

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

This document, the final rule, the NPRM, and all comments received by the U.S. Dockets Facility, Room PL-410, may be viewed through the Docket Management System (DMS) at <http://dms.dot.gov>. The DMS is available 24 hours each day, 365 days a 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 by using a computer, modem and suitable communication software from the Government Printing Office's Electronic Bulletin Board Service at (202) 512-1661.

Internet users may reach the Office of the Federal Register's home page at: <http://www.archives.gov> and the Government Printing Office's Web site at: <http://www.access.gpo.gov/nara>.

##### 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.

**Unfunded Mandates Reform Act of 1995**

This action will not impose unfunded mandates as defined by the Unfunded Mandates Reform Act of 1995 (Pub. L. 104-4, March 22, 1995, 109 Stat. 48). This action will not result in the expenditure by State, local, and tribal governments, in the aggregate, or by the private sector, of \$100 million or more in any one year. (2 U.S.C. 1531 *et seq.*). This action makes a ministerial correction to the final rule that allows STDs to use a contracting method that has only been used in the Federal-aid highway program on an experimental basis to date.

**Executive Order 13132 (Federalism)**

This action has been analyzed in accordance with the principles and criteria contained in Executive Order 13132, dated August 4, 1999, and the FHWA has determined that this action would not have sufficient federalism implications to warrant the preparation of a Federal assessment. Nothing in this document directly preempts any State law or regulation or affects the States' ability to discharge traditional State governmental functions.

**Executive Order 13175 (Tribal Consultation)**

The FHWA has analyzed this action under Executive Order 13175, dated November 6, 2000, and believes that the minor correction will not have substantial direct effects on one or more Indian tribes; will not impose substantial direct compliance costs on Indian tribal governments; and will not preempt tribal law. The final rule does not address issues that are related to tribal operations. Therefore, a tribal summary impact statement is not required.

**Executive Order 12372 (Intergovernmental Review)**

Catalog of Federal Domestic Assistance Program Number 20.205, Highway planning and construction. The regulations implementing Executive Order 12372 regarding intergovernmental consultation on Federal programs and activities apply to this program.

**Executive Order 12988 (Civil Justice Reform)**

This action 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.

**Executive Order 13045 (Protection of Children)**

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

**Executive Order 12630 (Taking of Private Property)**

This action 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.

**Executive Order 13211 (Energy Effects)**

We have analyzed this action under Executive Order 13211, Action Concerning Regulation That Significantly Affect Energy Supply, Distribution, or Use. We have determined that it is not a significant energy action under that order because it is not a significant regulatory action under Executive Order 12866 and it is not likely to have a significant adverse effect on the supply, distribution, or use of energy. Therefore, a Statement of Energy Effects under Executive Order 13211 is not required.

**Paperwork Reduction Act**

Under the Paperwork Reduction Act of 1995 (PRA) (44 U.S.C. 3501, *et seq.*), Federal agencies must obtain approval from the Office of Management and Budget (OMB) for each collection of information they conduct, sponsor, or require through regulations. The FHWA has reviewed this rule and determined that it does not contain collection of information requirements for the purposes of the PRA.

**National Environmental Policy Act**

The agency has analyzed this action for the purposes of the National Environmental Policy Act of 1969 (NEPA), as amended (42 U.S.C. 4321 *et seq.*), and has determined that this rule will not have any effect on the quality of the environment.

**Regulation Identification Number**

A regulation identification number (RIN) is assigned to each regulatory action listed in the Unified Agenda of Federal Regulations. The Regulatory Information Service Center publishes the Unified Agenda in April and October of each year. The RIN contained in the heading of this document can be used to cross reference this proposed action with the Unified Agenda.

**List of Subjects in 23 CFR Part 636**

Design-build, Grant programs-transportation, Highways and roads.

Issued on: February 13, 2003.

**James A. Rowland,**

*Chief Counsel, Federal Highway Administration.*

In consideration of the foregoing, the FHWA amends title 23, Code of Federal Regulations, part 636, as follows:

**PART 636—DESIGN-BUILD CONTRACTING**

1. The authority citation for 23 CFR part 636 continues to read as follows:

**Authority:** Sec. 1307 of Pub. L. 105-178, 112 Stat. 107; 23 U.S.C. 110, 109, 112, 113, 114, 115, 119, 128, and 315; 49 CFR 1.48(b).

**§ 636.211 [Corrected]**

2. Correct paragraph (b)(2)(i) of § 636.211 to remove the word "less" and replace it with the word "more".

[FR Doc. 03-3987 Filed 2-18-03; 8:45 am]

BILLING CODE 4910-22-P

**DEPARTMENT OF THE TREASURY****Internal Revenue Service****26 CFR Parts 157 and 602**

[TD 9042]

RIN 1545-BB24

**Excise Tax Relating to Structured Settlement Factoring Transactions**

**AGENCY:** Internal Revenue Service (IRS), Treasury.

**ACTION:** Temporary regulations.

**SUMMARY:** This document contains temporary regulations relating to the manner and method of reporting and paying the nondeductible 40-percent excise tax imposed on any person who acquires structured settlement payment rights in a structured settlement factoring transaction. The Victims of Terrorism Tax Relief Act of 2001 added this excise tax to the Internal Revenue Code of 1986. The text of the temporary regulations also serves as the text of the proposed regulations set forth in the notice of proposed rulemaking on this subject in the proposed rules section in this issue of the **Federal Register**.

**DATES:** *Effective Date:* These regulations are effective February 19, 2003.

*Applicability Date:* For dates of applicability, see § 157.5891-1T(e).

**FOR FURTHER INFORMATION CONTACT:** Shareen S. Pflanz at 202-622-8488 (not a toll-free call).

**SUPPLEMENTARY INFORMATION:**