Rules and Regulations

Federal Register
Vol. 67, No. 235
Friday, December 6, 2002

DEPARTMENT OF TRANSPORTATION

Federal Aviation Administration

14 CFR Part 39

[Docket No. 2000–NE–47–AD; Amendment 39–12916; AD 2002–21–10]

RIN 2120–AA64

Airworthiness Directives; Pratt & Whitney PW4000 Series Turbofan Engines, Correction

AGENCY: Federal Aviation Administration, DOT.

ACTION: Final rule; request for comments, correction.

SUMMARY: This document makes corrections to Airworthiness Directive (AD) 2002–21–10, applicable to Pratt and Whitney (PW) model 4000 series turbofan engines, that was published in the **Federal Register** on October 25, 2002 (67 FR 65484). A publish date for service information was inadvertently omitted from one of the compliance paragraphs in the regulatory information. Also, the same service information was inadvertently omitted from the table for Documents That Have Been Incorporated by Reference and the paragraph that follows the table. This document corrects these omissions. In all other respects, the original document remains the same.

EFFECTIVE DATE: November 12, 2002. The incorporation by reference of certain publications listed in the rule is approved by the Director of the **Federal Register** as of December 6, 2002.

FOR FURTHER INFORMATION CONTACT: Diane Cook, Aerospace Engineer, Engine Certification Office, FAA, Engine and Propeller Directorate, 12 New England Executive Park, Burlington, MA 01803–5299; telephone (781) 238–7133, fax (781) 238–7199.

SUPPLEMENTARY INFORMATION: A final rule; request for comments FR Doc. 02–26909, airworthiness directive applicable to Pratt and Whitney (PW) model 4000 series turbofan engines, was published in the **Federal Register** on October 25, 2002 (67 FR 65484). The following corrections are needed:

§ 39.13 [Corrected]

On page 65491, in the Regulatory Information, second column, paragraph (k)(2)(i), sixth line, remove the phrase ''September 15, 2001. If the HPC rear hook is.'' and add in its place ''March 15, 2002 or September 15, 2001. If the rear hook is.''

Also, on page 65492, in the Regulatory Information, the table for Documents That Have Been Incorporated by Reference is corrected by adding the following:

''PW CIR 51A357, section 72–35–68, Inspection/Check–04, Indexes 8–11.	All	Original	March 15, 2002.

Total pages: 5''

Also, on page 65493, in the Regulatory Information, first column, thirteenth line, remove the phrase ''PW4ENG72–749, dated June 17, 2002, EM'' and add in its place ''PW4ENG72–749, dated June 17, 2002, CIR 51A357, section 72–35–68, Inspection/Check–04, Indexes 8–11, dated March 15, 2002, EM''.

Issued in Burlington, MA, on November 13, 2002.

Mark C. Fulmer,

Acting Manager, Engine and Propeller Directorate, Aircraft Certification Service.

[FR Doc. 02–29672 Filed 12–5–02; 8:45 am]

BILLING CODE 4910–13–P

DEPARTMENT OF TRANSPORTATION

Federal Aviation Administration

14 CFR Part 97

[Docket No. 30342; Amdt. No. 3034]

Standard Instrument Approach Procedures; Miscellaneous Amendments

AGENCY: Federal Aviation Administration (FAA), DOT.

ACTION: Final rule.

SUMMARY: This amendment establishes, amends, suspends, or revokes Standard Instrument Approach Procedures (SIAPs) for operations at certain airports. These regulatory actions are needed because of changes occurring in the National Airspace System, such as the commissioning of new navigational facilities, addition of new obstacles, or changes in air traffic requirements. These changes are designed to provide safe and efficient use of the navigable airspace and to promote safe flight operations under instrument flight rules at the affected airports.

DATES: This rule is effective December 6, 2002. The compliance date for each SIAP is specified in the amendatory provisions.

The incorporation by reference of certain publications listed in the regulations is approved by the Director of the Federal Register as of December 6, 2002.

ADDRESSES: Availability of matter incorporated by reference in the amendment is as follows:

For Examination

1. FAA Rules Docket, FAA Headquarters Building, 800 Independence Avenue, SW., Washington, DC 20591;

2. The FAA Regional Office of the region in which affected airport is located; or

3. The Flight Inspection Area Office which originated the SIAP.

4. The Office of the Federal Register, 800 North Capitol Street, NW., Suite 700 Washington, DC.

For Purchase

Individual SIAP copies may be obtained from:

1. FAA Public Inquiry Center (APA–200), FAA Headquarters Building, 800 Independence Avenue, SW., Washington, DC 20591; or

2. The FAA Regional Office of the region in which the affected airport is located.

By Subscription

Copies of all SIAPs, mailed once every 2 weeks, are for sale by the Superintendent of Documents, U.S. Government Printing Office, Washington, DC 20402.

FOR FURTHER INFORMATION CONTACT: Donald P. Pate, Flight Procedure Standards Branch (AMCAFS–420), Flight Technologies and Programs Division, Flight Standards Service, Federal Aviation Administration, Mike Monroney Aeronautical Center, 6500 South MacArthur Blvd., Oklahoma City, OK 73169 (Mail Address: P.O. Box 25082 Oklahoma City, OK 73125) telephone: (405) 954–4164.

SUPPLEMENTARY INFORMATION: This amendment to part 97 of the Federal Aviation Regulations (14 CFR part 97) establishes, amends, suspends, or revokes Standards Instrument Approach Procedures (SIAPs). The complete regulatory description on each SIAP is contained in the appropriate FAA Form 8260 and the National Flight Data Center (FDC)/Permanent (P) Notices to Airmen (NOTAM) which are incorporated by reference in the amendment under 5 U.S.C. 552(a), 1 CFR part 51, and § 97.20 of the Federal Aviation's Regulations (FAR). Materials incorporated by reference are available for examination or purchase as stated above.

The large number of SIAPs, their complex nature, and the need for a special format make their verbatim publication the **Federal Register** expensive and impractical. Further, airmen do not use the regulatory text of the SIAPs, but refer to their graphic depiction of charts printed by publishers of aeronautical materials. Thus, the advantages of incorporation by reference are realized and publication of the complete description of each SIAP contained in FAA form documents is unnecessary. The provisions of this amendment state the affected CFR (and FAR) sections, with the types and effective dates of the SIAPs. This amendment also identifies the airport, its location, the procedure identification and the amendment number.

The Rule

This amendment to part 97 of the Federal Aviation Regulations (14 CFR part 97) establishes, amends, suspends, or revokes SIAPs. For safety and timeliness of change considerations, this amendment incorporates only specific changes contained in the content of the following FDC/P NOTAMs for each SIAP. The SIAP information is some previously designated FDC/Temporary (FDC/T) NOTAMs is of such duration as to be permanent. With conversion to FDC/P NOTAMs, the respective FDC/T NOTAMs have been canceled.

The FDC/P NOTAMs for the SIAPs contained in this amendment are based on the criteria contained in the U.S. Standard for Terminal Instrument Procedures (TERPS). In developing these chart changes to SIAPs by FDC/P NOTAMs, the TERPS criteria were applied to only these specific conditions existing at the affected airports. All SIAP amendments in this rule have been previously issued by the FAA in a National Flight Data Center (FDC) Notice to Airmen (NOTAM) as an emergency action of immediate flight safety relating directly to published aeronautical charts. The circumstances which created the need for all these SIAP amendments require making them effective in less than 30 days.

Further, the SIAPs contained in this amendment are based on the criteria contained in the TERPS. Because of the close and immediate relationship between these SIAPs and safety in air commerce, I find that notice and public procedure before adopting these SIAPs are impracticable and contrary to the public interest and, where applicable, that good cause exists for making these SIAPs effective in less than 30 days.

Conclusion

The FAA has determined that this regulation only involves an established body of technical regulations for which frequent and routine amendments are necessary to keep them operationally current. It, therefore—(1) is not a ''significant regulatory action'' under Executive Order 12866; (2) is not a ''significant rule'' under DOT Regulatory Policies and Procedures (44 FR 11034; February 26, 1979); and (3) does not warrant preparation of a regulatory evaluation as the anticipated impact is so minimal. For the same reason, the FAA certifies that this amendment will not have a significant economic impact on a substantial number of small entities under the criteria of the Regulatory Flexibility Act.

List of Subjects in 14 CFR Part 97

Air traffic control, Airports, Incorporation by reference, and Navigation (air).

Issued in Washington, DC on November 22, 2002.

James J. Ballough,

Director, Flight Standards Service.

Adoption of the Amendment

Accordingly, pursuant to the authority delegated to me, part 97 of the Federal Aviation Regulations (14 CFR part 97) is amended by establishing, amending, suspending, or revoking Standard Instrument Approach Procedures, effective at 0901 UTC on the dates specified, as follows:

PART 97—STANDARD INSTRUMENT APPROACH PROCEDURES

1. The authority citation for part 97 is revised to read as follows:

Authority: 49 U.S.C. 40103, 40113, 40120, 44701; 49 U.S.C. 106(g); and 14 CFR 11.49(b)(2)

2. Part 97 is amended to read as follows:

§ 97.23, § 97.25, § 97.27, § 97.29, § 97.31, § 97.33, and § 97.35 [Amended]

By amending: § 97.23 VOR, VOR/DME, VOR or TACAN, and VOR/DME or TACAN; § 97.25 LOC, LOC/DME, LDA, LDA/DME, SDF, SDF/DME; § 97.27 NDB, NDB/DME; § 97.29 ILS, ILS/DME, ISMLS, MLS/DME, MLS/RNAV; § 97.31 RADAR SIAPs; § 97.33 RNAV SIAPs; and § 97.35 COPTER SIAPs, Identified as follows:

** * * Effective Upon Publication.*

FDC date	State	City	Airport	FDC No.	Subject
03/11/02	MO	St Louis	Creve Couer	2/2128	RNAV (GPS) Rwy 34, Orig
11/06/02	NC	Raleigh/Durham	Raleigh-Durham Intl	2/1751	ILS Rwy 23L, Amdt 6A
11/07/02	TX	Houston	William P. Hobby	2/1774	RNAV (GPS) Rwy 30L, Orig-B
11/12/02	OK	Duncan	Halliburton Field	2/1875	LOC Rwy 35, Amdt 4B

FDC date	State	City	Airport	FDC No.	Subject
11/13/02	NJ	Lakewood	Lakewood	2/1904	RNAV (GPS) Rwy 6, Orig
11/13/02	NJ	Lakewood	Lakewood	2/1905	RNAV (GPS) Rwy 24, Orig
11/13/02	NJ	Lakewood	Lakewood	2/1906	VOR Rwy 6, Amdt 6
11/13/02	MI	Detroit	Grosse Ile Muni	2/1910	RNAV (GPS) Rwy 22, Orig
11/14/02	MI	Big Rapids	Roben-Hood	2/1942	GPS Rwy 27, Orig
11/15/02	MI	Hastings	Hastings	2/1984	VOR Rwy 12, Orig-A
11/15/02	IL	Salem	Salem-Leckrone	2/1992	NDB Rwy 18, Amdt 10A
11/18/02	MN	St Cloud	St Cloud Regional	2/2033	VOR/DME Rwy 13, Amdt 8B
11/19/02	MI	Detroit	Detroit Metropolitan Wayne County	2/2057	ILS Rwy 22R, Amdt 1

[FR Doc. 02–30440 Filed 12–5–02; 8:45 am]
BILLING CODE 4910–13–M

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

21 CFR Parts 336, 338, and 341

[Docket No. 97N–0128]

RIN 0910–AA01

Labeling of Diphenhydramine-Containing Drug Products for Over-the-Counter Human Use

AGENCY: Food and Drug Administration, HHS.

ACTION: Final rule.

SUMMARY: The Food and Drug Administration (FDA) is issuing a final rule amending the final monographs for over-the-counter (OTC) antiemetic, antihistamine, antitussive, and nighttime sleep-aid drug products to add a warning statement for oral products containing diphenhydramine citrate or diphenhydramine hydrochloride. The warning advises consumers not to use oral OTC diphenhydramine products with any other product containing diphenhydramine, including products used topically. This final rule also includes the agency's conclusions on additional warning statements and a direction statement for OTC external analgesic drug products containing diphenhydramine hydrochloride. These conclusions will be incorporated into the final monograph for OTC external analgesic drug products in a future issue of the **Federal Register**. FDA is issuing this final rule after considering public comments on the agency's proposed regulation and all new data and information on drug products containing diphenhydramine that have come to the agency's attention.

DATES:

Effective Date: This regulation is effective December 8, 2003.

Compliance Dates: The compliance date for oral products with annual sales less than $25,000 is December 6, 2004. The compliance date for all other oral products is December 8, 2003.

FOR FURTHER INFORMATION CONTACT: Michael T. Benson, Center for Drug Evaluation and Research (HFD–560), Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857, 301–827–2222.

SUPPLEMENTARY INFORMATION:

I. Background

In the **Federal Register** of August 29, 1997 (62 FR 45767), FDA published a notice of proposed rulemaking to amend the tentative final monograph (TFM) for OTC external analgesic drug products (proposed 21 CFR 348.50(c)(10)) to add the following warning statement for diphenhydramine hydrochloride: ''Do Not Use:'' (these three words in bold print) ''on chicken pox, poison ivy, sunburn, large areas of the body, broken, blistered, or oozing skin, more often than directed, or with any other product containing diphenhydramine, even one taken by mouth.'' The agency also proposed to amend the final monographs for OTC antiemetic (proposed 21 CFR 336.50(c)(8)), antihistamine (proposed 21 CFR 341.72(c)(6)(iv) and (c)(7)) and antitussive (proposed 21 CFR 341.74(c)(4)(viii)(C) and (c)(4)(ix)(C)), and nighttime sleep-aid (proposed 21 CFR 338.50(c)(5)) drug products to add the following warning statement for diphenhydramine ingredients: ''Do Not Use'' (these three words in bold print) ''with any other product containing diphenhydramine, including one applied topically.'' The agency proposed these warnings based on reports of adverse events when oral and topical diphenhydramine products were used concurrently. In response to that proposal, two manufacturers and a marketing association submitted comments. The agency is responding to those comments and publishing a final rule that applies to oral diphenhydramine products now and to topical diphenhydramine products at a future date.

Twenty-four months after the date of publication in the **Federal Register**, for oral diphenhydramine-containing products with sales less than $25,000, and 12 months after the after the date of publication in the **Federal Register**, for all other such oral products, no OTC drug product that is subject to this final rule and that contains a nonmonograph condition may be initially introduced or initially delivered for introduction into interstate commerce unless it is the subject of an approved new drug application or abbreviated new drug application. Further, any OTC drug product subject to this final rule that is repackaged or relabeled after the compliance dates of the final rule must be in compliance with the applicable monograph regardless of the date the product was initially introduced or initially delivered for introduction into interstate commerce. Manufacturers are encouraged to comply voluntarily as soon as possible.

II. The Agency's Conclusion on the Comments

(Comment 1) One comment contended that the proposed label changes for diphenhydramine products are not necessary and would have no significant impact. The comment stated that the 23 reported cases of toxicity between 1979 and 1989 discussed in the proposal (62 FR 45767 at 45768) are minute compared to the millions of applications of these topical products. Further, in all cases, the toxicity was due to consumer noncompliance with directions and indications. In the majority of cases, no treatment was required except for discontinuance of the drug, with affected consumers released from medical care in 24 hours. The comment concluded that additional warnings would have no effect on consumers who have obviously ignored the existing warnings.

The agency disagrees. The agency recognizes that the number of reports is small compared to the total doses used. However, there is particular concern because of the reports of toxic psychosis, especially in children, discussed in the proposed rule. There is also concern of underreporting because there is no current reporting