dental Devices; Classification for Intraoral Devices for Snoring and/or Obstructive Sleep Apnea

AGENCY: Food and Drug Administration, HHS.

ACTION: Final rule.

SUMMARY: The Food and Drug Administration (FDA) is classifying the intraoral devices for snoring and/or obstructive sleep apnea into class II (special controls). These devices are used to control or treat simple snoring and/or obstructive sleep apnea. This classification is based on the recommendations of the Dental Devices Panel (the Panel), and is being taken to establish sufficient regulatory controls that will provide reasonable assurance of the safety and effectiveness of these devices. This action is being taken 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 the guidance document that will serve as the special control for this final rule.

DATES: This rule is effective December 12, 2002.

FOR FURTHER INFORMATION CONTACT:

Susan Runner, Center for Devices and Radiological Health (HFZ-480), Food and Drug Administration, 9200 Corporate Blvd., Rockville, MD 20850, 301-827-5283.

SUPPLEMENTARY INFORMATION:

I. Background

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 the 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), are generally referred to as preamendments devices, and 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, and 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 the 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.

Consistent with the act and the regulations, FDA consulted with the Panel, an FDA advisory committee, regarding the classification of these devices.

II. Regulatory History of the Device

In the **Federal Register** of April 5, 2002 (67 FR 16338), FDA issued a proposed rule to classify the intraoral devices for snoring and/or obstructive sleep apnea, used to control or treat simple snoring and/or obstructive sleep apnea into class II. The agency also issued a guidance document as the special control. Interested persons were given until July 5, 2002, to comment on the proposed regulation and guidance document.

FDA received one comment from the National Association of Dental Laboratories.

III. Summary of Final Rule

As required by 21 CFR 860.84(g)(2) of the regulations, FDA is classifying intraoral devices for snoring and/or obstructive sleep apnea into class II with the guidance document "Class II Special Controls Guidance Document: Intraoral Devices for Snoring and/or Obstructive Sleep Apnea" (Ref. 1), as the special control.

IV. Analysis of Comment and FDA's Response

The one comment FDA received expressed concerns about the effect the guidance document would have on dental laboratories. FDA has concluded that the guidance document does not change the regulatory requirements for dental laboratories.

Therefore, under section 513 of the act, FDA is adopting the summary of reasons for the Panel's recommendation and the summary of data upon which the Panel's recommendation is based, in their entirety. FDA also agrees with the Panel's assessment of the risks to public health stated in the proposed rule published on April 5, 2002. FDA is issuing this final rule, which classifies these generic type of intraoral devices for snoring and obstructive sleep apnea into class II.

V. Environmental Impact

The agency has determined under 21 CFR 25.34(b) that this action is of a type that does not individually or cumulatively have a significant effect on the human environment. Therefore, neither an environment assessment nor an environmental impact statement is required.

VI. Analysis of Impacts

FDA has examined the impacts of the final rule under Executive Order 12866 and the Regulatory Flexibility Act (5 U.S.C. 601–612), and the Unfunded Mandates Reform Act of 1995 (Public Law 104–4). Executive Order 12866 directs agencies to assess all costs and benefits of available regulatory alternatives and, when regulation is necessary, to select regulatory approaches that maximize net benefits (including potential economic, environmental, public health and safety, and other advantages; distributive impacts; and equity). The agency believes that this final rule is consistent with the regulatory philosophy and principles identified in the Executive order. In addition, the final rule is not a significant regulatory action as defined by the Executive order and so is not subject to review under the Executive order.

The Regulatory Flexibility Act requires agencies to analyze regulatory options that would minimize any significant impact of a rule on small entities. The classification of these devices into class II is not adding any additional burden to manufacturers, because most manufacturers, including small manufacturers, are already substantially in compliance with the recommendations of the guidance

document that is the special control for the devices. The agency, therefore, certifies that this final rule will not have a significant economic impact on a substantial number of small entities. In addition, this final rule will not impose costs of \$100 million or more on either the private sector or State, local, and tribal governments in the aggregate, and, therefore, a summary statement of analysis under section 202(a) of the Unfunded Mandates Reform Act of 1995 is not required.

VII. Federalism

FDA has analyzed this final rule in accordance with the principles set forth in Executive Order 13132. FDA has determined that the rule does not contain policies that have substantial direct effects 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. Accordingly, the agency has concluded that the rule does not contain policies that have federalism implications as defined in the Executive order and, consequently, a federalism summary impact statement is not required.

VIII. Paperwork Reduction Act of 1995

FDA concludes that this final rule contains no collections of information. Therefore, clearance by the Office of Management and Budget under the Paperwork Reduction Act of 1995 (44 U.S.C. 3501–3520) is not required.

IX. Reference

The following reference has been placed on display in the Dockets Management Branch (HFA–305), 5630 Fishers Lane, rm. 1061, Rockville, MD 20852, and may be seen by interested persons between 9 a.m. and 4 p.m., Monday through Friday.

1. FDA, Center for Devices and Radiological Health, Office of Device Evaluation, "Class II Special Controls Guidance Document: Intraoral Devices for Snoring and/or Obstructive Sleep Apnea; Guidance for Industry and FDA," April 5, 2002.

List of Subjects in 21 CFR Part 872

Medical devices.

Therefore, under the Federal Food, Drug, and Cosmetic Act and under authority delegated to the Commissioner of Food and Drugs, 21 CFR part 872 in subpart F is amended as follows:

PART 872—DENTAL DEVICES

1. The authority citation for 21 CFR part 872 continues to read as follows:

Authority: 21 U.S.C. 351, 360, 360c, 360e, 360j, 371.

2. Section 872.5570 is added to subpart F to read as follows:

§ 872.5570 Intraoral devices for snoring and intraoral devices for snoring and obstructive sleep apnea.

(a) *Identification.* Intraoral devices for snoring and intraoral devices for snoring and obstructive sleep apnea are devices that are worn during sleep to reduce the incidence of snoring and to treat obstructive sleep apnea. The devices are designed to increase the patency of the airway and to decrease air turbulence and airway obstruction. The classification includes palatal lifting devices, tongue retaining devices, and mandibular repositioning devices.

(b) *Classification.* Class II (special controls). The special control for these devices is the FDA guidance document entitled "Class II Special Controls Guidance Document: Intraoral Devices for Snoring and/or Obstructive Sleep Apnea; Guidance for Industry and FDA."

Dated: October 28, 2002.

Linda S. Kahan,

Deputy Director, Center for Devices and Radiological Health.

[FR Doc. 02-28549 Filed 11-8-02; 8:45 am]

BILLING CODE 4160-01-S

DEPARTMENT OF TRANSPORTATION

Federal Highway Administration

23 CFR Part 450

[FHWA Docket No. FHWA-2001-10836]

FHWA RIN 2125-AE92

Metropolitan Transportation Planning and Programming

AGENCY: Federal Highway Administration (FHWA), DOT.

ACTION: Correction to final rule.

SUMMARY: This document corrects a typographical error in the FHWA final rule, published jointly with the Federal Transit Administration (FTA), on October 7, 2002, at 67 FR 62370. The final rule amends the regulation on Planning and Assistance Standards that govern the development of transportation plans and programs for urbanized (metropolitan) areas. The FTA has codified the FHWA regulations for Metropolitan Transportation Planning and Programming into its regulations at 49 CFR 613 and joins the FHWA in making this change. The final rule provides the New York City metropolitan area additional time to

review and update its transportation plan by waiving the regulatory requirement for a triennial plan update for the New York City metropolitan area for up to three years, until September 30, 2005. The docket number that appeared at the heading of the final rule was incorrect. This notice provides the current docket number regarding the Metropolitan Transportation Planning and Programming final rule as FHWA-2001-10836.

EFFECTIVE DATE: October 7, 2002.

FOR FURTHER INFORMATION CONTACT: Mr. John Humeston, Metropolitan Planning and Policies Team (HEPM), (404) 562-3667 (metropolitan planning), 60 Forsyth Street, Suite 8M5; Atlanta, Georgia 30303-3104; or Mr. Reid Alsop, Office of the Chief Counsel (HCC-31), (202) 366-1371; 400 Seventh Street, SW., Washington, D.C. 20590. Office hours are from 7:45 a.m. to 4:15 p.m., e.t., Monday through Friday, except Federal holidays.

SUPPLEMENTARY INFORMATION:

Electronic Access

An electronic copy of this document may be downloaded using a computer, modem and suitable communications software from the Government Printing Office's Electronic Bulletin Board Service at (202) 512-1661. Internet users may reach the Office of the Federal Register's home page at: <http://www.archives.gov> and the Government Printing Office's Web page at: <http://www.access.gpo.gov/nara>.

Background

On October 7, 2002, at 67 FR 62370, the FHWA, jointly with the FTA, issued a final rule to provide the New York City metropolitan area additional time to review and update its transportation plan by waiving the regulatory requirement for a triennial plan update for the New York City metropolitan area for up to three years, until September 30, 2005. This action was necessary because the New York City Metropolitan Transportation Council's (NYMTC) offices were destroyed by the terrorist attacks that occurred on September 11, 2001, and without this waiver, Federal highway and transit funding could be disrupted after September 30, 2002. The purpose of this notice is to correct the docket number to the final rule. The correct docket number for the final rule is FHWA-2001-10836.

Authority: 23 U.S.C. 134, 135, 217(g), 315; 42 U.S.C. 7410 *et seq.*; 49 U.S.C. 5303-5306; 49 CFR 1.48(b) and 1.51.

Issued on: November 5, 2002.

James A. Rowland,

Chief Counsel, Federal Highway Administration.

[FR Doc. 02-28643 Filed 11-8-02; 8:45 am]

BILLING CODE 4910-22-P

DEPARTMENT OF THE TREASURY

Internal Revenue Service

26 CFR Part 1

[TD 9020]

RIN 1545-BB19

Substantiation of Incidental Expenses

AGENCY: Internal Revenue Service (IRS), Treasury.

ACTION: Final and temporary regulations.

SUMMARY: This document contains amendments to regulations relating to the requirement to substantiate business expenses for traveling expenses while away from home. The regulations affect taxpayers who deduct expenses for incidental expenses while traveling away from home. The text of the temporary regulations also serves as text for the proposed regulations set forth in the notice of proposed rulemaking on this subject in the Proposed Rules section in this issue of the **Federal Register**.

DATES: *Effective Date:* These regulations are effective November 12, 2002.

Applicability Date: For dates of applicability, see § 1.274-5T(m).

FOR FURTHER INFORMATION CONTACT: John Moriarty (202) 622-4930 (not a toll free call).

SUPPLEMENTARY INFORMATION:

Background and Explanation of Provisions

Section 274(d) provides that a taxpayer is not allowed a deduction or credit for certain expenses unless the expense is substantiated. These substantiation requirements apply to deductions under section 162 or 212 for any traveling expense (including meals and lodging) while away from home. Under section 274(d), the Secretary may issue regulations that provide that some or all of the substantiation requirements will not apply to expenses that do not exceed a prescribed amount. Section 1.274-5(j)(1) of the regulations permits the Commissioner to establish a method under which a taxpayer may substantiate the amount of meal expenses paid or incurred while traveling away from home by means of