§ 12.10 Service.

(a) * * *

(2) *Filing with the Proceedings Clerk; proof of service.* All documents which are required to be served upon a party shall be filed concurrently with the Proceedings Clerk, and shall meet the requirements as to form prescribed by §§ 12.11 and 12.12 of this part. Unless otherwise provided in these rules, a document shall be filed by:

(i) Delivering it in person;

(ii) Mailing it by first-class or a more expeditious form of United States mail, or delivering it to a similar commercial package delivery service;

(iii) Transmitting the documents via facsimile machine (''fax''); or

(iv) Via electronic mail (''e-mail.'')

(v) Mailed documents must be addressed to: Proceedings Clerk, Office of Proceedings, Commodity Futures Trading Commission, Three Lafayette Centre, 1155 21st Street, NW., Washington, DC 20581. Faxed documents should be sent to (202) 418–5532 and e-mailed documents to (*PROC_Filings@cftc.gov*), directed to the Proceedings Clerk. Electronic filing and service in a given case shall be at the discretion of the Presiding Officer, with the parties' consent. Signed documents that are served by e-mail attachment must be in PDF or other non-alterable form. To be timely filed under this part, a document must be delivered; mailed by first-class or a more expeditious form of United States mail or a similar commercial package delivery service; or faxed or e-mailed to the Proceedings Clerk within the time prescribed for filing. Proof of filing shall be made by attaching to the document to be filed an affidavit certifying that the attached document was either deposited in the mail or with the commercial package delivery service, with postage or delivery service fees prepaid, addressed to the Proceedings Clerk, Office of Proceedings, Three Lafayette Centre, 1155 21st Street, NW., Washington, DC 20581; or faxed or e-mailed to the Proceeding Clerk on the date specified in the affidavit. Proof of service of a document shall be made by filing with the Proceedings Clerk, simultaneously with the filing of the required document, an affidavit of service executed by any person 18 years of age or older or a certificate of service executed by an attorney-at-law qualified to practice before the Commission. The proof of service shall identify the persons served, state that service has been made, set forth the date of service, and recite the manner of service.

(3) *Service of orders and decisions.* A copy of all notices, rulings, opinions, and orders of the Proceedings Clerk, the Director of the Office of Proceedings, a Judgment Officer, Administrative Law Judge, the Deputy General Counsel for Opinions and Review or the Commission shall be served by the Proceedings Clerk on each of the parties. The Commission, in its discretion and with due consideration for the convenience of the parties, may serve the aforementioned documents to the parties by electronic means.

(b) *How service is made.* (1) Service shall be made by:

(i) Personal service;

(ii) First-class or a more expeditious form of United States mail or a similar commercial package delivery service;

(iii) Fax; or

(iv) E-mail in accordance with the conditions set forth in paragraph (a)(2) of this section.

(v) Service shall be complete at the time of personal service upon deposit in the mail or with a commercial package delivery service of a properly addressed document for which postage or delivery service fees have been prepaid; or upon transmission by fax or e-mail. Where service is effected by mail or a commercial package delivery service (but not by fax or e-mail), the time within which the person served may respond thereto shall be increased by five (5) days. Signed documents that are served by e-mail attachment must be in PDF or other non-alterable form. For the purposes of this Rule, service of any document by the Proceedings Clerk upon the Commission shall be regarded as service by mail.

* * * * *

■ 3. Section 12.11 is amended by revising paragraphs (a) and (c) to read as follows:

§ 12.11 Formalities of filing of documents with the Proceedings Clerk.

(a) *Number of copies.* Unless otherwise specifically provided, or unless filed by fax or e-mail in accordance with the requirements of § 12.10(a)(2), an original and one conformed copy of all documents shall be filed with the Proceedings Clerk.

* * * * *

(c) *Format.* All documents filed under the Reparation Rules shall be typewritten, printed, or, if a party is not represented by counsel, in plainly legible handwriting. Documents sent in hardcopy must be on good quality white paper, 8½ by 11½ inches and bound at the top only. Documents e-mailed in accordance with the requirements of § 12.10(a)(2) must be in PDF or other non-alterable form. All documents must be double-spaced, except for quotations more than 3 lines and footnotes, both of which should be single-spaced.

* * * * *

Issued in Washington, DC, on the 8th of October 2008, by the Commission.

David A. Stawick,

Secretary of the Commission.

[FR Doc. E8–25354 Filed 10–23–08; 8:45 am]

BILLING CODE 6351–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

21 CFR Parts 210 and 211

[Docket No. FDA–2007–N–0379] (formerly Docket No. 2007N–0280)

Amendments to the Current Good Manufacturing Practice Regulations for Finished Pharmaceuticals; Final Rule; Correction

AGENCY: Food and Drug Administration, HHS.

ACTION: Final rule; correction.

SUMMARY: The Food and Drug Administration (FDA) is correcting a final rule that appeared in the **Federal Register** of Monday, September 8, 2008 (73 FR 51919). The final rule was published with an inadvertent error in the ''Analysis of Impacts'' section. This document corrects that error.

FOR FURTHER INFORMATION CONTACT: Diane Sullivan, Office of Policy (HF–26), Food and Drug Administration, 5600 Fishers Lane, rm. 12A–11, Rockville, MD 20857, 301–827–7069, e-mail: *diane.sullivan@fda.hhs.gov*.

SUPPLEMENTARY INFORMATION: In FR Doc. E8–20709, appearing on page 51919 in the **Federal Register** of Monday, September 8, 2008, the following correction is made:

1. On page 51931, in the first column, under ''IV. Analysis of Impacts,'' in the first full paragraph, the sentence ''The agency believes that this final rule is not a significant regulatory action as defined by the Executive order, because the rule either clarifies the agency's longstanding interpretation of, or increases latitude for manufacturers in complying with, existing CGMP requirements'' is corrected to read ''The agency certifies that this final rule is not a significant regulatory action as defined by the Executive order, because the rule either clarifies the agency's longstanding interpretation of, or increases latitude for manufacturers in complying with, existing CGMP requirements.''

Dated: October 16, 2008.

Jeffrey Shuren,

Associate Commissioner for Policy and Planning.

[FR Doc. E8–25471 Filed 10–23–08; 8:45 am]

BILLING CODE 4160–01–S

DEPARTMENT OF TRANSPORTATION

Federal Highway Administration

23 CFR Part 505

[Docket No. FHWA–05–23393]

RIN 2125–AF08

Projects of National and Regional Significance Evaluation and Rating

AGENCY: Federal Highway Administration (FHWA), DOT.

ACTION: Final rule.

SUMMARY: Section 1301 of the Safe, Accountable, Flexible, Efficient Transportation Equity Act: A Legacy for Users (SAFETEA–LU) (Pub. L. 109–59; 119 Stat. 1144) established a program to provide grants to States for Projects of National and Regional Significance (PNRS) to improve the safe, secure, and efficient movement of people and goods throughout the United States and to improve the health and welfare of the national economy. Section 1301 requires the Secretary of Transportation (Secretary) to establish regulations on the manner in which the proposed projects will be evaluated and rated, in order to determine which projects shall receive grant funding. This rule establishes the required evaluation and rating guidelines for proposed projects. Under this rule, a proposed project would be eligible for funding under the PNRS Program (Program) only if the Secretary finds that the project meets the eligibility requirements of the rule. The Secretary will then evaluate and rate each project as ''highly recommended,'' ''recommended,'' or ''not recommended'' based on the results of preliminary engineering, the project justification criteria, and the degree of non-Federal financial commitment.

All funds authorized by section 1101(a)(15) of SAFETEA–LU for the Program are fully designated to the 25 projects listed in section 1301(m) of SAFETEA–LU. For the duration of SAFETEA–LU there are no additional funds available for distribution beyond those already designated, and there are no assurances that any additional funds will become available. Funding in future highway reauthorization bills is at the discretion of Congress.

DATES: *Effective Date:* This rule is effective November 24, 2008.

FOR FURTHER INFORMATION CONTACT: Mr. Edward Strocko, Office of Freight Management and Operations, HOFM–1, (202) 366–2997, or Ms. Alla Shaw, Office of the Chief Counsel, (202) 366–1042, Federal Highway Administration, 1200 New Jersey Avenue, SE., 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 and Filing

You may retrieve a copy of the NPRM, comments submitted to the docket, and a copy of this final rule online through the Federal eRulemaking portal at: *www.regulations.gov.* The Web site is available 24 hours each day, 365 days each year. Electronic retrieval help and guidelines are available under the help section of the Web site.

An electronic copy of this document may also be downloaded by accessing the Office of the Federal Register's home page at: *http://www.archives.gov* and the Government Printing Office's Web page at: *http://www.gpoaccess.gov/nara.*

Background

Section 1301 of SAFETEA–LU establishes a program to finance critical, high-cost transportation infrastructure facilities that address critical national economic and transportation needs. These projects often involve multiple levels of government, agencies, modes of transportation, and transportation goals and planning processes that are not easily addressed or funded within existing surface transportation program categories. Projects of National and Regional Significance would have national and regional benefits, including improving economic productivity by facilitating international trade, relieving congestion, and improving transportation safety by facilitating passenger and freight movement. Additionally, this Program would further the goals of the Secretary's National Strategy to Reduce Congestion on America's Transportation Network (Congestion Initiative).[1]

The benefits of PNRS would accrue beyond local areas and States, to the Nation as a whole. A program dedicated to constructing PNRS would improve the safe, secure, and efficient movement of people and goods throughout the United States as well as improve the health and welfare of the national economy.

Under these regulations, a State seeking a grant for a proposed PNRS would submit to the Secretary an application that demonstrates the ability of the proposed project to enhance the national transportation system, generate national or regional economic benefits, reduce congestion, improve transportation safety, and attract non-Federal investment.

The Secretary shall evaluate and rate each proposed project as ''highly recommended,'' ''recommended,'' or ''not recommended'' based on the results of preliminary engineering, the project criteria set forth in the regulations, and degree of non-Federal financial commitments. If the Secretary finds that the proposed project meets the requirements of the regulations, and there is a reasonable likelihood that the project will continue to meet such requirements, the Secretary may issue a letter of intent to obligate funds from future available budget authority specified in law or execute a full funding grant agreement with a State. A full funding grant agreement (FFGA) would establish the terms of Federal participation in the project, maximum amount of Federal financial assistance, cover the period of time for completing the project, and address the timely and efficient management of the project in accordance with applicable Federal statutes, regulations, and policy, including oversight roles and responsibilities, and other terms and conditions.

The designated projects in section 1301(m) of SAFETEA–LU are not subject to the criteria established in this part, and the projects will not be subject to the evaluation and rating as proposed in this part in order to receive the SAFETEA–LU authorized funding. However, projects currently designated under SAFETEA–LU section 1301(m) would be required to compete in the evaluation and rating process should any new or additional funding be authorized for this Program.

Notice of Proposed Rulemaking

On July 24, 2006, FHWA published in the **Federal Register** at 71 FR 41748 a notice of proposed rulemaking (NPRM) to establish regulations on the manner in which the proposed projects under the Projects of National and Regional Significance Program will be evaluated and rated, in order to determine which projects shall receive grant funding. The

[1] Speaking before the National Retail Foundation's annual conference on May 16, 2006, in Washington, DC, U.S. Transportation Secretary Norman Mineta unveiled a new plan to reduce congestion plaguing America's roads, rail and airports. The National Strategy to Reduce Congestion on America's Transportation Network includes a number of initiatives designed to reduce transportation congestion and is available at the following URL: *http://fightgridlocknow.com.*