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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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[FR Doc. 97-55501 Filed 2-13-97; 8:45 am]

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DEPARTMENT OF TRANSPORTATION

Federal Highway Administration

23 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 Sett, Office of Chief Counsel, 202-366-0780, 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

rule has also been significantly shortened, focusing on minimum programmatic needs to ensure proper VE studies are conducted and utilized by the States on qualifying projects. Beyond these minimum needs, the goal is to provide maximum flexibility to the States to conduct VE programs consistent with the rest of their transportation programs.

Specific provisions that were included in the NPRM, but have been eliminated from the final rule due to the NHS Act requirement and in response to the comments received on the NPRM, include: The State reporting requirement; specific language describing the VE process; written procedural requirements; suggested project selection criteria; VE change proposal requirements; and VE training requirements. All of these changes give States greater authority to determine their own program requirements.

Consistent with the Conference Report language, the rule text no longer contains any prescription regarding the form of VE a State must undertake on a specific qualifying project. The final rule does not provide for FHWA oversight of each VE study, instead focusing FHWA's efforts on State implementation of VE programs. Because the method of conducting a VE study has become standardized and widely recognized in the field, study-by-study review is unnecessary. Instead, the final rule makes reference to the widely recognized process of VE studies.

The statutory definition of VE is clarified. The end product of the study is described in greater detail in the rule's definition of value engineering and, in § 627.5(a)(2), examples of the components of a multi-disciplined team are provided. Both of these additions are based on the widely-recognized VE study process.

In order to provide States time to establish VE programs, States need not delay project approvals and letting schedules when establishing or changing VE programs to comply with these requirements. Many States already employ techniques that will meet these VE requirements, however, States should review all projects being designed, without delaying projects expected to be available for letting during the current fiscal year, to identify those needing a VE analysis.

Any State choosing to use an innovative design/build concept to expedite the completion of an applicable NHS project must still comply with the requirement to perform a VE analysis on the project. In most cases the VE analysis should be

performed prior to awarding the design/build contract. The FHWA's division offices will have program oversight responsibility.

Rulemaking Analyses and Notices

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 significant within the meaning of Department of Transportation regulatory policies and procedures. This regulation requires States to carry out a VE analysis for all projects on the NHS with an estimated total cost of \$25 million or more.

The threshold triggering the requirement to conduct a VE analysis under this regulation—projects on the NHS with an estimated total cost of \$25 million or more—will greatly limit the economic impact of this final rule because the total number of federally-funded projects requiring VE analysis each year under this standard will be small. It is estimated that States use a substantial portion of their Federal-aid highway funds, approximately 59 percent, on non-NHS routes. In addition, the FHWA has found that States with VE programs, usually States with medium and large Federal-aid programs, already include these high cost NHS projects in their selection process and should not have to adjust their programs to comply with this regulation. The FHWA contends that States with small Federal-aid highway programs will not encounter NHS projects large enough to meet the dollar threshold requiring a VE analysis on a yearly basis and the regulation's impact on these States will be limited. Therefore, the FHWA anticipates that the economic impacts of this rulemaking will be minimal, and has determined that a full regulatory evaluation is not required.

The regulation may affect staffing levels in States that do not currently utilize VE. Establishing programs to assure that VE studies are performed on all applicable NHS projects will require each SHA to assign staff to carry out specific VE functions. The FHWA contends that the staff assignments needed to perform the functions required by this regulation will be minimal due to the limited number of projects that require an analysis and the fact that States may choose to hire consultants to perform the studies, thereby reducing the regulation's impact on SHA staff. In addition, States with existing programs probably already have

adequate staff assigned to carry out the VE functions of this rule. In either case, the study costs are eligible for reimbursement with Federal-aid highway funds at the appropriate pro-rata share for the type of project studied.

Historically, any additional costs due to the need to hire or reassign staff to manage the VE program have been more than offset by the overall monetary savings resulting from the application of VE studies to highway projects. States with active VE programs report a return on investments of between 30 to 1 and 50 to 1. The opportunity for substantial overall savings exists. In 1994, California, Florida, and Massachusetts reported savings in excess of \$100 million as a result of VE study recommendations.

Since this regulation only requires a VE analysis of large (\$25 million or greater) NHS projects, most local agencies' projects will not fall into the category of projects requiring a VE analysis. Some local agencies, however, that receive large amounts of Federal-aid highway funds may find that they occasionally have a large NHS project that requires a VE analysis. When this occurs, the local agency, in the same manner as an SHA, may choose to conduct the study itself or hire a VE consultant to perform the study. As stated above, the cost of performing VE studies is project-related and is, therefore, eligible for reimbursement with Federal-aid highway funds.

Regulatory Flexibility Act

In compliance with the Regulatory Flexibility Act (5 U.S.C. 601-612), the FHWA has evaluated the effects of this rule on small entities. Based on the evaluation, the FHWA hereby certifies that this action will not have a significant economic impact on a substantial number of small entities. The FHWA has determined that most small entities (which generally receive small amounts of Federal-aid highway funds) will not have to perform VE studies because their projects are small and are not expected to fit the project selection criteria set forth in this regulation for performing VE studies.

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 12612 (Federalism Assessment)

This action has been analyzed in accordance with the principles and criteria contained in Executive Order 12612. Under the Federal-aid highway program, the FHWA reimburses States for costs incurred in highway construction projects. This regulation would simply provide that, as a condition of receiving such grants, States must carry out a value engineering (VE) analysis for all projects on the National Highway System (NHS) with an estimated cost of \$25 million or more. This regulation recognizes the role of the States in employing VE and gives States wide latitude in establishing, administering, and monitoring their VE programs. Therefore, the FHWA has determined that this action does not have sufficient federalism implications to warrant the preparation of a separate federalism assessment.

Paperwork Reduction Act

This action does not require the collection of information for the purpose of the Paperwork Reduction Act of 1995, 44 U.S.C. 3501-3520.

National Environmental Policy Act

The agency has analyzed this action for the purpose of the National Environmental Policy Act of 1969 (42 U.S.C. 4321 *et seq.*) and has determined that this action would 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 action with the Unified Agenda.

List of Subjects in 23 CFR Part 627

Government procurement, Grant programs—transportation, Highways and roads.

In consideration of the foregoing, the FHWA hereby adds part 627 to Chapter I of title 23, Code of Federal Regulations, as set forth below.

Issued on: February 4, 1997.

Rodney E. Slater,

Federal Highway Administrator.

The FHWA amends 23 CFR to add Part 627 to read as follows:

PART 627—VALUE ENGINEERING

Sec.

627.1 Purpose and applicability.

627.3 Definitions.

627.5 General principles and procedures.

Authority: 23 U.S.C. 106(d), 106(f), 302, 307, and 315; 49 CFR 18.

§ 627.1 Purpose and applicability.

(a) This regulation will establish a program to improve project quality, reduce project costs, foster innovation, eliminate unnecessary and costly design elements, and ensure efficient investments by requiring the application of value engineering (VE) to all Federal-aid highway projects on the National Highway System (NHS) with an estimated cost of \$25 million or more.

(b) In accordance with the Federal-State relationship established under the Federal-aid highway program, State highway agencies (SHA) shall assure that a VE analysis has been performed on all applicable projects and that all resulting, approved recommendations are incorporated into the plans, specifications and estimate.

§ 627.3 Definitions.

Project. A portion of a highway that a State proposes to construct, reconstruct, or improve as described in the preliminary design report or applicable environmental document. A project may consist of several contracts or phases over several years.

Value engineering. The systematic application of recognized techniques by a multi-disciplined team to identify the function of a product or service, establish a worth for that function, generate alternatives through the use of creative thinking, and provide the needed functions to accomplish the original purpose of the project, reliably, and at the lowest life-cycle cost without sacrificing safety, necessary quality, and environmental attributes of the project.

§ 627.5 General principles and procedures.

(a) *State VE programs.* State highway agencies must establish programs to assure that VE studies are performed on all Federal-aid highway projects on the NHS with an estimated cost of \$25 million or more. Program procedures should provide for the identification of candidate projects for VE studies early in the development of the State's multi-year Statewide Transportation Improvement Program.

(1) *Project selection.* The program may, at the State's discretion, establish specific criteria and guidelines for selecting other highway projects for VE studies.

(2) *Studies.* Value engineering studies shall follow the widely recognized systematic problem-solving analysis process that is used throughout private industry and governmental agencies. Studies must be performed using multi-disciplined teams of individuals not personally involved in the design of the project. Study teams should consist of a team leader and individuals from different speciality areas, such as design, construction, environment, planning, maintenance, right-of-way, and other areas depending upon the type of project being reviewed. Individuals from the public and other agencies may also be included on the team when their inclusion is found to be in the public interest.

(i) Each team leader should be trained and knowledgeable in VE techniques and be able to serve as the coordinator and facilitator of the team.

(ii) Studies should be employed as early as possible in the project development or design process so that accepted VE recommendations can be implemented without delaying the progress of the project.

(iii) Studies should conclude with a formal report outlining the study team's recommendations for improving the project and reducing its overall cost.

(3) *Recommendations.* The program should include procedures to approve or reject recommendations and ensure the prompt review of VE recommendations by staff offices whose speciality areas are implicated in proposed changes and by offices responsible for implementing accepted recommendations. Reviews by these offices should be performed promptly to minimize delays to the project.

(4) *Incentives.* The program may include a VE or cost reduction incentive clause in an SHA's standard specifications or project special provisions that allows construction contractors to submit change proposals and share the resulting cost savings with the SHA.

(5) *Monitoring.* The program should include procedures for monitoring the implementation of VE study team recommendations and VE change proposal recommendations submitted by construction contractors.

(b) *State VE coordinators.* Individuals knowledgeable in VE shall be assigned responsibilities to coordinate and monitor the SHA's program and be actively involved in all phases of the program.

(c) *Use of consultants.* Consultants or firms with experience in VE may be retained by SHAs to conduct the studies of Federal-aid highway projects or elements of Federal-aid highway

projects required under § 627.1(a) of this part. Consultants or firms should not be retained to conduct studies of their own designs unless they maintain separate and distinct organizational separation of their VE and design sections.

(d) *Funding eligibility.* The cost of performing VE studies is project related and is, therefore, eligible for reimbursement with Federal-aid highway funds at the appropriate pro-rata share for the project studied.

[FR Doc. 97-3758 Filed 2-13-97; 8:45 am]

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23 CFR Parts 630, 635, and 771

[FHWA Docket No. 96-3]

RIN 2125-AD58

Federal-Aid Project Agreement

AGENCY: Federal Highway Administration (FHWA), DOT.

ACTION: Final rule.

SUMMARY: The FHWA is amending its regulation on project agreements. The Intermodal Surface Transportation Efficiency Act (ISTEA) of 1991 modified the requirement that preliminary engineering and right-of-way projects must be advanced to the construction stage within certain time limits. Changes to the agreement provisions reflect these adjustments. The new procedures provide more flexibility in the format of the agreement document and permit the development of a single document to serve as both the project authorization and project agreement document. Other changes were made to shorten the agreement document and to add clarity to the process.

EFFECTIVE DATE: This final rule is effective March 17, 1997.

FOR FURTHER INFORMATION CONTACT: Jack Wasley, Office of Engineering, 202-366-0450, or Wilbert Baccus, Office of the Chief Counsel, 202-366-0780, FHWA, 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 amendments in this final rule are based primarily on the notice of proposed rulemaking (NPRM) published in the January 30, 1996, Federal Register at 61 FR 2973 (FHWA Docket No. 96-3). All comments received in response to this NPRM have been considered in adopting these amendments.

Under the provisions of 23 U.S.C. 110, a formal agreement between the State highway agency and the FHWA is required for Federal-aid highway projects. This agreement, referred to as

the "project agreement," is in essence a written contract between the State and the Federal government defining the extent of the work to be undertaken and commitments made concerning the project.

Requirements covering project agreements are contained in this final rule. This final rule updates and modifies the existing Federal-aid project agreement regulation to incorporate changes mandated by the ISTEA, Pub. L. 102-240, 105 Stat. 1914, to streamline the project agreement form and provisions, and to allow more versatility in its use. This final rule amends the existing regulation in the following manner and for the reasons indicated below.

Section 630.301 Purpose

The statement of purpose is revised with minor changes for clarity.

Section 630.303 Preparation of Agreement

This section no longer requires the use of a specific form. Instead, a State has the flexibility to use whatever format is suitable to provide the information required for a project agreement document.

Section 630.305 Modification of Original Agreement

A State is still required to prepare a modification to a project agreement as changes occur. However, this section no longer requires the use of a specific form. Instead, a State is allowed to develop its own form for modification of the project agreement, provided it contains necessary information as identified by the regulation.

Section 630.307 Agreement Provisions

This section identifies the provisions that must be a part of each agreement. The project agreement has been simplified by eliminating all the boilerplate provisions that are not required from the agreement itself. The provisions that are necessary have been included in this section of the regulation. The simplified project agreement would incorporate, by reference to this section, these provisions into each agreement. The following discussion covers each of the required provisions.

Section 630.307(a) is a general provision under which the State agrees to comply with title 23, United States Code (U.S.C.), the regulations implementing title 23, and the policies and procedures established by the FHWA. In addition, States must also comply with all other applicable Federal laws and regulations. This

general provision is broad in scope and there is little need for other provisions which cover only a limited feature of title 23, U.S.C.

Section 630.307(b) represents an acknowledgment by the State that it has a financial obligation for the non-Federal share of the cost of the project.

Sections 630.307(c)(1) and (c)(2) contain provisions that implement statutory requirements concerning a State's payback of Federal funds it has received for right-of-way acquisition or preliminary engineering should the project not be advanced within the designated statutory time frames. Paragraph (c)(1), Project for Acquisition of Rights-of-Way, implements the requirement in 23 U.S.C. 108(a) that the agreement between the State and the FHWA for right-of-way acquisition projects shall include a provision that construction shall begin within 20 years. This reflects an amendment to 23 U.S.C. 108(a) resulting from passage of section 1017(a) of the ISTEA.

With regard to paragraph (c)(2), Preliminary engineering project, prior to passage of the ISTEA, an administrative decision by the FHWA required repayment of Federal-aid highway funds authorized for preliminary engineering if right-of-way acquisition or actual construction had not begun within 5 years after authorization of the preliminary engineering. The general concept of this provision is now found in the statute; section 1016(a) of the ISTEA incorporated this provision into 23 U.S.C. 102(b). One significant difference between the statutory provision and the existing FHWA practice is that 10 years instead of 5 years must pass before payback is required. Paragraph (c)(2) reflects the 10-year payback period.

Sections 630.307(c)(3), (c)(4) and (c)(5) contain provisions for a drug-free workplace, suspension/debarment, and lobbying required by 49 CFR 29.630, 49 CFR 29.510 and 49 CFR 20.110, respectively.

According to 49 CFR 29.630(c), a State is allowed to make one yearly certification for the drug-free workplace certification. Although the FHWA has used annual or quarterly program certifications for the others in the past, it was determined that these certifications do not fully comply with the provisions of previously cited requirements in 49 CFR 29.510 and 49 CFR 20.110. Placing language in the project agreement as part of the general provisions provides the separate certification action required for every project. Project-by-project certifications are deemed to fully satisfy the requirements in title 49, CFR, and