Background

On October 19, 2001, the FAA proposed to amend 14 CFR part 73 to modify the designated altitudes for Restricted Area R–5201, Fort Drum, NY (66 FR 53132). Interested parties were invited to participate in this rulemaking by submitting comments. No comments were received.

The Rule

This action amends 14 CFR part 73 by changing the designated altitudes of R–5201, Fort Drum, NY. Specifically, this action changes the designated altitudes from ''Surface to 23,000 feet MSL, April 1 through September 30; surface to 20,000 feet MSL, October 1 through March 31'' to ''Surface to 23,000 feet MSL.'' This amendment deletes the seasonal changes to the upper altitude limit of R–5201 and establishes 23,000 feet MSL as the permanent upper altitude limit on a year-round basis. The 20,000 feet MSL limit for 6 months of the year adversely affects military training at Fort Drum and requires units to alter their training profiles when the 23,000 feet MSL ceiling is not available. This limitation is disruptive to training continuity and precludes the most cost-effective accomplishment of training activities. The U.S. Army requested this modification to better accommodate existing and forecast training requirements at Fort Drum. This action does not change the current boundaries, time of designation, or activities conducted within R–5201.

Section 73.52 of 14 CFR part 73 was republished in FAA Order 7400.8J, dated September 20, 2001.

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. Therefore, this regulation: (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. Since this is a routine matter that will only affect air traffic procedures and air navigation, it is certified that this rule, when promulgated, will not have a significant economic impact on a substantial number of small entities under the criteria of the Regulatory Flexibility Act.

Environmental Review

The FAA determined that this change applies to on-going military activities occurring between 20,000 feet MSL and 23,000 feet MSL, and not over noise-sensitive areas; that there will be no significant noise increase associated with this change; and no significant air quality impacts. The FAA further determined that this action does not trigger any extraordinary circumstances that would warrant further environmental review. The FAA concluded that this action is categorically excluded from further environmental analysis in accordance with FAA Order 1050.1D, Policies and Procedures for Considering Environmental Impacts; and the FAA/DOD Memorandum of Understanding concerning Special Use Airspace Environmental Actions, dated January 26, 1998.

List of Subjects in 14 CFR Part 73

Airspace, Navigation (air).

Adoption of the Amendment

In consideration of the foregoing, the Federal Aviation Administration amends 14 CFR part 73 as follows:

PART 73—SPECIAL USE AIRSPACE

1. The authority citation for part 73 continues to read as follows:

Authority: 49 U.S.C. 106(g), 40103, 40113, 40120; E.O. 10854, 24 FR 9565, 3 CFR, 1959–1963 Comp., p. 389.

§ 73.52 [Amended]

2. Section 73.52 is amended as follows:

* * * * *

R–5201 Fort Drum, NY [Amended]

By removing ''Designated altitudes. Surface to 23,000 feet MSL, April 1 though September 30; surface to 20,000 feet MSL, October 1 through March 31'' and inserting ''Designated altitudes. Surface to 23,000 feet MSL.''

* * * * *

Issued in Washington, DC on February 6, 2002.

Reginald C. Matthews,

Manager, Airspace and Rules Division.

[FR Doc. 02–3530 Filed 2–12–02; 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 No. 92N–0297]

RIN 0905–AC81

Prescription Drug Marketing Act of 1987; Prescription Drug Amendments of 1992; Policies, Requirements, and Administrative Procedures; Delay of Effective Date

AGENCY: Food and Drug Administration, HHS.

ACTION: Final rule; delay of effective date.

SUMMARY: The Food and Drug Administration (FDA) is further delaying, until April 1, 2003, the effective date of certain requirements of a final rule published in the **Federal Register** of December 3, 1999 (64 FR 67720). In the **Federal Register** of May 3, 2000 (65 FR 25639), the agency delayed until October 1, 2001, the effective date of certain requirements in the final rule relating to wholesale distribution of prescription drugs by distributors that are not authorized distributors of record, and distribution of blood derivatives by entities that meet the definition of a ''health care entity'' in the final rule. In the **Federal Register** of March 1, 2001 (66 FR 12850), the agency further delayed the effective date of those requirements until April 1, 2002. This action further delays the effective date of these requirements until April 1, 2003. The final rule implements the Prescription Drug Marketing Act of 1987 (PDMA), as modified by the Prescription Drug Amendments of 1992 (PDA), and the Food and Drug Administration Modernization Act of 1997 (the Modernization Act). The agency is taking this action to address concerns about the requirements raised by affected parties. As explained in the **SUPPLEMENTARY INFORMATION** section, the delay will allow additional time for Congress and FDA to consider whether legislative and regulatory changes are appropriate.

To the extent that 5 U.S.C. 553 applies to this action, it is exempt from notice and comment because it constitutes a rule of procedure under 5 U.S.C. 553(b)(A). Alternatively, the agency's implementation of this action without opportunity for public comment, effective immediately upon publication today in the **Federal Register**, is based on the good cause exceptions in 5 U.S.C.

553(b)(B) and (d)(3). Seeking public comment is impracticable, unnecessary, and contrary to the public interest. As explained in the **SUPPLEMENTARY INFORMATION** section, FDA has prepared a report for Congress and concluded that although the agency can address some of industry's concerns with the PDMA regulation through regulatory changes, other concerns would have to be addressed by Congress through legislative action. The further delay is necessary to give Congress time to consider the information and conclusions contained in the agency's report, and to determine if legislative action is appropriate. The further delay will also give the agency additional time to consider whether regulatory changes are appropriate and, if so, to initiate such changes.

DATES: The effective date for §§ 203.3(u) and 203.50, and the applicability of § 203.3(q) to wholesale distribution of blood derivatives by health care entities, added at 64 FR 67720, December 3, 1999, is delayed until April 1, 2003. Submit written or electronic comments by April 15, 2002.

ADDRESSES: Submit written comments to the Dockets Management Branch (HFA–305), Food and Drug Administration, 5630 Fishers Lane, rm. 1061, Rockville, MD 20852. All comments should be identified with the docket number found in brackets in the heading of this document. Submit electronic comments on the Internet at http://www.fda.gov/dockets/ecomments.

FOR FURTHER INFORMATION CONTACT: Lee D. Korb, Center for Drug Evaluation and Research (HFD–7), Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857, 301–594–2041.

SUPPLEMENTARY INFORMATION: PDMA (Public Law 100–293) was enacted on April 22, 1988, and was modified by the PDA (Public Law 102–353, 106 Stat. 941) on August 26, 1992. The PDMA, as modified by the PDA, amended sections 301, 303, 503, and 801 of the Federal Food, Drug, and Cosmetic Act (the act) (21 U.S.C. 331, 333, 353, 381) to, among other things, establish requirements for the wholesale distribution of prescription drugs and for the distribution of blood derived prescription drug products by health care entities.

On December 3, 1999, the agency published final regulations in part 203 (21 CFR part 203) implementing PDMA (64 FR 67720). After publication of the final rule, the agency received letters and petitions and had other communications with industry, industry trade associations, and members of Congress objecting to the provisions in §§ 203.3(u) and 203.50. On March 29, 2000, the agency met with representatives from the wholesale drug industry and industry associations to discuss their concerns. In addition, FDA received a petition for stay of action requesting that the relevant provisions of the final rule be stayed until October 1, 2001. The agency also received a petition for reconsideration from the Small Business Administration requesting that FDA reconsider the final rule and suspend its effective date based on the severe economic impact it would have on more than 4,000 small businesses.

In addition to the submissions on wholesale distribution by unauthorized distributors, the agency received several letters on, and held several meetings to discuss, the implications of the final regulations for blood centers that distribute blood derivative products and provide health care as a service to the hospitals and patients they serve.

Based on the concerns expressed by industry, industry associations, and Congress about implementing §§ 203.3(u) and 203.50 by the December 4, 2000, effective date, the agency published a document in the **Federal Register** of May 3, 2000 (65 FR 25639), delaying the effective date for those provisions until October 1, 2001. In addition, the May 2000 action delayed the applicability of § 203.3(q) to wholesale distribution of blood derivatives by health care entities until October 1, 2001. The May 2000 action also reopened the administrative record and gave interested persons until July 3, 2000, to submit written comments. As stated in the May 2000 action, the purpose of delaying the effective date for these provisions was to give the agency time to obtain more information about the possible consequences of implementing them and to further evaluate the issues involved.

On May 16, 2000, the House Committee on Appropriations (the Committee) stated in its report accompanying the Agriculture, Rural Development, FDA, and Related Agencies Appropriations Bill, 2001 (H. Rept. 106–619) that it supported the ''recent FDA action to delay the effective date for implementing certain requirements of the Prescription Drug Marketing Act until October 1, 2001, and reopen the administrative record in order to receive additional comments.'' In addition, the Committee stated that it ''believes the agency should thoroughly review the potential impact of the proposed provisions on the secondary wholesale pharmaceutical industry.'' The Committee directed the agency to provide a report to the Committee summarizing the comments and issues raised and agency plans to address the concerns.

After issuing the delay of the effective date for the relevant requirements of the final rule, the agency decided to hold a public hearing to elicit comment from interested persons on the requirements. In the **Federal Register** of September 19, 2000 (65 FR 56480), the agency announced that a public hearing would be held on October 27, 2000, to discuss the requirements at issue (i.e., the requirements for unauthorized distributors and the provisions relating to distribution of blood derivatives by health care entities). The hearing was held on October 27, 2000, and comments were accepted until November 20, 2000.

In the **Federal Register** of March 1, 2001 (66 FR 12850), the agency announced that it was further delaying, until April 1, 2002, the effective date of the provisions relating to wholesale distribution of prescription drugs by unauthorized distributors (i.e., §§ 203.3(u) and 203.50). The agency also further delayed the applicability of § 203.3(q) to wholesale distribution of blood derivatives by health care entities. As explained by the agency, the effective date was further delayed to give FDA additional time to consider comments and testimony received on unauthorized distributor and blood derivative issues, for FDA to prepare its report to Congress, and, if appropriate, for Congress or the agency to make legislative or regulatory changes. The report was completed and submitted to Congress on June 7, 2001.

In its report to Congress, the agency concluded that it could address some, but not all, of the concerns raised by the secondary wholesale industry and the blood industry through regulatory changes. However, Congress would have to act to amend section 503(e) of the act to make the types of changes requested by the secondary wholesale industry.

FDA has decided that, in light of the fact that only legislative action can address some of the concerns raised by the secondary wholesale industry, it is appropriate to further delay the effective date of the relevant provisions of the final rule for another year until April 1, 2003. The delay will give Congress time to consider the information and conclusions contained in the agency's report and to determine if legislative action is appropriate. The further delay will also give the agency additional time to consider whether regulatory changes are appropriate and, if so, to initiate such changes.

This action is being taken under FDA's authority under 21 CFR 10.35(a). The Commissioner of Food and Drugs finds that this further delay of the effective date is in the public interest.

Dated: February 5, 2002.

Margaret M. Dotzel,

Associate Commissioner for Policy.

[FR Doc. 02–3282 Filed 2–12–02; 8:45 am]

BILLING CODE 4160–01–S

DEPARTMENT OF TRANSPORTATION

Coast Guard

33 CFR Part 117

[CGD01–02–007]

RIN 2115–AE47

Drawbridge Operation Regulations: Harlem River, NY

AGENCY: Coast Guard, DOT.

ACTION: Temporary final rule.

SUMMARY: The Coast Guard is temporarily changing the drawbridge operation regulations for the Madison Avenue Bridge, mile 2.3 and the Macombs Dam Bridge, at mile 3.2, both across the Harlem River at New York City, New York. This temporary rule will allow the bridges to remain in the closed position at various times to facilitate necessary bridge maintenance.

DATES: This rule is effective from February 18, 2002 through February 28, 2003.

ADDRESSES: Comments and material received from the public, as well as documents indicated in this preamble as being available in the docket, are part of docket (CGD01–02–007) and are available for inspection or copying at the First Coast Guard District, Bridge Branch Office, 408 Atlantic Avenue, Boston, Massachusetts, 02110, 7 a.m. to 3 p.m., Monday through Friday, except Federal holidays.

FOR FURTHER INFORMATION CONTACT: Mr. Joe Arca, Project Officer, First Coast Guard District, (212) 668–7165.

SUPPLEMENTARY INFORMATION:

Regulatory Information

Pursuant to 5 U.S.C. 553, a notice of proposed rulemaking (NPRM) was not published for this regulation. Good cause exists for not publishing a NPRM and for making this regulation effective in less than 30 days after publication in the **Federal Register**.

These closures are not expected to impact navigation because the vessels that normally use this waterway were designed to fit under the bridges on the Harlem River without requiring bridge openings. There have been no requests to open these bridges for several years. Accordingly, an NPRM was considered unnecessary and the rule may be made effective in less than 30 days after publication.

Background and Purpose

The Madison Avenue Bridge has a vertical clearance in the closed position of 25 feet at mean high water and 29 feet at mean low water. The Macombs Dam Bridge has a vertical clearance in the closed position of 27 feet at mean high water and 32 feet at mean low water. The existing drawbridge operating regulations, listed at 33 CFR 117.789(c), require the bridges to open on signal from 10 a.m. to 5 p.m., after a four-hour advance notice is given.

The owner of the bridges, the New York City Department of Transportation (NYCDOT), requested a temporary final rule to facilitate scheduled maintenance and replacement of electrical and mechanical systems at the bridges. These bridge closures are not expected to effect vessel traffic because there have been no requests to open the bridges for several years. Vessels that can pass under the bridges without openings may do so at all times during these closures.

Regulatory Evaluation

This rule is not a ''significant regulatory action'' under section 3(f) of Executive Order 12866 and does not require an assessment of potential costs and benefits under section 6(a)(3) of that Order. The Office of Management and Budget has not reviewed it under that Order. It is not ''significant'' under the regulatory policies and procedures of the Department of Transportation (DOT) (44 FR 11040; February 26, 1979). This conclusion is based on the fact that keeping the bridges closed should have no impact on navigation because the bridges have not had any requests to open for several years.

Small Entities

Under the Regulatory Flexibility Act (5 U.S.C. 601–612) we considered whether this rule would have a significant economic impact on a substantial number of small entities. ''Small entities'' comprises small businesses, not-for profit organizations that are independently owned and operated and are not dominant in their fields, and governmental jurisdictions with populations less than 50,000.

The Coast Guard certifies under 5 U.S.C. 605(b) that this rule will not have a significant economic impact on a substantial number of small entities. This conclusion is based on the fact that the closure of the bridges should have no impact on navigation because the bridges have not had any requests to open for several years.

Collection of Information

This rule calls for no new collection of information under the Paperwork Reduction Act of 1995 (44 U.S.C. 3501–3520).

Federalism

We have analyzed this rule under Executive Order 13132 and have determined that this rule does not have implications for federalism under that Order.

Unfunded Mandates Reform Act

The Unfunded Mandates Reform Act of 1995 (2 U.S.C. 1531–1538) governs the issuance of Federal regulations that require unfunded mandates. An unfunded mandate is a regulation that requires a State, local, or tribal government or the private sector to incur direct costs without the Federal Government's having first provided the funds to pay those unfunded mandate costs. This rule will not impose an unfunded mandate.

Taking of Private Property

This rule will not effect a taking of private property or otherwise have taking implications under Executive Order 12630, Governmental Actions and Interference with Constitutionally Protected Property Rights.

Civil Justice Reform

This rule meets applicable standards in sections 3(a) and 3(b)(2) of Executive Order 12988, Civil Justice Reform, to minimize litigation, eliminate ambiguity, and reduce burden.

Protection of Children

We have analyzed this rule under Executive Order 13045, Protection of Children from Environmental Health Risks and Safety Risks. This rule is not an economically significant rule and does not concern an environmental risk to health or risk to safety that may disproportionately affect children.

Environment

The Coast Guard considered the environmental impact of this rule and concluded that under figure 2–1, paragraph (32)(e) of Commandant Instruction M16475.1C, this rule is categorically excluded from further environmental documentation because promulgation of changes to drawbridge regulations have been found to not have a significant effect on the environment. A written ''Categorical Exclusion