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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

21 CFR Part 341

Cold, Cough, Allergy, Bronchodilator, and Antiasthmatic Drug Products for Over-the-Counter Human Use

CFR Correction

In title 21 of the Code of Federal Regulations, parts 300 to 499, revised as of April 1, 1996, on page 247, in § 341.12, paragraph (h) should read:

§ 341.12 Antihistamine active ingredients.

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(h) Doxylamine succinate.

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DEPARTMENT OF TRANSPORTATION

National Highway Administration

CFR Part 627

[FHWA Docket No. 94-12]

RIN 2125-AD33

Value Engineering

AGENCY: Federal Highway Administration (FHWA), DOT.

ACTION: Final rule.

SUMMARY: The FHWA is establishing a program requiring the application of a value engineering (VE) analysis for all Federal-aid highway projects on the National Highway System (NHS) with an estimated cost of \$25 million or more. The regulation also provides State highway agencies (SHA) with information and guidance on performing VE reviews. This final rule also implements the VE provisions of section 303(b) of the National Highway System Designation Act of 1995.

EFFECTIVE DATE: March 17, 1997.

FOR FURTHER INFORMATION CONTACT: Keith Borkenhagen, Office of Engineering, 202-366-4630, or David Scott, Office of Chief Counsel, 202-366- 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: The FHWA recognizes that VE, when applied in the development of highway projects, is an effective and proven technique for improving quality, fostering innovation, reducing project costs, and eliminating unnecessary and costly design elements. An FHWA study has confirmed the effectiveness of VE in States with active VE programs and concluded that a significant improvement in program effectiveness would result if all States had active programs. As a result of this study, the FHWA published a notice of proposed rulemaking (NPRM) on November 16, 1994, seeking comments on a proposal to require all States to apply VE to selected Federal-aid highway projects.

In the NPRM, the FHWA proposed to require States to establish, administer, and monitor VE programs; develop written procedures for implementing VE programs; and provide a trained staff or hire a qualified consultant to conduct studies on projects representing 50 percent of the dollar value of their Federal-aid highway program. In addition, the FHWA proposed to allow States to exempt certain categories of projects from reviews and be required to report the yearly results achieved through the application of VE to projects financed with Federal-aid highway funds.

Comments were received from 39 SHAs, 22 consultant/contractor firms, 8 associations/agencies, 14 individuals, and the American Association of State Highway and Transportation Officials' VE task force. The following discussion summarizes the major comments.

Eighteen States and thirty-eight organizations, firms, and/or individuals provided comments supporting VE. Sixteen States and two organizations provided comments opposing a Federal VE mandate. Three firms/individuals suggested that FHWA's projected additional VE savings under the proposed rule of \$100 million could approach \$500 million. Twenty-one States requested clarification of the type and amounts of Federal-aid highway funds involved in determining the 50 percent dollar value while fourteen States, five organizations and four individuals suggested replacing this requirement with a dollar threshold or lower percentage. Two firms thought the 50 percent value was excellent because it gave States great flexibility in selecting projects while four individuals suggested that all projects should

receive a VE analysis. Six States suggested that additional staff might be required to conduct all of the studies necessary to represent 50 percent of their Federal-aid program. Six States requested that VE change proposals and VE studies of standards be used to help meet the 50 percent dollar value, and five States requested that they be allowed to deduct the dollar value of exempted programs from the 50 percent requirement. Each of these comments concerns the threshold for application of Federal VE requirements. Because the National Highway System (NHS) Designation Act mandates a threshold of \$25 million for projects on the NHS, the agency has virtually no discretion in the area.

Eight comments suggested various changes to the training guidelines to require specific VE certification of team leaders and training workshops. All training requirements have been eliminated from the rule text.

One firm suggested that a VE team leader be a Certified Value Specialist (CVS), as approved by the Society of American Value Engineers and a Professional Engineer (PE) while another firm suggested that a team leader be a CVS when leading studies of projects larger than a specific dollar threshold. The FHWA did not include these suggested requirements into the final rule because the States have the responsibility for establishing any certification and training requirements (e.g., CVS, PE) for their VE personnel.

While the FHWA was in the process of analyzing these comments, the National Highway System Designation Act of 1995 (NHS Act) (Pub. L. 104-59, 109 Stat. 568) was enacted on November 28, 1995. Section 303(b) of the NHS Act directs the Secretary of Transportation to establish a program to require States to carry out a VE analysis for all projects on the NHS with an estimated total cost of \$25 million or more. The Conference Report accompanying the NHS Act explains that this provision prohibits the Secretary from requiring VE on other projects, though "[a] State remains free to choose to undertake such analyses on additional projects at a State's discretion." The report also prohibits DOT from being prescriptive as to the form of VE analysis a State must undertake to satisfy the requirement. H.R. Conf. Rep. No. 345, 104th Cong., 1st Sess. 80 (1995).

Based on this mandate, as well as the public comments made as part of the rulemaking process, the final rule has been revised substantially from the NPRM. The threshold for application of the VE requirement has been modified to be consistent with the statute. The