

instead of “* * * updated yearly * * *” This technical amendment corrects those errors.

EFFECTIVE DATE: 0901 UTC, April 3, 2007. The Director of the Federal Register approves this incorporation by reference action under 1 CFR part 51, subject to the annual revision of FAA Order 7400.9 and publication of conforming amendments.

FOR FURTHER INFORMATION CONTACT: Tameka Bentley, Airspace and Rules, Office of System Operations Airspace and AIM, Federal Aviation Administration, 800 Independence Avenue, SW., Washington, DC 20591; telephone: (202) 267-8783.

SUPPLEMENTARY INFORMATION:

History

On July 24, 2006, a final rule was published in the **Federal Register**, Docket No. FAA-2005-23157, Airspace Docket No. 05-ANM-15 that amended Title 14 Code of Federal Regulations part 71 by amending Class E Airspace; Kalispell, MT (71 FR 41727). In that rule, the reference to FAA Order 7400.9 was published as FAA Order 7400.90. The correct reference is FAA Order 7400.9P. In addition, the corresponding date that refers to the date the Order was signed had been omitted. The final rule should state “* * * dated September 1, 2006 * * *” (prior to the effective date), instead of “* * * updated yearly * * *”

Amendment to Final Rule

■ Accordingly, pursuant to the authority delegated to me, the reference to FAA Order 7400.9 for Airspace Docket No. FAA-2005-23157, Airspace Docket No. 05-ANM-15, as published in the **Federal Register** on July 24, 2006 (71 FR 41727), is corrected as follows:

■ On page 41727, column 2, (from the bottom, counting up) line 3, and column 3, (from the bottom, counting up) lines 7, and 9, amend the language to read:

§ 71.1 [Amended]

* * * * *

“FAA Order 7400.9P” instead of “FAA Order 7400.90”

Remove “* * * updated yearly * * *” and insert “* * * dated September 1, 2006 * * *”

* * * * *

Issued in Washington, DC, March 23, 2007.

Edith V. Parish,

Manager, Airspace and Rules.

[FR Doc. E7-6098 Filed 4-2-07; 8:45 am]

BILLING CODE 4910-13-P

DEPARTMENT OF TRANSPORTATION

Federal Aviation Administration

14 CFR Part 71

[Docket No. FAA-2005-23361; Airspace Docket No. 05-ANM-17]

RIN 2120-AA66

Revision of Class E Airspace; Pinedale, WY

AGENCY: Federal Aviation Administration (FAA), DOT.

ACTION: Final rule; technical amendment.

SUMMARY: This technical amendment corrects a final rule published in the **Federal Register** on July 24, 2006 (71 FR 41728), Docket No. FAA-2005-23361, Airspace Docket No. 05-ANM-17. In that rule, the reference to FAA Order 7400.9 was published as FAA Order 7400.90. The correct reference is FAA Order 7400.9P. Also, the corresponding date that refers to the date the Order was signed was omitted. The final rule should state “* * * dated September 1, 2006 * * *” (prior to the effective date), instead of “* * * updated yearly * * *”. This technical amendment corrects those errors.

EFFECTIVE DATE: 0901 UTC, April 3, 2007. The Director of the Federal Register approves this incorporation by reference action under 1 CFR part 51, subject to the annual revision of FAA Order 7400.9 and publication of conforming amendments.

FOR FURTHER INFORMATION CONTACT: Tameka Bentley, Airspace and Rules, Office of System Operations Airspace and AIM, Federal Aviation Administration, 800 Independence Avenue, SW., Washington, DC 20591; telephone: (202) 267-8783.

SUPPLEMENTARY INFORMATION:

History

On July 24, 2006, a final rule was published in the **Federal Register**, Docket No. FAA-2005-23361, Airspace Docket No. 05-ANM-17 that amended Title 14 Code of Federal Regulations part 71 by revising Class E Airspace; Pinedale, WY (71 FR 41728). In that rule, the reference to FAA Order 7400.9 was published as FAA Order 7400.90. The correct reference is FAA Order 7400.9P. In addition, the corresponding date that refers to the date the Order was signed had been omitted. The final rule should state “* * * dated September 1, 2006 * * *” (prior to the effective date), instead of “* * * updated yearly * * *”.

Amendment to Final Rule

■ Accordingly, pursuant to the authority delegated to me, the reference to FAA Order 7400.9 for Airspace Docket No. FAA-2005-23361, Airspace Docket No. 05-ANM-17, as published in the **Federal Register** on July 24, 2006 (71 FR 41728), is corrected as follows:

■ On page 41728, column 2, line 13, and column 3, lines 5, and 7, amend the language to read:

§ 71.1 [Amended]

* * * * *

“FAA Order 7400.9P” instead of “FAA Order 7400.90”

Remove “* * * updated yearly * * *” and insert “* * * dated September 1, 2006 * * *”

* * * * *

Issued in Washington, DC, March 23, 2007.

Edith V. Parish,

Manager, Airspace and Rules.

[FR Doc. E7-6100 Filed 4-2-07; 8:45 am]

BILLING CODE 4910-13-P

DEPARTMENT OF TRANSPORTATION

Federal Aviation Administration

14 CFR Part 97

[Docket No. 30543 Amdt. No. 3212]

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 April 3, 2007. 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 April 3, 2007.

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 March 23, 2007.

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 10 May 2007

Bessemer, AL, Bessemer, ILS OR LOC RWY 5, Amdt 1

Bessemer, AL, Bessemer, RNAV (GPS) RWY 5, Orig

Bessemer, AL, Bessemer, GPS RWY 5, Orig, CANCELLED

Bessemer, AL, Bessemer, Takeoff Minimums and Obstacle DP, Orig

Huntsville, AL, Madison County Executive, ILS OR LOC/DME RWY 18, Orig

Fort Yukon, AK, Fort Yukon, RNAV (GPS) RWY 4, Orig

Fort Yukon, AK, Fort Yukon, RNAV (GPS) RWY 22, Orig

- Fort Yukon, AK, Fort Yukon, GPS RWY 3, Orig, CANCELLED
- Fort Yukon, AK, Fort Yukon, GPS RWY 21, Orig, CANCELLED
- Fort Yukon, AK, Fort Yukon, VOR/DME OR TACAN-A, Orig
- Fort Yukon, AK, Fort Yukon, VOR/DME OR TACAN RWY 3, Amdt 1C, CANCELLED
- Fort Yukon, AK, Fort Yukon, VOR/DME OR TACAN RWY 22, Amdt 2
- Fort Yukon, AK, Fort Yukon, VOR RWY 3, Amdt 4B, CANCELLED
- Fort Yukon, AK, Fort Yukon, VOR RWY 21, Amdt 4A, CANCELLED
- Fort Yukon, AK, Fort Yukon, Takeoff Minimums and Obstacle DP, Amdt 1
- Hemet, CA, Hemet-Ryan, NDB-A, Amdt 1A, CANCELLED
- Marysville, CA, Yuba County, VOR RWY 32, Amdt 10D, CANCELLED
- Colorado Springs, CO, City of Colorado Springs Muni, RNAV (GPS) RWY 17R, Amdt 1A
- Middletown, DE, Summit, RNAV (GPS) RWY 17, Amdt 1
- Middletown, DE, Summit, RNAV (GPS) RWY 35, Orig
- Middletown, DE, Summit, GPS RWY 35, ORIG-A, CANCELLED
- Jacksonville, FL, Jacksonville Intl, VOR/DME RWY 31, Amdt 1
- Jacksonville, FL, Jacksonville Intl, Takeoff Minimums and Textual DP, Orig
- Miami, FL, Miami Intl, RNAV (GPS) RWY 8L, Amdt 1
- Miami, FL, Miami Intl, RNAV (GPS) RWY 26R, Amdt 1
- West Palm Beach, FL, Palm Beach Intl, RNAV (GPS) RWY 31, Amdt 1
- Atlanta, GA, Hartsfield-Jackson Atlanta Intl, ILS OR LOC RWY 10, Amdt 1, ILS RWY 10 (CAT II), ILS RWY 10 (CAT III)
- Atlanta, GA, Hartsfield-Jackson Atlanta Intl, ILS OR LOC RWY 28, Amdt 1, ILS RWY 28 (CAT II)
- Atlanta, GA, Hartsfield-Jackson Atlanta Intl, ILS PRM RWY 10, Amdt 1, ILS PRM RWY 10 (CAT II), ILS PRM RWY 10 (CAT III) (SIMULTANEOUS CLOSE PARALLEL)
- Atlanta, GA, Hartsfield-Jackson Atlanta Intl, ILS PRM RWY 28, Amdt 1, ILS PRM RWY 28 (CAT II) (SIMULTANEOUS CLOSE PARALLEL)
- Atlanta, GA, Hartsfield-Jackson Atlanta Intl, RNAV (GPS) Y RWY 9L, Amdt 2
- Atlanta, GA, Hartsfield-Jackson Atlanta Intl, RNAV (GPS) Y RWY 8L, Amdt 2
- Atlanta, GA, Hartsfield-Jackson Atlanta Intl, RNAV (GPS) Y RWY 8R, Amdt 2
- Atlanta, GA, Hartsfield-Jackson Atlanta Intl, RNAV (GPS) Y RWY 9R, Amdt 2
- Atlanta, GA, Hartsfield-Jackson Atlanta Intl, RNAV (GPS) Y RWY 10, Amdt 1
- Atlanta, GA, Hartsfield-Jackson Atlanta Intl, RNAV (GPS) Y RWY 26L, Amdt 2
- Atlanta, GA, Hartsfield-Jackson Atlanta Intl, RNAV (GPS) Y RWY 26R, Amdt 2
- Atlanta, GA, Hartsfield-Jackson Atlanta Intl, RNAV (GPS) Y RWY 27L, Amdt 2
- Atlanta, GA, Hartsfield-Jackson Atlanta Intl, RNAV (GPS) Y RWY 27R, Amdt 2
- Atlanta, GA, Hartsfield-Jackson Atlanta Intl, RNAV (GPS) Y RWY 28, Amdt 1
- Atlanta, GA, Hartsfield-Jackson Atlanta Intl, RNAV (RNP) Z RWY 8L, Orig
- Atlanta, GA, Hartsfield-Jackson Atlanta Intl, RNAV (RNP) Z RWY 8R, Orig
- Atlanta, GA, Hartsfield-Jackson Atlanta Intl, RNAV (RNP) Z RWY 9L, Orig
- Atlanta, GA, Hartsfield-Jackson Atlanta Intl, RNAV (RNP) Z RWY 9R, Orig
- Atlanta, GA, Hartsfield-Jackson Atlanta Intl, RNAV (RNP) Z RWY 10, Orig
- Atlanta, GA, Hartsfield-Jackson Atlanta Intl, RNAV (RNP) Z RWY 26L, Orig
- Atlanta, GA, Hartsfield-Jackson Atlanta Intl, RNAV (RNP) Z RWY 26R, Orig
- Atlanta, GA, Hartsfield-Jackson Atlanta Intl, RNAV (RNP) Z RWY 27L, Orig
- Atlanta, GA, Hartsfield-Jackson Atlanta Intl, RNAV (RNP) Z RWY 27R, Orig
- Atlanta, GA, Hartsfield-Jackson Atlanta Intl, RNAV (RNP) Z RWY 28, Orig
- Brunswick, GA, Brunswick Golden Isles, ILS OR LOC RWY 7, Amdt 9
- Freeport, IL, Albertus, RNAV (GPS) RWY 24, Orig
- Freeport, IL, Albertus, VOR RWY 24, Amdt 7
- Freeport, IL, Albertus, Takeoff Minimums and Textual DP, Orig
- Seymour, IN, Freeman Muni, RNAV (GPS) RWY 14, Orig
- Seymour, IN, Freeman Muni, RNAV (GPS) RWY 23, Amdt 1
- Seymour, IN, Freeman Muni, RNAV (GPS) RWY 32, Orig
- Seymour, IN, Freeman Muni, RNAV (GPS) RWY 5, Orig
- Seymour, IN, Freeman Muni, NDB RWY 5, Amdt 4
- Seymour, IN, Freeman Muni, LOC/NDB RWY 5, Orig
- Seymour, IN, Freeman Muni, LOC RWY 5, Amdt 3, CANCELLED
- Seymour, IN, Freeman Muni, Takeoff Minimums and Textual DP, Orig
- Shelbyville, IN, Shelbyville Muni, RNAV (GPS) RWY 1, Amdt 1
- Shelbyville, IN, Shelbyville Muni, RNAV (GPS) RWY 19, Amdt 1
- Middlesboro, KY, Middlesboro-Bell County, RNAV (GPS)-A, Orig
- Williamsburg, KY, Williamsburg-Whitley County, RNAV (GPS) RWY 2, Orig
- Williamsburg, KY, Williamsburg-Whitley County, RNAV (GPS) RWY 20, Orig
- Williamsburg, KY, Williamsburg-Whitley County, Takeoff Minimums and Textual DP, Orig
- Belfast, ME, Belfast Muni, RNAV (GPS) RWY 15, Orig
- Belfast, ME, Belfast Muni, RNAV (GPS) RWY 33, Orig
- Belfast, ME, Belfast Muni, Takeoff Minimums and Textual DP, Amdt 2
- Belfast, ME, Belfast Muni, GPS RWY 15, Amdt 1, CANCELLED
- Belfast, ME, Belfast Muni, GPS RWY 33, Amdt 1, CANCELLED
- Holland, MI, Tulip City, Takeoff Minimums and Textual DP, Orig
- Holland, MI, Tulip City, ILS OR LOC/DME RWY 26, Amdt 1
- Holland, MI, Tulip City, RNAV (GPS) RWY 26, Amdt 2
- Holland, MI, Tulip City, RNAV (GPS) RWY 8, Amdt 1
- Minneapolis, MN, Minneapolis-St Paul Intl/Wold-Chamberlain, Takeoff Minimums and Obstacle DP, Amdt 11
- Oxford, MS, University-Oxford, RNAV (GPS) RWY 9, Orig
- Oxford, MS, University-Oxford, RNAV (GPS) RWY 27, Orig
- Oxford, MS, University-Oxford, GPS RWY 9, Orig, CANCELLED
- Oxford, MS, University-Oxford, GPS RWY 27, Orig, CANCELLED
- Albany, NY, Albany Intl, RNAV (GPS) RWY 1, Orig
- Albany, NY, Albany Intl, RNAV (GPS) RWY 19, Orig
- Albany, NY, Albany Intl, GPS RWY 1, Orig-B, CANCELLED
- Albany, NY, Albany Intl, GPS RWY 19, Orig-B, CANCELLED
- Elmira, NY, Elmira/Corning Rgnl, Takeoff Minimums and Textual DP, Amdt 8
- Penn Yan, NY, Penn Yan, RNAV (GPS) RWY 1, Amdt 2
- Plattsburgh, NY, Plattsburgh Intl, ILS or LOC/DME RWY 35, Orig
- Mocksville, NC, Twin Lakes, RNAV (GPS) RWY 9, Orig
- Mocksville, NC, Twin Lakes, NDB OR GPS RWY 9, Amdt 5, CANCELLED
- Columbus, OH, Port Columbus Intl, ILS OR LOC RWY 10L, Amdt 18
- Columbus, OH, Port Columbus Intl, ILS OR LOC RWY 28L, Amdt 28
- Columbus, OH, Port Columbus Intl, ILS OR LOC RWY 28R, Amdt 3
- Columbus, OH, Port Columbus Intl, RNAV (GPS) RWY 10L, Amdt 1
- Columbus, OH, Port Columbus Intl, RNAV (GPS) RWY 28L, Amdt 1
- Columbus, OH, Port Columbus Intl, RNAV (GPS) RWY 10R, Amdt 1
- Columbus, OH, Port Columbus Intl, Takeoff Minimums and Obstacle DP, Amdt 6
- Ottawa, OH, Putnam County, NDB RWY 27, Amdt 1B, CANCELLED
- North Bend, OR, Southwest Oregon Regional, COPTER ILS OR LOC RWY 4, Orig
- The Dalles, OR, Columbia Gorge Regional/The Dalles Muni, LDA/DME RWY 25, Orig
- The Dalles, OR, Columbia Gorge Regional/The Dalles Muni, COPTER LDA/DME RWY 25, Orig
- Greer, SC, Greenville-Spartanburg Intl-Roger Milliken, RNAV (GPS) RWY 4, Amdt 1
- Greer, SC, Greenville-Spartanburg Intl-Roger Milliken, RNAV (GPS) RWY 22, Amdt 1
- Rapid City, SD, Rapid City Regional, Takeoff Minimums and Obstacle DP, Amdt 6
- Elizabethton, TN, Elizabethton Muni, RNAV (GPS) RWY 6, Orig
- Jacksboro, TN, Campbell County, Takeoff Minimums and Obstacle DP, Amdt 2
- Roanoke, VA, Roanoke Regional/Woodrum Field, ILS OR LOC RWY 33, Amdt 12
- Moses Lake, WA, Grant County Intl, ILS OR LOC RWY 32R, Amdt 20
- Moses Lake, WA, Grant County Intl, Takeoff Minimums and Obstacle DP, Orig
- Spokane, WA, Felts Field, Takeoff Minimums and Textual DP, Amdt 4
- Spokane, WA, Spokane Intl, ILS OR LOC RWY 3, Amdt 5, ILS RWY 3 (CAT II), ILS RWY 3 (CAT III)
- Spokane, WA, Spokane Intl, ILS OR LOC/DME RWY 21, Amdt 21, ILS RWY 21 (CAT II), ILS RWY 21 (CAT III)
- Ashland, WI, John F. Kennedy Memorial, LOC/DME RWY 2, Orig
- Ashland, WI, John F. Kennedy Memorial, Takeoff Minimums and Textual DP, Orig
- Eagle River, WI, Eagle River Union, LOC/DME RWY 4, Orig

Juneau, WI, Dodge County, RNAV (GPS) RWY 2, Orig
 Juneau, WI, Dodge County, RNAV (GPS) RWY 8, Orig
 Juneau, WI, Dodge County, RNAV (GPS) RWY 20, Orig
 Juneau, WI, Dodge County, RNAV (GPS) RWY 26, Orig
 Juneau, WI, Dodge County, NDB RWY 2, Orig
 Juneau, WI, Dodge County, NDB RWY 20, Orig
 Juneau, WI, Dodge County, LOC RWY 26, Amdt 1
 Juneau, WI, Dodge County, GPS RWY 20, Orig, CANCELLED
 Juneau, WI, Dodge County, NDB RWY 2, Amdt 10A, CANCELLED
 Juneau, WI, Dodge County, NDB RWY 20, Amdt 8A, CANCELLED
 Lone Rock, WI, Tri-County Regional, VOR/DME RNAV OR GPS RWY 27, Amdt 6, CANCELLED

[FR Doc. E7-5952 Filed 4-2-07; 8:45 am]

BILLING CODE 4910-13-P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

21 CFR Part 866

[Docket No. 2005N-0471]

Microbiology Devices; Reclassification of Herpes Simplex Virus Types 1 and 2 Serological Assays

AGENCY: Food and Drug Administration, HHS.

ACTION: Final rule.

SUMMARY: The Food and Drug Administration (FDA) is reclassifying herpes simplex virus (HSV) types 1 and/or 2 (HSV 1 and 2) serological assays from class III (premarket approval) to class II (special controls). FDA had earlier proposed this reclassification on its own initiative based on new information. Elsewhere in this issue of the **Federal Register**, FDA is announcing the availability of a class II special controls guidance entitled "Class II Special Controls Guidance Document: Herpes Simplex Virus Types 1 and 2 Serological Assays."

DATES: This rule is effective May 3, 2007.

FOR FURTHER INFORMATION CONTACT: Sally Hojvat, Center for Devices and Radiological Health (HFZ-440), Food and Drug Administration, 2098 Gaither Rd., Rockville, MD 20850, 240-276-0496.

SUPPLEMENTARY INFORMATION:

I. Background

A. Regulatory Authorities

The Federal Food, Drug, and Cosmetic Act (the act) (21 U.S.C. 301 *et seq.*), as amended by the Medical Device Amendments of 1976 (the 1976 amendments) (Public Law 94-295), the Safe Medical Devices Act of 1990 (SMDA) (Public Law 101-629), the Food and Drug Administration Modernization Act of 1997 (FDAMA) (Public Law 105-115), and the Medical Device User Fee and Modernization Act (Public Law 107-250), 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, defined by 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 the 1976 amendments, class II devices were defined as devices for which there was insufficient information to show that general controls themselves would provide reasonable assurance of safety and effectiveness, but for which there was sufficient information to establish performance standards to provide such assurance. SMDA broadened the definition of class II devices to mean those devices for which the general controls by themselves are insufficient to provide reasonable assurance of safety and effectiveness, but for which there is sufficient information to establish special controls to provide such assurance, including performance standards, postmarket surveillance, patient registries, development and dissemination of guidelines, recommendations, and any other appropriate actions the agency deems necessary (section 513(a)(1)(B) of the act).

Under section 513 of the act, FDA refers to devices that were in commercial distribution before May 28, 1976 (the date of enactment of the 1976 amendments), as preamendments devices. FDA classifies these devices after it takes the following steps: (1) Receives a recommendation from a device classification panel (an FDA advisory committee); (2) publishes the panel's recommendation for comment, along with a proposed regulation classifying the device; and (3) publishes a final regulation classifying the device. FDA has classified most preamendments devices under these procedures. A person may market a preamendments device that has been

classified into class III through 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.

Devices that were not in commercial distribution before 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 FDA does the following: (1) Reclassifies the device into class I or II; (2) issues an order classifying the device into class I or II in accordance with section 513(f)(2) of the act, as amended by FDAMA; or (3) issues an order finding the device to be substantially equivalent, under section 513(i) of the act, to a legally marketed device that has been classified into class I or class II. The agency determines whether new devices are substantially equivalent to a legally marketed device by means of premarket notification procedures in section 510(k) of the act (21 U.S.C. 360(k)) and 21 CFR part 807.

Section 513(e) of the act governs reclassification of classified devices. This section provides that FDA may, by rulemaking, reclassify a device based upon "new information." FDA can initiate a reclassification under section 513(e) of the act or an interested person may petition FDA to reclassify a preamendments device. 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 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). Whether data before the agency are past or new, 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