

[FR Doc. 2011-17974 Filed 7-20-11; 8:45 am]

BILLING CODE 4910-13-P

DEPARTMENT OF TRANSPORTATION

Federal Aviation Administration

14 CFR Part 97

[Docket No. 30792; Amdt. No. 3434]

Standard Instrument Approach Procedures, and Takeoff Minimums and Obstacle Departure Procedures; Miscellaneous Amendments

AGENCY: Federal Aviation Administration (FAA), DOT.

ACTION: Final rule.

SUMMARY: This establishes, amends, suspends, or revokes Standard Instrument Approach Procedures (SIAPs) and associated Takeoff Minimums and Obstacle Departure Procedures 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, adding new obstacles, or changing 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 July 21, 2011. The compliance date for each SIAP, associated Takeoff Minimums, and ODP 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 July 21, 2011.

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.*

Availability—All SIAPs and Takeoff Minimums and ODPs are available online free of charge. Visit <http://www.nfdc.faa.gov> to register. Additionally, individual SIAP and Takeoff Minimums and ODP 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.

FOR FURTHER INFORMATION CONTACT:

Harry J. Hodges, Flight Procedure Standards Branch (AFS-420), Flight Technologies and Programs Divisions, 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 rule amends Title 14 of the Code of Federal Regulations, Part 97 (14 CFR part 97), by establishing, amending, suspending, or revoking SIAPs, Takeoff Minimums and/or ODPs. The complete regulators description of each SIAP and its associated Takeoff Minimums or ODP for an identified airport is listed on 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 FAA Forms 8260-3, 8260-4, 8260-5, 8260-15A, and 8260-15B when required by an entry on 8260-15A.

The large number of SIAPs, Takeoff Minimums and ODPs, in addition to their complex nature and the need for a special format make publication in the **Federal Register** expensive and impractical. Furthermore, airmen do not use the regulatory text of the SIAPs, Takeoff Minimums or ODPs, but instead refer to their depiction on charts printed by publishers of aeronautical materials. The advantages of incorporation by reference are realized and publication of the complete description of each SIAP, Takeoff Minimums and ODP listed on FAA forms is unnecessary. This amendment provides the affected CFR sections and specifies the types of SIAPs and the effective dates of the associated Takeoff Minimums and ODPs. This amendment also identifies the airport and its location, the procedure, and the amendment number.

The Rule

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

Further, the SIAPs and Takeoff Minimums and ODPs 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 Takeoff Minimums and ODPs, 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, Takeoff Minimums and ODPs, and safety in air commerce, I find that notice and public procedures before adopting these SIAPs, Takeoff Minimums and ODPs are impracticable and contrary to the public interest and, where applicable, that good cause exists for making some 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 July 8, 2011.

John M. Allen,

Director, Flight Standards Service.

Adoption of the Amendment

Accordingly, pursuant to the authority delegated to me, 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/or Takeoff Minimums and/or Obstacle Departure Procedures effective at 0902 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 28 JUL 2011

Brunswick, ME, Brunswick Executive, RNAV (GPS) RWY 1R, Orig
Brunswick, ME, Brunswick Executive, RNAV (GPS) RWY 19L, Orig
Brunswick, ME, Brunswick Executive, Takeoff Minimums and Obstacle DP, Orig

Effective 25 AUG 2011

Allakaket, AK, Allakaket, RNAV (GPS) RWY 5, Amdt 1
Allakaket, AK, Allakaket, RNAV (GPS) RWY 23, Amdt 1
Dillingham, AK, Dillingham, RNAV (GPS) RWY 1, Amdt 2
Dillingham, AK, Dillingham, RNAV (GPS) RWY 19, Amdt 2
Hooper Bay, AK, Hooper Bay, RNAV (GPS) RWY 13, Amdt 1
Hooper Bay, AK, Hooper Bay, RNAV (GPS) RWY 31, Amdt 1
Nuiqsut, AK, Nuiqsut, RNAV (GPS) RWY 5, Amdt 1
Nuiqsut, AK, Nuiqsut, RNAV (GPS) RWY 23, Amdt 1
Palmer, AK, Palmer Muni, RNAV (GPS) RWY 9, Amdt 1
Toksook Bay, AK, Toksook Bay, RNAV (GPS) RWY 34, Amdt 2
Haleyville, AL, Posey Field, GPS RWY 36, Orig, CANCELLED
Haleyville, AL, Posey Field, RNAV (GPS) RWY 18, Orig
Haleyville, AL, Posey Field, RNAV (GPS) RWY 36, Orig
Haleyville, AL, Posey Field, VOR/DME RWY 18, Amdt 5
Haleyville, AL, Posey Field, VOR/DME–A, Amdt 4
Tuskegee, AL, Moton Field Muni, RNAV (GPS) RWY 13, Amdt 1
Tuskegee, AL, Moton Field Muni, RNAV (GPS) RWY 31, Amdt 1
Bullhead City, AZ, Laughlin/Bullhead Intl, RNAV (GPS) RWY 16, Amdt 2

Fort Huachuca Sierra Vista, AZ, Sierra Vista Muni-Libby AAF, RNAV (GPS) RWY 8, Amdt 1
Tucson, AZ, Marana Rgnl, RNAV (GPS) RWY 12, Amdt 1
Tucson, AZ, Marana Rgnl, RNAV (GPS) RWY 21, Amdt 1
Window Rock, AZ, Window Rock, RNAV (GPS) RWY 2, Amdt 1
Mojave, CA, Mojave, Takeoff Minimums and Obstacle DP, Amdt 2
Grand Junction, CO, Grand Junction Rgnl, RNAV (GPS) Y RWY 11, Amdt 1A
Grand Junction, CO, Grand Junction Rgnl, RNAV (RNP) Z RWY 11, Orig
Hayden, CO, Yampa Valley, RNAV (GPS) RWY 28, Amdt 2
Oxford, CT, Waterbury-Oxford, ILS OR LOC RWY 36, Amdt 14
Oxford, CT, Waterbury-Oxford, RNAV (GPS) RWY 36, Amdt 1
Willimantic, CT, Windham, RNAV (GPS) RWY 9, Amdt 1
Willimantic, CT, Windham, RNAV (GPS) RWY 27, Amdt 1
Cairo, GA, Cairo-Grady County, NDB RWY 13, Amdt 5
Cairo, GA, Cairo-Grady County, RNAV (GPS) RWY 13, Amdt 1
Cairo, GA, Cairo-Grady County, RNAV (GPS) RWY 31, Amdt 1
Douglas, GA, Douglas Muni, ILS OR LOC/ NDB RWY 4, Amdt 2
Douglas, GA, Douglas Muni, RNAV (GPS) RWY 4, Amdt 1
Douglas, GA, Douglas Muni, RNAV (GPS) RWY 22, Amdt 1
Hana, HI, Hana, LINDBERG TWO Graphic DP
Kailua/Kona, HI, Kona Intl at Keahole, Takeoff Minimums and Obstacle DP, Amdt 5
Pocahontas, IA, Pocahontas Muni, NDB RWY 12, Amdt 5
Pocahontas, IA, Pocahontas Muni, RNAV (GPS) RWY 12, Orig
Pocahontas, IA, Pocahontas Muni, RNAV (GPS) RWY 30, Orig
Pocahontas, IA, Pocahontas Muni, Takeoff Minimums & Obstacle DP, Amdt 3
Bedford, IN, Virgil I Grissom Muni, GPS RWY 13, Orig, CANCELLED
Bedford, IN, Virgil I Grissom Muni, GPS RWY 31, Orig, CANCELLED
Bedford, IN, Virgil I Grissom Muni, RNAV (GPS) RWY 13, Orig
Bedford, IN, Virgil I Grissom Muni, RNAV (GPS) RWY 31, Orig
Bedford, IN, Virgil I Grissom Muni, VOR/ DME RWY 31, Amdt 9, CANCELLED
Gary, IN, Gary/Chicago Intl, RNAV (GPS) Y RWY 12, Orig
Gary, IN, Gary/Chicago Intl, RNAV (GPS) Y RWY 30, Orig
Tell City, IN, Perry County Muni, NDB OR GPS RWY 13, Orig, CANCELLED
Tell City, IN, Perry County Muni, RNAV (GPS) RWY 13, Orig
Tell City, IN, Perry County Muni, RNAV (GPS) RWY 31, Orig
Tell City, IN, Perry County Muni, Takeoff Minimums & Obstacle DP, Amdt 2
Tell City, IN, Perry County Muni, VOR OR GPS RWY 31, Amdt 5, CANCELLED
Hazard, KY, Wendell H. Ford, RNAV (GPS) RWY 14, Amdt 1
Hazard, KY, Wendell H. Ford, RNAV (GPS) RWY 32, Orig

Springfield, KY, Lebanon-Springfield, NDB RWY 11, Orig, CANCELLED
Springfield, KY, Lebanon-Springfield, VOR/ DME RWY 11, Amdt 4
Springhill, LA, Springhill, NDB RWY 36, Orig, CANCELLED
Springhill, LA, Springhill, RNAV (GPS) RWY 18, Orig
Springhill, LA, Springhill, RNAV (GPS) RWY 36, Orig
Springhill, LA, Springhill, Takeoff Minimums and Obstacle DP, Orig
Hyannis, MA, Barnstable Muni-Boardman/ Polando Field, RNAV (GPS) RWY 33, Orig
Benton Harbor, MI, Southwest Michigan Rgnl, LOC BC RWY 9, Amdt 9A, CANCELLED
Benton Harbor, MI, Southwest Michigan Rgnl, NDB RWY 28, Amdt 10
Benton Harbor, MI, Southwest Michigan Rgnl, RNAV (GPS) RWY 10, Amdt 1
Benton Harbor, MI, Southwest Michigan Rgnl, RNAV (GPS) RWY 28, Orig
Benton Harbor, MI, Southwest Michigan Rgnl, Takeoff Minimums and Obstacle DP, Amdt 7
Benton Harbor, MI, Southwest Michigan Rgnl, VOR RWY 10, Amdt 10
Benton Harbor, MI, Southwest Michigan Rgnl, VOR RWY 28, Amdt 19
Holland, MI, Tulip City, RNAV (GPS) RWY 8, Amdt 2
Port Huron, MI, St. Clair County Intl, Takeoff Minimums and Obstacle DP, Amdt 6
McComb, MS, McComb/Pike County/John E Lewis Field, RNAV (GPS) RWY 15, Amdt 1
Raymond, MS, John Bell Williams, ILS OR LOC RWY 12, Orig
Raymond, MS, John Bell Williams, NDB RWY 12, Amdt 2
Raymond, MS, John Bell Williams, RNAV (GPS) RWY 12, Amdt 2
Raymond, MS, John Bell Williams, RNAV (GPS) RWY 30, Amdt 2
Raymond, MS, John Bell Williams, Takeoff Minimums & Obstacle DP, Amdt 4
Bozeman, MT, Gallatin Field, RNAV (GPS) –A, Amdt 2
Forsyth, MT, Tillitt Field, GPS RWY 26, Orig, CANCELLED
Forsyth, MT, Tillitt Field, RNAV (GPS) RWY 26, Orig.
Glendive, MT, Dawson Community, NDB RWY 12, Amdt 4B
Glendive, MT, Dawson Community, RNAV (GPS) RWY 12, Orig
Glendive, MT, Dawson Community, RNAV (GPS) RWY 30, Orig
Glendive, MT, Dawson Community, Takeoff Minimums & Obstacle DP, Orig
Miles City, MT, Frank Wiley Field, RNAV (GPS) RWY 4, Amdt 2
Miles City, MT, Frank Wiley Field, RNAV (GPS) RWY 22, Orig
Miles City, MT, Frank Wiley Field, VOR/ DME RWY 22, Amdt 8B
Hickory, NC, Hickory Rgnl, HICKORY TWO Graphic DP
Roanoke Rapids, NC, Halifax-Northampton Rgnl, RNAV (GPS) RWY 2, Amdt 1
Roanoke Rapids, NC, Halifax-Northampton Rgnl, RNAV (GPS) RWY 20, Amdt 1
Sanford, NC, Raleigh Exec Jetport at Sanford-Lee County, ILS OR LOC RWY 3, Amdt 1
Sanford, NC, Raleigh Exec Jetport at Sanford-Lee County, RNAV (GPS) RWY 3, Amdt 1

Sanford, NC, Raleigh Exec Jetport at Sanford-Lee County, RNAV (GPS) RWY 21, Amdt 1

Sanford, NC, Raleigh Exec Jetport at Sanford-Lee County, Takeoff Minimums and Obstacle DP, Amdt 1

Rugby, ND, Rugby Muni, GPS RWY 12, Orig, CANCELLED

Rugby, ND, Rugby Muni, GPS RWY 30, Orig-B, CANCELLED

Rugby, ND, Rugby Muni, RNAV (GPS) RWY 12, Orig

Rugby, ND, Rugby Muni, RNAV (GPS) RWY 30, Orig

Rugby, ND, Rugby Muni, Takeoff Minimums and Obstacle DP, Orig

Chadron, NE, Chadron Muni, ILS OR LOC RWY 2, Amdt 2

Chadron, NE, Chadron Muni, RNAV (GPS) RWY 2, Orig-A

Chadron, NE, Chadron Muni, RNAV (GPS) RWY 11, Orig

Chadron, NE, Chadron Muni, RNAV (GPS) RWY 20, Amdt 1

Chadron, NE, Chadron Muni, RNAV (GPS) RWY 29, Orig

Chadron, NE, Chadron Muni, Takeoff Minimums and Obstacle DP, Orig

Chadron, NE, Chadron Muni, VOR/DME RWY 2, Amdt 2A, CANCELLED

Chadron, NE, Chadron Muni, VOR/DME RWY 20, Orig-A, CANCELLED

Hartington, NE, Hartington Muni, GPS RWY 13, Orig, CANCELLED

Hartington, NE, Hartington Muni, GPS RWY 31, Orig, CANCELLED

Hartington, NE, Hartington Muni/Bud Becker Fld, RNAV (GPS) RWY 13, Orig

Hartington, NE, Hartington Muni/Bud Becker Fld, RNAV (GPS) RWY 31, Orig

Hartington, NE, Hartington Muni/Bud Becker Fld, Takeoff Minimums and Obstacle DP, Orig

Manville, NJ, Central Jersey Rgnl, RNAV (GPS) RWY 25, Amdt 1A

Morristown, NJ, Morristown Muni, RNAV (GPS) Z RWY 23, Orig-A

Morristown, NJ, Morristown Muni, RNAV (RNP) Y RWY 23, Orig

Albany, NY, Albany Intl, COPTER ILS OR LOC/DME RWY 1, Amdt 1, CANCELLED

Albany, NY, Albany Intl, GPS RWY 10, Orig, CANCELLED

Albany, NY, Albany Intl, GPS RWY 28, Orig-B, CANCELLED

Albany, NY, Albany Intl, ILS OR LOC RWY 1, ILS RWY 1 (SA CAT II), Amdt 11

Albany, NY, Albany Intl, ILS OR LOC RWY 19, Amdt 23

Albany, NY, Albany Intl, RNAV (GPS) RWY 10, Orig

Albany, NY, Albany Intl, RNAV (GPS) RWY 28, Orig

Albany, NY, Albany Intl, RNAV (GPS) Y RWY 1, Amdt 1

Albany, NY, Albany Intl, RNAV (GPS) Y RWY 19, Amdt 1

Albany, NY, Albany Intl, RNAV (RNP) Z RWY 1, Orig

Albany, NY, Albany Intl, RNAV (RNP) Z RWY 19, Orig

Albany, NY, Albany Intl, Takeoff Minimums and Obstacle DP, Amdt 12

Buffalo, NY, Buffalo Airfield, RNAV (GPS) RWY 6, Orig

Buffalo, NY, Buffalo Airfield, RNAV (GPS) RWY 24, Amdt 1

New York, NY, La Guardia, ILS OR LOC RWY 22, ILS RWY 22 (SA CAT I), ILS RWY 22 (SA CAT II), Amdt 20

Eugene, OR, Mahlon Sweet Field, RNAV (GPS) Y RWY 16L, Amdt 2

Eugene, OR, Mahlon Sweet Field, RNAV (GPS) Y RWY 16R, Amdt 1

Eugene, OR, Mahlon Sweet Field, RNAV (GPS) Y RWY 34L, Amdt 2

Eugene, OR, Mahlon Sweet Field, RNAV (GPS) Y RWY 34R, Amdt 2

Eugene, OR, Mahlon Sweet Field, RNAV (RNP) Z RWY 16L, Orig

Eugene, OR, Mahlon Sweet Field, RNAV (RNP) Z RWY 16R, Orig

Eugene, OR, Mahlon Sweet Field, RNAV (RNP) Z RWY 34L, Orig

Eugene, OR, Mahlon Sweet Field, RNAV (RNP) Z RWY 34R, Orig

Redmond, OR, Roberts Field, RNAV (GPS) Y RWY 4, Orig-A

Redmond, OR, Roberts Field, RNAV (GPS) Y RWY 22, Orig-A

Redmond, OR, Roberts Field, RNAV (RNP) Z RWY 4, Orig

Redmond, OR, Roberts Field, RNAV (RNP) Z RWY 22, Orig

Meadville, PA, Port Meadville, RNAV (GPS) RWY 7, Amdt 1

Meadville, PA, Port Meadville, RNAV (GPS) RWY 25, Amdt 1

Philadelphia, PA, Philadelphia Intl, ILS OR LOC RWY 26, Amdt 4

Philadelphia, PA, Philadelphia Intl, ILS PRM RWY 26 (Sim. Close Parallel), Amdt 4

Philadelphia, PA, Philadelphia Intl, RNAV (GPS) RWY 26, Amdt 1

Miller, SD, Miller Muni, GPS RWY 15, Orig, CANCELLED

Miller, SD, Miller Muni, GPS RWY 33, Orig, CANCELLED

Miller, SD, Miller Muni, RNAV (GPS) RWY 15, Orig

Miller, SD, Miller Muni, RNAV (GPS) RWY 33, Orig

Sioux Falls, SD, Joe Foss Field, ILS OR LOC RWY 21, Amdt 10

Sioux Falls, SD, Joe Foss Field, RNAV (GPS) RWY 3, Amdt 1

Sioux Falls, SD, Joe Foss Field, RNAV (GPS) RWY 21, Amdt 1

Alpine, TX, Alpine-Casparis Muni, GPS RWY 19, Orig-A, CANCELLED

Alpine, TX, Alpine-Casparis Muni, RNAV (GPS) RWY 19, Orig

Bonham, TX, Jones Field, RNAV (GPS) RWY 17, Amdt 2

Bonham, TX, Jones Field, RNAV (GPS) RWY 35, Amdt 1

Bonham, TX, Jones Field, Takeoff Minimums and Obstacle DP, Amdt 2

El Paso, TX, El Paso Intl, RNAV (GPS) Y RWY 22, Orig-C

El Paso, TX, El Paso Intl, RNAV (RNP) Z RWY 22, Orig

El Paso, TX, El Paso Intl, Takeoff Minimums and Obstacle DP, Amdt 6

Fort Worth, TX, Fort Worth Alliance, ILS OR LOC RWY 34R, Amdt 6

San Antonio, TX, San Antonio Intl, RNAV (RNP) Z RWY 21, Orig-A

Sulphur Springs, TX, Sulphur Springs Muni, RNAV (GPS) RWY 1, Amdt 1

Sulphur Springs, TX, Sulphur Springs Muni, RNAV (GPS) RWY 19, Orig

Winters, TX, Winters Muni, NDB OR GPS RWY 35, Orig-A, CANCELLED

Winters, TX, Winters Muni, RNAV (GPS) RWY 17, Orig

Winters, TX, Winters Muni, RNAV (GPS) RWY 35, Orig

Winters, TX, Winters Muni, Takeoff Minimums and Obstacle DP, Orig

Richland, WA, Richland, VOR RWY 26, Amdt 7A, CANCELLED

Wenatchee, WA, Pangborn Memorial, RNAV (RNP) RWY 12, Orig-B

Sparta, WI, Sparta/Fort McCoy, RNAV (GPS) RWY 29, Amdt 1

Laramie, WY, Laramie Rgnl, RNAV (GPS) RWY 3, Orig

Laramie, WY, Laramie Rgnl, RNAV (GPS) RWY 21, Orig

[FR Doc. 2011-17984 Filed 7-20-11; 8:45 am]

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

21 CFR Part 870

[Docket No. FDA-2007-N-0092] (Formerly Docket No. 2007N-0308)

Cardiovascular Devices; Classification of Electrocardiograph Electrodes

AGENCY: Food and Drug Administration, HHS.

ACTION: Final rule.

SUMMARY: The Food and Drug Administration (FDA) is classifying the electrocardiograph electrode, intended to acquire and transmit the electrical signal at the body surface to a processor that produces an electrocardiogram (ECG) or vectorcardiogram, into class II (special controls). FDA is also exempting this device from the premarket notification requirement.

DATES: This rule is effective August 22, 2011.

FOR FURTHER INFORMATION CONTACT: Sharon Lappalainen, Center for Devices and Radiological Health, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 66, rm. 1238, Silver Spring, MD 20993, 301-796-6322.

SUPPLEMENTARY INFORMATION:

I. Regulatory Authorities

The Federal Food, Drug, and Cosmetic Act (the FD&C Act) (21 U.S.C. 301 *et seq.*), as amended by the Medical Device Amendments of 1976 (the 1976 amendments) (Pub. L. 94-295), the Safe Medical Devices Act of 1990 (SMDA) (Pub. L. 101-629), the Food and Drug Administration Modernization Act of 1997 (FDAMA) (Pub. L. 105-115), and the Medical Device User Fee and Modernization Act of 2002 (MDUFMA) (Pub. L. 107-250), established a comprehensive system for the regulation