

paragraphs (f)(10)(i) through (f)(10)(v) of this section is appropriate or relevant to the labeling of a particular drug, the sponsor shall provide reasons for omission of the statements and may propose an alternative statement. FDA may permit omission of the statements if FDA determines that no statement described in those paragraphs is appropriate or relevant to the drug's labeling. FDA may permit use of an alternative statement if the agency determines that such statement is accurate and appropriate.

* * * * *

Dated: July 31, 1997.

William B. Schultz,

Deputy Commissioner for Policy.

[FR Doc. 97-22701 Filed 8-26-97; 8:45 am]

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DEPARTMENT OF TRANSPORTATION

Federal Highway Administration

23 CFR Parts 140 and 646

[FHWA Docket No. FHWA-97-2681]

RIN 2125-AD86

Railroad/Highway Projects

AGENCY: Federal Highway Administration (FHWA), DOT.

ACTION: Interim final rule; request for comments.

SUMMARY: The FHWA is amending its regulations on railroad/highway projects and reimbursement for railroad work on Federal-aid highway projects. The amendments require railroads to: Submit final billings within one year following completion of the railroad work; remove the requirement of a State's certification that work is complete; remove the "G" Funds terminology; increase the ceiling for lump sum agreements from \$25,000 to \$100,000; incorporate changes brought about by the Intermodal Surface Transportation Efficiency Act of 1991 (ISTEA), Public Law 102-240, 105 Stat. 1914; and show dimensions for participation limits in metric units. The FHWA makes these changes to conform the existing railroad/highway regulations to more recent laws or regulations, and to provide State highway agencies with clarification and more flexibility in implementing the current law. This rulemaking is part of the FHWA's effort to implement the President's Regulatory Reinvention Initiative.

DATES: This interim final rule is effective August 27, 1997. Written

comments must be submitted on or before October 27, 1997.

ADDRESSES: Submit written, signed comments to the docket number that appears in the heading of this document to the Docket Clerk, U.S. DOT Dockets, Room PL-401, 400 Seventh Street, SW., Washington, D.C. 20590-0001. All comments received will be available for examination at the above address between 10 a.m. and 5 p.m., e.t., Monday through Friday, except Federal holidays. Those desiring notification of receipt of comments must include a self-addressed, stamped envelope or postcard.

FOR FURTHER INFORMATION CONTACT:

Robert Winans, Office of Engineering, (202) 366-0450, or Wilbert Baccus, Office of the Chief Counsel, (202) 366-0780, FHWA, 400 Seventh Street, SW., Washington, D.C. 20590. Office hours are from 7:45 a.m. to 4:15 p.m., e.t., Monday through Friday, except Federal holidays.

SUPPLEMENTARY INFORMATION: Present FHWA regulations regarding railroad/highway projects and reimbursement for railroad work on Federal-aid highway projects have evolved from basic principles established decades ago, with many of the policies remaining unchanged. The present regulations are found at 23 CFR part 140, subpart I, and part 646, subpart B. The FHWA amends these regulations in the following manner and for the reasons set forth below.

In part 140, subpart I, § 140.904, paragraph (b)(1) is amended to clarify that the approved program of projects is the approved statewide transportation improvement program, as is now required under 23 U.S.C. 135.

In § 140.922, paragraph (b) is amended to require railroads to submit final billings within one year following completion of the railroad work. Otherwise, previous payments to railroads may be considered final and projects may be closed out. This change will assist highway agencies in their efforts to obtain timely final billings from the railroads. Prior to this action, it had been common for some railroad bills to be received years after the work was completed, thus delaying audit activity and project closure. With the amended language, billings received from railroads after one year following completion of the railroad work can be paid at the discretion of the highway agency. Paragraph (b) is further amended to remove the requirement for State certification that the work is complete, acceptable, and in accordance with the terms of the agreement. The FHWA believes that such certificates are

not necessary on individual projects. Instead, compliance can be reviewed on a program basis.

In part 646, subpart B, § 646.200, paragraph (c) is amended to refer to current sections of highway law. Section 405 of title 23, U.S.C., was repealed and section 203 of the Highway Safety Act of 1973 (Pub. L. 93-87, 87 Stat. 282) was codified as part of 23 U.S.C. 130. Paragraph (f) is removed because part 170 of title 23, CFR, no longer exists.

Section 646.202, Authority, is removed and reserved. This section is removed because the authority citation is placed at the part level and, therefore, redundant as a separate section in subpart B.

Section 646.204 is amended to remove paragraph (d) which defines obsolete terminology, to remove the paragraph designations from all definitions, and to place the definitions in alphabetical order.

In § 646.208, paragraphs (a) and (b) are revised to describe only funding sources for rail/highway crossing projects. Information contained in this section on Federal share is moved to § 646.212.

The current text of § 646.212, paragraph (b) is removed. Section 1012(a) of the ISTEA amended 23 U.S.C. 120 by removing subsection (d) concerning Federal share payable for reconstruction of existing grade separation projects on railway/highway crossings. Such projects are no longer eligible for 100 percent Federal funding. Regulatory text from § 646.208(b) is redesignated and revised as a new paragraph (b) in § 646.212 in order to provide information on Federal share in one place.

In § 646.214, paragraph (a)(2) is amended to clarify that the FHWA no longer is required to approve standards for all Federal-aid projects. Section 1016(d) of the ISTEA amended 23 U.S.C. 109 by adding a new subsection (p) which provided that non-NHS projects now follow State approved standards.

In § 646.216, paragraph (d)(3)(ii) is amended to increase the ceiling from \$25,000 to \$100,000 for using the lump sum payment arrangement for reimbursement for railroad adjustments (other than installation or improvement of grade crossing warning devices and/or grade crossing surfaces) on Federal-aid and direct Federal highway projects. The amendment provides the States greater flexibility in utilizing the lump sum payment arrangement. The purpose of allowing lump sum agreements, in lieu of agreements based on an accounting of actual costs, is to reduce the administrative burden associated

with railroad adjustment projects. Under the lump sum process, cost accounting is easier, project billings are simplified, and final audit of detailed cost records is not required. Typically, final project costs are quite close to the costs estimated for small, routine projects. If more detailed cost accounting methods were followed, however, the FHWA believes that the small degree of accuracy that might be realized would not justify the extra cost involved in carrying out detailed audits. This revision increases the number of railroad adjustments potentially eligible for lump sum payment, anticipates future needs and responds, in part, to the fact that since the \$25,000 limit was established in 1982, inflation has reduced the number and limited the scope of projects eligible for lump sum payments.

In § 646.216, paragraph (e)(1) is amended to clarify that the approved program of projects is the approved statewide transportation improvement program now required under 23 U.S.C. 135.

The appendix to subpart B is amended to change the dimensions for horizontal and vertical clearances to metric units, in keeping with FHWA's metric transition timetable of September 30, 1996, published on August 31, 1993, at 58 FR 46036. Since that time, section 205(c) of the National Highway System Designation Act of 1995, Public Law 104-59, 109 Stat. 568, 577, amended the compliance date for use of the metric system (SI) on Federal-aid projects to September 30, 2000.

Rulemaking Analyses and Notices

The Administrative Procedure Act (APA), 5 U.S.C. 551 *et seq.*, allows agencies engaged in rulemaking to dispense with prior notice and opportunity for comment when the agency for good cause finds that such procedures are impracticable, unnecessary, or contrary to the public interest. 5 U.S.C. 553(b)(3)(B). For the reasons set further below, the FHWA has determined that prior notice to the public and opportunity for comment on this action are unnecessary and contrary to the public interest.

The changes made by this rulemaking provide greater flexibility to the States and conform the existing regulations to current law. First, the changes provide the States with greater flexibility in their billing procedures by allowing them to require railroads to submit final billings on a timely basis and by removing the requirement that States certify that work is complete for each project. Second, the changes increase the ceiling for lump sum agreements, which gives States

greater flexibility in utilizing the lump sum payment arrangement, an option already available to them. Finally, the changes set forth in this interim final rule conform existing regulations to more current laws or regulations. Given the nature of these changes, the FHWA is not exercising its discretion in such a way that could meaningfully be affected by public comment. Moreover, the FHWA believes that it is in the public interest to make these changes effective without the delay associated with prior notice and opportunity for comment.

Under the APA, 5 U.S.C. 553(d)(3), agencies can, upon a finding of good cause, make a rule effective immediately and avoid the 30-day delay effective requirement. The FHWA has determined that good cause exists to make this rule effective upon publication for the following reasons. First, the FHWA finds that good cause exists to dispense with the 30-day delay effective requirement because the changes adopted by this action give the States greater flexibility in billing and rid the States of the burden to provide certification that railroad work is complete. Second, good cause further exists because the increased ceiling for lump sum agreements reduces the administrative burden on the States associated with railroad adjustment projects. Finally, the additional changes made by this rulemaking are merely technical in nature, ensuring that the existing regulations conform to current law.

For these same reasons, the FHWA has also determined that prior notice and opportunity for comment are not required under the Department of Transportation's regulatory policies and procedures, as it is not anticipated that such action would result in the receipt of useful information. Therefore, the FHWA is proceeding directly to an interim final rule which is effective upon publication. Nevertheless, in issuing an interim final rule, the FHWA affords interested persons with an opportunity to comment on this action. Comments received will be carefully considered in evaluating whether any change to this interim final rule is needed.

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. It is anticipated that the

economic impact of this rulemaking will be minimal; therefore, a full regulatory evaluation is not required. The FHWA does not consider this action to be a significant regulatory action because the amendments would merely update the railroad regulations for Federal-aid highway projects to conform to recent laws or regulations, and provide States with clarification and flexibility to implement the current law.

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 that evaluation, the FHWA certifies that this action will not have a significant economic impact on a substantial number of small entities. The amendments only clarify or simplify procedures used by State highway agencies in accordance with existing laws or regulations.

Executive Order 12612 (Federalism Assessment)

This action has been analyzed in accordance with the principles and criteria contained in Executive Order 12612, and it has been determined that this action does not have sufficient federalism implications to warrant the preparation of a separate federalism assessment. This rule does not impose additional costs or burdens on the States, including the likely sources of funding for the States, nor does it affect the ability of the States to discharge the traditional State government functions. This document merely assists the States by giving them additional flexibility and clarification in implementing railroad/highway regulations.

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.

Paperwork Reduction Act

This action does not contain a collection of information requirement for purposes 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

23 CFR Part 140

Bonds, Claims, Grant programs—transportation, Highways and roads, Railroads.

23 CFR Part 646

Grant programs—transportation, Highways and roads, Insurance, Railroads.

Issued on: August 20, 1997.

Gloria J. Jeff,

Acting Administrator.

In consideration of the foregoing, the FHWA amends title 23, Code of Federal Regulations, by revising part 140, subpart I, and part 646, subpart B, to read as set forth below.

PART 140—REIMBURSEMENT

1. The authority citation for part 140 continues to read as follows:

Authority: 23 U.S.C. 101(e), 106(c), 109(e), 114(a), 120(g), 121(d), 122, 130, and 315; and 49 CFR 1.48(b).

Subpart I—Reimbursement for Railroad Work

2. In § 140.904, paragraph (b)(1) is revised to read as follows:

§ 140.904 Reimbursement basis.

* * * * *

(b) * * *

(1) For work which is included in an approved statewide transportation improvement program.

* * * * *

3. In § 140.922, paragraph (b) is revised to read as follows:

§ 140.922 Billings.

* * * * *

(b) The company shall provide one final and complete billing of all incurred costs, or of the agreed-to lump sum, within one year following completion of the reimbursable railroad work. Otherwise, previous payments to the company may be considered final,

except as agreed to between the SHA and the railroad.

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PART 646—RAILROADS

4. The authority citation for part 646 is revised to read as follows:

Authority: 23 U.S.C. 109(e), 120(c), 130, 133(d)(1), and 315; 49 CFR 1.48(b).

Subpart B—Railroad-Highway Projects

5. In § 646.200, paragraph (f) is removed and paragraph (c) is revised to read as follows:

§ 646.200 Purpose and applicability.

* * * * *

(c) Additional instructions for projects involving the elimination of hazards of railroad/highway grade crossings pursuant to 23 U.S.C. 130 are set forth in 23 CFR part 924.

* * * * *

§ 646.202 [Removed and Reserved]

6. Section 646.202 is removed and reserved.

7. Section 646.204 is amended by removing paragraph (d); by removing the paragraph designations; and by placing the definitions in alphabetical order.

8. Section 646.208 is revised to read as follows:

§ 646.208 Funding.

(a) Railroad/highway crossing projects may be funded through the Federal-aid funding source appropriate for the involved project.

(b) Projects for the elimination of hazards at railroad/highway crossings may, at the option of the State, be funded with the funds provided by 23 U.S.C. 133(d)(1).

9. In § 646.212, paragraph (b) is revised to read as follows:

§ 646.212 Federal share.

* * * * *

(b) The Federal share of railroad/highway crossing projects may be:

(1) Regular pro rata sharing as provided by 23 U.S.C. 120(a) and 120(b).

(2) One hundred percent Federal share, as provided by 23 U.S.C. 120(c).

(3) Ninety percent Federal share for funds made available through 23 U.S.C. 133(d)(1).

10. In § 646.214, paragraph (a)(2) is revised to read as follows:

§ 646.214 Design.

(a) * * *

(2) Facilities that are the responsibility of the highway agency for maintenance and operation shall conform to the specifications and design

standards and guides used by the highway agency in its normal practice for Federal-aid projects.

* * * * *

11. Section 646.216 is amended in paragraph (d)(3)(ii) by replacing the figure "\$25,000" with the figure "\$100,000"; and by revising paragraph (e)(1) to read as follows:

§ 646.216 General procedures.

* * * * *

(e) *Authorizations.* (1) The costs of preliminary engineering, right-of-way acquisition, and construction incurred after the date each phase of the work is included in an approved statewide transportation improvement program and authorized by the FHWA are eligible for Federal-aid participation. Preliminary engineering and right-of-way acquisition costs which are otherwise eligible, but incurred by a railroad prior to authorization by the FHWA, although not reimbursable, may be included as part of the railroad share of project cost where such a share is required.

* * * * *

Appendix to Subpart B—Horizontal and Vertical Clearance Provisions for Overpass and Underpass Structures—[Amended]

12. The appendix to subpart B is amended as follows:

A. By replacing the words "20 feet" with

"6.1 meters" wherever they appear;

B. By replacing the words "20-foot" with

"6.1-meters" wherever they appear;

C. By replacing the words "8 feet" with

"2.5 meters" wherever they appear;

D. By replacing the words "9 feet" with

"2.8 meters" wherever they appear;

E. By replacing the words "23 feet" with

"7.1 meters" wherever they appear;

F. By replacing the words "24 feet 3

inches" with "7.4 meters" wherever they

appear; and

G. By replacing the words "26 feet" with

"8.0 meters" wherever they appear.

F. By replacing the words "Nine feet" with "Two and eight tenths meters" wherever they appear.

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FEDERAL EMERGENCY MANAGEMENT AGENCY

44 CFR Part 206

RIN 3067-AC58

Disaster Assistance; Snow Assistance

AGENCY: Federal Emergency Management Agency (FEMA).

ACTION: Final rule.