

of any written comments, except that individuals may submit one hard copy. Comments are to be identified with the docket number found in brackets in the heading of this document and may be accompanied by a supporting memorandum or brief. Received comments may be seen in the Dockets Management Branch between 9 a.m. and 4 p.m., Monday through Friday.

List of Subjects in 21 CFR Part 349

Labeling, Ophthalmic goods and services, Over-the-counter drugs.

Therefore, under the Federal Food, Drug, and Cosmetic Act and under authority delegated to the Commissioner of Food and Drugs, 21 CFR part 349 is amended as follows:

PART 349—OPHTHALMIC DRUG PRODUCTS FOR OVER-THE-COUNTER HUMAN USE

1. The authority citation for 21 CFR part 349 continues to read as follows:

Authority: 21 U.S.C. 321, 351, 352, 353, 355, 360, 371.

2. Section 349.20 is revised to read as follows:

§ 349.20 Eyewashes.

The active ingredient of the product is purified water. The product also contains suitable tonicity agents to establish isotonicity with tears, suitable agents for establishing pH and buffering to achieve the same pH as tears, and a suitable preservative agent.

3. Section 349.78 is amended by revising paragraph (a) to read as follows:

§ 349.78 Labeling of eyewash drug products.

(a) *Statement of identity.* The labeling of the product identifies the product with one or more of the following terms: “eyewash,” “eye irrigation,” or “eye irrigating solution.”

* * * * *

Dated: January 31, 2003.

Margaret M. Dotzel,

Associate Commissioner for Policy.

[FR Doc. 03-3926 Filed 2-18-03; 8:45 am]

BILLING CODE 4160-01-S

DEPARTMENT OF TRANSPORTATION

Federal Highway Administration

23 CFR Part 636

[FHWA Docket No. FHWA-2000-7799]

RIN 2125-AE79

Design-Build Contracting

AGENCY: Federal Highway Administration (FHWA), DOT.

ACTION: Correction to final rule.

SUMMARY: This document corrects the final rule on design-build contracting published in the **Federal Register** on December 10, 2002 (67 FR 75902). The FHWA is correcting a typographical error concerning the relative weight of evaluation factors other than cost or price.

EFFECTIVE DATE: The final rule is effective January 9, 2003.

FOR FURTHER INFORMATION CONTACT: For technical information: Mr. Gerald Yakowenko, Office of Program Administration (HIPA), (202) 366-1562. For legal information: Mr. Harold Aikens, Office of the Chief Counsel (HCC-30), (202) 366-1373, Federal Highway Administration, 400 Seventh Street, SW., Washington, DC 20590-0001. Office hours are from 8 a.m. to 4:30 p.m., e.t., Monday through Friday, except Federal holidays.

SUPPLEMENTARY INFORMATION:

Electronic Access

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Background

Section 1307 of the Transportation Equity Act for the 21st Century (TEA-21, Public Law 105-178, 112 Stat. 107 (1998)) amends 23 U.S.C. 112 to allow the design-build contracting method after the FHWA promulgates a regulation prescribing the Secretary's approval criteria and procedures on qualified projects. The TEA-21 defined qualified projects as projects that comply with the criteria in this regulation and whose total costs are estimated to exceed: (1) \$5 million for intelligent transportation system projects, and (2) \$50 million for any other project. It also provides certain key requirements that the FHWA must

address in the development of these regulations.

On December 10, 2002, at 67 FR 75902, the FHWA published a final rule on Design-Build Contracting that implemented the regulations for design-build contracting as mandated by section 1307 of TEA-21. The regulations list the criteria and procedures that will be used by the FHWA in approving the use of design-build contracting by the State transportation departments. The regulation does not require the use of design-build contracting, but allows State transportation departments to use it as an optional technique in addition to traditional contracting methods.

After publication of the final rule, we realized that § 636.211(b)(2)(i) and (b)(2)(iii) read word for word identical to say, “Significantly less important than cost or price.” However, § 636.211(b)(2)(i) should read, “Significantly more important than cost or price.” This was stated clearly in the preamble to the final rule in the section-by-section analysis; however, when the rule language was typed in, both sections were identical, and the word “less” appeared in both sections. The FHWA is correcting § 636.211(b)(2)(i) to replace the word “less” with the word “more.”

Executive Order 12866 (Regulatory Planning and Review) and DOT Regulatory Policies and Procedures

The FHWA has determined that this action is not a significant regulatory action within the meaning of Executive Order 12866, or within the meaning of the U.S. Department of Transportation's regulatory policies and procedures because it is merely a correction of a minor mistake in the regulatory language. This correction will not adversely affect, in a material way, any section of the economy.

In addition, this correction to the rule will not interfere with any action taken or planned by another agency and will not materially alter the budgetary impact of any entitlements, grants, user fees, or loan programs.

Regulatory Flexibility Act

In compliance with the Regulatory Flexibility Act (5 U.S.C. 601-612), the FHWA has evaluated the effects of this action on small entities and has determined that the final rule will not have a significant economic impact on a substantial number of small entities and hereby certifies that this correction to the final rule will not have a significant economic impact on a substantial number of small entities.