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 November 3, 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 23 November 2006

Jonesville, VA, Lee County, RNAV (GPS) RWY 7, Orig
Jonesville, VA, Lee County, RNAV (GPS) RWY 25, Orig
Jonesville, VA, Lee County, Takeoff Minimums and Textual DP, Orig

Effective 21 December 2006

Fort Myers, FL, Southwest Florida Intl, LOC RWY 5, Orig

Effective 18 January 2007

Greensboro, AL, Greensboro Muni, RNAV (GPS) RWY 18, Orig
Greensboro, AL, Greensboro Muni, RNAV (GPS) RWY 36, Orig
Greensboro, AL, Greensboro Muni, NDB OR GPS RWY 36, Orig-B, CANCELLED
Greensboro, AL, Greensboro Muni, Takeoff Minimums and Textual DP, Orig
Gulkana, AK, Gulkana, RNAV (GPS) RWY 15, Amdt 1
Gulkana, AK, Gulkana, RNAV (GPS) RWY 33, Amdt 1
Gulkana, AK, Gulkana, VOR/DME RWY 15, Orig
Gulkana, AK, Gulkana, VOR/DME RWY 33, Orig
Gulkana, AK, Gulkana, VOR RWY 14, Amdt 7, CANCELLED
Gulkana, AK, Gulkana, VOR RWY 32, Amdt 6A, CANCELLED
Gulkana, AK, Gulkana, DF RWY 15, Amdt 2
Gulkana, AK, Gulkana, Takeoff Minimums & Textual DPs, Amdt 7
Orlando, FL, Kissimmee Gateway, ILS OR LOC RWY 15, Orig
Louisville, KY, Bowman Field, RNAV (GPS) RWY 24, Orig
Louisville, KY, Bowman Field, GPS RWY 24, Orig-B, CANCELLED
Brookhaven, MS, Brookhaven-Lincoln County, RNAV (GPS) RWY 22, Orig
Brookhaven, MS, Brookhaven-Lincoln County, VOR/DME–A, Amdt 9
Brookhaven, MS, Brookhaven-Lincoln County, NDB OR GPS RWY 22, Amdt 3, CANCELLED
Great Falls, MT, Great Falls Intl, Takeoff Minimums and Textual DP, Orig
Gastonia, NC, Gastonia Muni, RNAV (GPS) RWY 21, Orig
Gastonia, NC, Gastonia Muni, RNAV (GPS) RWY 3, Amdt 1
Dayton, OH, Greene County—Lewis A Jackson Regional, RNAV (GPS) RWY 7, Orig
Dayton, OH, Greene County—Lewis A Jackson Regional, RNAV (GPS) RWY 25, Orig
Dayton, OH, Greene County—Lewis A Jackson Regional, NDB RWY 25, Amdt 1
Dayton, OH, Greene County—Lewis A Jackson Regional, GPS RWY 7, Orig-A, CANCELLED
Dayton, OH, Greene County—Lewis A Jackson Regional, Takeoff Minimums and Textual DP, Amdt 1
Elk City, OK, Elk City Regional Business, RNAV (GPS) RWY 17, Orig
Elk City, OK, Elk City Regional Business, RNAV (GPS) RWY 35, Orig
Elk City, OK, Elk City Regional Business, NDB RWY 17, Amdt 5
Elk City, OK, Elk City Regional Business, VOR/DME RNAV RWY 17, Amdt 2A, CANCELLED
Elk City, OK, Elk City Regional Business, GPS RWY 35, Orig, CANCELLED
Elk City, OK, Elk City Regional Business, GPS RWY 17, Orig, CANCELLED
Elk City, OK, Elk City Regional Business, Takeoff Minimums and Textual DP, Amdt 1
Fayetteville, TN, Fayetteville Muni, RNAV (GPS) RWY 20, Orig
Fayetteville, TN, Fayetteville Muni, SDF RWY 20, Amdt 4
Fayetteville, TN, Fayetteville Muni, GPS RWY 20, Orig-A, CANCELLED
Olympia, WA, Olympia, VOR/DME RWY 35, Amdt 12
Olympia, WA, Olympia, VOR–A, Amdt 1
Olympia, WA, Olympia, RNAV (GPS) RWY 35, Orig
Olympia, WA, Olympia, RNAV (GPS) RWY 17, Orig

The FAA published an Amendment in Docket No. 30513, Amdt No. 3184 to Part 97 of the Federal Aviation Regulations (Vol 71, FR No. 179, Page 54404; dated September 15, 2006) under section 97.27, effective 23 November 2006, published in TL 06–21 are hereby RESCINDED as follows:

Saratoga, WY, Shively Field, NDB–A, Amdt 1
Saratoga, WY, Shively Field, RNAV (GPS)–B, Orig

[FR Doc. E6–19112 Filed 11–14–06; 8:45 am]

BILLING CODE 4910–13–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

21 CFR Parts 203 and 205

[Docket Nos. 1992N–0297 (Formerly 92N–0297), 1988N–0258 (Formerly 88N–0258), 2006D–0226]

Prescription Drug Marketing Act Pedigree Requirements under 21 CFR Part 203 Compliance Policy Guide and Guidance for Industry: Prescription Drug Marketing Act Pedigree Requirements Questions and Answers; Notice of Availability

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice of availability of guidances.

SUMMARY: The Food and Drug Administration (FDA) is announcing the availability of a final Compliance Policy Guide (CPG) 160.900 entitled ''Prescription Drug Marketing Act—Pedigree Requirements under 21 CFR Part 203'' (PDMA CPG). This CPG describes how the agency intends to prioritize its enforcement efforts in the first year after the December 1, 2006, effective date of 21 CFR §§ 203.3(u) and 203.50. In addition, the FDA is announcing the availability of ''Guidance for Industry: Prescription Drug Marketing Act (PDMA) Pedigree

Requirements Questions and Answers'' (PDMA Q & A). The PDMA Q & A guidance is issued in response to the many questions received regarding the Prescription Drug Marketing Act (PDMA) pedigree requirements. The two guidance documents explain FDA's current thinking on issues related to the pedigree requirements of the PDMA.

DATES: The effective date for the PDMA CPG is December 1, 2006. The PDMA CPG expires December 1, 2007. The PDMA Q & A guidance is effective November 15, 2006. Submit written or electronic comments on the PDMA Q & A guidance or the PDMA CPG at any time.

ADDRESSES: Submit written comments on the PDMA Q & A guidance or the PDMA CPG identified by the docket numbers found in the heading of this document by any of the following methods:

Electronic Submissions

Submit electronic comments in the following ways:

- Federal eRulemaking Portal: *http://www.regulations.gov*. Follow the instructions for submitting comments.
- Agency Web site: *http://www.fda.gov/dockets/ecomments*. Follow the instructions for submitting comments on the agency Web site.

Written Submissions

Submit written submissions in the following ways:

- FAX: 301–827–6870.
- Mail/Hand delivery/Courier [For paper, disk, or CD–ROM submissions]: Division of Dockets Management (HFA–305), Food and Drug Administration, 5630 Fishers Lane, rm. 1061, Rockville, MD 20852.

To ensure more timely processing of comments, FDA is no longer accepting comments submitted to the agency by e-mail. FDA encourages you to continue to submit electronic comments by using the Federal eRulemaking Portal or the agency Web site, as described in the *Electronic Submissions* portion of this paragraph.

Instructions: All submissions received must include the agency name and docket numbers for this rulemaking. All comments received may be posted without change to *http://www.fda.gov/ohrms/dockets/default.htm*, including any personal information provided. For additional information on submitting comments, see the ''Comments'' heading of the **SUPPLEMENTARY INFORMATION** section of this document.

Docket: For access to the docket to read background documents or comments received, go to *http://www.fda.gov/ohrms/dockets/default.htm* and insert the docket numbers, found in brackets in the heading of this document, into the ''Search'' box and follow the prompts and/or go to the Division of Dockets Management, 5630 Fishers Lane, rm. 1061, Rockville, MD 20852.

FOR FURTHER INFORMATION CONTACT: Ilisa Bernstein, Office of the Commissioner, Office of Policy (HF–11), Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857, 301–827–3360, or by e-mail *ilisa.bernstein@fda.hhs.gov*.

SUPPLEMENTARY INFORMATION:

I. Background

A. Implementation of 21 CFR §§ 203.3(u) and 203.50

The PDMA, as modified by the Prescription Drug Amendments of 1992, amended sections 301, 303, 503, and 801 of the Federal Food, Drug, and Cosmetic Act (the act) (21 U.S.C. 331, 333, 353, and 381) to establish, among other things, requirements related to the wholesale distribution of prescription drugs. A primary purpose of the PDMA is to increase safeguards to prevent the introduction and retail sale of substandard, ineffective, and counterfeit drugs in the U.S. drug supply chain.

Section 503(e)(1)(A) of the Federal Food, Drug, and Cosmetic Act (act) establishes the so-called ''pedigree'' requirement for prescription drugs. A drug pedigree is a statement of origin that identifies each prior sale, purchase, or trade of a drug, including the dates of those transactions and the names and addresses of all parties to them. Under the pedigree requirement, each person who is engaged in the wholesale distribution of a prescription drug in interstate commerce, who is not the manufacturer or an authorized distributor of record for that drug, must provide a pedigree for that drug to the person who receives the drug. The PDMA states that an authorized distributor of record is a wholesaler that has an ''ongoing relationship'' with a manufacturer to distribute that manufacturer's drug. However, the PDMA does not define ''ongoing relationship.''

In 1999, FDA published final regulations related to the PDMA (part 203 (21 CFR part 203)). The regulations were to take effect in December 2000. After publication of the 1999 final rule, the agency received comments objecting to the provisions in §§ 203.3(u) and 203.50. Section 203.3(u) defines ''ongoing relationship'' to include a written agreement between a manufacturer and a distributor. Section 203.50 specifies the fields of information that must be included in the drug pedigree, and states that the information must be traceable back to the first sale by the manufacturer. Based on concerns raised by various stakeholders, the agency delayed the effective date of §§ 203.3(u) and 203.50 several times.

Most recently, in February 2004, FDA delayed the effective date of §§ 203.3(u) and 203.50 until December 1, 2006, in part because we were informed by stakeholders in the U.S. drug supply chain that the industry would voluntarily implement electronic track and trace technology by 2007. If widely adopted, this technology could create a de facto electronic pedigree (e-pedigree) documenting the sale of a drug product from its place of manufacture through the U.S. drug supply chain to the final dispenser. If properly implemented, an electronic record could thus meet the pedigree requirements in section 503(e)(1)(A) of the act. Based on a recent fact-finding effort by FDA to assess the use of e-pedigree across the supply chain, however, it appears that industry will not fully implement track and trace technology by 2007.

As a result of this fact finding, FDA published a notice in the **Federal Register** on June 14, 2006 (71 FR 34249), announcing that it does not intend to delay the effective date of §§ 203.3(u) and 203.50 beyond December 1, 2006. Thus, these provisions defining ''ongoing relationship'' and setting forth requirements regarding the information that must appear in pedigrees will go into effect as of December 1, 2006. As part of its June 14, 2006, announcement, FDA also issued and requested comment on draft Compliance Policy Guide 160.900 entitled ''Prescription Drug Marketing Act Pedigree Requirements under 21 CFR Part 203.''

B. PDMA Compliance Policy Guide

We are issuing the final PDMA CPG, which describes how we plan to prioritize our enforcement efforts during the first year in which §§ 203.3(u) and 203.50 are effective. This PDMA CPG lists factors that FDA field personnel are expected to consider in prioritizing FDA's pedigree related enforcement efforts. Consistent with our risk-based approach to the regulation of pharmaceuticals, utilizing these factors will focus our efforts on drug products that are most vulnerable to counterfeiting and diversion or that are otherwise involved in illegal activity.

The priorities described in the PDMA CPG reflect a phased-in type approach to the enforcement of the previously stayed pedigree provisions. The PDMA CPG will expire December 1, 2007. By providing guidance on the types of drugs that are currently of greatest

concern to FDA, we believe that wholesale distributors will have a better idea of where and how to focus their initial energies as they implement systems and approaches to come into complete compliance with 21 CFR part 203.

FDA is issuing this PDMA CPG as a level 1 guidance consistent with FDA's good guidance practices (21 CFR § 10.115).

We note that guidance documents are not binding on FDA or industry, and, under appropriate circumstances, the agency may initiate regulatory action, including criminal prosecution, for violations of the pedigree requirements.

C. Guidance for Industry: Prescription Drug Marketing Act Pedigree Requirements Questions and Answers

We are also issuing the PDMA Q & A, which represents FDA's current thinking on several issues regarding the PDMA pedigree requirements. It addresses numerous questions that FDA received as comments to the PDMA CPG docket, as well as through e-mail and other communications, regarding the PDMA pedigree requirements. The questions and answers in the guidance address issues pertaining to manufacturers, wholesale distributors, pharmacies, and other entities affected by the PDMA pedigree requirements.

FDA is issuing the PDMA Q & A as a level 1 guidance consistent with FDA's good guidance practices (21 CFR § 10.115). Given that the relevant PDMA pedigree provisions will go into effect as of December 1, 2006, FDA is implementing the PDMA Q&A immediately, in accordance with § 10.115(g)(2) (21 CFR 10.115(g)(2)), because the agency has determined that prior public input is not feasible or appropriate. As noted, the pedigree requirements set forth in §§ 203.3(u) and 203.50, which had been stayed on several occasions, will apply to prescription drug products as of December 1, 2006. Promptly clarifying FDA's current thinking on the questions in the guidance should facilitate industry's compliance with the PDMA pedigree requirements.

Under § 10.115(g), FDA is opening a docket on the PDMA Q & A, and we invite interested persons to submit comments and questions. FDA intends to review the comments and questions and to revise the PDMA Q & A when appropriate, using the question and answer format in the PDMA Q & A guidance. For purposes of transparency, efficiency, and clarity, the agency believes that, at the present time, it is important to maintain FDA's written responses to the significant questions concerning the PDMA pedigree requirements in a single guidance document that is periodically updated as the agency receives and responds to additional questions. We also intend to use the following four indicators to help users of the guidance identify future additions or revisions: (1) The updated guidance will be identified as a revision of the previously issued document, (2) the revision date of the guidance will appear on its cover, (3) the edition number of the guidance will be included in its title, and (4) questions and answers that have been added to the guidance, or prior answers that have been in any way modified, will be identified as such in the body of the guidance.

The PDMA CPG and PDMA Q & A guidance represent the agency's current thinking on issues related to the PDMA pedigree requirements. The guidances do not create or confer any rights for or on any person and do not operate to bind FDA or the public. An alternative approach may be used if such approach satisfies the requirements of the applicable statutes and regulations.

II. Electronic Access

An electronic version of the PDMA CPG is available on the Internet at *http://www.fda.gov/ora* under ''Compliance Reference''. An electronic version of the PDMA Q & A guidance is available at *http://www.fda.gov/pdma*.

III. Comments

Interested persons may submit to the Division of Dockets Management (see **ADDRESSES**) written or electronic comments regarding the PDMA Q & A guidance or PDMA CPG at any time. Submit a single copy of electronic comments or two paper copies of any mailed comments, except that individuals may submit one paper copy. Comments are to be identified with the docket number found in brackets in the heading of this document. Received comments and the guidance may be seen in the Division of Dockets management between 9 a.m. and 4 p.m., Monday through Friday.

Dated: November 8, 2006.

Jeffrey Shuren,

Assistant Commissioner for Policy.

[FR Doc. 06–9211 Filed 11–13–06; 8:45 am]

BILLING CODE 4160–01–S

DEPARTMENT OF TRANSPORTATION

Federal Highway Administration

23 CFR Part 635

[FHWA Docket No. FHWA–2006–23552]

RIN 2125–AF18

Construction and Maintenance

AGENCY: Federal Highway Administration (FHWA), DOT.

ACTION: Final rule.

SUMMARY: The FHWA is revising its regulations in 23 CFR part 635 subpart D to address Section 5514 of the Safe, Accountable, Flexible, Efficient Transportation Equity Act: A Legacy for Users (SAFETEA–LU). This law requires the FHWA to ensure that States provide for competition with respect to the specification of alternative types of culvert pipes. These revisions will ensure that States provide for competition in the specification of alternative types of culvert pipes.

DATES: *Effective Date:* December 15, 2006.

FOR FURTHER INFORMATION CONTACT: For technical information: Mr. Gerald Yakowenko, Office of Program Administration (HIPA), (202) 366–1562. For legal information: Mr. Michael Harkins, Office of the Chief Counsel (HCC–30), (202) 366–4928, Federal Highway Administration, 400 Seventh Street, SW., Washington, DC 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

This document and all comments received by the U.S. DOT Dockets, Room PL–401, may be viewed through the Docket Management System (DMS) at *http://dms.dot.gov*. It is available 24 hours each day, 365 days each year. Electronic submission and retrieval help and guidelines are available under the help section of this Web site.

An electronic copy of this document may be downloaded from 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

Section 5514 of the SAFETEA–LU (Pub. L. 109–59; Aug. 10, 2005), titled ''Competition for Specification of Alternative Types of Culvert Pipes,'' requires the Secretary of Transportation to ensure that States provide for competition with respect to the