

a substantial number of small entities. Therefore, under the Regulatory Flexibility Act, no further analysis is required.

Because the proposed rule does not impose any mandates on State, local, or tribal governments, or the private sector that will result in an expenditure of \$100 million or more in any one year, FDA is not required to perform a cost-benefit analysis under the Unfunded Mandates Reform Act of 1995.

Interested persons may submit to the Dockets Management Branch (address above) written or electronic comments regarding this proposal by September 17, 2002. Two copies of any comments are to be submitted, except that individuals may submit one copy. Comments are to be identified with the docket number found in brackets in the heading of this document. 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 312**

Drugs, Exports, Imports, Investigations, Labeling, Medical research, Reporting and recordkeeping requirements, Safety.

Therefore, under the Federal Food, Drug, and Cosmetic Act and under authority delegated to the Commissioner of Food and Drugs, it is proposed that 21 CFR part 312 be amended as follows:

**PART 312—INVESTIGATIONAL NEW DRUG APPLICATION**

1. The authority citation for 21 CFR part 312 is revised to read as follows:

**Authority:** 21 U.S.C. 321, 331, 351, 352, 353, 355, 356, 357, 371, 381, 382, 383, 393; 42 U.S.C. 241, 243, 262.

2. Section 312.110 is amended by revising paragraph (b) and by adding paragraphs (c) and (d) to read as follows:

**§ 312.110 Import and export requirements.**

\* \* \* \* \*

(b) *Exports.* An investigational new drug may be exported from the United States for use in a clinical investigation under any of the following conditions:

(1) An IND is in effect for the drug under § 312.40, the drug complies with the laws of the country to which it is being exported, and each person who receives the drug is an investigator in a study submitted to and allowed to proceed under the IND; or

(2) The drug has valid marketing authorization in Australia, Canada, Israel, Japan, New Zealand, Switzerland, South Africa, or in any country in the European Union or the European Economic Area, and complies with the laws of the country to which it is being

exported, section 802(b)(1)(A), (f), and (g) of the act, and § 1.101 of this chapter; or

(3) The drug is being exported to Australia, Canada, Israel, Japan, New Zealand, Switzerland, South Africa, or to any country in the European Union or the European Economic Area, and complies with the laws of the country to which it is being exported, the applicable provisions of section 802(c), (f), and (g) of the act, and § 1.101 of this chapter. Drugs exported under this paragraph that are not the subject of an IND are exempt from the label requirement in § 312.6(a); or

(4) The person exporting the drug sends a written certification to the Office of International Programs, Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857, at the time the drug is first exported and maintains records documenting compliance with this paragraph. The certification shall describe the drug that is to be exported (i.e., trade name (if any), generic name, and dosage form), identify the country or countries to which the drug is to be exported, and affirm that:

- (i) The drug is intended for export;
- (ii) The drug is intended for investigational use in a foreign country;
- (iii) The drug meets the foreign purchaser's or consignee's specifications;

(iv) The drug is not in conflict with the importing country's laws;

(v) The outer shipping package is labeled to show that the package is intended for export from the United States;

(vi) The drug is not sold or offered for sale in the United States;

(vii) The clinical investigation will be conducted in accordance with § 312.120;

(viii) The drug is manufactured, processed, packaged, and held in substantial conformity with current good manufacturing practices;

(ix) The drug is not adulterated within the meaning of section 501(a)(1), (a)(2)(A), (a)(3), (c), or (d) of the act;

(x) The drug does not present an imminent hazard to public health, either in the United States, if the drug were to be reimported, or in the foreign country;

(xi) The drug is labeled in accordance with the foreign country's laws; and

(xii) The drug is promoted in accordance with its labeling.

(c) *Limitations.* Exportation under paragraph (b) of this section may not occur if:

(1) For drugs exported under paragraph (b)(1) of this section, the IND pertaining to the clinical investigation is no longer in effect;

(2) For drugs exported under paragraph (b)(2) of this section, the

requirements in section 802(b)(1), (f), or (g) of the act are no longer met;

(3) For drugs exported under paragraph (b)(3) of this section, the requirements in section 802(c), (f), or (g) of the act are no longer met; or

(4) For drugs exported under paragraph (b)(4) of this section, the conditions underlying the certification are no longer met.

(5) For any investigational new drugs under this section, the drug no longer complies with the laws of the importing country.

(d) *Insulin and antibiotics.* New insulin and antibiotic drug products may be exported for investigational use in accordance with section 801(e)(1) of the act without complying with this section.

Dated: September 18, 2001.

**Margaret M. Dotzel,**

*Associate Commissioner for Policy.*

[FR Doc. 02-15358 Filed 6-18-02; 8:45 am]

BILLING CODE 4160-01-S

**DEPARTMENT OF TRANSPORTATION**

**Federal Highway Administration**

**23 CFR Part 450**

[FHWA Docket No. FHWA-99-5933]

FHWA RIN 2125-AE95; FTA RIN 2132-AA75

**Statewide Transportation Planning; Metropolitan Transportation Planning**

**AGENCY:** Federal Highway Administration (FHWA).

**ACTION:** Supplemental notice of proposed rulemaking (SNPRM); request for comments.

**SUMMARY:** As a result of recent congressional direction regarding consultation with non-metropolitan local officials in transportation planning, and based on the comments the FHWA and the FTA received to the May 25, 2000, Planning NPRM, and the congressional hearings on the NPRM, we are proposing another option on non-metropolitan local official consultation in addition to that proposed in the May 2000 Planning NPRM. This proposal would revise the current statewide planning regulation at 23 CFR 450. Specifically, this SNPRM proposes to closely follow the Transportation Equity Act for the 21st Century (TEA-21), but allows State flexibility to determine who are non-metropolitan local officials and how to consult with them. Consequently, we are soliciting public comment on an additional proposal to incorporate

consultation with non-metropolitan local officials into our current planning regulations.

**DATES:** Comments must be received on or before August 19, 2002.

**ADDRESSES:** Mail or hand deliver comments to the U.S. Department of Transportation, Dockets Management Facility, Room PL-401, 400 Seventh Street, SW., Washington, DC 20590, or submit electronically at <http://dmses.dot.gov/submit>. All comments should include the docket number that appears in the heading of this document. All comments received will be available for examination and copying at the above address from 9 a.m. to 5 p.m., e.t., Monday through Friday, except Federal holidays. Those desiring notification of receipt of comments must include a self-addressed, stamped postcard or you may print the acknowledgment page that appears after submitting comments electronically.

**FOR FURTHER INFORMATION CONTACT:** For the FHWA: Mr. Dee Spann, Statewide Planning Team (HEPS), (202) 366-4086 or Mr. Reid Alsop, Office of the Chief Counsel (HCC-31), (202) 366-1371. For the FTA: Mr. Paul Verchinski, Statewide Planning Division (TPL-11) or Mr. Scott Biehl, Office of the Chief Counsel (TCC-30), (202) 366-0952. Both agencies are located at 400 Seventh Street, SW., Washington, DC 20590-0001. Office hours for the FHWA are from 7:45 a.m. to 4:15 p.m., e.t., and for the FTA are from 8:30 a.m. to 5 p.m., e.t., Monday through Friday, except Federal holidays.

#### **SUPPLEMENTARY INFORMATION:**

##### **Electronic Access and Filing**

You may submit or retrieve comments online through the Document Management System (DMS) at: <http://dmses.dot.gov/submit>. Acceptable formats include: MS Word (versions 95 to 97), MS Word for Mac (versions 6 to 8), Rich Text File (RTF), American Standard Code Information Interchange (ASCII)(TXT), Portable Document Format (PDF), and WordPerfect (versions 7 to 8). The DMS is available 24 hours each day, 365 days each year. Electronic submission and retrieval help and guidelines are available under the help section of the web site.

An electronic copy of this document may be downloaded using a computer, modem and suitable communications software from the Government Printing Office's Electronic Bulletin Board Service at (202) 512-1661. Internet users may also reach the Office of the Federal Register's home page at: <http://www.nara.gov/fedreg> and the

Government Printing Office's web page at: <http://www.access.gpo.gov/nara>.

##### **Background**

Section 1025 of the Intermodal Surface Transportation Efficiency Act of 1991 (ISTEA), Public Law 102-240, 105 Stat. 1914, (December 18, 1991), amended title 23, United States Code (U.S.C.), section 135 and established a requirement for Statewide Transportation Planning and stated, "The transportation needs of non-metropolitan areas should be considered through a process that includes consultation with local elected officials with jurisdiction over transportation." The ISTEA further stated "Projects undertaken in areas of less than 50,000 population (excluding projects undertaken on the National Highway System and pursuant to the bridge and Interstate maintenance programs) shall be selected by the State in cooperation with the affected local officials. Projects undertaken in such areas on the National Highway System or pursuant to the bridge and Interstate maintenance programs shall be selected by the State in consultation with the affected local officials."

Section 1204 of the TEA-21, Public Law 105-178, 112 Stat. 107 (June 9, 1998), further amended 23 U.S.C. 135, while preserving the statewide planning requirement for a continuing, comprehensive and cooperative planning process. The TEA-21 did not significantly alter the current decisionmaking relationship among governmental units. This amendment demonstrates Congress' continued emphasis on State decisionmaking, but requires States to consult with non-metropolitan local officials in transportation planning and programming. This consultation with non-metropolitan local officials in transportation planning and programming is the specific subject of this SNPRM.

The FHWA and the FTA published a notice of proposed rulemaking (NPRM) on May 25, 2000 (65 FR 33922), that detailed proposed revisions to the existing planning regulations issued on October 28, 1993, at 58 FR 58040. The May 2000 Planning NPRM included provisions, different from those offered herein, regarding consultation with non-metropolitan local officials. Comments were solicited until August 23, 2000 (later extended to September 23, 2000, by a July 7, 2000, **Federal Register** notice at 65 FR 41891). The docket is still open, and comments to this SNPRM will be placed in that docket.

##### **Input to Development of the SNPRM**

During the comment period on the proposed rule (May 25, 2000, through September 23, 2000), the FTA and the FHWA held seven public meetings to present information on the May 2000 Planning NPRM. Although the attendees were encouraged to submit all comments to the docket, several raised questions at the meetings. Therefore, a summary of questions raised at the meetings and the general responses of the FHWA and the FTA presenters is included in the docket.

A summary of all comments by section of the May 2000 Planning NPRM has been prepared by the FHWA and the FTA and inserted in the docket. We have carefully reviewed all comments. Those comments that pertain to the sections relating to consultation with non-metropolitan local officials are discussed below.

During the comment period (on September 12 and 13, 2000) the Senate Environment and Public Works and House Transportation and Infrastructure Committees held hearings regarding the May 2000 Planning NPRM. The FHWA and the FTA have reviewed the comments and questions raised at these hearings.

The House report that accompanied the U.S. DOT Appropriations Act for fiscal year (FY) 2002, and the conference report for the Department of Defense FY 02 Appropriations Act, which contained several transportation issues, included language directing the U.S. DOT to promulgate a final rule, no later than February 1, 2002, to amend the FHWA and FTA planning regulations to ensure transportation officials from rural areas are consulted in long range transportation planning and programming.

##### **Discussion of Comments on the NPRM Related to Local Official Consultation**

There were over 400 documents (representing just over 300 discrete comments) submitted to the May 2000 Planning NPRM docket. We received diverse and opposing comments. The following discussion addresses only the comments related to consultation with non-metropolitan local officials.

We received 50 comments on the non-metropolitan local official participation provisions we proposed in 23 CFR Part 1410. These comments focused mostly on § 1410.212, "Participation by interested parties," which we proposed as the primary section on consultation with non-metropolitan local officials in the May 2000 Planning NPRM. Seven of the comments were from groups representing a total of 42 separate

entities, resulting in a total of 85 commenters on this provision. There were 19 opposing comments, primarily from State DOTs and the American Association of State Highway and Transportation Officials (AASHTO). There were 31 supporting comments, primarily from local entities (local governments, local officials and regional agencies) and associations representing local entities, including the National Association of Counties (NACO) and the National Association of Development Organizations (NADO).

The AASHTO, representing the State DOTs, commented that the FHWA and the FTA should clarify that it would not be necessary for States to obtain the consent of other parties to the consultation procedures for their State and that the State is the responsible party for establishing and implementing a consultation process. The NACO and the NADO, representing local officials, county governments and regional organizations, supported the language requiring a documented process for each State which retains the flexibility to tailor a consultation process to fit local circumstances. Several commenters were concerned that the proposal would be misinterpreted as creating a "co-equal" role in State decisionmaking by local officials and requested this be clarified.

The FHWA and the FTA have reviewed these comments and have formulated an alternate option calling for consultation with non-metropolitan local officials in the statewide planning process. The option is being proposed as a revision to the current regulation and as an additional option to that proposed in the May 2000 Planning NPRM. We welcome comments on this alternate option.

#### Section-by-Section Analysis

The FHWA and the FTA specifically request comments and ideas on the non-metropolitan local official consultation language proposed in this SNPRM. Comparison assessments with the non-metropolitan local official consultation language proposed in the May 2000 Planning NPRM are welcome also. In this SNPRM we are not soliciting comment on the other features of the May 2000 Planning NPRM, nor are we proposing language in this SNPRM on any other features of the May 2000 Planning NPRM other than the section on consultation with non-metropolitan local officials.

The May 2000 Planning NPRM proposed to amend the existing planning regulation, 23 CFR part 450, by replacing it with a new part 1410. Consultation with non-metropolitan

local officials provisions appeared in several sections of the May 2000 Planning NPRM: portions of §§ 1410.104, 1410.208, 1410.212, 1410.214, 1410.216 and 1410.224. Although in the May 2000 Planning NPRM we proposed to remove 23 CFR 450 and replace it with 23 CFR 1410, in this SNPRM we are proposing not to remove 23 CFR 450, but rather, to amend sections of 23 CFR 450 to include language that addresses consultation with non-metropolitan local officials. Accordingly, we are proposing amendments to the provisions of the following sections of the existing planning regulation: §§ 450.104, 450.206, 450.212, 450.214, 450.216 and 450.224. We are not proposing amendments to the provisions of § 450.222 that relate to consultation with non-metropolitan local officials. The primary section on consultation with non-metropolitan local officials is proposed as § 450.212(h). This section-by-section analysis only addresses those sections that cover consultation with non-metropolitan local officials.

#### Section 450.104

Based on comments received on the May 2000 Planning NPRM, in this SNPRM we propose new definitions of "consultation" and "non-metropolitan area."

More than twenty discrete comments were received on the proposed definition of consultation; some were opposed and some were supportive. The FTA and the FHWA now propose a definition of "consultation" that is more consistent with the legislative language. The proposed definition eliminates the reference to a process and focuses on keeping other parties informed.

In the May 2000 Planning NPRM we proposed adding the definition of a "non-metropolitan local official." In this SNPRM, we are proposing to add the definition of "non-metropolitan area." The definition we propose of a "non-metropolitan area" recognizes that there are a variety of local officials that serve non-metropolitan areas "this could include local elected officials, local officials with responsibility for transportation, officials of general purpose local government, officials associated with Federal lands managing agencies, and possibly tribal officials. This definition focuses on specifying the geographic area served by non-metropolitan officials to distinguish them from local officials representing metropolitan areas who are involved through the metropolitan planning organization (MPO).

The FHWA and the FTA do not propose to change the definition of "cooperation" and "coordination," because common practice has revealed no issues with the meaning of these terms.

#### Section 450.206

This section of the existing regulation deals with the general requirements of the statewide transportation planning process. The TEA-21 clearly emphasizes the importance of recognizing non-metropolitan transportation issues and consulting with non-metropolitan local officials. The FHWA and the FTA propose revising § 450.206(b) and adding a new § 450.206(c) to clarify that effective consideration of non-metropolitan transportation issues and concerns and involvement of non-metropolitan local officials can be enhanced by coordinating statewide transportation planning with related planning in non-metropolitan areas.

#### Section 450.212

We received over 150 comments on the May 2000 Planning NPRM § 1410.212, Participation by Interested Parties. The proposed § 1410.212 of the May 2000 Planning NPRM was proposed to replace § 450.212 of the current planning regulation. The majority of these comments focused on consultation with non-metropolitan local officials. In addition to the comments submitted to the docket, the FHWA and the FTA used information from other activities, including the FHWA-FTA study on participation of non-metropolitan local officials required by the TEA-21 and ten rural listening sessions held throughout the country to develop the SNPRM.<sup>1</sup>

We propose to revise the provisions of § 450.212 to reflect more closely the language of the legislation concerning consultation with non-metropolitan local officials and the comments received to date in the docket. The language we propose focuses on the intended result of the process to be "effective participation" of local officials in statewide transportation planning. Because the statutory

<sup>1</sup> The study on the non-metropolitan local officials report is currently being reviewed within DOT; however, two of the study products (Rural Transportation Consultation Processes, May 2000, and Rural Transportation Consultation Processes; State by State Summaries, April 2001) are available at the following URL: <http://www.napawash.org>. A summary of each of the ten rural workshops held in 1998-99 (Rural Transportation Planning Workshops, Summary 1999) is available at the following URL: <http://www.fhwa.dot.gov/hep10/state/rural.html>. The reports mentioned in this footnote are also in the May 2000 Planning NPRM docket.

language refers to a variety of types of local officials, our proposal does not specify whether they must be elected officials or non-elected officials. Rather, we propose State flexibility for determination of which local officials should be most appropriately involved in their State's statewide transportation planning process.

#### *Section 450.214*

The TEA-21 specifically states "with respect to each non-metropolitan area, the long-range transportation plan shall be developed in consultation with affected local officials with responsibility for transportation," now codified at 23 U.S.C. 135(e)(2)(B). Therefore, the FHWA and the FTA propose adding § 450.214(f) to reflect the intent of the statute by proposing language that requires affected local officials with responsibility for transportation to be involved on a consultation basis in developing the statewide transportation plan as it relates to the non-metropolitan areas of the State.

#### *Section 450.216*

The TEA-21 specifically states "with respect to each non-metropolitan area in the State, the program shall be developed in consultation with affected local officials with responsibility for transportation," now codified at 23 U.S.C. 135(f)(1)(B)(ii)(I). Therefore, the FHWA and the FTA propose adding § 450.216(e) to reflect the intent of the statute by proposing language that requires affected local officials with responsibility for transportation to be involved on a consultation basis in developing the statewide transportation improvement program as it relates to the non-metropolitan areas of the State.

#### *Section 450.224*

This SNPRM proposes a six-month phase-in period (to end six months after the effective date of a final rule, if we decide to issue a final rule). After this period, the consultation aspects of the statewide transportation planning process will be emphasized as we assess the planning process and make the Federal planning finding required in 23 CFR 450.220(b) and 23 U.S.C. 135(f)(4). We considered a longer phase-in period, but decided not to propose it since the statutory language has been in effect for almost four years and this proposal mirrors statutory language.

There is one other section in the existing regulation with language related to consultation with non-metropolitan local officials, 23 CFR 450.222 "Project selection for implementation." However, the FHWA

and the FTA do not propose to modify that section in this SNPRM.

#### **Rulemaking Analyses and Notices**

All comments received before the close of business on the comment closing date indicated above will be considered and will be available for examination in the docket at the above address. Comments received after the comment closing date will be filed in the docket and will be considered to the extent practicable, but the agencies may issue a final rule at any time after the close of the comment period. In addition to late comments, the FHWA and the FTA will also continue to file relevant information in the docket as it becomes available after the comment period closing date, and interested persons should continue to examine the docket for new material.

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

This rulemaking is an alternative option to the agencies' May 2000 Planning NPRM proposing to amend the agencies' planning regulations regarding the consultation with non-metropolitan local officials. The FHWA and the FTA have determined preliminarily that this action would be a significant regulatory action within the meaning of Executive Order 12866 and the Department of Transportation regulatory policies and procedures, because the proposed action concerns a matter on which there is substantial public interest. The agencies anticipate that the economic impact of this rulemaking would be minimal. This action proposes to amend a portion of the current planning regulations for which substantial financial assistance is provided to the States by both the FHWA and the FTA to support compliance with the requirements of the regulation.

These proposed changes would not adversely affect, in a material way, any sector of the economy. In addition, these changes would not create a serious inconsistency with any other agency's action or materially alter the budgetary impact of any entitlements, grants, user fees, or loan programs; nor will the proposed amendment of this regulation raise any novel legal or policy issues. Therefore, a full regulatory evaluation is not required.

#### **Regulatory Flexibility Act**

In compliance with the Regulatory Flexibility Act (Pub. L. 96-354, 5 U.S.C. 601-612), the FHWA and the FTA have evaluated the effects of this SNPRM on small entities and has determined it would not have a significant economic

impact on a substantial number of small entities.

The modifications proposed in this SNPRM are substantially dictated by the statutory provisions of the TEA-21 and the agencies believe that the flexibility available to the States in those provisions has been maintained. For these reasons, the FHWA and the FTA certify that this proposed action would not have a significant economic impact on a substantial number of small entities. We are interested in any comments regarding the potential economic impacts of this proposed rule on small entities and governments.

#### **Unfunded Mandates Reform Act of 1995**

The FHWA and the FTA have analyzed this proposal under the provisions of the Unfunded Mandates Reform Act of 1995 (Pub. L. 104-4, March 22, 1995, 109 Stat. 48) and believe that this SNPRM would not impose a Federal mandate resulting in the expenditure by State, local, and tribal governments, in the aggregate, or by the private sector, of \$100 million in any one year.

The requirements of 23 U.S.C. 135 are supported by Federal funds administered by the FHWA and the FTA. There is a legislatively established local matching requirement for these funds of up to twenty percent of the total cost. The FHWA and the FTA believe that the cost of complying with these requirements is predominately covered by the funds they administer. The costs of compliance with the requirements of the planning program as a whole are eligible for funding; therefore, this proposal would not create an unfunded mandate.

Additionally, the definition of "Federal mandate" in the Unfunded Mandates Reform Act excludes financial assistance of the type in which State, local, or tribal governments have authority to adjust their participation in the program in accordance with changes made in the program by the Federal government. The Federal-aid highway program and the Transit program permit this type of flexibility to the States.

#### **Executive Order 13132 (Federalism)**

This action has been analyzed in accordance with the principles and criteria contained in Executive Order 13132, and the agencies have determined that this action does not raise sufficient federalism implications to warrant the preparation of a Federalism assessment, and will not adversely affect the States' ability to discharge traditional State governmental functions.

Concern was raised by some States about burdens from the May 2000 Planning NPRM. One of the concerns is the burden resulting from the requirement for consultation with non-metropolitan local officials. The TEA-21 requires such consultation. In this SNPRM the FHWA and the FTA make it clear that already existing consultation procedures could be used to comply with these requirements.

The agencies further note that the transportation planning activities required by the planning regulations, as amended by this proposed rule, are conditions for the receipt of Federal transportation financial assistance and are reimbursable expenses. Under the provisions of title 23, U.S.C., the Federal government reimburses at least 80 percent of the costs to complete required transportation plans and transportation improvement programs.

**Executive Order 12372 (Intergovernmental Review)**

Catalog of Federal Domestic Assistance Program Number 20.205, Highway Planning and Construction; 20.500 Federal Transit Capital Improvement Grants; 20.505, Federal Transit Metropolitan Planning Grants; 20.507, Federal Transit Formula Grants; 20515, State Planning and Research. The regulations implementing Executive Order 12372 regarding intergovernmental consultation on Federal programs and activities apply to this program.

**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 and the FTA have determined that this proposal does not contain collection of information requirements for the purposes of the PRA.

**National Environmental Policy Act**

The FHWA and the FTA have analyzed this rulemaking for the purpose of the National Environmental Policy Act of 1969 (42 U.S.C. 4321-4347). This proposal would not constitute a major Federal action significantly affecting the quality of the human environment.

**Executive Order 13175 (Tribal Consultation)**

The FHWA and the FTA have analyzed this proposal under Executive Order 13175, dated November 6, 2000. The proposed action 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. Therefore, a tribal summary impact statement is not required. Consultation with tribal governments is separately referenced in TEA-21 and is not included in this SNPRM.

**Executive Order 13211 (Energy Effects)**

We have analyzed this proposed rule under Executive Order 13211, Actions Concerning Regulations That Significantly Affect Energy Supply, Distribution, or Use. Although this proposal is a significant regulatory action under Executive Order 12866, we have determined that it is not a significant energy action under that order, because 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.

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

This proposal 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 proposal under Executive Order 13045, protection of Children from Environmental Health Risks and Safety Risks. This proposal is not an economically significant rule and does not concern an environmental risk to health or safety that may disproportionately affect children.

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

This proposal would not effect a taking of private property or otherwise have taking implications under Executive Order 12630, Government Actions and Interference with Constitutionally Protected Property Rights.

**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 450**

Grant programs—transportation, Highways and roads, Mass transportation, Reporting and recordkeeping requirements.

Issued on: June 12, 2002.

**Mary E. Peters,**  
*Administrator, Federal Highway Administration.*

**Jennifer L. Dorn,**  
*Administrator, Federal Highway Administration.*

In consideration of the foregoing, the FHWA proposes to amend title 23, Code of Federal Regulations, part 450, as set forth below:

**PART 450—PLANNING ASSISTANCE AND STANDARDS**

1. The authority citation for part 450 continues to read as follows:

**Authority:** 23 U.S.C. 134, 23 U.S.C. 135, 23 U.S.C. 315, and 49 U.S.C. 5303-06.

2. Amend § 450.104 to revise the definition of “consultation” and add a definition for “non-metropolitan area” to read as follows:

**§ 450.104 Definitions.**

\* \* \* \* \*

*Consultation* means that one party confers with another identified party and, prior to taking action(s), considers that party's views and then keeps that party informed about action(s) taken.

\* \* \* \* \*

*Non-metropolitan area* means the geographic area outside designated metropolitan planning areas, as designated under 23 USC § 134 and 49 USC § 5303.

\* \* \* \* \*

3. Amend § 450.206 to revise paragraph (b) and to add a paragraph (c) to read as follows:

**§ 450.206 Statewide transportation planning process: General requirements.**

\* \* \* \* \*

(b) The statewide transportation planning process shall be coordinated with the metropolitan planning process required by subpart C of this part and with related planning activities being carried out outside of metropolitan planning areas.

(c) In carrying out statewide transportation planning, the State shall consider, with respect to non-metropolitan areas, the concerns of local elected officials representing units of general purpose local government.

4. Amend § 450.212 by adding a new paragraph (h) to read as follows:

**§ 450.212 Public involvement.**

\* \* \* \* \*

(h) The State shall provide for non-metropolitan local official participation. The State shall have a documented process(es) for consulting with non-metropolitan local officials representing units of general purpose local government and/or local officials with responsibility for transportation that results in their effective participation in the statewide transportation planning process and development of the statewide transportation improvement program.

5. Amend § 450.214 by adding a paragraph (f) to read as follows:

**§ 450.214 Statewide transportation plan.**

\* \* \* \* \*

(f) In developing the statewide transportation plan, affected local officials with responsibility for transportation shall be involved on a consultation basis for the portions of the plan in non-metropolitan areas of the State.

6. Amend § 450.216 by adding a paragraph (e) to read as follows:

**§ 450.216 Statewide transportation improvement program (STIP).**

\* \* \* \* \*

(e) In developing the statewide transportation improvement program, affected local officials with responsibility for transportation shall be involved on a consultation basis for the portions of the program in non-metropolitan areas of the State.

7. Amend § 450.224 by designating the existing text as paragraph (a) and by adding a new paragraph (b) to read as follows:

**§ 450.224 Phase-in of new requirements.**

\* \* \* \* \*

(b) The State has a period of six months after [30 days after publication of the final rule in the **Federal Register**] to document and implement the consultation process discussed in § 450.212(h).

[FR Doc. 02-15280 Filed 6-17-02; 4:45 pm]

BILLING CODE 4910-22-P

## DEPARTMENT OF THE TREASURY

### Internal Revenue Service

#### 26 CFR Part 1

[REG-248110-96]

RIN 1545-AY48

#### Guidance Under Section 817A Regarding Modified Guaranteed Contracts; Correction

AGENCY: Internal Revenue Service (IRS), Treasury.

**ACTION:** Correction to notice of proposed rulemaking and notice of public hearing.

**SUMMARY:** This document contains a correction to a notice of proposed rulemaking and notice of public hearing (REG-248110-96) that was published in the **Federal Register** on Monday, June 3, 2002 (67 FR 38214). These regulations affect insurance companies that define the interest rate to be used with respect to certain insurance contracts that guarantee higher returns for an initial, temporary period.

**FOR FURTHER INFORMATION CONTACT:** Ann H. Logan, (202) 622-3970 (not a toll-free number).

#### SUPPLEMENTARY INFORMATION:

##### Background

The notice of proposed rulemaking and notice of public hearing that is the subject of this correction is under section 817A of the Internal Revenue Code.

##### Need for Correction

As published REG-248110-96 contains an error which may prove to be misleading and is in need of clarification.

##### Correction of Publication

Accordingly, the publication of the notice of proposed rulemaking and notice of public hearing (REG-248110-96), which is the subject of FR Doc. 02-13848, is corrected as follows:

On page 38215, column 2, in the preamble under the paragraph heading “*Interest Rates Affecting Modified Guaranteed Contracts*” first paragraph, lines twelve through fifteen, the language “The temporary guarantee may be a fixed rate (non-equity indexed modified guaranteed contracts) or a rate based on bond or equity yields (equity-indexed)” is corrected to read “The temporary guarantee may be a rate based on stocks, other equity instruments, or equity-based derivatives (equity-indexed modified guaranteed contracts) or a rate that is not related to equity performance (non-equity-indexed modified guaranteed contracts).”.

**Cynthia Grigsby,**

*Chief, Regulations Unit, Associate Chief Counsel (Income Tax and Accounting).*

[FR Doc. 02-15353 Filed 6-18-02; 8:45 am]

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## DEPARTMENT OF THE INTERIOR

### Office of Surface Mining Reclamation and Enforcement

#### 30 CFR Part 917

[KY-238-FOR]

#### Kentucky Regulatory Program

**AGENCY:** Office of Surface Mining Reclamation and Enforcement(OSM), Interior.

**ACTION:** Proposed rule; public comment period and opportunity for public hearing on proposed amendment.

**SUMMARY:** We are announcing a proposed amendment to the Kentucky regulatory program (the “Kentucky program”) under the Surface Mining Control and Reclamation Act of 1977 (SMCRA or the Act). Kentucky proposes additions to its statutes about permittees’ access to land to abate violations and intends to revise its program to be consistent with SMCRA. This document gives the times and locations that the Kentucky program and proposed amendment to that program are available for your inspection, the comment period during which you may submit written comments on the amendment, and the procedures that we will follow for the public hearing, if one is requested.

**DATES:** We will accept written comments on this amendment until 4 p.m., e.s.t. July 19, 2002. If requested, we will hold a public hearing on the amendment on July 15, 2002. We will accept requests to speak at a hearing until 4 p.m., e.s.t. on July 5, 2002.

**ADDRESSES:** You should mail or hand deliver written comments and requests to speak at the hearing to William J. Kovacic at the address listed below.

You may review copies of the Kentucky program, this amendment, a listing of any scheduled public hearings, and all written comments received in response to this document at the addresses listed below during normal business hours, Monday through Friday, excluding holidays. You may receive one free copy of the amendment by contacting OSM’s Lexington Field Office.

William J. Kovacic, Lexington Field Office, Office of Surface Mining Reclamation and Enforcement, 2675 Regency Road, Lexington, Kentucky 40503, Telephone: (859) 260-8400. E-mail: [bkovacic@osmre.gov](mailto:bkovacic@osmre.gov).

Department of Surface Mining Reclamation and Enforcement, 2 Hudson Hollow Complex, Frankfort, Kentucky 40601, Telephone: (502) 564-6940.