

[FR Doc. E6-20941 Filed 12-12-06; 8:45 am]
BILLING CODE 4910-13-P

DEPARTMENT OF TRANSPORTATION

Federal Aviation Administration

14 CFR Part 97

[Docket No. 30525 Amdt. No. 3196]

Standard Instrument Approach Procedures, Weather Takeoff Minimums; Miscellaneous Amendments

AGENCY: Federal Aviation Administration (FAA), DOT.

ACTION: Final rule.

SUMMARY: This amendment establishes, amends, suspends, or revokes Standard Instrument Approach Procedures (SIAPs) and/or Weather Takeoff Minimums for operations at certain airports. These regulatory actions are needed because of the adoption of new or revised criteria, or 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 13, 2006. The compliance date for each SIAP and/or Weather Takeoff Minimums 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 13, 2006.

ADDRESSES: Availability of matters 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 the affected airport is located;

3. The National Flight Procedures Office, 6500 South MacArthur Blvd., Oklahoma City, OK 73169 or,

4. 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/

code_of_federal_regulations/ibr_locations.html.

*For Purchase—*Individual SIAP and Weather Takeoff Minimums 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 and Weather Takeoff Minimums 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 (AFS-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 Title 14 of the Code of Federal Regulations, Part 97 (14 CFR part 97), establishes, amends, suspends, or revokes SIAPs and/or Weather Takeoff Minimums. The complete regulatory description of each SIAP and/or Weather Takeoff Minimums is contained in official FAA form documents which are incorporated by reference in this amendment under 5 U.S.C. 552(a), 1 CFR part 51, and 14 CFR part 97.20. The applicable FAA Forms are identified as FAA Forms 8260-3, 8260-4, 8260-5 and 8260-15A. Materials incorporated by reference are available for examination or purchase as stated above.

The large number of SIAPs and/or Weather Takeoff Minimums, their complex nature, and the need for a special format make their verbatim publication in the **Federal Register** expensive and impractical. Further, airmen do not use the regulatory text of the SIAPs and/or Weather Takeoff Minimums but refer to their depiction on 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 and/or Weather Takeoff Minimums contained in FAA form documents is unnecessary. The provisions of this amendment state the affected CFR sections, with the types and effective dates of the SIAPs and/or Weather Takeoff Minimums. This amendment

also identifies the airport, its location, the procedure identification and the amendment number.

The Rule

This amendment to 14 CFR part 97 is effective upon publication of each separate SIAP and/or Weather Takeoff Minimums as contained in the transmittal. Some SIAP and/or Weather Takeoff Minimums amendments may have been previously issued by the FAA in a 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 some SIAP, and/or Weather Takeoff Minimums amendments may require making them effective in less than 30 days. For the remaining SIAPs and/or Weather Takeoff Minimums, an effective date at least 30 days after publication is provided.

Further, the SIAPs and/or Weather Takeoff Minimums contained in this amendment are based on the criteria contained in the U.S. Standard for Terminal Instrument Procedures (TERPS). In developing these SIAPs and/or Weather Takeoff Minimums, the TERPS criteria were applied to the conditions existing or anticipated at the affected airports. Because of the close and immediate relationship between these SIAPs and/or Weather Takeoff Minimums and safety in air commerce, I find that notice and public procedure before adopting these SIAPs and/or Weather Takeoff Minimums are impracticable and contrary to the public interest and, where applicable, that good cause exists for making some SIAPs and/or Weather Takeoff Minimums 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 December 1, 2006.

James J. Ballough,

Director, Flight Standards Service.

Adoption of the Amendment

■ Accordingly, pursuant to the authority delegated to me, under Title 14, Code of Federal Regulations, Part 97 (14 CFR part 97) is amended by establishing, amending, suspending, or revoking Standard Instrument Approach Procedures and Weather Takeoff Minimums effective at 0901 UTC on the dates specified, as follows:

PART 97—STANDARD INSTRUMENT APPROACH PROCEDURES

■ 1. The authority citation for part 97 continues to read as follows:

Authority: 49 U.S.C. 106(g), 40103, 40106, 40113, 40114, 40120, 44502, 44514, 44701, 44719, 44721–44722.

■ 2. Part 97 is amended to read as follows:

Effective 21 December 2006

Lynchburg, VA, Falwell, RNAV (GPS) RWY 28, Orig

Effective 18 January 2007

Deadhorse, AK, Deadhorse, ILS OR LOC/DME RWY 4, Amdt 1
 Deadhorse, AK, Deadhorse, Takeoff Minimums & Textual DPs, Orig
 Homer, AK, Homer, RNAV (GPS) Y RWY 21, Orig
 Homer, AK, Homer, RNAV (GPS) Y RWY 3, Orig
 Homer, AK, Homer, GPS RWY 21, Orig-B, CANCELLED
 Homer, AK, Homer, GPS RWY 3, Orig-B, CANCELLED
 Juneau, AK, Juneau Intl, RNAV (GPS) V RWY 8, Amdt 1
 Juneau, AK, Juneau Intl, LDA X RWY 8, Amdt 11
 Juneau, AK, Juneau Intl, Takeoff Minimums & Textual DPs, Amdt 3
 Northway, AK, Northway, RNAV(GPS) RWY 5, Orig
 Northway, AK, Northway, RNAV(GPS) RWY 23, Orig
 Northway, AK, Northway, NDB OR GPS RWY 4, Orig, CANCELLED
 Northway, AK, Northway, NDB OR GPS RWY 22, Orig, CANCELLED
 Northway, AK, Northway, VOR–B, Amdt 3, CANCELLED
 Northway, AK, Northway, VOR/DME–A, Amdt 1
 Northway, AK, Northway, Takeoff Minimums & Textual DPs, Amdt 2
 Perryville, AK, Perryville, RNAV (GPS) RWY 2, Orig
 Perryville, AK, Perryville, RNAV (GPS) RWY 3, Orig, CANCELLED

Perryville, AK, Perryville, Takeoff Minimums & Textual DPs, Amdt 1
 Sitka, AK, Sitka Rocky Gutierrez, Takeoff Minimums & Textual DPs, Amdt 3
 Togiak Village, AK, Togiak, Takeoff Minimums & Textual DPs, Amdt 1
 Oakland, CA, Metropolitan Oakland Intl, ILS OR LOC/DME RWY 27R, Amdt 35
 Sacramento, CA, Sacramento Mather, RNAV (GPS) RWY 4R, Amdt 1
 Albany, GA, Southwest Georgia Regional, RNAV (GPS) RWY 22, Orig
 Albany, GA, Southwest Georgia Regional, RNAV (GPS) RWY 16, Orig
 Albany, GA, Southwest Georgia Regional, RNAV (GPS) RWY 4, Orig
 Albany, GA, Southwest Georgia Regional, RNAV (GPS) RWY 34, Orig
 Albany, GA, Southwest Georgia Regional, Takeoff Minimums and Textual DP, Orig
 Valdosta, GA, Valdosta Regional, RNAV (GPS) RWY 17, Orig
 Valdosta, GA, Valdosta Regional, VOR RWY 17, Amdt 1
 Valdosta, GA, Valdosta Regional, Takeoff Minimums and Textual DP, Orig
 Hailey, ID, Friedman Memorial, RNAV (RNP) Z RWY 31, Orig, CANCELLED
 Peru, IN, Peru Muni, RNAV (GPS) RWY 1, Orig
 Peru, IN, Peru Muni, RNAV (GPS) RWY 19, Orig
 Peru, IN, Peru Muni, VOR RWY 1, Amdt 8
 Peru, IN, Peru Muni, Takeoff Minimums and Textual DPs, Amdt 3
 Portland, IN, Portland Muni, NDB OR GPS RWY 9, Amdt 2A, CANCELLED
 Portland, IN, Portland Muni, NDB RWY 27, Amdt 7A, CANCELLED
 Creston, IA, Creston Muni, RNAV (GPS) RWY 16, Orig
 Creston, IA, Creston Muni, RNAV (GPS) RWY 34, Orig
 Creston, IA, Creston Muni, NDB RWY 34, Amdt 2
 Creston, IA, Creston Muni, Takeoff Minimums and Textual DPs, Amdt 2
 Des Moines, IA, Des Moines Intl, RNAV (GPS) RWY 5, Amdt 1
 Des Moines, IA, Des Moines Intl, RNAV (GPS) RWY 13, Amdt 1
 Des Moines, IA, Des Moines Intl, RNAV (GPS) RWY 31, Amdt 1
 Iowa City, IA, Iowa City Muni, VOR–A, Orig
 Iowa City, IA, Iowa City Muni, VOR OR GPS RWY 36, Amdt 10C, CANCELLED
 Iowa City, IA, Iowa City Muni, Takeoff Minimums and Textual DPs, Amdt 3
 Phillipsburg, KS, Phillipsburg Muni, RNAV (GPS) RWY 13, Amdt 1
 Phillipsburg, KS, Phillipsburg Muni, RNAV (GPS) RWY 31, Amdt 1
 Phillipsburg, KS, Phillipsburg Muni, Takeoff Minimums and Textual DP, Orig
 Opelousas, LA, St Landry Parish-Ahart Field, RNAV (GPS) RWY 18, Orig
 Opelousas, LA, St Landry Parish-Ahart Field, RNAV (GPS) RWY 36, Orig
 Opelousas, LA, St Landry Parish-Ahart Field, NDB RWY 18, Amdt 2
 Opelousas, LA, St Landry Parish-Ahart Field, VOR/DME RWY 36, Amdt 1
 Opelousas, LA, St Landry Parish-Ahart Field, GPS RWY 35, Orig-A, CANCELLED
 Minneapolis, MN, Anoka County-Blaine Arpt (Janes Field), ILS OR LOC/DME RWY 27, Orig

Minneapolis, MN, Anoka County-Blaine Arpt (Janes Field), RNAV (GPS) RWY 27, Orig
 Minneapolis, MN, Anoka County-Blaine Arpt (Janes Field), GPS RWY 27, Orig
 CANCELLED
 Minneapolis, MN, Anoka County-Blaine Arpt (Janes Field), Takeoff Minimums & Textual DPs, Amdt 4
 Sidney, NE, Sidney Muni/Lloyd W. Carr Field, RNAV (GPS) RWY 12, Amdt 1
 Sidney, NE, Sidney Muni/Lloyd W. Carr Field, RNAV (GPS) RWY 30, Amdt 1
 Sidney, NE, Sidney Muni/Lloyd W. Carr Field, Takeoff Minimums and Textual DPs, Orig
 Thedford, NE, Thomas County, RNAV (GPS) RWY 11, Orig
 Thedford, NE, Thomas County, RNAV (GPS) RWY 29, Orig
 Thedford, NE, Thomas County, VOR RWY 11, Amdt 1
 Thedford, NE, Thomas County, VOR/DME RWY 29, Orig
 Thedford, NE, Thomas County, GPS RWY 11, Orig, CANCELLED
 Thedford, NE, Thomas County, GPS RWY 29, Orig, CANCELLED
 Thedford, NE, Thomas County, Takeoff Minimums and Textual DPs, Orig
 Manchester, NH, Manchester, ILS OR LOC RWY 6, Amdt 1A
 Manchester, NH, Manchester, RNAV (GPS) RWY 6, Amdt 1
 Albany, NY, Albany Intl, ILS OR LOC RWY 1, Amdt 10
 Albany, NY, Albany Intl, ILS OR LOC RWY 19, Amdt 22
 New York, NY, LaGuardia, RNAV (GPS)–B, Orig
 New York, NY, LaGuardia, Takeoff Minimums and Textual DPs, Amdt 7
 Elizabeth City, NC, Elizabeth City CG Air Station/Regional, RNAV (GPS) RWY 10, Amdt 1
 Myerstown, PA, Deck, RNAV (GPS) RWY 19, Orig
 Anderson, SC, Anderson Rgnl, ILS OR LOC RWY 5, Amdt 1
 Anderson, SC, Anderson Rgnl, Takeoff Minimums and Textual DP, Orig
 Kingstree, SC, Williamsburg Regional, RNAV (GPS) RWY 32, Orig
 Kingstree, SC, Williamsburg Regional, NDB RWY 14, Amdt 4
 Kingstree, SC, Williamsburg Regional, Takeoff Minimums and Textual DP, Amdt 1
 San Antonio, TX, Boerne Stage Field, RNAV (GPS) RWY 17, ORIG
 San Antonio, TX, Boerne Stage Field, RNAV (GPS) RWY 35, ORIG
 San Antonio, TX, Boerne Stage Field, Takeoff Minimums and Textual DP's, Orig
 Galax/Hillsville, VA, Twin County, RNAV (GPS) RWY 1, Orig
 Galax/Hillsville, VA, Twin County, RNAV (GPS) RWY 19, Orig
 Marion/Wytheville, VA, Mountain Empire, RNAV (GPS) RWY 26, Orig
 Marion/Wytheville, VA, Mountain Empire, GPS RWY 26, Orig-A, CANCELLED
 Norfolk, VA, Norfolk Intl, Takeoff Minimums and Textual DP's, Orig
 Lyndonville, VT, Caledonia County, NDB RWY 2, Amdt 4
 Lyndonville, VT, Caledonia County, RNAV (GPS) RWY 2, Orig

Lyndonville, VT, Caledonia County, GPS RWY 2, Orig, CANCELLED

Lyndonville, VT, Caledonia County, Takeoff Minimums and Textual DP, Amdt 5

Seattle, WA, Seattle-Tacoma Intl, RNAV (GPS) RWY 16L, Amdt 1

Seattle, WA, Seattle-Tacoma Intl, ILS OR LOC RWY 16L, ILS RWY 16L(CAT II), ILS RWY 16L (CAT III), Amdt 3

Green Bay, WI, Austin Straubel International, RNAV (GPS) RWY 18, Amdt 1

Green Bay, WI, Austin Straubel International, RNAV (GPS) RWY 36, Amdt 2

Green Bay, WI, Austin Straubel International, VOR/DME OR TACAN RWY 36, Amdt 9

Fairmont, WV, Fairmont Muni-Frankman Field, RNAV (GPS) RWY 22, Orig

Fairmont, WV, Fairmont Muni-Frankman Field, GPS RWY 22, Amdt 1, CANCELLED

Fairmont, WV, Fairmont Muni-Frankman Field, Takeoff Minimums and Textual DP's, Amdt 5

Morgantown, WV, Morgantown Muni-Walter L. Bill Hart Field, ILS OR LOC RWY 18, Amdt 13

Morgantown, WV, Morgantown Muni-Walter L. Bill Hart Field, VOR-A, Amdt 13

Morgantown, WV, Morgantown Muni-Walter L. Bill Hart Field, RNAV (GPS) RWY 18, Amdt 2

Morgantown, WV, Morgantown Muni-Walter L. Bill Hart Field, RNAV (GPS) RWY 36, Orig

Evanston, WY, Evanston-Uinta County Burns Field, ILS OR LOC/DME RWY 23, Orig

Jackson, WY, Jackson Hole, RNAV (RNP) Y RWY 1, Orig

Jackson, WY, Jackson Hole, RNAV (RNP) Z RWY 1, Orig

Jackson, WY, Jackson Hole, RNAV (RNP) Z RWY 19, Orig

[FR Doc. E6-20919 Filed 12-12-06; 8:45 am]

BILLING CODE 4910-13-P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

21 CFR Parts 25, 500, 514, and 558

[Docket No. 1999N-1415] (formerly Docket No. 99N-1415)

RIN 0910-AF59

Supplements and Other Changes to Approved New Animal Drug Applications

AGENCY: Food and Drug Administration, HHS.

ACTION: Final rule.

SUMMARY: The Food and Drug Administration (FDA) is amending its regulations on supplements and other changes to approved new animal drug applications (NADAs) or abbreviated new animal drug applications (ANADAs) to implement the manufacturing changes provision of the Food and Drug Administration

Modernization Act of 1997 (the Modernization Act). The final rule requires manufacturers to assess the effect of a manufacturing change on the identity, strength, quality, purity, and potency of a drug as those factors relate to the safety or effectiveness of the drug. The final rule sets forth requirements for changes requiring submission and approval of a supplement before the distribution of the drug made using the change, changes requiring the submission of a supplement at least 30 days prior to the distribution of the drug, changes requiring the submission of a supplement at the time of distribution of the drug, and changes to be described in an annual report.

DATES: The final rule is effective February 12, 2007.

FOR FURTHER INFORMATION CONTACT: Dennis M. Bensley, Jr., Center for Veterinary Medicine (HFV-140), Food and Drug Administration, 7500 Standish Pl., Rockville, MD 20855, 301-827-6956, E-mail: dennis.bensley@fda.hhs.gov.

SUPPLEMENTARY INFORMATION:

Table of Contents

I. Background

- A. Development of the Regulation
- B. Risk-Based Approach

II. Harmonization and Highlights of Revisions to the Proposed Rule

- A. Section 514.8(a)—Definitions
- B. Section 514.8(b)—Manufacturing Changes to an Approved Application Manufacturing Changes Requiring Preapproval of a Supplement (Proposed § 514.8(b)(1)(ii))

- C. Labeling and Other Changes to an Approved Application

III. Responses to Comments on the Propose Rule

- A. Section 514.8(a)—Definitions
- B. Section 514.8(b)—Manufacturing Changes to an Approved Application

- C. Changes Requiring Submission and Approval of a Supplement Prior to Distribution of the Drug Made Using the Change (Major Changes)

- D. Changes Requiring Submission of a Supplement at Least 30 Days Prior to Distribution of the Drug Made Using the Change (Moderate Changes)

- E. Changes and Updated Stability Data to be Described and Submitted in and Annual Report (Minor Changes)

- F. Labeling and Other Changes to an

Approved Application

G. Implementation of the Final Rule and Guidance

H. General Comments

IV. Unrelated Referenced Comments to the Proposed Rule

V. Conforming Amendments

VI. Environmental Impact

VII. Analysis of Impacts

VIII. Paperwork Reduction Act of 1995

IX. Federalism

X. References

I. Background

Section 116 of the Modernization Act (Public Law 105-115) amended the Federal Food, Drug, and Cosmetic Act (the act) by adding section 506A (21 U.S.C. 356a). That section describes requirements and procedures for making and reporting manufacturing changes to approved new drug and abbreviated new drug applications, to approved new animal drug and abbreviated new animal drug applications, and to license applications for biological products under section 351 of the Public Health Service (PHS) Act. Section 506A of the act revises current procedures for approving manufacturing changes. Major manufacturing changes, as defined in section 506A, are of a type determined by FDA to have a substantial potential to adversely affect the identity, strength, quality, purity, and potency as they may relate to the safety and effectiveness of a drug and require prior approval of a supplemental application. Under section 506A, FDA may require submission of a supplemental application for drugs made with manufacturing changes that are not major and may establish categories of manufacturing changes for which a supplemental application is required. In such a case, the applicant may begin distribution of a drug 30 days after FDA receives a supplemental application unless the agency notifies the applicant within the 30-day period that prior approval of the application is required. Under the statute, FDA may also designate a category of manufacturing changes that permit the applicant to begin distributing a drug made with such changes upon receipt by the agency of a supplemental application for the change. Finally, FDA may also authorize applicants to distribute drugs manufactured with a change without submitting a supplemental application. The law provides that FDA may establish categories of manufacturing changes that may be made without submitting a supplemental application.